PSORIASIS AS PREDICTOR FOR CARDIOVASCULAR AND METABOLIC COMORBIDITY IN MIDDLE-AGED WOMEN

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A metagenomics study of the elbow of psoriasis subjects and their healthy relatives

Nail disorders in patients with Psoriasis vulgaris

Psoriasis hidden in Gottron’s papules

Characteristics of psoriasis in obese patients versus non-obese patients; a multicenter study

Psoriasis and comorbidity

Risk of periodontal disease in patients with chronic plaque psoriasis

Splenomegaly and Psoriasis - A case report

Psoriasis as predictor for cardiovascular and metabolic comorbidity in middle-aged women

A Case of Concurrent Psoriasis and Vitiligo

Successful long-term double disease control by adalimumab in a patient with psoriasis vulgaris and hidradenitis suppurativa

Clinical and epidemiological characterization of psoriasis and psoriatic arthritis on a multidisciplinary assessment model.

“Psoriasis and Cancer: Retrospective study in the Psoriasis sector of the Dermatology Service at Ramos Mejia Hospital”

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Certolizumab Pegol Improves Patient-Reported Outcomes in Chronic Plaque Psoriasis Over 1 Year

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Treating the pain, not the problem? Results from a Swedish online survey on psoriatic arthritis and psoriasis with joint pain.

An International Delphi survey to define screening for psoriatic arthritis and measurement of psoriatic arthritis symptoms in psoriasis clinical trials

The impact of a diagnosis on the patients’ perception of treatment and care. Results from an online survey on psoriatic arthritis and psoriasis with joint pain.
Results: To investigate differentially abundant taxa. PERMANOVA was resolute the skin microbiota. Partially overlapping t-test was used lives with. Shotgun metagenomic sequencing was adapted to The rest were from a healthy family member whom the subject 21 were from 7 psoriasis subjects’ lesion side and normal side. vulgaris is a chronic inflammatory skin disease and has been associated with other comorbidities. Previous studies in psoriasis reported the abundance of microbial taxa above the species rank (family *Firmicutes* and genus *Staphylococcus*), or the combined abundance of multiple taxa (*Corynebacterium*, *Propionibacterium*, *Staphylococcus*, and *Streptococcus*) were associated with psoriasis [1–3]. Characterizing the skin microbiome of psoriasis subjects and family controls can further our understanding of microbiota’s role in this disease.

Objectives: This study aims to reveal the difference of skin microbiome between skin lesion area and normal area of the elbow as well as family controls.

Methods: DNA samples was extracted from 21 elbow-skin, 14 of 21 were from 7 psoriasis subjects’ lesion side and normal side. The rest were from a healthy family member whom the subject lives with. Shotgun metagenomic sequencing was adapted to resolve the skin microbiota. Partially overlapping t-test was used to investigate differentially abundant taxa. PERMANOVA was used to test the difference of microbial community composition influenced by psoriasis and sampling families.

Results: Bacteria phyla *Proteobacteria*, *Actinobacteria*, and *Bacteroidetes* were three most abundant microbial taxa in both lesion and normal skin. Bacteria phyla *Cyanobacteria* and *Candidatus Paracoccus*, family *Hymenobacteraceae* were less abundant on lesion skin than normal skin (p < 0.05). Sampling families had significantly different elbow-skin microbial composition for bacterial genus level profile (p = 0.001).

Conclusions: Several bacterial taxa different from those previously discovered are more abundant on normal skin than lesion skin in the elbow.

References:

P002

NAIL DISORDERS IN PATIENTS WITH PSORIASIS VULGARIS

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Introduction: Psoriasis vulgaris is a chronic inflammatory skin disease characterized by T-cell-mediated hyperproliferation of keratinocytes in the skin. Approximately, 10–78% of patients with psoriasis have concurrent nail psoriasis while isolated nail involvement is seen in 5–10% of patients. Affected nail plates often thicken and crumble and because they are very visible patients tend to avoid normal day-to-day activities and social interactions. Importantly, 70–80% of patients with psoriatic arthritis have nail psoriasis. In this overview, we review the clinical manifestations of psoriasis affecting the nails.

Objectives: To correlate frequency of certain nail disorders in patients with psoriasis vulgaris. The observed disorders were: onicholysis, subungual hyperkeratosis, oil spots, and pitting in both male and female patients aged 15–75 and combined with psoriatic arthritis.

Methods: A total of 60 patients who were treated in our Inpatients Service with diagnosis of Psoriasis vulgaris from January 2017 to July 2017 at Dermatology Department, University Clinical of Sarajevo. We searched for specific nail disorders.

Results: A total number of 60 patients with Psoriasis vulgaris, both male and female aged 15–75 were examined. Out of that number, 43 patients reported to have specific nail disorders and/or psoriatic arthritis, and 17 of them were without any nail disorders or psoriatic arthritis. Among the number of 43 examined psoriasis patients with nail disorders, there were 23 female and 20 male patients, all of them aged between 45–60. Seven female and eight male patients had previously diagnosed psoriatic arthritis combined with psoriasis and nail disorders, while the rest of them, 28 patients, only had psoriasis followed by progressive changes on their nails, but without any signs of psoriatic arthritis. The presented nail disorders in all patients included in these two groups were: subungual hyperkeratosis, onycholysis and pitting all combined in 14 patients, only subungual hyperkeratosis in 10 patients, pitting in 7 patients, 7 of them showed only onycholysis on both hands and 6 patients had oil spotting and pitting together. In patients without psoriatic arthritis the prevalence of disorders in all affected groups was in male patients.

Conclusion: Nail psoriasis engenders both physical and psychological handicap, leading to significant negative repercussions in the quality of life. The presence of nail disease in a patient with psoriasis may indicate a severe form of the disease and must be taken into account when selecting a treatment option, with an aim to reduce pain, functional impairment as well as emotional distress.

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Introduction. In recent years special attention has been paid not only to the systemic nature of the process in psoriasis, but also to its association with comorbidities. Comorbidity is a regular combination of various diseases or conditions in one patient, it occurs in many inflammatory processes. Objectives: The study of the incidence of concomitant diseases in patients with psoriasis in relation to patients with allergic contact dermatitis, analysis by age group. Methods: A retrospective analysis of data of 804 patients, who were treated in 2016–2017 in Mogilev Regional Dermatology and Venerology Centre with different forms of psoriasis, was conducted. 492 males, 312 females. The mean age was 43.05 years. The control group consisted of patients with allergic contact dermatitis, comparable in age and sex, in an amount of 397 people. Results: Specific gravity and incidence of comorbidity in patients with psoriasis: cardiovascular damage 41% (331), gastrointestinal tract - 30.4% (245), endocrine system - 22.7% (183), metabolic syndrome - 28.2% (227), chronic otorhinolaryngological diseases - 11.4% (92), diseases of urinary system - 6.2% (50), respiratory system - 4.7% (38). Significant differences between the groups were obtained for all the comorbidity except respiratory diseases. Psoriatic polyarthropathies were observed in 219 patients (27.3%), nail psoriasis – in 117 patients (14.6%). The average body mass index in the psoriasis group was 27.2, in the allergic contact dermatitis group - 25.3. Significant differences between the groups were obtained for all the laboratory test changes except the general bilirubin, C-reactive protein and urinalysis. The percentage of diseases changed with increasing age: diseases of the cardiovascular system from 10% to 87%, gastrointestinal diseases from 20% to 61%, endocrine system diseases - from 14.5% to 38%, metabolic syndrome - from 11% to 34%, otorhinolaryngological diseases - from 15% to 8.5%, diseases of the urinary system - from 1.8% to 8.5%, respiratory system diseases – from 1.8% to 13%. Conclusions: The analysis showed that in patients with psoriasis the most frequent comorbidity are: cardiovascular and gastrointestinal diseases, endocrine disorders, polyarthritis, nail psoriasis and metabolic syndrome. A rather high risk of comorbidity is established, in comparison with the population, which can directly affect the severity of the course of the disease, the effectiveness of the therapy and life expectancy.

References:
Results: During the study enrolment period 40 patients with psoriasis and 40 age- and gender-matched controls were included in this study. Probing depth and periodontal attachment level showed significant higher values in psoriasis group compared to healthy subjects.

Conclusions: We found evidence of a psoriasis-associated increased risk of periodontitis. Thus, dermatologists should be aware of this comorbidity because these patients should be closely followed-up by a dentist for the adequate and early treatment of periodontitis. Periodontitis may be associated with psoriasis but further studies are needed to elucidate their relationship.

References:

P007
SPLENOMEGALY AND PSORIASIS - A CASE REPORT
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Psoriasis is a chronic, systemic, inflammatory disease associated with numerous comorbidities that have been well documented in the literature. Comorbidities often become clinically evident years after the onset of psoriasis and are related to persistent low-grade inflammation with secretion of proinflammatory cytokines, as seen in metabolic syndrome(1). Nevertheless, the evidence shows new emerging comorbidities that share link with psoriasis. Hjuler et al. observed increased splenic inflammation in patients with moderate-to-severe psoriasis (2). They also showed that splenic activity was correlating with aortic wall inflammation in psoriasis patients, explaining the increased risk of heart disease (2).

A 56-year-old patient with chronic plaque psoriasis (Fig 1) for more than thirty years, presented with splenomegaly, diabetes type two, arterial hypertension, chronic kidney disease stage III, obesity, with BMI > 40, and depression. Psoriasis severely flared up in 2012, and on workup up for cataract operation, enlarged lymph nodes were observed and further confirmed on CT scans in axillae, inguinal, mediastinum and upper abdomen. Patient was hospitalized at haematology department and reactive lymphadenopathy due to skin inflammation was diagnosed. Acitretin was started and stopped after a week for worsening of pancytopenia, and Methotrexate was stopped after two weeks for triple increase in liver enzymes, although the dose was of only 5 mg weekly. In August 2017, repeated blood tests were normal and abdominal US showed no progression in hepatosplenomegaly, with spleen measuring 23 cm. Psoriasis was severe, with PASI 36, BSA 31% and DLQI 19. Ustekinumab 90 mg was started in October 2017 with PASI75 achieved after 12 weeks of treatment. Patient has been closely monitored with no haematological side-effects on last assessment.

Significant splenomegaly and lymphadenopathy with no underlying haematological disease has not been described as a comorbidity of psoriasis. The treatment with biologics was delayed in our patient as underlying haematological malignancy was suspected. The untreated severe psoriasis flared up in the mean time the whole spectrum of comorbidities, led by depression. Ustekinumab has significantly improved his psoriasis (Fig 2), with improvement in depression that was best observed in patient’s motivation to lose weight and be referred for gastric bypass.

Effective control of psoriasis and associated conditions requires not only appropriate treatment, but also management of comorbidities, including screening and treatment by various specialists, as disease is known for its cumulative impairment over patient’s lifetime (3).
underwent any diagnostic procedure, nor treatment. Clinical and histopathological diagnosis of erythemasquamous areas on the patients' right elbow and right and left lower leg was a plaque psoriasis, while hypopigmented patches on his wrists were diagnosed as vitiligo. Blood work up and T3, T4, TSH, ANA laboratory tests were within normal ranges. 

Conclusion: Psoriasis and vitiligo, although seemingly unrelated skin disorders, have a lot in common. Causes, incidence, and even distribution seem to strongly correlate between these two.

**P010**

**SUCCESSFUL LONG-TERM DOUBLE DISEASE CONTROL BY ADALIMUMAB IN A PATIENT WITH PSORIASIS VULGARIS AND HIDRADENITIS SUPPURATIVA**

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Introduction: Psoriasis vulgaris /PV/ is a chronic inflammatory skin disease1. Studies have shown the role of genes important for the transcription of inflammatory cytokines, such as TNF alpha and IL-23, which play main role in the pathogenesis of psoriasis2. Hidradenitis suppurativa /HS/ is chronic inflammatory skin disease2, in which pathogenesis are IL-23 and TNF alpha, supporting the theory of the immunologic disease3. Adalimumab is human monoclonal antibody that has a great affinity for the membrane of TNF alpha4. We report the case of a 44-year-old Caucasian woman with a history of PV and HS, both diseases are in remission during the therapy with adalimumab.

Case report: We report the case of a 44-year-old Caucasian woman with a history of PV and HS that started adalimumab therapy 3 years ago. PV started 14 years ago and was verified by skin biopsy. Initially, the clinical course of psoriasis was mild and later she took course to moderate psoriasis with PASI 10. Psoriasis was treated only with local therapy. HS started when she was 38-years-old in her left groin, as swelling and pain on palpation and in movement. Skin changes started to develop also on the right groin and perianal region as painful nodules, with pus draining, and fistula tracts. Skin biopsy confirmed HS.Chest X-ray and gastroenterology examination were performed to exclude any additional illnesses and also a psychological testing. She was treated with different antibiotics also prednison and isotretinoin in a dose 1mg/kg/day. Topical therapy was consisting of antibiotics, antiseptics and hydrocolloid dressings. She had 3 surgical interventions. In 2015, she started adalimumab according to the scheme. On the day of the initial aplication of adalimumab, patient had 4 absceses, 13 nodules and 16 fistula tracts. She had successful clinical response to the drug and is without psoriatic symptoms or HS active lesions. Both diseases are successfully controled and quality of life has improved.

References:


**P011**

**CLINICAL AND EPIDEMIOLOGICAL CHARACTERIZATION OF PSORIASIS AND PSORIATIC ARTHRITIS ON A MULTIDISCIPLINARY ASSESSMENT MODEL**

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Dermatologic Country

Introduction: Presentation and clinical course in Psoriasis are heterogeneous. A multidisciplinary assessment model was designed by five specialties: dermatology, rheumatology, internal medicine, nutrition and psychiatry, to evaluate at the same time and place, patients with psoriasis.

Objective: To ascertain frequency of comorbidities in psoriatic patients and conduct a clinical and epidemiological characterization.

Methods: Prospective study, from August 2016 to February 2018, patients attending to Multidisciplinary Clinic for psoriasis in Dermatologic Country were included.

Results: 53 patients were included. Median age was 42 years old and 62.3% were female. Family history of psoriasis was found in 26.4% patients and 19.4% had spodyloarthropathy family history. Most common comorbidities found obesity, metabolic syndrome, diabetes mellitus, dyslipidemia, hypertension and fatty liver. Affective assessment was found for 49.1% met criteria for anxiety. Psoriasis found 96.2% with psoriasis in skin and 56.6% in nails. Most common presentation of psoriasis, was plaque psoriasis in 66%. PASI score showed 50.9% with mild disease, 15.1% moderate, and 34% severe. NAPSI score was from 0 to 61, with a median of 3 (0.13). DLQI indicated that only 13.2% had no condition in life quality, meanwhile 86.8% patients had impaired quality of life. Psoriatic arthritis, and identify 58.5% patients that met CASPAR criteria, axial disease was present in 51.6%, peripheral joint disease in 71% and in 13.2% both were present. 54.8%(17) patients had enthesitis and 16.1% had dactilitis. DAS28 was performed, and showed 45.2% with severe activity. Total number of subjects with peripheral disease 100%, did not met criteria for MDA. HAQ score to assess PsA patients quality of life, revealed a median of 1.38 (1.10, 2.25).

Conclusions: we found that more than half of the patients presented a severe form of psoriasis with significant quality of life impairment. The number of psoriatic arthritics was higher than expected with both axial and peripheral manifestations. We found a high proportion of patients with comorbidities such as metabolic syndrome, diabetes mellitus, hypertension, dyslipidemia and obesity. We also found a high frequency of psychiatric illness. The limitations of our study are the small sample to highlight if comorbidities had an impact on the severity of skin and joint disease. This multidisciplinary model has identified psoriasis as a disease with an unpredictable course, which requires several evaluations by a multidisciplinary model, with a group of experts beyond Dermatologist and Rheumatologist.

**P012**

**ALCOHOL AND PSORIASIS- A PROSPECTIVE SWEDISH STUDY**

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Background: We have earlier in a limited cross-sectional study shown a correlation in females for alcohol consumption and extent

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of psoriasis. There are few prospective studies on the relation of alcohol with the extent of psoriasis.

**Objectives:** The purpose of this prospective study was to further investigate how alcohol affects psoriasis in female patients.

**Methods:** Twenty-two female psoriasis patients with light to moderate psoriasis, with only local treatment and with a regular alcohol intake, were recruited. The study was run for three years, starting in 2014. We used Christmas and New Year, as intervention period, when the amount of alcohol is expected to exceed normal consumption. The total study period was 8 weeks. During the study period, the alcohol intake was measured by the patients filling a calendar, specifying the alcohol intake per day, moreover, the degree of severity of psoriasis, degree of pruritus, and of perceived stress, using a visual analog scale. In addition, the patients once a week determined Self-Administered Psoriasis Area and Severity Index (SAPASI).

**Results:** The alcohol intake, which was generally low to moderate, increased during Christmas and New Year, reaching its maximum during week 52 (Christmas week). There was a marginal increase in the extent of psoriasis, determined by SAPASI, during week 52. There was no correlation with alcohol intake nor pruritus. The level of perceived stress decreased shortly after week 52, and reached its lowest value during week 1, after that increasing.

**Conclusion:** Even if there is an increased alcohol consumption during Christmas and New Year, there is no evident worsening of psoriasis.

**P014**

**HEMATOLOGICAL DISORDERS IN THE PATIENT WITH PSORIATIC ARTHRITIS TREATED WITH METHOTREXATE AND TUMOR NECROSIS ALPHA (TNFALPHA) INHIBITOR**

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**Introduction:** Non-Hodgkin lymphomas are a heterogeneous group of neoplastic disorders characterized by clonal lymphoid cell proliferation. They rank sixth among the cancers in terms of the frequency of occurrence in adults. Waldenstrom macroglobulinemia is lymphoplasmic hyperplasia with excessive production of monoclonal M-protein. According to literature data, patients with psoriasis have more frequent lymphomas than healthy population. The real risk of lymphoproliferative disease in psoriatic arthritis patients has not yet been defined.

**Objectives:** The aim of the study was to describe a case of a patient with psoriatic arthritis and concurrent monoclonal gammopathy, who did not respond to treatment with TNFalpha inhibitor in combination with methotrexate.

**Methods:** A 57 year old woman with psoriasis and psoriatic arthritis diagnosed in 2012 (presence of HLA B27 antigen, arthritis of the sacroiliac joints, peripheral arthritis) with monoclonal gammopathy of undetermined significance, was treated with non-steroid anti-inflammatory drugs, methotrexate (20 mg once a week), folic acid 15 mg and inhibitor of TNFalpha. At the beginning of biological therapy she presented with laboratory results: ESR 126, total protein 8 g/dl, abnormal IgM 11.6 g/l (normal range 0.4–2.3 g/l), IgG 2.25 g/l (normal range 7–16 g/l), IgA 0.32 g/l (normal range 0.7–4 g/l). Immunofixation test revealed positive for IgM kappa monoclonal protein. There were no abnormalities in the bone marrow aspiration biopsy, no lymphadenopathy was observed. She complained of general weakness and polineuropathy. Analysis of spinocerebral fluid showed type V of oligoclonal band.

**Results:** In 2017, after 2 years of TNFalpha inhibitor combined with methotrexate therapy, the diagnosis of Waldenstrom macroglobulinemia has been done. The patient presented with high ESR 103 and monoclonal IgM 33 g/l. Repeated aspiration bone marrow biopsy showed 3% of plasmocytes and 21% of lymphocytes.

**Conclusions:** The patient started standard RCD chemotherapy regimen (rituximab, cyclophosphamide, dexamethason) with good clinical response to therapy.
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Introduction: Psoriasis is a complex, systemic disease associated with comorbidities extending beyond the skin, often affecting psychological well-being which may manifest as clinical depression. Psoriasis can be viewed narrowly by focusing on the skin, or holistically to include associated comorbidities. To date, the complex interplay between psoriasis, comorbidities, and depression has not been adequately described, and an innovative approach is necessary to understand interrelationship between them.

Objectives: Calculate incidence rates of depression in psoriasis patients compared to the general population and subsequently explore the risk factors associated with depression onset. Determine the contributions of comorbidities compared to narrowly defined, psoriasis-only symptoms.

Methods: 96,666 psoriasis patients were matched to 15 controls psoriasis-only symptoms. Patients with psoriasis have a higher incidence of clinical depression than those without the disease. Holistically, psoriasis was associated with an increased risk of depression onset of 40% (HR = 1.404, p < 0.001), compared to 12% increase (HR = 1.115, p < 0.001) when narrowly defined. The proportional hazards assumption appeared to hold in each survival analysis. A substantial portion, but not all, of psoriasis patients’ risk of depression onset was attributable to comorbidities, and sociodemographic factors did not affect the estimates of association between depression and psoriasis. Major differences were found between antidepressant- and diagnosis-based definitions of depression, while inclusion of psoriatic arthropathy, alternative depression definitions, and searched for unobserved confounding.

Results: Patients with psoriasis have a higher incidence of clinical depression than those without the disease. Holistically, psoriasis was associated with an increased risk of depression onset of 40% (HR = 1.404, p < 0.001), compared to 12% increase (HR = 1.115, p < 0.001) when narrowly defined. The proportional hazards assumption appeared to hold in each survival analysis. A substantial portion, but not all, of psoriasis patients’ risk of depression onset was attributable to comorbidities, and sociodemographic factors did not affect the estimates of association between depression and psoriasis. Major differences were found between antidepressant- and diagnosis-based definitions of depression, while inclusion of psoriatic arthropathy did not affect the results. No unmeasured confounding was identified.

Conclusions: Due to the elevated risk of depression in psoriasis patients, treating physicians should ensure patients’ psychological well-being is addressed, especially in those presenting with additional risk factors, to break the cyclical relationship between depression and psoriasis and improve patients’ quality of life. Contemporary, holistic management of psoriasis patients should encourage routine screening for depression.

P018

ATTAINMENT OF REMISSION AND MINIMAL DISEASE ACTIVITY AFTER STARTING METHOTREXATE SUBCUTANEOUS THERAPY

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Introduction: Methotrexate (MTX) is the first-choice therapy in psoriatic arthritis (PsA). There is limited data concerning efficacy of early administration and rapidly dose escalation of MTX subcutaneous (s/c) in early (E) PsA patients (pts).

Objective: to study attainment of remission (REM) or minimal disease activity (MDA) after starting MTX s/c therapy in EPsA pts treated according to treat-to-target (T2T) strategy.

Methods: 77 (M-37/F-40) pts with active EPsA, according to the CASPAR criteria were included. Mean age 37.4±10.8 years (yrs.), PsA duration 11±10 months (mon.), psoriasis duration 86±91.6 mon., DAPSA 32.45±12.7. At baseline all pts started MTX s/c therapy. The dose of MTX s/c was escalated by 5 mg every 2 weeks from 10 mg/wk to appropriate dose 20–25 mg/wk according to the drug intolerance. If the patient did not achieve remission or MDA on MTX mono-therapy, biological (b)DMARDs was added. At baseline and every 3 mon. of study (till 24 mon.) all pts underwent assessment of PsA activity by DAPSA and MDA criteria (tender joint count ≤1, swollen joint count ≤1, PASI ≤1 or BSA ≤3, patient pain global assessment VAS ≤15, patient’s global disease activity VAS ≤20, HAQ <0.5, enthesitis count ≤1). The proportion of pts who achieved REM by DAPSA ≤4 and MDA (5 of 7 cutpoints), the timing of REM/MDA, the mean dose of MTX during the study were performed. M:SD, Me [Q75; Q50], (%), W-test were calculated. All p < 0.05 were considered to indicate statistical significance.

Results: 36 out of 77 pts (46.75%) did not achieve REM or MDA in MTX therapy within 7.5 mon. and bDMARDs were added. 5 out of 77 pts (6.5%) stopped MTX therapy due to intolerance within 6±2 mon. 36 out of 77 pts (46.75%) went on taking MTX mono-therapy. In 22 out of 36 pts, who had mean DAPSA 27.7±10.0 at baseline, data was available by the 24 mon. of study. At baseline median dose of MTX s/c was 15 [10;20], Min 10–Max 20 mg/wk. At the third mon. of study median dose of MTX s/c was escalated to 20 [20;20], Min 0–Max 25 mg/wk. After attainment of REM/MDA the dose of MTX was decreased. At the end of the study median dose of MTX s/c was 7.5 [0;15], Min 0–Max 20 mg/wk.
mg/wk (fig.1). After starting MTX disease activity by DAPSA significantly decreased by the third mon. and maintained till the end of the study (fig.2). DAPSA-REM and MDA was reached within 9.7±7.7 and 13.7±7.6 mon. accordingly. By the 24 mon. of therapy stable REM by DAPSA and MDA was seen in 10 out of 22 pts (45.5%) and in 16 out of 22 pts (72.7%) accordingly.

**Conclusions:** In half of EPPA pts early administration of MTX s/c and rapidly dose escalation is effective and well tolerated. After achieving REM or MDA, a decrease of the dose of MTX is possible in most cases.

**P019**

**SECUKINUMAB IN PREGNANCY: OUTCOMES IN PSORIASIS, PSORIATIC ARTHRITIS AND ANKYLOSING SPONDYLITIS FROM THE GLOBAL SAFETY DATABASE**

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**Introduction:** Secukinumab, a fully human monoclonal antibody selectively targeting IL-17A, is highly efficacious in the treatment of moderate to severe psoriasis, psoriatic arthritis (PsA) and ankylosing spondylitis (AS), with sustained efficacy and favorable safety profile. Long term treatment with targeted therapies such as secukinumab may be necessary in women of childbearing age. Pre-clinical animal studies with secukinumab, which can cross the placenta, do not indicate harmful effects with respect to pregnancy, embryonic/fetal development, parturition or postnatal development, however only limited data has been reported on human pregnancies.

**Objectives:** Using the Novartis global safety database, we analyzed the outcome of pregnancies where there was maternal or paternal exposure to secukinumab.

**Methods:** The Novartis global safety database (covering all secukinumab indications and including clinical trial and post-marketing data) was searched for cases reporting pregnancy and secukinumab indications and including clinical trial and post-marketing data. All pregnancies where there was either maternal or paternal exposure to secukinumab were included in the systematic, independently validated analysis. The cut-off date was 25th June, 2017.

**Results:** Of 292 pregnancies reported, 141 (48.3%) came from clinical trials, 79 (27.1%) were spontaneous reports and 72 (24.7%) were from post-marketing surveillance, with 238 cases of maternal and 54 cases of paternal exposure. 175 patients received secukinumab for psoriasis, 38 for PsA, 15 for AS and 62 for other/unknown indications. The majority of patients discontinued secukinumab in the first trimester of pregnancy, 18 did not discontinue. Of 153 cases where the outcome was known, there were 73 full term normal neonates and 37 elective terminations. Rates of spontaneous abortions were 30/292, 10.3% overall (30/153 known outcomes, 19.6%). These are in line with previously reported rates (15–20%) for the general population with maternal age of 30.6 (study mean). No still births (< 15–20%) for the general population with maternal age of 30.6 (study mean). No still births (< 15–20%) for the general population with maternal age of 30.6 (study mean). No still births (< 15–20%) for the general population with maternal age of 30.6 (study mean).

**Conclusions:** There was no evidence for increased rates of adverse pregnancy outcomes across indications with secukinumab in this review of the safety database. Given the limited exposure reported to date, the safe continuous use of secukinumab throughout pregnancy requires further research.

**P020**

**IXEKIZUMAB IMPROVES IMPACT OF GENITAL PSORIASIS ON SEXUAL ACTIVITY: RESULTS FROM A PHASE 3B STUDY**

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**Introduction:** Genital psoriasis (GP) is often associated with impaired sexual health. Ixekizumab (IXE) is a high-affinity monoclonal antibody that selectively targets interleukin-17A.

**Objective:** To evaluate the effect of IXE on the impact of GP on sexual activity during 12 weeks of treatment compared to placebo (PBO) in patients with moderate-to-severe GP.

**Methods:** In this double-blind, placebo-controlled study, patients (n = 149) with moderate-to-severe GP were randomized (1:1) to receive PBO or 80 mg IXE every 2 weeks following an initial dose of PBO or 160 mg IXE. The impact of GP on sexual activity was measured by pre-specified patient-reported outcomes including the Genital Psoriasis Sexual Impact Scale (GPSIS), which is composed of the Sexual Activity Avoidance (Avoidance) and Impact of Sexual Activity on Genital Psoriasis Symptoms (Impact) subscales, the Sexual Frequency Questionnaire (SFQ) item 2, and the Dermatology Life Quality Index (DLQI) item 9. Of patients with a baseline SFQ item 2 score ≥2, the percentage of patients whose frequency of sexual activity was never (0) or rarely (1) limited by GP (SFQ item 2 0/1) was examined. Among patients with respective GPSIS subscale scores ≥3 at baseline, response was measured as the percentage of patients whose frequency of avoiding sexual activity was never (0) or rarely (2) impacted by GP (GPSIS-Avoidance 1/2) and whose GP symptom worsening after sexual activity was very low/none at all (1) or low (2) (GPSIS-Impact 1/2). DLQI item 9 response was measured as the percentage of patients with no (0) or a little (1) impairment of sexual activity.

**Results:** IXE treatment reduced the impact of GP on sexual activity at Week 12 versus PBO as assessed by SFQ item 2 0/1 (IXE 78.4%, PBO 21.4%; p < 0.001), GPSIS-Avoidance 1/2 (IXE 76.7%, PBO 25.7%; p < 0.001), and DLQI item 9 0/1 (IXE 92.0%, PBO 56.8%; p < 0.001). IXE was superior to PBO as early as Week 1 for SFQ item 2 0/1 (p < 0.05), Week 2 for DLQI item 9 0/1 (p < 0.001), and Week 4 for GPSIS-Avoidance 1/2 (p < 0.01). GPSIS-Impact 1/2 response rates suggested a trend of reduced impact of sexual activity on GP symptoms (IXE 85.7%, PBO 52.9%; p = 0.062).

**Conclusions:** During 12 weeks of treatment, IXE resulted in a rapid and significant decrease in the impact of GP on sexual activity, including how often GP limited sexual frequency among patients with moderate-to-severe GP.


**P021**

**DOSE OPTIMIZATION OF SECUKINUMAB IN SUBJECTS WITH MODERATE TO SEVERE PLAQUE PSORIASIS: OPTIMISE STUDY**

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**Introduction:** Secukinumab (SEC) is a fully human monoclonal antibody that selectively targets interleukin-17A. After achieving REM or MDA, a decrease of the dose of MTX is possible in most cases.
Introduction: Secukinumab is a fully human monoclonal antibody that selectively neutralizes IL-17A, a key cytokine involved in the development of psoriasis. Heterogeneity in clinical response to targeted therapies such as seukinumab may be addressed by flexible dosing.

Objectives: To compare downtitration of PASI90 responders to 6-weekly and initiation of PASI≥75 to <90 responders to two-weekly seukinumab dosing with standard 4-weekly dosing.

Methods: OPTIMISE was a randomized, multicenter, open-label, rater blinded Phase 3b study. 1647 subjects received seukinumab 300 mg at baseline, Weeks 1, 2, 3 and 4 then 4-weekly to Week 24. At Week 24, PASI90 responders were randomized to seukinumab 300 mg q4w (n = 664) or q6w (n = 662) to Week 52; PASI75 responders were randomized to seukinumab 300 mg q4w (n = 114) or 2-weekly (q2w) (n = 92) to Week 52. Groups were stratified by body weight (<90kg, ≥90kg).

Results: PASI90 response was maintained at Week 52 by 85.7% of subjects with q4w dosing vs 74.9% with q6w dosing; OR 1.91 (95% CI 1.44, 2.55). The primary endpoint, non-inferiority of q6w vs q4w dosing in PASI90 responders, was not met. In PASI75 to <90 responders, 46.5% of subjects achieved PASI90 response by Week 52 with q4w dosing. PASI90 response at Week 52 was numerically higher for q2w compared to q4w dosing (56.5% vs 46.5%), but this difference did not reach statistical significance (p = 0.1013). This numerical benefit of q2w dosing was even higher in subjects weighing ≥90 kg (n = 49; 57.1% vs 39.6%; p = 0.1053). No new or unexpected safety signals were observed.

Conclusions: Non-inferiority of q6w vs q4w dosing cannot be claimed in maintaining PASI90 response achieved at Week 24. Around half of PASI75 to <90 responders at 24 weeks, can achieve PASI90 response with continued q4w dosing. Subjects with higher body weight may benefit from the q2w dosing.

P023

TREATMENT USE AND SATISFACTION AMONG PATIENTS WITH PSORIASIS AND PSORIATIC ARTHRITIS IN SCANDINAVIA

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Introduction: Patients’ perspectives on psoriasis (PsO) and psoriatic arthritis (PsA) treatment are important in establishing better approaches to their care.

Objectives: To assess treatment use and satisfaction among patients with PsO/PsA in Scandinavia.

Methods: NORPAPP was an on-line survey carried out in Nov/Dec 2015 using YouGov panels in Sweden, Denmark, and Norway. Adults with physician-diagnosed PsO or PsA (n = 1221), answered questions about contact with the healthcare system, and treatment experience and satisfaction. Self-perceived disease severity was dichotomised to severe (responses of “quite severe”, “very severe” or “extremely severe”) and non-severe (“not particularly severe” or “not severe at all”).
Results: Among respondents with PsO alone 38.9% had seen a dermatologist in the past year, and 10.7% had never seen a dermatologist; 60.9% of those with PsA+PsO had seen a rheumatologist in the past year; 14.3% had never seen a rheumatologist. Systemic treatments had been used by 14.6% of respondents with PsO alone and 58.5% with PsA+PsO. Respondents with self-perceived severe symptoms and patient organization members (POMs) were more likely than those with non-severe symptoms or non-members, to have discussed systemic treatments with their physician and to have used the treatments; however, 35.2% of respondents with self-perceived severe symptoms had never discussed systemic treatment with their physician. Asked about long-term health risks of systemic treatments, 18–44 year-olds and POMs were less likely to answer “don’t know” than 45–74 year-olds (47.7–49.1% vs 66.7–72.9%) or non-members (26.1–30.7% vs 66.8–70.4%). Biologics had been used by 40.7% of POMs vs 6.9% of non-members, and 21.5% of 18–44 year-olds vs 8.1% of 45–74 year-olds. Among respondents using oral/injectable methotrexate 30.5% were dissatisfied, 60.2% citing side-effects as the reason; 22.9% of biologics users were dissatisfied, 28.9% citing lack of effect and 28.1% citing side-effects.

Conclusion: In Scandinavia POMs and young patients are more likely to receive systematic treatment. A high proportion of patients are dissatisfied with their treatment because of side effects.

P024
FIRST PATIENT-REPORTED INSIGHTS FROM A MULTINATIONAL, RETROSPECTIVE, CROSS-SECTIONAL STUDY OF REAL-WORLD EXPERIENCE OF PSORIASIS PATIENTS TREATED WITH APREMILAST IN CLINICAL DERMATOLOGY PRACTICE (APPRECIATE)
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Introduction: Patient (pt)-centered care is gaining traction in long-term disease management. We report on a multinational, retrospective, cross-sectional study in psoriasis pts treated with apremilast (APR), an oral phosphodiesterase 4 inhibitor, in a real-world clinical setting.

Objectives: The study aims to identify important pt needs and therapeutic benefits of APR.

Methods: Consecutive pts with chronic plaque psoriasis treated according to routine clinical practice who could be contacted 6–1 mo after APR initiation were enrolled. Medical chart review, standardized pt-reported outcome tools (PBI, TSQM-9), and pt/physician questionnaires were used. An interim analysis of the first 104 pts from 40 sites in Germany (42), UK (31), and Sweden (31) was performed using predefined descriptive statistics.

Results: 102 pt questionnaires were analyzed (98%). At 6–1 mo, 74 pts (71%) continued APR; 30 (29%) had discontinued APR (lack of efficacy [14%], safety/tolerability [11%], other [4%]). Assessment of pts’ main needs from a therapy (quite/very important on the PBI) revealed the importance pts attributed to skin involvement (93% of responders), confidence in healing (92%), being itch free (85%), fewer side effects (84%), being able to lead a normal everyday life (83%), and needing less time for daily treatment (80%). Based on a clinically meaningful PBI score ≥1, 78% of pts achieved a benefit with APR after 6 mo. Mean (SD) PBI score was 2.2 (1.3) and increased to 2.5 (1.2) for pts on continued APR at 6 mo vs 1.6 (1.3) for pts who discontinued APR. Pts achieved benefit related to skin involvement (60%), confidence in healing (70%), itch (69%), side effects (60%), being able to lead a normal everyday life (72%), and needing less time for daily treatment (65%). Consistent with phase 3 studies, most frequently reported AEs were diarrhea (19.2%), nausea (16.4%), and headache (11.5%); 25% of pts reported weight loss (no change, 71%; gain, 4%).

Conclusions: This interim analysis indicates main pt needs from a therapy extend beyond skin improvement. Findings indicate APR may address diverse pt needs.

Prior Presentation: EADV 2017

P025
PHYSICIAN- AND PATIENT-REPORTED OUTCOMES WITH APREMILAST FOR PATIENTS WITH PLAQUE PSORIASIS DURING ROUTINE DERMATOLOGY CARE IN GERMANY: A SECOND INTERIM ANALYSIS
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Introduction: LAPIS-PSO is an ongoing, 52-week, prospective, multicenter, observational cohort study in real-world dermatology clinical settings in Germany.

Objectives: To present a 4-month interim analysis of patient (pt)-reported outcomes and efficacy assessments of apremilast (APR) among pts (n = 294; full analysis set [FAS], n = 196) who were continuing APR at 4 mo.

Methods: Physician- and pt-reported outcomes for QOL, treatment effectiveness, and treatment satisfaction were evaluated in pts with psoriasis vulgaris during long-term APR treatment. The primary endpoint at Visit 2 (~4 mo after baseline [BL]) is the proportion of pts who achieve DLQI score ≤5 or improvement from BL in DLQI score ≥5 points.

Results: At BL, mean (SD) age was 51.7 (13.2) years in the FAS; 90 pts (45.9%) were female. At APR initiation, 171 pts (87.3%) had Physician’s Global Assessment of disease severity (PGA) ≥3 and 174 (89.2%) had Patient’s Global Assessment of disease severity (PaGA) ≥3; mean psoriasis-involved BSA was 22.2%, mean pruritus VAS score was 56.6 mm, and mean DLQI score was 14.1. In all, 62.7% of pts had scab PGA (ScPGA) ≥3; 42.5% had palmoplantar PGA (PPPGA) ≥3. Among pts continuing APR at 4 mo, 120/181 (66.3%) achieved DLQI score ≤5 or improvement by ≥5 points. Mean (SD) improvement in BSA was −9.5% (14.91) and mean (SD) percentage improvement in pruritus VAS score was −47.3% (32.29). A total of 32.1% of pts achieved PGA 0 (clear) or 1 (minimal); 32.6% achieved PaGA 0 or 1. NAPSI-50 was achieved by 62.4% (53/85) of pts. In all, 58.4% (87/149) of pts achieved ScPGA 0 or 1 and 69.0% (29/42) had PPPGA 0 or 1. AEs were consistent with the known safety profile of APR.

Eighty pts (27.8%) reported ≥1 AE; 1 AE occurred in ≥5% of pts (diarrhea, n = 21 [7.3%]).

Conclusion: In routine clinical care in Germany, APR treatment outcomes for pts with psoriasis vulgaris, including difficult-to-treat locations such as the nails, scalp, palms, and soles, confirm the broad efficacy of APR observed in clinical trials.

Prior Presentation: AAD 2018
**P026**

**IMPROVEMENTS IN WORK PRODUCTIVITY WITH UP TO 104 WEEKS OF APREMILAST MONOTHERAPY: RESULTS FROM A PHASE 3B, RANDOMIZED, CONTROLLED STUDY IN BIOLOGIC-NAIVE SUBJECTS WITH ACTIVE PSORIATIC ARTHRITIS**

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*Introduction*: PsA patients may have impaired functioning in home or work activities. The phase 3b ACTIVE study assessed efficacy of apremilast (APR) monotherapy in biologic-naive subjects with active PsA who may have had exposure to 1 conventional DMARD.

*Objectives*: Assess work productivity through Wk104.

*Methods*: Subjects were randomized (1:1) to APR 30 mg BID or placebo (PBO). Subjects whose SJC/TJC did not improve ≥10% at Wk16 were eligible for early escape. At Wk24, remaining PBO subjects switched to APR. Work productivity and activity impairment were assessed at baseline (BL) and Wk16 using the WPAI:PsA; WPAI:PsA Absenteeism, Presenteeism, Work Productivity Loss, and Activity Impairment subscale scores range from 0% to 100%; higher scores indicate greater impairment. Work-related subscales were assessed in employed subjects; activity impairment was assessed in all subjects. Correlations were examined at Wk16 between WPAI:PsA subscale and SF-36v2 domain scores (Physical Functioning [PF], Bodily Pain [Pain], and Vitality [VIT]) associations with ACR20 response. Work productivity improvement was assessed to Wk104.

*Results*: BL characteristics were similar between groups. At Wk16, APR improved work productivity and ability to carry out daily activities vs PBO, with greater mean improvements in overall Work Productivity Loss (p = 0.001) and Activity Impairment (p < 0.001). Estimated mean change in Absenteeism score was similar with APR vs PBO (p = 0.679). The Presenteeism score showed significant improvement with APR vs worsening with PBO (−10.8% vs 4.1%; P = 0.002). At Wk16, statistically significant correlations were observed between WPAI:PsA subscale (except Absenteeism) and SF-36v2 domain scores, as were associations with ACR20 response. In subjects randomized to APR at BL, Wk16 improvements were generally maintained to Wk104 in those continuing APR.

*Conclusions*: In biologic-naive subjects with PsA, APR contributed to overall improvement in work productivity at Wk16, which correlated with SF-36v2 PF, Pain, and VIT scores and was associated with ACR20 response; improvements in WPAI:PsA subscale scores were generally maintained to Wk104.

Prior Presentation: EULAR 2018

**P027**

**EXAMINING DISEASE SEVERITY AND SYMPTOM IMPROVEMENT WITH PATIENT AND PHYSICIAN ASSESSMENTS: RESULTS FROM A PHASE IV ANALYSIS OF APREMILAST IN PATIENTS WITH MODERATE PLAQUE PSORIASIS**

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*Introduction*: Psoriasis and psoriatic arthritis (PsA) are associated with high prevalence of obesity and metabolic syndrome. In phase 3 trials, apremilast, an oral PDE4 inhibitor, was efficacious in patients (pts) with moderate to severe plaque psoriasis (ESTEEM 1 and 2 [EST]) and active PsA (PALACE 1–3 [PAL]).

*Objectives*: To explore potential effects of apremilast on metabolic parameters, we assessed weight change and A1c in pts receiving placebo (PBO) or apremilast 30 mg twice daily (APR) in a pooled analysis of EST and PAL.

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Methods: Mean A1c change and mean percent weight change at Wk16 were compared among pts with baseline (BL) A1c <5.7%, 5.7% to 6.4% (prediabetes), and ≥6.5% (diabetes) and between pts reporting/not reporting concomitant insulin use. Spearman rank correlations between percent change from BL in weight and change in A1c at Wk16 were calculated; p < 0.05 was considered significant.

Results: In the pooled EST-PAL population, 2,242 pts (PBO n = 913; APR n = 1,329) received study medication at BL. In all, 230 pts had BL A1c ≥6.5%. At Wk16, A1c change in pts with BL A1c <5.7% was 0.02 with PBO and 0.04 with APR. In pts with BL A1c 5.7% to 6.4%, small changes were observed (PBO −0.07; APR −0.12). Greatest A1c changes were in pts with BL A1c ≥6.5% (PBO −0.08; APR −0.31). At Wk16, mean weight change was 0.11% (PBO) and −1.32% (APR). In pts reporting and not reporting concomitant insulin use, mean weight change was 0.05% and 0.12% with PBO, respectively, and −1.83% and −1.31% with APR. Weight change in pts with BL A1c <5.7%, 5.7% to 6.4%, and ≥6.5% was 0.02%, 0.26%, and 0.11% with PBO, respectively, and −1.24%, −1.35%, and −1.68% with APR. Correlations between changes in weight and A1c were generally low, with greater correlation in APR pts with higher BL A1c. Correlation was statistically significant in APR pts with BL A1c ≥6.5%.

Conclusion: APR, decreases in weight and A1c were greater in pts with higher BL A1c. Pts receiving APR and insulin had weight loss despite the association between insulin use and weight gain. Future studies may be warranted to determine whether reductions in A1c with APR are independent of weight loss.

Prior presentation: AAD 2018

P029

CANADIAN HUMIRA POST-MARKETING OBSERVATIONAL EPIDEMIOLOGICAL STUDY ASSESSING THE EFFECTIVENESS OF ADALIMUMAB VS NON-BILOGIC DMARDS IN PSORIATIC ARTHRITIS (COMPLETE-PSA): 12-MONTH EFFECTIVENESS DATA

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Background: Observational studies comparing the effectiveness of adalimumab (ADA) to non-biologic DMARDs (nbDMARD) in PsA patients failing prior treatment are scarce. COMPLETE-PSA is a Canadian observational study which assessed effectiveness of ADA and non-biological therapies (NSAIDs and DMARDs) among PsA patients failing previous therapy.

Objectives: To describe the baseline (BL) demographic and disease parameters and to compare 12-month real-life effectiveness of patients initiating nbDMARD or ADA.

Methods: Eligible patients eligible are anti-TNFα naïve adults, with active PsA requiring a treatment regimen change, per the treating physician’s judgment. This analysis included patients enrolled during Jul 2011–Jun 2016. Outcome measures analyzed were: DAS28, SF-12, DLQI, presence of extra-articular manifestations (EAMs; enthesis & dactylitis), psoriasis BSA, achievement of modified mMDA (achievement of [i] 4/6 (MDA 1) and [ii] 5/6 following criteria (MDA 2): TJC ≤1, SJC ≤1, BSA ≤3%, pain VAS ≤15mm, PtGA ≤20 and HAQ ≤0.5), modified remission (SJC = 0, TJC = 0, absence of enthesis and dactylitis, BSA ≤3% and HAQ ≤0.5), DAPSA LDA (≤14), and DAPSA remission (REM; ≤4). Analyses were conducted by initial group assignment (intent-to-treat approach).

Results: 406 patients were included (nbDMARD n = 146, ADA n = 260). BL demographics were comparable between treatment groups. However, patients initiating ADA were more likely to be unemployed (47.3% ADA vs 34.9% nbDMARD, p = 0.015), had higher DAS28 (4.8 vs 4.4, p = 0.002) and total DLQI score (6.1 vs 4.3, p = 0.007), and were more likely to have BSA ≥3% (44.6% vs 35.0%, p = 0.063) and high DAPSA disease activity (50.8% vs 32.3%, p = 0.015). A higher proportion of nbDMARD patients had dactylitis (36.1% vs 25.3%, p = 0.023). No differences were observed between groups in enthesis, overall EAMs, or QoL at BL. Following 12 months, mean adjusted DAS28 (2.6 vs 3.4, p < 0.001) and DLQI (2.2 vs 2.9, p = 0.530) scores, but not SF-12, were lower in the ADA group. Furthermore, even though statistical significance was not always met, ADA patients had lower DAPSA score (p = 0.025) (LDA/REM: 64.9% vs 58.6%; REM: 37.7% vs 17.1%), were more likely to be in modified remission (14.7% vs 9.7%, p = 0.311), and to have mMDA (mMDA 1: 15.6% vs 12.6%, p = 0.529; mMDA 2: 17% vs 11.5%, p = 0.253) and BSA <3% (89.3% vs 83.9%, p = 0.207). Also, EAM prevalence decreased in both groups but was significantly lower in the ADA group (17.4% vs 35.8%, p < 0.001). Over time, 9.6% of ADA patients initiated another biologic and 32.2% of patients in the nbDMARD group initiated biologic treatment (p < 0.001).

Conclusions: PsA patients initiating ADA in Canadian routine clinical care have significantly greater BL disease severity compared with those initiating nbDMARDs. However, 12-month ADA treatment resulted in improved disease control and EAMs. DAPSA-REM evaluation seems more sensitive than mMDDA in differentiating both populations.

P030

SECUKINUMAB EFFICACY IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS: META-ANALYSIS OF 4 PHASE 3 TRIALS

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Introduction: Secukinumab (SEC) has exhibited rapid, significant and sustained improvement in the signs and symptoms of psoriatic arthritis (PsA) in 4 Phase 3 studies.1–4 Objective: To report meta-analyzed efficacy results for SEC versus placebo at Weck (Wk) 16 in PsA patients (pts) by prior TNF inhibitor (TNFi) use and with/without concomitant methotrexate (MTX) use from 4 Phase 3 studies: FUTURE 2,3,4,5.

Methods: A total of 2148 pts with active PsA were randomised in FUTURE 2, 3, 4 and 5 studies (397, 414, 341 and 996, respectively). Study designs were described elsewhere.1–4 Assessments included ACR20/50 by prior TNFi use (naive/inadequate response or intolerance [-IR]) and with/without MTX use.

Results: Out of 2049 pts in analysis, 461, 572, 335, and 681 pts received SEC 300mg, 150mg, 150mg without load (NL) and placebo (PBO), respectively. ACR 20/50 responses were improved with SEC vs PBO at Wk 16 in both TNFi-naive/-IR pts and pts with/without concomitant MTX use (Table); improvements were also observed with SEC vs PBO for all other secondary endpoints.

Conclusions: SEC provided improvement in the signs and symptoms of active PsA regardless of previous TNFi therapy or concomitant MTX use. Higher response rates were observed in TNFi-naive pts compared to TNFi-IR pts. SEC 300mg was associated with higher responses compared to 150mg in pts with TNFi-IR and no concomitant MTX use.
Impact of Adalimumab vs. Non-Biologic Treatments on Skin Outcomes of Psoriatic Arthritis Patients: Real-World Data from the Complete Study

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Background: Previous studies have shown the efficacy of anti-TNFα agents in improving nail, skin and joint manifestations of psoriatic arthritis (PsA). However, real-world data on the comparative effectiveness of switching to or adding these agents vs. continuing non-biologic treatments in patients having failed prior non-biologic treatment are necessary to support the integration of treatment algorithms into routine care.

Objectives: The aim of this analysis was to compare the effect of adalimumab (ADA) vs. non-biologic treatments (nbDMARD; NSAIDs and DMARDs) on skin outcomes and patient reported outcomes following initial treatment failure. In addition, the impact of the extent of baseline skin disease on treatment outcomes was examined.

Methods: Patients eligible for COMPLETE PsA are anti-TNFα naïve adults, with active PsA who require change in their treatment regimen, per the judgment of the treating physician. In the current analysis patients enrolled between July 2011 – Jun 2016 who had available information on baseline psoriasis body surface area (BSA) were included. Outcome measures analyzed were: BSA, Dermatology Life Quality Index (DLQI), Short Form Health Survey (SF-12), and the Beck Depression Inventory (BDI). Analyses were conducted by initial group assignment (intent-to-treat approach).

Results: A total of 392 patients were included (ADA n = 249, nbDMARD n = 143). Baseline demographics and disease characteristics were comparable between treatment groups. However, patients initiating ADA were more likely to have BSA≥3% (44.6% vs. 35%, p = 0.063) and had higher DLQI (6.2 vs. 4.3, p = 0.006) scores. No differences were observed in SF-12 physical (PCS) and mental (MCS) component scores at baseline. During treatment, BSA levels significantly improved in both groups but more patients achieved a BSA<3% when treated with ADA vs. nbDMARD both at 6 months (89.7% vs. 80.2%, p = 0.027) and 12 months (89.0% vs. 83.7%, p = 0.222). Furthermore, upon adjusting for baseline scores, patients in the ADA group experienced greater improvements in DLQI (ΔLSM = -1.62, p = 0.004), particularly in the daily activities, leisure, and work/patient reported outcomes following initial treatment failure. In addition, the impact of the extent of baseline skin disease on treatment outcomes was examined.

Conclusions: Patients starting ADA following initial failure of non-biologic treatment in Canadian routine clinical care experience greater benefits in skin outcomes and quality of life compared to switching to different non-biologic treatment. These benefits are particularly evident among patients with more severe skin disease at baseline.
Methods: Data were analyzed from 2 double-blind, phase 3 trials investigating the efficacy and safety of IXE in active PsA patients (pts). For SPIRIT-1 [1] biologic disease-modifying antirheumatic drug-naive pts were randomized to placebo (PBO; \( n = 106 \)) or 80 mg IXE every 4 wks (Q4W; \( n = 107 \)) or every 2 wks (Q2W; \( n = 103 \)) post 160 mg starting dose. Minimal disease activity (MDA), MDA very low disease activity (VLDA), Disease Activity in Psoriatic Arthritis (DAPSA) LDA, DAPSA remission, Psoriatic Arthritis Disease Activity Score (PASDAS) LDA, and PASDAS VLDA composite endpoints were evaluated. Imputation for categorical responses was non-responder imputation. Treatment comparisons (with placebo up to Wk 24) based on the intent-to-treat population were made using a logistic regression model. Data up to Wk52 are summarized.

Results: At Wk 24, percentage of pts achieving MDA (SPIRIT-P1 Q4W: 29.9; Q2W: 40.8; PBO: 15.1; SPIRIT-P2 Q4W: 27.9; Q2W: 31.9; PBO: 3.4), MDA VLDA (SPIRIT-P1 Q4W: 10.3; Q2W: 11.7; PBO: 0.9; SPIRIT-P2 Q4W: 12.3; ILEXQW: 3.3; PBO: 0.8), DAPSA LDA (SPIRIT-P1 Q4W: 31.8; Q2W: 34.0; PBO: 17.9; SPIRIT-P2 Q4W: 25.4; Q2W: 27.6; PBO: 11.1), DAPSA remission (SPIRIT-P1 Q4W: 15.9; Q2W: 24.3; PBO: 4.7; SPIRIT-P2 Q4W: 14.8; Q2W: 7.3; PBO: 0.8), PASDAS LDA (SPIRIT-P1 Q4W: 42.1; Q2W: 50.5; PBO: 18.9; SPIRIT-P2 Q4W: 39.3; Q2W: 35.0; PBO: 6.8), and PASDAS VLDA (SPIRIT-P1 Q4W: 11.2; Q2W: 20.4; PBO: 1.9; SPIRIT-P2 Q4W: 13.1; Q2W: 7.3; PBO: 0.0) was greater with Q4W and Q2W versus placebo. Similarly, at Wk 52 the response rates were either sustained or improved: MDA (SPIRIT-P1 Q4W: 39.3; Q2W: 36.9; SPIRIT-P2 Q4W: 34.4; Q2W: 23.6), MDA VLDA (SPIRIT-P1 Q4W: 14.0; Q2W: 15.5; SPIRIT-P2 Q4W: 12.3; Q2W: 6.5), DAPSA LDA (SPIRIT-P1 Q4W: 30.8; Q2W: 29.1; SPIRIT-P2 Q4W: 34.4; Q2W: 26.0), DAPSA remission (SPIRIT-P1 Q4W: 22.4; Q2W: 29.1; SPIRIT-P2 Q4W: 18.9; Q2W: 11.4), PASDAS LDA (SPIRIT-P1 Q4W: 43.0; Q2W: 50.5; SPIRIT-P2 Q4W: 45.1; Q2W: 30.9), and PASDAS VLDA (SPIRIT-P1 Q4W: 17.8; Q2W: 26.2; SPIRIT-P2 Q4W: 17.2; Q2W: 11.4).

Conclusions: Regardless of previous TNFi exposure, a higher proportion of IXE-treated pts achieved MDA and MDA VLDA, DAPSA LDA and DAPSA remission, and PASDAS LDA and PASDAS VLDA at Wk 24 versus placebo. At Wk 52, the effect of IXE clinical response sustained or further improved.

Reference:

P035

THE MACROPHAGE MODULATOR MP1032 SHOWS SAFETY AND EFFICACY IN A HUMAN PHASE IIA STUDY FOR THE TREATMENT OF MODERATE-TO-SEVERE PLACQUE PSORIASIS

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Introduction: MP1032 belongs to a new class of anti-inflammatory drugs that modulate the redox state of activated macrophages. MP1032 attenuates pro-inflammatory cytokine secretion in vivo and in vitro and has pronounced disease-modifying effects in various preclinical models.

Objectives: This randomized, double-blind, parallel, and placebo-controlled trial aimed to evaluate pharmacokinetics, safety, and efficacy of orally administered MP1032 in patients with moderate-to-severe plaque psoriasis.

Methods: Forty-six patients with chronic plaque psoriasis (PASI > 10; disease duration ≥ 6 months) were equally randomized to receive either 100 mg MP1032 or placebo by twice daily oral administration. The study design consisted of a 42 day treatment period with a follow-up of 28 days. Pharmacokinetic sampling occurred on day 1 at 15, 30, 60, and 120 min post-dose. Adverse events were coded according to the Medical Dictionary for Regulatory Activities. Efficacy parameters were assessed at screening and on day 1, 15, 29, 43, 57, and 71.

Results: Enrolled patients had an average age of 41 years (21–65 years) and a median baseline PASI of 13.6 (range from 10.1 to 40.8). Pharmacokinetic evaluation demonstrated that MP1032 was rapidly absorbed, reaching maximum plasma concentrations within 15 min after administration. Then, MP1032 plasma levels were quickly declining, indicating a fast elimination. Safety analysis did not reveal any clinically important safety issues. No serious adverse events or deaths were reported and the incidence of treatment emergent adverse events (TEAEs) between placebo and the MP1032 treatment group was comparable. The majority of TEAEs were mild to moderate in nature (mostly common cold, headache, and itching). Analysis of clinical laboratory data and vital signs did also not reveal any adverse effects of MP1032. After only six weeks of treatment, MP1032 led to a PASI reduction of about 25% in patients who entered the study with a PASI of 10–15.

In contrast, placebo administration reduced the respective PASI score only about 12%. During the four-week follow-up period, median PASI scores in the MP1032 group trended back upward while the placebo group remained unchanged, suggesting a positive therapeutic effect of MP1032. Since, patients with a lower basal PASI had greater improvements during therapy than those with higher scores, MP1032 seems to be a treatment option for patients with mainly moderate psoriasis.

Conclusion: After six weeks of treatment, there was a clinically relevant response in patients who entered the study with PASI scores of 10–15. Overall, MP1032 demonstrated an excellent safety profile and was well tolerated. Hence, redox modulation targeted at the innate immune response represents a promising new therapeutic mechanism for psoriasis and other chronic inflammatory diseases.

P036

SECUKINUMAB IMPROVES SIGNS AND SYMPTOMS OF PSORIATIC ARTHRITIS: RESULTS FROM A PHASE 3 STUDY, FUTURE 5

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Introduction/Objectives: Secukinumab (SEC), a fully human mAb to IL-17A, has shown efficacy in psoriatic arthritis (PsA). Here we present the primary results of FUTURE 5, assessing efficacy, including inhibition of radiographic progression of subcutaneous (sc) SEC 300 and 150mg in patients (pts) with PsA (1).

Methods: Pts (\( n = 996 \)) with active PsA were randomized (2:2:2:3) to sc SEC 300mg with loading dosage (LD; \( n = 222 \)), 150mg with LD (\( n = 220 \)), 150mg without LD (\( n = 222 \)), or placebo (PBO; \( n = 332 \)). All groups received SEC or PBO at baseline (BL), Weeks (Wks) 1, 2, 3, and 4, and then every 4 wks. Primary endpoint was ACR20 at Wk16. Key secondary endpoint was radiographic structural progression, as measured by modified total van der Heijde Sharp score (mTSS).

Results: SEC significantly improved ACR20 at Wk16 vs PBO.
P037
INCIDENCE OF INFLAMMATORY BOWEL DISEASE IN PATIENTS TREATED WITH SECUKINUMAB: POOLED ANALYSIS OF 21 RANDOMISED CONTROLLED PHASE 3/4 CLINICAL TRIALS OF PSORIASIS, PSORIATIC ARTHRITIS, AND ANKYLOSING SPONDYLITIS

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Introduction: Inflammatory bowel disease (IBD) including Crohn’s disease (CD) and ulcerative colitis (UC) are common comorbidities associated with psoriasis, psoriatic arthritis (PsA), and ankylosing spondylitis (AS). Compared with the general population, epidemiological studies have shown that patients (pts) with psoriasis or PsA are at a 2–4-fold increased risk of developing CD and a 2–3-fold increased risk of developing UC.1–5 Additionally, in pts with AS, there is a 3–5-fold increased risk of IBD compared with the general population.6 Secukinumab is a fully human monoclonal antibody that neutralizes interleukin-17A and is approved for the treatment of psoriasis, PsA, and AS.

Objectives: To evaluate the incidence of IBD, CD, and UC in pts with psoriasis, PsA, or AS who received IL-17A-inhibition with secukinumab from 21 phase 3/4 clinical trials of secukinumab for psoriasis, PsA, or AS.

Methods: This analysis evaluated pooled data from fourteen phase 3 and one phase 4 psoriasis trials, three phase 3 PsA trials, and three phase 3 AS trials. Pts with a history of IBD, but not active ongoing IBD, were eligible for enrollment in these trials. Data from all pts that received at least one dose of secukinumab were included in this analysis. IBD reporting includes cases of CD, UC, and IBD not otherwise specified (NOS).

Results: A total of 7355 pts receiving secukinumab were assessed for the presence of IBD: 5181 with psoriasis, 1380 with PsA, and 794 with AS. Over the entire treatment period, the mean total exposure to secukinumab was 10,416.9 patient-years (pt-yrs) in pts with psoriasis, 3866.9 pt-yrs in pts with PsA, and 1943.1 pt-yrs in pts with AS. The exposure-adjusted incidence rate (EAIR) per 100 pt-yrs (95% confidence interval) of CD, UC, and IBD NOS in secukinumab-treated pts were 0.05 [0.02, 0.07], 0.13 [0.07, 0.23], and 0.01 [0.00, 0.05], respectively in the psoriasis studies; 0.08 [0.02, 0.23], 0.08 [0.02, 0.23], and 0.05 [0.01, 0.19], respectively in the PsA studies; and 0.4 [0.2, 0.8], 0.2 [0.1, 0.5], and 0.1 [0.0, 0.3], respectively in the AS studies. Additionally, the incidence of IBD, CD, and UC did not increase over time.

Conclusion: Pooled data from 21 studies indicated that the observed exposure-adjusted incidence rates of IBD, CD, and UC were similar in secukinumab treatment and did not increase over time in pts with moderate to severe plaque psoriasis, PsA, or AS.

References:

P038
ANALYSIS OF THE POSITION OF THE FUMARIC ACID ESTERS IN CURRENT EUROPEAN PSORIASIS GUIDELINES

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Introduction: Since 1994 a combination of fumaric acid esters (FAEs) (dimethylfumarate [DMF] plus three salts of monoeethylfumarate [MEF]) has been approved in Germany for moderate-to-severe psoriasis, however it is not widely licensed elsewhere. While a new formulation of DMF has been recently approved by the European Commission (June 2017) as monotherapy for adults with moderate-to-severe psoriasis, only UK (NICE) guidelines mention DMF to date.1

Method: Current treatment guidelines for plaque psoriasis in several European countries are reviewed to determine if these guidelines include therapy with FAEs and how these may guide the use of DMF monotherapy in the future.

Results: FAE status varies across Europe. Current European guidelines recommend FAEs for the initial and long-term treatment of psoriasis. These guidelines (based on consensus/expert opinion) also recommend a gradual increase in dose.2 Country-specific guidelines vary in their individual recommendations. German guidelines endorse FAEs as 1st-line treatment for moderate-to-severe psoriasis, based on BSA > 10% or a PASI score of > 10, and recommend clinical assessments after 16–24 weeks of treatment.[3] UK guidelines approve FAEs only as a 2nd-line option for severe plaque psoriasis (PASI ≥10 or DLQI ≥10),[1] whilst in the Netherlands FAEs are indicated only for initial treatment of moderate-to-severe disease.[4] Swiss guidelines also recommend the use of FAEs for moderate-to-severe psoriasis, but only in patients who are unresponsive to topical therapy.[5] In Sweden, FAEs can be considered as a 2nd-line treatment option.[6]

Other country-specific guidelines are less clear. While Spanish guidelines discuss FAEs as a slower-acting therapy requiring treatment goals to be set at week 16, no specific guidance on the use of FAEs is given.[7] Likewise, while Italian guidelines mention FAEs, they are not included in treatment recommendations as they are currently not licensed in Italy.[8] In contrast, there is no mention of FAEs in guidelines in Denmark, Portugal and Norway.

Conclusion: European guidelines recommend FAEs for both the...
initial and long-term treatment of moderate-to-severe psoriasis. In Germany, FAEs have been licensed for >20 years and are commonly used as 1st-line therapy. In the rest of Europe, there is growing acceptance of FAEs as a systemic therapy option in moderate-to-severe disease. Guidelines continue to evolve as experience grows outside Germany, and will need to be updated to guide the use of the newly approved DMF monotherapy in future.

References:

P041
LONG-TERM SAFETY OF ADALIMUMAB (HUMIRA) IN ADULT PATIENTS FROM GLOBAL CLINICAL TRIALS ACROSS MULTIPLE INDICATIONS: AN UPDATED ANALYSIS IN 29,987 PATIENTS REPRESENTING 56,951 PATIENT-YEARS
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Introduction: Adalimumab is an anti–tumor necrosis factor-α (TNF-α) agent indicated for the treatment of immune-mediated diseases. The long-term safety of adalimumab was previously reported in 23,458 patients representing up to 12 years of clinical trial exposure in rheumatoid arthritis (RA), juvenile idiopathic arthritis, ankylosing spondylitis, peripheral arthritis, plaque psoriasis (Ps), and Crohn’s disease (CD).
Objectives: Here we report an updated analysis examining the long-term safety of adalimumab in adult patients with RA, AS, non-radiographic axial spondylarthropathies (nr-axSpA), peripheral SpA (pSpA), PsA, Ps, hidradenitis suppurativa (HS), CD, ulcerative colitis (UC), and non-infectious uveitis (UV).
Methods: Data from 78 clinical trials of adalimumab (RA, AS, 33; AS, 5; nr-axSpA, 2; pSpA, 1; PsA, 3; Ps, 13; HS, 3; CD, 11; UC, 4; UV, 2; other, 1) were included in these analyses, including randomized controlled, open-label, and long-term extension studies conducted in Europe, North America, South America, Asia, Australia, New Zealand, and South Africa through December 31, 2016. Adalimumab postmarketing surveillance data were not included in this analysis. Safety assessments included all adverse events (AEs) and serious AEs (SAEs) that occurred after the first adalimumab study dose and up to 70 days (5 half-lives) after the last study dose.
Results: This analysis included 29,987 patients, representing 56,951 patient-years of exposure. The majority of adalimumab exposure was in RA studies (37,106 PYs). The most frequently reported SAE of interest was infection (highest incidences in CD: 6.9, UV: 4.1, RA: 3.9, and UC: 3.5). The overall standardized mortality ratio was 0.65, 95% CI [0.5, 0.74]. For most of the adalimumab populations (AS, PsA, Ps, UC, CD, and RA), the observed number of deaths was below what would be expected in an age- and sexadjusted population. For HS, nr-axSpA, pSpA, and UV studies, the small size of these trials precluded accurate assessment of the standardized mortality ratio, and the 95% CIs all included 1.0.
Conclusion: This analysis of data from clinical trials of adalimumab demonstrated an overall safety profile consistent with previous findings and with the TNF inhibitor class. No new safety signals or tolerability issues with adalimumab treatment were identified and, for most indications, the mortality rate was below what would be expected in an age- and sexadjusted population. Efficacy and safety data continue to support the well-established benefits of adalimumab for the approved indications.
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References:
**P042**

**CLINICAL RESPONSE AFTER GUSELKUMAB TREATMENT AMONG ADALIMUMAB PASI 90 NON-RESPONDERS: RESULTS FROM THE VOYAGE 1 AND 2 TRIALS**

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**Objective:** To evaluate the levels of response to guselkumab (GUS) among adalimumab (ADA) PASI 90 non-responders in the VOYAGE 1 and VOYAGE 2 trials.

**Materials/Methods:** In VOYAGE 1 (n = 837), patients were randomized to GUS 100 mg at Weeks (Wks) 0/4/12, then every 8 wks; placebo (PBO) at Wks 0/4/12 followed by GUS 100 mg at Wks 16/20 and then every 8 wks; or ADA 80 mg at Wk 0, 40 mg at Wk 1, and 40 mg every 2 wks through Wk 47. In VOYAGE 2 (n = 992), patients were randomized to GUS 100 mg at Wks 0/4/12/20; PBO at Wks 0/4/12 then GUS 100 mg at Wks 16/20; or ADA 80 mg at Wk 0, 40 mg at Wk 1, and then every 2 wks through Wk 23. ADA PASI 90 non-responders initiated GUS at Wk 52 (VOYAGE 1) or at Wk 28 (VOYAGE 2) and continued GUS treatment through Wk 100. Here we report PASI 100, PASI 90, IGA 0 (cleared) and IGA 0/1 (cleared/minimal disease), Dermatology Quality of Life Index (DLQI), and Psoriasis Symptom and Sign Diary (PSSD) outcomes across these ADA PASI 90 non-responders after initiating GUS treatment through Wk 100.

**Results:** In VOYAGE 1, among 138 ADA-treated PASI 90 non-responders who initiated GUS treatment at Wk 52, a PASI 90 response was achieved by 75.0% of patients at Wk 76, and 72.6% of patients at Wk 100. At Wk 100, 78.5% of patients achieved an IGA 0/1 response, 74.8% of patients reported a DLQI 0/1 score, 33.3% of patients reported a PSSD symptom score of 0, and 18.9% reported a PSSD sign score of 0. In VOYAGE 2, among 112 ADA-treated PASI 90 non-responders who initiated GUS at Wk 28, a PASI 90 response was achieved by 66.1% of patients at Wk 48 and 75.5% of patients at Wk 100. At Wk 100, 81.0% of patients achieved an IGA 0/1 response, 65.3% of patients reported a DLQI 0/1 score, 32.6% of patients reported a PSSD symptom score of 0, and 18.0% reported a PSSD sign score of 0.

**Conclusions:** Among ADA PASI 90 non-responders, GUS treatment provided robust levels of efficacy, which were maintained through Wk 100.

**P043**

**CONSISTENCY OF RESPONSE BY WEIGHT ACROSS SUBGROUPS OF PATIENTS WITH PSORIASIS TREATED WITH GUSELKUMAB: RESULTS FROM THE VOYAGE 1 AND 2 TRIALS**

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**Objective:** To evaluate the consistency of response of guselkumab (GUS) across predetermined weight quartile subgroups of psoriasis patients.

**Materials/Methods:** In VOYAGE 1 (n = 837) and VOYAGE 2 (n = 992), patients were randomized to GUS 100 mg at Weeks 0/4/12/20; placebo (PBO) at Weeks 0/4/12 followed by GUS 100 mg at Weeks 16/20; or ADA 80 mg at Week 0, 40 mg at Week 1, and 40 mg every 2 weeks through Week 23. The co-primary endpoints were the proportions of GUS vs PBO patients achieving: 1) ≥90% improvement in PASI score (PASI 90), and 2) cleared/minimal disease (IGA 0/1) responses at Week 16. Response rates across endpoints were evaluated for predetermined subgroups by baseline weight quartiles.

**Results:** Pooled data from the two studies at Week 16 and Week 24 demonstrated that patients in the guselkumab group achieved substantially higher clinical responses compared with placebo at Week 16 and ADA at Week 24 across all quartiles of weight as cutoffs. At Week 16, for each quartile, defined by <74.6, ≥74.6–<86.4, ≥86.4–<100, and ≥100 kg, the proportions of GUS patients with a PASI 90 response were 76.0%, 78.6%, 66.2%, and 65.2%, respectively and the proportions with an IGA 0/1 response were 89.1%, 88.6%, 78.7%, and 82.6%, respectively. The proportions of PBO patients with a PASI 90 response by these quartiles were 5.0%, 2.9%, 1.2%, and 0.9%, respectively and the proportions with an IGA 0/1 response were 11.6%, 10.5%, 4.9%, and 3.5%, respectively.

At Week 24, the proportions of GUS patients with a PASI 90 response by weight quartile were 79.7%, 81.1%, 75.1%, and 73.4%, respectively and the proportions with an IGA 0/1 response were 85.9%, 88.1%, 83.1%, and 78.3%, respectively. The proportions of ADA patients with a PASI 90 response by these quartiles were 62.4%, 66.0%, 52.7%, and 35.5%, respectively and the proportions with an IGA 0/1 response were 70.9%, 76.5%, 61.1%, and 45.2%, respectively.

**Conclusions:** The efficacy of GUS treatment was demonstrated across all predefined weight quartiles and high efficacy responses were observed in psoriasis patients without regard to weight.

**P044**

**IMPACT OF CLINICAL SPECIALTY SETTING ON DISEASE MANAGEMENT IN PATIENTS WITH PSORIATIC ARTHRITIS**

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**Introduction:** Evidence suggests that timely and effective management can improve long-term outcomes in patients (pts) with psoriatic arthritis (PsA); however factors influencing treatment management decisions are not well understood.

**Objective:** To evaluate the association between the clinical specialty setting and time from inflammatory musculoskeletal symptom onset to PsA diagnosis and to different management steps in pts with a diagnosis of PsA.

**Methods:** LOOP is a large cross-sectional, multi-center, observational study conducted in 17 countries across Western and Eastern Europe, Latin America, and Asia. Adult pts (≥18 years) with a suspected or an established diagnosis of PsA routinely visiting a rheumatologist (rheum), dermatologist (derm) or non-rheum/non-derm site were eligible to participate in this study. Each enrolled patient in the study was assessed by both rheum and derm. Main endpoints assessed were time from inflammatory musculoskeletal symptom onset to PsA diagnosis, time from PsA diagnosis to first csDMARD and to first bDMARD, and time from first csDMARD to first bDMARD.

**Results:** Of the 1483 pts enrolled in this study, 1273 pts with a confirmed diagnosis of PsA were included in this analysis. A ma-
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SPEED OF RESPONSE OF GUSELKUMAB COMPARED WITH ADALIMMUB FOR THE TREATMENT OF MODERATE-TO-SEVERE PSORIASIS: RESULTS THROUGH WEEK 24 FROM THE PHASE 3, DOUBLE-BLINDED, PLACEBO- AND ACTIVE COMPARATOR-CONTROLLED VOYAGE 1 AND VOYAGE 2 TRIALS
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Background: VOYAGE 1 and 2 were two phase 3 double-blinded, placebo/active comparator-controlled trials evaluating guselkumab (GUS), a fully human monoclonal antibody targeting interleukin (IL)-23, compared with adalimumab (ADA) in the treatment of patients with moderate-to-severe plaque psoriasis. Here, we report speed of response results based on Psoriasis Area and Severity Index (PASI) outcomes through Week 24 from pooled VOYAGE 1 and 2 data.

Methods: In VOYAGE 1 and 2, patients with plaque psoriasis were randomized at baseline to GUS 100 mg (Weeks 0 and 4, then every 8 weeks [q8w]; pooled n = 825), ADA (80 mg Week 0, 40 mg Week 1, then 40 mg every 2 weeks [q2w]; pooled n = 582), or placebo (Weeks 0, 4, and 12, then GUS 100 mg at Weeks 16 and 20; pooled n = 422). Efficacy was evaluated using PASI 75, PASI 90, and PASI 100 responses (patients achieving ≥75%, ≥90%, and 100% PASI improvement from baseline, respectively) through Week 24. Median time to achieve a response was defined as the time taken for ≥50% of the patients to ever achieve a response.

Results: Based on the pooled VOYAGE 1 and 2 data, median time to achieve a PASI 75 response was ≤8 weeks for both the GUS and ADA groups. However, median time to achieve a PASI 90 response was ≤12 weeks for GUS and ≤16 weeks for ADA. Median time to achieve a PASI 100 response was ≤24 weeks for GUS, but was not achieved for ADA. Median time to achieve any defined endpoint was not achieved for the placebo group.

Conclusions: Taken together, these results demonstrate that patients with moderate-to-severe psoriasis treated with GUS rapidly achieved high levels of response, and more efficiently and more quickly than with ADA.
Objective: To assess the proportion of pts treated with secukinumab (SEC) reaching DAPSA remission (REM) or low disease activity (LDA) and those who reached either MDA or very low disease activity (VLDA) at Weeks (wks) 16 and 104 in the FUTURE 2 study (2).

Methods: DAPSA-REM, DAPSA-REM/LDA, MDA, and VLDA and their core components were assessed in the overall population and in pts stratified by prior anti-TNF use (TNF-Naïve/IR) and time since first PsA diagnosis (<2 vs ≥2 years) using as observed data. Results: At Wk16, in the overall population, the proportion of pts treated with SEC 300/150 mg achieving remission was 14%/10% (DAPSA-REM) and 8%/6% (LDA) and achieving LDA was 42%/44% (DAPSA-REM/LDA) and 28%/33% (MDA). A higher proportion of anti-TNF-naïve pts and pts with early diagnosis (<2 years) treated with SEC achieved and sustained DAPSA-REM/ LDA and MDA than in the overall population (Table). DAPSA-REM/LDA and MDA responses with SEC were sustained through Wk104.

Conclusions: In the overall population, a higher proportion of SEC treated pts at Wk16 achieved DAPSA-REM, VLD A, DAPSA-REM/LDA, and MDA than those treated with placebo with a greater number of pts achieving DAPSA-REM or LDA than VLD A or MDA, respectively. These responses were sustained through Wk104.

References:

Table.

<table>
<thead>
<tr>
<th>% Response</th>
<th>DAPSA-REM/ LDA</th>
<th>MDA</th>
<th>DAPSA-REM/ LDA</th>
<th>MDA</th>
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</thead>
<tbody>
<tr>
<td>TNF-Naïve/IR</td>
<td>≤2 years</td>
<td>&lt;2 years</td>
<td>MDA &gt; 2 years</td>
<td>LDA</td>
</tr>
<tr>
<td>Wk16 300 mg</td>
<td>52/22</td>
<td>34/15</td>
<td>3/40</td>
<td>43/25</td>
</tr>
<tr>
<td>Wk104 150/300 mg</td>
<td>32/8</td>
<td>42/45</td>
<td>27/28</td>
<td>21/24</td>
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<tr>
<td>Placebo</td>
<td>14/3</td>
<td>17/19</td>
<td>7/12</td>
<td></td>
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<tr>
<td>300 mg</td>
<td>75/46</td>
<td>49/23</td>
<td>63/96</td>
<td>33/45</td>
</tr>
</tbody>
</table>

Total number of pts providing data to the analysis: secukinumab 300 mg (n=1000), 150 mg (n=100) and placebo (n=98).

P048

PREDICTORS OF RESPONSE TO TILDRAKIZUMAB FOR MODERATE TO SEVERE CHRONIC PLAQUE PSORIASIS

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Introduction: Efficacy of tildrakizumab (TIL), a high affinity, humanized, immunoglobulin G1x monoclonal antibody against interleukin-23p19, has been evaluated for chronic plaque psoriasis (PsO) in 2 phase 3 randomized controlled trials. Objective: The aim of our analysis was to determine predictors of response to TIL treatment in the 2 trials. Methods: Patients (pts) with moderate to severe PsO were randomized in reSURFACE 1 (phase 3; NCT01722331) and reSURFACE 2 (phase 3; NCT01722954) [1]. In Part 1 (Week [W]1–W12), pts received subcutaneous TIL 200 mg, TIL 100 mg, or placebo (PBO) at W0 and W4. Pts receiving PBO in Part 1 were rerandomized to TIL 200 mg or 100 mg in Part 2 (W12–W28). For each trial, continuous variables of mean baseline Psoriasis Area and Severity Index (PASI), body mass index (BMI), Physician’s Global Assessment (PGA), and PASI component for head region as well as dichotomous variables of baseline PASI > 20 or ≤ 20 and PASI 50 response or nonresponse at W8 were evaluated as predictors of response. Response was defined in this analysis as PASI 50 or PASI 90 at W12 and W28. Results: None of the continuous variables appeared to be consistently predictive of PASI 50 or PASI 90 response, nor were baseline PASI > 20 or ≤ 20 definitive predictors of response. PASI 50 response vs nonresponse at W8 with TIL 200 mg appeared to be predictive of a PASI 50 response at W12 (percentage of patients: SD: 98%/±0.9% vs 59%/±6.1%, respectively, in reSURFACE 1, and 99%/±0.8% vs 57%/±5.7%, respectively, in reSURFACE 2) and of a PASI 90 response at W12 (47%/±3.3% vs 0%/±0%, respectively, in reSURFACE 1, and 50%/±3.5% vs 5%/±2.6%, respectively, in reSURFACE 2). The percentage of patients with PASI 50 vs nonresponse at W8 with TIL 200 mg who achieved PASI 50 by W28 was 99%/±0.6% vs 90%/±3.8%, respectively, in reSURFACE 1, and 99%/±0.8% vs 86%/±4.0%, respectively, in reSURFACE 2; the percentage who achieved PASI 90 by W28 was 70%/±3.1% vs 23%/±5.4%, respectively, in reSURFACE 1, and 70%/±3.1% vs 21%/±4.7%, respectively, in reSURFACE 2. Similar trends in predictive responses were observed with TIL 100-mg treatment. Conclusions: Achievement of PASI 50 by W8 was predictive of a PASI 50 and PASI 90 response at W12 and W28. Most of the patients who had not achieved PASI 50 by W8 were able to achieve a PASI 50 response by W28. Baseline PASI score, PGA, and BMI were not predictive of PASI 50 or PASI 90 response.

Reference:

Acknowledgements: The studies were funded by Merck Sharp & Dohme, Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA. Analyses were presented at the American Academy of Dermatology Annual Meeting, February 16–20, 2018, San Diego, CA, USA.

P049

LONG-TERM EFFICACY OF GUSELKUMAB TREATMENT AFTER DRUG WITHDRAWAL AND RETREATMENT IN PATIENTS WITH MODERATE-SEVERE PLAQUE PSORIASIS: RESULTS FROM VOYAGE 2

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Objective: To report long-term efficacy of guselkumab (GUS) after drug withdrawal and retreatment in patients with moderate-severe psoriasis (PsO) in the Phase 3 VOYAGE 2 study. Methods: At Wk28, patients initially randomized to GUS who achieved a PAS190 response were re-randomized to either PBO/withdrawal (with retreatment upon loss of ≥50% PASI improvement achieved at Wk28 or at Wk72 if retreatment criteria were not met) or continued GUS treatment through Wk72. Results: Among 375 patients initially randomized to GUS who achieved a PAS190 response at Wk28, 182 were re-randomized to PBO/withdrawal and 193 to GUS/maintenance treatment. Efficacy for the continued GUS treatment group was maintained through Wk72, while responses for the withdrawal group diminished, with PAS190 responses of 86.0% vs 11.5% respectively at W28.
Wk72. Among the 182 patients in the withdrawal arm, 117 were retreated with GUS prior to Wk72; 56 did not meet retreatment criteria and initiated retreatment at Wk72 per protocol. Of 173 patients retreated, 87.6% achieved PASI90 within 6 months of commencing retreatment. No new safety signals were observed with GUS withdrawal and retreatment through Wk100. Maintenance of PASI90 response after drug withdrawal was associated with continued suppression of IL-17A, IL-17F, & IL-22, while loss of response was associated with increased levels of these circulating cytokines. 

Conclusion: Superior maintenance of high efficacy response rates was achieved with continuous GUS treatment vs withdrawal, and the majority of retreated patients achieved PASI90. Maintenance of PASI90 after drug withdrawal was associated with continued suppression of IL-17A, IL-17F, and IL-22.

P050 OUTCOMES ASSOCIATED WITH ACHIEVEMENT OF VARIOUS TREATMENT TARGETS IN PATIENTS WITH PSORIATIC ARTHRITIS RECEIVING ADAHUMAB

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Background: Various instruments are currently used for disease activity and outcome assessment in psoriatic arthritis (PsA). Some measures attempt to incorporate the total spectrum of psoriatic disease manifestations [eg, minimal disease activity (MDA)] while others focus on arthritis assessments [eg, disease activity index for PsA (DAPSA)]. Whether in patients (pts) with PsA it is sufficient to primarily consider joint disease aspects remains unclear.

Objective: To compare DAPSA remission and low disease activity (LDA) with MDA and very low disease activity (VLDA) for the presence of residual abnormalities of the respective composing variables.

Methods: This post hoc analysis included pts with PsA receiving adalimumab (ADA) in one of two multicenter studies: ADEPT was a 24-week (wk), randomized, double-blind, placebo-controlled trial; ACCLAIM was a 12-wk, open-label study conducted in Canada in care settings that reflected usual practice. Frequencies of DAPSA remission/LDA and MDA/VLDA were summarized, and the individual PsA manifestations within these states were assessed. DAPSA was summed from the following continuous variables: swollen (66) and tender (68) joints, pt global assessment (PGA, cm), pt pain (PP, cm), and C-reactive protein (CRP, mg/dL). DAPSA remission was defined as ≤4 and DAPSA LDA as >4 and ≤14. MDA criteria were as follows: ≤1 tender, ≤1 swollen joint, ≤1 enthesal point, PP ≤15mm, PGA ≤20mm, HAQ ≤0.5, and PASI ≤3. MDA was calculated as fulfilling 5 of the 7 criteria, and VLDA calculated as fulfilling all 7 criteria. Data were as observed.

Results: Among 151 pts receiving ADA in ADEPT, 33 (22%) each achieved DAPSA remission and LDA at wk 24, and 20 (14%) and 11 (7%) achieved MDA and VLDA, respectively. Pts achieving DAPSA LDA appeared to mirror those in MDA, with the exception of experiencing numerically higher PP, PGA, and PASI scores at wk 24. Pts in DAPSA LDA did experience numerically lower SJC when compared with the MDA achievers, and, like MDA achievers, displayed little residual enthesitis. Only VLDA, but not MDA, could match the stringency of DAPSA remission, a finding that was confirmed through analysis of the ACCLAIM cohort. However, VLDA allowed for numerically higher residual PP and PGA levels when compared with DAPSA remission. Importantly, residual enthesitis did not differ among pts achieving DAPSA remission or VLDA. Irrespective of disease activity assessment, pts receiving ADA displayed little to no radiographic progression.

Conclusions: In the ADEPT and ACCLAIM cohorts, pts who achieved DAPSA remission or VLDA demonstrated similar outcomes with respect to the individual components of both scores, despite the omission of several of these within the DAPSA. Given the DAPSA’s continuous nature, its use may offer a good alternative to fulfillment of the VLDA criteria, but these results require confirmation in different pt populations.


P051 EFFICACY AND SAFETY OF IXEKIZUMAB IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS: THREE YEAR RESULTS FROM A PHASE 3 STUDY (SPIRIT-P1)

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Introduction: Ixekizumab (IXE), an interleukin-17A antagonist, was superior to placebo (PBO) in improving the signs and symptoms of psoriatic arthritis (PsA) at Week 24 in biologic-naïve patients (pts).

Objective: To determine the efficacy and safety of IXE treatment up to 3 years in biologic-naïve pts with PsA.

Methods: In the SPIRIT-P1 Phase 3 trial (NCT01695239), 210 pts were randomized to IXE (80 mg every 4 [Q4W] or 2 [Q2W] weeks), 101 pts to adalimumab (active reference arm), and 106 pts to PBO at Week 0. ADA and PBO patients were re-randomized to IXE at the end of the double-blind treatment period. Ad-hoc efficacy for all pts initially randomized to IXE (intent-to-treat [ITT]) is presented. Modified non-responder imputation (missing data considered non-response for pts discontinued due to lack of efficacy or adverse events [AEs]; multiple imputation for all other missing data) was applied to efficacy response outcomes. Ad hoc safety data, for all pts who received at least one IXE dose during the trial (n = 386), are presented as exposure-adjusted incidence rates (IRs; number of pts with events*100/total pt years [PY]).

Results: Efficacy results are summarized for ITT IXE-treated pts (Table 1). Improvements in ACR (American College of Rheumatology) responses, enthesitis, dactylitis, PASI (Psoriasis Area and Severity Index), and NAPSI (Nail Psoriasis Severity Index) persisted up to 3 years. Safety assessments for all pts initially randomized to IXE or re-randomized to IXE during SPIRIT-P1 are summarized (Table 2). IRs of treatment-emergent AEs (TEAEs) were similar between IXE Q4W and Q2W treatment groups.

Table 1. Efficacy Outcome Measures at Week 156 (ITT IXE-Treated Population)

<table>
<thead>
<tr>
<th></th>
<th>IXE Q4W (n = 107)</th>
<th>IXE Q2W (n = 103)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACR20</td>
<td>69%</td>
<td>62%</td>
</tr>
<tr>
<td>ACR50</td>
<td>51%</td>
<td>56%</td>
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<tr>
<td>ACR70</td>
<td>33%</td>
<td>44%</td>
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<tr>
<td>LEI = 0a</td>
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<td>LDLH = 0b</td>
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<td>69%</td>
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<tr>
<td>PASI75c</td>
<td>63%</td>
<td>69%</td>
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<tr>
<td>PASI90c</td>
<td>51%</td>
<td>65%</td>
</tr>
<tr>
<td>PASI100c</td>
<td>44%</td>
<td>61%</td>
</tr>
<tr>
<td>NAPSI ≤10a</td>
<td>77%</td>
<td>77%</td>
</tr>
</tbody>
</table>

Pts with Leeds Enthesitis Index (LEI) = 0 at baseline. aPts with Leeds Dactylitis Index Basic (LDI-B) > 0 at baseline. bPts with psoriatic lesions >3% of body surface area at baseline. cPts with fingernail psoriasis at baseline.

Table 2.

<table>
<thead>
<tr>
<th></th>
<th>Total IXE Q4W</th>
<th>Total IXE Q2W</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total (n = 195; Mean PY = 450.4)</td>
<td>(n = 191; Mean PY = 442.1)</td>
<td></td>
</tr>
<tr>
<td>TEAEs</td>
<td>169 (37.5)</td>
<td>168 (38.0)</td>
</tr>
<tr>
<td>Serious AEs</td>
<td>38 (8.4)</td>
<td>21 (5.2)</td>
</tr>
<tr>
<td>Serious Infections</td>
<td>8 (1.8)</td>
<td>2 (0.5)</td>
</tr>
<tr>
<td>Discontinued due to AEs</td>
<td>17 (3.8)</td>
<td>23 (5.2)</td>
</tr>
<tr>
<td>Serious infections</td>
<td>14 (0.2)</td>
<td>12 (0.2)</td>
</tr>
<tr>
<td>Infections</td>
<td>111 (24.6)</td>
<td>112 (24.3)</td>
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<tr>
<td>Injection/Site Reactions</td>
<td>40 (8.9)</td>
<td>43 (9.7)</td>
</tr>
<tr>
<td>Hypersensitivities</td>
<td>10 (2.2)</td>
<td>21 (4.7)</td>
</tr>
</tbody>
</table>

*Pts with ≥3 designated AE. Data presented as n (%). For safety analyses, baseline was defined as the time of the first IXE injection. Total PYS is the total time pts were in the treatment period following the first IXE injection. aPt experienced a cerebrovascular accident.

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Conclusion: In pts treated with IXE, improvements in the signs and symptoms of PsA persisted up to 3 years. The safety profile was consistent with previous studies of IXE. Previously presented as Chandran et al. 2018 EULAR Congress. June 13-16th

P052 INCIDENCE OF SERIOUS GASTROINTESTINAL EVENTS AMONG TILDRAKIZUMAB-TREATED PATIENTS WITH PSORIASIS
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Introduction: Tildrakizumab is a high-affinity, humanized, immunoglobulin G1κ monoclonal antibody against interleukin-23p19 for the treatment of chronic plaque psoriasis.

Objectives: We evaluated gastrointestinal (GI) adverse events (AE) and, specifically, cases of inflammatory bowel disease (IBD: ie: Crohn’s disease or ulcerative colitis) in the clinical development program for tildrakizumab.

Methods: Patients with moderate to severe plaque psoriasis were randomized in 3 large clinical trials: P05495 (phase 2; NCT01225731), reSURFACE 1 (phase 3; NCT01722331), and reSURFACE 2 (phase 3; NCT01729754) [1,2]. In this post hoc analysis, we sought to identify serious GI AEs and new-onset or exacerbation of pre-existing IBD from a pooled dataset of tildrakizumab-treated patients from these 3 trials, which followed patients up to 52 (reSURFACE 2) or 64 (reSURFACE 1) weeks. This analysis evaluated patients who received tildrakizumab 100 mg and 200 mg in P05495 and the reSURFACE trials.

Results: In this analysis, we pooled 1911 patients from the 3 trials who received either tildrakizumab 100 or 200 mg. There were no new cases of IBD reported; among 6 patients with a history of IBD randomized to tildrakizumab, none experienced an exacerbation. The numbers (rate per 100 patient-years) of patients with serious GI AEs included abdominal pain, constipation, diverticulum, dyspepsia, gastritis, thrombosed hemorrhoids, esophageal polyph, pancreatitis (1 patient each) among patients treated with tildrakizumab 100 mg and 200 mg (0.43) for tildrakizumab 200 mg. These serious GI AEs included abdominal pain, constipation, diverticulum, dyspepsia, gastritis, thrombosed hemorrhoids, esophageal polyph, pancreatitis (1 patient each) among patients treated with tildrakizumab 100 mg, and abdominal hernia, upper abdominal pain, acute pancreatitis, and salivary gland enlargement (1 patient each) among patients treated with tildrakizumab 200 mg.

Conclusion: In this post hoc analysis of patients from 3 large randomized clinical trials, serious GI AEs were infrequent and there were no new cases of IBD or exacerbations of IBD.

Acknowledgements: The studies were funded by Merck Sharp & Dohme, Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.


P053 DURABLE REDUCTION IN ABSOLUTE PASI WITH CERTOLIZUMAB PEGOL IN PATIENTS WITH CHRONIC PLACQUE PSORIASIS
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Introduction: Certolizumab pegol (CZP), an Fc-free, PEGylated, anti-tumor necrosis factor, has shown efficacy in chronic plaque psoriasis (PASI)[1,2]

Objectives: To assess the proportions of patients (pts) achieving selected PASI thresholds over 48 weeks of CZP treatment.

Methods: Data were pooled from CIMPASI-1 (NCT02326298) and CIMPASI-2 (NCT02326272), ongoing phase 3 trials in adults with moderate to severe PSO ≥6 months (Psoriasis Area Severity Index [PASI] ≥12, ≥10% body surface area affected, physician’s global assessment ≥3/5). Pts were randomized 2:2:1 to CZP 400 mg every 2 weeks (Q2W), 200 mg Q2W (400 mg loading dose [LD] at Weeks 0/2/4), or placebo (PBO). Week 16 PASI 50 responders receiving CZP continued the same dose to Week 48. We present the proportions of patients reaching PASI ≤1, ≤2, and ≤3 at Weeks 16 and 48. Responder rate estimates were calculated using a logistic regression model. Pts not achieving PASI 50 at Weeks 16/24/48 were subsequently classified as non-responders. Other missing data were imputed using multiple imputation (Markov Chain Monte Carlo method).

Results: At Week 0, 175, 186 and 100 pts were randomized to CZP 400 mg Q2W, CZP 200 mg Q2W, and PBO. Baseline mean PASI was comparable across CZP 400 mg Q2W/CZP 200 mg Q2W/PBO pts: 19.6 (SD:7.3)/19.2 (7.2)/18.6 (6.6). At Week 16, PASI ≤1 was achieved by 39.9% pts receiving CZP 400 mg Q2W and 36.2% CZP 200 mg pts, vs 2.6% PBO pts. Similarly, a higher proportion of CZP vs PBO pts achieved PASI ≤2, PASI ≤3 and PASI ≤5 (Table). In CZP-treated pts, PASI was maintained or further reduced to Week 48, with 48.2% CZP 400 mg Q2W pts and 39.9% CZP 200 mg Q2W pts achieving PASI ≤1 after 48 weeks’ treatment (Table).

Conclusions: Higher proportions of CZP vs PBO pts met absolute PASI cut-offs over 16 weeks and response was maintained or further improved to Week 48. Although durability of response was observed with both doses, higher proportions of pts treated with CZP 400 mg Q2W than 200 mg Q2W were able to reach the most stringent cut-offs at Week 48.


Table. Pts achieving absolute PASI cut-offs at Weeks 16 and 48

<table>
<thead>
<tr>
<th>PASI</th>
<th>Week (n = 100)</th>
<th>% (95% CI)</th>
<th>% (95% CI)</th>
<th>% (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤1 16</td>
<td>2.6% (0.0–6.2)</td>
<td>39.9% (29.3–50.4)</td>
<td>36.2% (26.5–45.9)</td>
<td></td>
</tr>
<tr>
<td>48 26</td>
<td>3.0% (1.1–6.0)</td>
<td>48.2% (37.4–59.0)</td>
<td>39.9% (29.5–50.0)</td>
<td></td>
</tr>
<tr>
<td>≤2 16</td>
<td>3.0% (0.0–7.0)</td>
<td>48.2% (37.4–59.0)</td>
<td>39.9% (29.5–50.0)</td>
<td></td>
</tr>
<tr>
<td>48 26</td>
<td>3.0% (1.1–6.0)</td>
<td>48.2% (37.4–59.0)</td>
<td>39.9% (29.5–50.0)</td>
<td></td>
</tr>
<tr>
<td>≤3 16</td>
<td>6.8% (1.0–12.5)</td>
<td>70.5% (59.3–81.6)</td>
<td>65.1% (53.4–76.7)</td>
<td></td>
</tr>
<tr>
<td>48 26</td>
<td>6.8% (1.0–12.5)</td>
<td>70.5% (59.3–81.6)</td>
<td>65.1% (53.4–76.7)</td>
<td></td>
</tr>
<tr>
<td>≤5 16</td>
<td>12.2% (4.3–20.1)</td>
<td>83.0% (74.9–91.1)</td>
<td>77.6% (68.4–86.9)</td>
<td></td>
</tr>
<tr>
<td>48 26</td>
<td>12.2% (4.3–20.1)</td>
<td>83.0% (74.9–91.1)</td>
<td>77.6% (68.4–86.9)</td>
<td></td>
</tr>
</tbody>
</table>

aPts received CZP 400 mg Q2W LD at Weeks 0/2/4. CI: Confidence interval.

P054 RELATIONSHIPS BETWEEN TILDRAKIZUMAB DOSE, EXPOSURE, EFFICACY AND SAFETY IN PSORIASIS

Phase 3 STUDIES
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Introduction: Tildrakizumab (TIL) is a high-affinity, humanized,
anti-interleukin-23p19 monoclonal antibody that demonstrated efficacy in phase 3 trials in moderate to severe chronic plaque psoriasis (reSURFACE 1 [NCT01722331] and 2 [NCT01729754]) [1].

Objective: Here we investigated the relationship between TIL serum concentration, and efficacy and safety outcomes, in reSURFACE 1 and 2.

Methods: Placebo or TIL 100 mg or 200 mg was administered at Weeks 0 and 4, then every 12 weeks. Endpoints included proportion of patients achieving 75% Psoriasis Area and Severity Index (PASI 75) improvement from baseline (PASI 75 responders). Pooled efficacy data for each dose from reSURFACE 1 and 2 were grouped into quartiles based on average (mean) serum TIL concentration during Weeks 0–12 (Cav12). Associations between median Cav12 for each quartile (Q) and TIL dose were analyzed for PASI 75 response at Week 12 and adverse events (AEs).

Results: TIL steady-state concentrations were achieved by Week 16 and were proportional to the dose administered. Median Cav12 (range) for TIL Q1–Q4, respectively, were 4.4 (2.1–5.2), 5.7 (5.2–6.4), 7.0 (6.4–7.8), and 8.7 (7.8–16.1) µg/mL for TIL 100 mg (n = 616) and 8.7 (4.2–10.4), 11.5 (10.4–12.5), 14.1 (12.5–15.5), and 17.3 (15.5–30.6) µg/mL for TIL 200 mg (n = 622). PASI responses were similar for corresponding quartiles across doses, with no relationship between serum concentration and patient response for Q1–Q3. Greater PASI 75 responses were associated with the highest Cav12 (Q4), particularly for TIL 100 mg where 75 rates (95% CIs) were: any event, 352 (250.9), serious AEs, 21 (15.0); and serious infections, 9 (6.4). AE’s were similar to those observed in phase 3 clinical trials of ADA for Ps.

Conclusion: ADA treatment of nail Ps across 52 weeks demonstrated short- and long-term efficacy. No new safety signals were identified in these pts receiving ≥1 dose of ADA.

P056

EIGHT-YEAR INTERIM RESULTS FROM THE ESPRIT 10-YEAR POSTMARKETING SURVEILLANCE REGISTRY OF ADALUMUMAB FOR MODERATE TO SEVERE PSORIASIS

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Introduction: ESPRIT is a 10-year (y) international prospective observational registry evaluating the long-term safety and effectiveness of originator adalumab (ADA) in adult patients (pts) with moderate to severe chronic plaque psoriasis.

Objectives: To determine safety, effectiveness, and pt-reported outcomes (PROs) over an 8-y period from an interim analysis of data collected from the ESPRIT registry.

Methods: ESPRIT enrolled pts who were continuing ADA treatment from a current prescription or previous study participation, or initiating ADA ≤4 weeks of entering the registry. The All-Treated pt population (All-Rx) received at least 1 ADA dose in this registry. Pts were evaluated at 3 and 6 months (mos) post-enrollment, and then every 6 mos for up to 10 y. This interim analysis includes data collected from 26 Sep 2008 through 30 Nov 2016. Incidence rates (IR) for all treatment-emergent adverse events (All-TEAEs) in All-Rx pts are reported as events per 100 pt-ys (E/100PYs) of exposure.

Results: Of the 217 randomized pts, 203 received ≥1 dose of ADA, 188 entered Period B, and 168 completed the trial. Of those receiving continuous ADA treatment for 52 weeks (n = 109), response rates (MI) for key efficacy outcomes at weeks 26 and 52, respectively, were as follows: ≥75% improvement from baseline in modified Nail Ps Severity Index (mNAPSI 75): 47.4% and 54.5%. Physician’s Global Assessment of fingernail Ps of 0 (clear) or 1 (minimal) with ≥2 grades improvement from baseline (PGA-F 0/1): 51.1% and 55.6%. Mean change (improvement) from baseline in Nail Ps pain (numerical rating scale [NRS]): 3.6 and 3.8. Mean change (improvement) from baseline in Nail Ps Physical Functioning Severity score (NPFFS): 3.4 and 3.9. Mean change (improvement) from baseline in Dermatology Life Quality Index score (DLQI): 9.1 and 9.0 (n = 94).

As observed response rates at weeks 26 and 52 respectively, were as follows: mNAPSI 75: 47/88 (53.4%) and 52/80 (65.0%). PGA-F 0/1: 48/88 (54.5%) and 49/80 (61.3%). Mean change (improvement) in baseline in NAPSI pain (NRS): 3.8 (n = 92) and 4.4 (n = 80). Mean change (improvement) from baseline in NPFFS: 3.9 (n = 92) and 4.4 (n = 80). Mean change (improvement) from baseline in DLQI: 9.3 (n = 69) and 9.7 (n = 65).

Adverse events (AEs) per 100 pt years (E/100PYs) in 140.3 PYs were: any event, 352 (250.9), serious AEs, 21 (15.0); and serious infections, 9 (6.4). AE’s were similar to those observed in phase 3 clinical trials of ADA for Ps.

Conclusion: ADA treatment of nail Ps across 52 weeks demonstrated short- and long-term efficacy. No new safety signals were identified in these pts receiving ≥1 dose of ADA.
1.1, serious infections 1.0; non-melanoma skin cancer 0.7; active TB < 0.1; and All-TEAEs leading to death 0.2. Standardized mortality ratio was 0.34 (95% CI, 0.25–0.46), indicating the observed number of deaths was below expected in an age-, sex- and country-matched population. PGA clear/minimal was achieved by 57.0%, 58.7%, 59.1%, 62.6%, 61.9%, 63.8%, 65.5%, and 45.0% of pts at 12, 24, 36, 48, 60, 72, 84, and 96 mos, respectively. In 4202 US pts, mean change from baseline in Dermatology Quality of Life Index, total work productivity impairment, and total activity impairment at 12-mo intervals were -3.1/-5.5/-8.3, -3.2/-5.4/-9.1, -3.3/-5.3/-8.4, -3.5/-5.6/-8.7, -3.9/-5.8/-9.3, -3.7/-6.3/-8.7, -5.1/-9.1/-11.4, and -5.9/-7.5/-13.8.

Conclusions: In this 8-y interim analysis, no new safety signals were observed and safety was consistent with the known safety profile of ADA. The number of TE deaths in the registry was below the expected rate. As-observed effectiveness of ADA and improvement from baseline in PROs were maintained through 96 mos.

P057
DURABILITY OF RESPONSE IN CERTOLIZUMAB PEGOL-TREATED PATIENTS OVER 48 WEEKS IN CIMPASI-1 & 2 TRIALS
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Introduction: Certolizumab pegol (CZP), the only Fe-free, PEGylated, anti-tumor necrosis factor biologic, has shown clinical improvements and a safety profile consistent with the class in adults with chronic plaque psoriasis (PsO).[1,2,3] Objectives: To assess durability to Week 48 of the initial Week 16 clinical response with CZP in PsO patients (pts) in two identical phase 3 trials. Methods: Data were pooled from CIMPASI-1 (NCT02326298) and CIMPASI-2 (NCT02326722), ongoing CZP phase 3 trials in adults with PsO ≥6 months (Psoriasis Area Severity Index [PASI] ≥12, ≥10% body surface area affected, physician’s global assessment [PGA] ≥3/5). Pts were randomized 2:2:1 to CZP 400 mg every two weeks (Q2W), 200 mg Q2W (400 mg loading dose [LD] at Weeks 0/2/4), or placebo (PBO). At Week 16, PASI 50 responders receiving CZP continued the same dose through the maintenance period to Week 48. PASI 50 non-responders at Weeks 32/40/48 were classed as non-responders at subsequent time points. These analyses do not include PBO pts or Week 16 PASI 50 non-responders. We report number needed to treat (NNT) to achieve PASI 75 at Week 16, and PASI 50 at Week 48 in pts who achieved PASI 75 at Week 16. Week 16 NNT, 95% confidence intervals (95% CI) and Week 48 PASI 75 responder rates were estimated using logistic regression in which missing data and patients withdrawn due to relapse (< PASI 50 during the maintenance period) were imputed using multiple imputation (Markov Chain Monte Carlo [MCMC] method). Sensitivity analyses on PASI 75 were conducted using non-responder imputation (NRI). Results: At Week 16, NNT to achieve a PASI 75 response was 1.41 (95% CI: 1.26–1.60) for the CZP 400 mg Q2W dose group and 1.53 (1.35–1.77) for the CZP 200 mg Q2W dose group. Of the pts randomized to CZP 400 mg Q2W and CZP 200 mg Q2W at Week 0 who entered the blinded maintenance phase, 132/149 and 130/150 achieved PASI 75, respectively. Out of Week 16 PASI 75 responders, 98.0% of patients treated with CZP 400 mg Q2W and 87.5% of patients treated with CZP 200 mg Q2W also reported a PASI 75 response at Week 48 (Table). Sensitivity analyses using NRI showed similar trends with both doses, and similar trends were seen in PASI 90 response rates.
Conclusions: These analyses show that patients in both CZP dose groups demonstrate durability of their initial Week 16 high-level response to Week 48, with greatest durability seen in the CZP 400 mg Q2W dose group (98.0% maintenance between Weeks 16 and 48).

Table: Pts achieving PASI 75 at Week 48 among Week 16 PASI 75 responders pooled for CIMPASI-1 and CIMPASI-2

<table>
<thead>
<tr>
<th></th>
<th>CZP 400 mg Q2W</th>
<th>CZP 200 mg Q2Wa</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 16 responders, n</td>
<td>132</td>
<td>130</td>
</tr>
<tr>
<td>Week 48 responders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NNT, % (95% CI)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>98.0% (95.6–100)</td>
<td>87.5% (79.7–95.4)</td>
<td></td>
</tr>
<tr>
<td>NRI, % of Week 16 (n)</td>
<td>88.6% (117)</td>
<td>78.3% (102)</td>
</tr>
</tbody>
</table>

aPts received 400 mg CZP LD at Weeks 0/2/4.

P058
PRIMARY EFFICACY AND SAFETY OF ADALIMUMAB IN NAIL PSORIASIS FROM THE FIRST 26 WEEKS OF A PHASE-3, RANDOMIZED, PLACEBO-CONTROLLED TRIAL WITH SUBANALYSIS IN PATIENTS WITH AND WITHOUT PSORIATIC ARTHRITIS
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Introduction: Psoriasis (Ps) disease burden for patients with psoriasis (PsO) and concomitant fingernail Ps plus psoriatic arthritis (PsA) is higher compared with patients with Ps alone. Objective: We report safety and efficacy of originator adalimumab (ADA) in patients with fingernail Ps, and also for patients with or without concomitant PsA. Methods: Results are reported from the double-blind PBO-controlled, Period A in which 217 patients with moderate to severe plaque Ps and fingernail Ps were included and randomized 1:1 to receive 40 mg ADA every other week (eow) from week 1 (initial 80mg dose at week 0), or matching PBO, for 26 weeks. The primary endpoints were the proportion of patients with ≥75% improvement in modified Nail Ps Severity Index (mNAPSI) 75 and the proportion of patients with Physician’s Global Assessment of Fingernail Psoriasis (PGA-F) of clear (0) or minimal (1) with ≥2-grade reduction from baseline (primary in US only; for regulatory purposes). Missing data were handled by multiple imputation. Safety was assessed using treatment-emergent adverse events (AEs).
Results: Of the 217 randomized patients (108 PBO, 109 ADA), 84.3% were male; mean age was 46.7 years; 188 (86.6%) completed 26 weeks of treatment or early escaped to Period B according to protocol. At baseline, 28.6% had PsA (29.6% PBO, 27.5% ADA) with mean duration 7.91 years [SD 8.3]. Total fingernail mNAPSI 75 was achieved by 0.5% PBO vs 61.5% ADA of patients with PsA and 4.6% PBO vs 40.9% ADA without PsA (p < 0.001 for both groups). PGA-F 0 or 1 with ≥2-grade reduction was achieved by 4.4% PBO vs 59.3% ADA with PsA and 7.9% PBO vs 44.9% ADA without PsA (p < 0.001 for both groups). Adverse
events (AEs) in Period A were reported by 55.6% PBO vs 56.9% ADA (with PsA: 56.3% PBO vs 56.7% ADA; without PsA: 55.3% PBO vs 57.0% ADA without PsA); serious AEs by 4.6% PBO vs 7.3% ADA (with PsA: 9.4% PBO vs 10.0% ADA; without PsA: 2.6% PBO vs 6.3% ADA).

Conclusions: The results demonstrated that in this population, ADA was more effective than PBO for the treatment of fingernail Ps, and significantly improved signs and symptoms, both overall and regardless of the presence or absence of PsA; no new safety risks were identified with ADA eos treatment for 26 weeks. Previously published J Am Acad Derm. 2017. 76(6 suppl 1): AB204.

P059
CERTOLIZUMAB PEGOL IS EFFECTIVE FOR CHRONIC PLAQUE PSORIASIS ACROSS PATIENT SUBGROUPS
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Introduction: The Fe-cure, PEGylated, anti-tumor necrosis factor certolizumab pegol (CZP) has shown efficacy in chronic plaque psoriasis (PSO). [1,2]

Objectives: To assess the efficacy of CZP to 48 weeks across patient (pt) demographic and baseline disease characteristic subgroups in phase 3 trials.

Methods: In this prespecified, pooled subgroup analysis, data were pooled from CIMPASI-1 (NCT02326298) and CIMPASI-2 (NCT02326272), ongoing phase 3 trials in adults with moderate to severe PSO ≥6 months (psoriasis area and severity index [PASI] ≥12, affected body surface area [BSA] ≥10%, physician’s global assessment [PGA] ≥2/5). Pts were randomized 2:2:1 to CZP 400 mg every 2 weeks (Q2W), 200 mg Q2W (400 mg loading dose at Weeks 0/2/4), or placebo (PBO). At Week 16, PASI 50 responders receiving CZP continued the same dose through the maintenance period to Week 48. PASI 50 nonresponders at Weeks 32/40/48 were classed as nonresponders at subsequent time points. Subgroups included age, weight, body mass index (BMI), baseline PASI, BSA and PZO duration. PASI 75, PGA 0/1, and PASI 90 responder rates were summarized at Week 16 using a logistic regression model with multiple imputation (over all populations) and descriptively at Week 48 based on nonresponse imputation (subgroups).

Results: 175/186/100 pts received CZP 400 mg Q2W/CZP 200 mg Q2W/PBO. Efficacy was observed across all subgroups for both CZP 400 mg Q2W and 200 mg Q2W, with higher Week 48 PASI 75 responder rates in CZP 400 mg Q2W vs CZP 200 mg Q2W treated pts (Table). Similar trends were observed for PGA 0/1 and PASI 90.

Conclusions: Treatment with either dose of CZP resulted in clinically meaningful improvements in signs and symptoms of PSO at Week 16 maintained at Week 48. Similar to the overall population, PASI 75, PGA 0/1, and PASI 90 responder rates were greater for CZP 400 mg Q2W versus 200 mg Q2W across most subgroups at Week 48.


P060
DISCONTINUATION OF BIOLOGIC THERAPIES IN CHRONIC PLAQUE PSORIASIS: A RETROSPECTIVE COHORT
Susanne Gulliver, Wayne Gulliver, Shane Randell
NewLab Clinical Research

Introduction: Psoriasis is a chronic debilitating autoimmune disease which manifests on the skin through red scaly plaques. Biologic treatment have been very successful in controlling moderate to severe psoriasis, however they are quite expensive and not all treatments work for all patients. This study looks to understand the demographics, treatment patterns, treatment failures, number of therapies and time to switching. A cohort of 459 patients treated with biologics was examined

Objectives: 1. To understand the demographics, treatment patterns, treatment failures, number of therapies and time to switching. 2. To decipher patterns in biologic use in order to prescribe more efficiently and optimize health care resources.

Methods: This was a retrospective cohort of all patients exposed to biologic or PD-4 inhibitors within a single Dermatologist's private practice. A simple summary of patient demographics including gender, treatment patterns, reasons and length of time before discontinuation was compiled. Reasons for discontinuation included lack of efficacy (primary or secondary), adverse events (AEs), patient choice or other.

Results: There were 189 females (41.2%) and 270 males (58.8%) with 914 incidences of biologic or PD-4 inhibitor treatment. The mean age was 53.48 (±12.6 and the mean treatment duration was 37.3 months (±39.5). Reasons for discontinuation included lack of efficacy (57.3%), adverse events (12.6%), patient choice or other. Reasons for discontinuation included lack of efficacy (primary or secondary), adverse events (AEs), patient choice or other.

Conclusion: More male patients stayed on their first biologic (74.2%) in ustekinumab-treated patients and in the Apremilast group 32.3%.

Reasons for discontinuation: AEs (14.69%) and non-response (30%); highest rates were in etanercept (78.0%), and infliximab (75.4%); lowest rates was in etanercept 12.8% (14 of 109 patients), highest in infliximab 34.9%, (44 of 126 patients).

Conclusions: The most common cause for discontinuation of biologics was an AE and non-respondiveness (45.69%). Women
were more likely to discontinue therapy than men. Males were more likely to remain on the first biologic therapy. Adalimumab and ustekinumab had lowest rates of discontinuation. Etanercept, infliximab and apremilast had the highest.

References:

P061 INCIDENCE OF INFECTIONS IN CLINICAL TRIALS OF TILDRAKIZUMAB FOR MODERATE TO SEVERE PLAQUE PSORIASIS
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Introduction: Risk of infections is a concern with cytokine inhibitor treatments.

Objective: This analysis assessed infections during phase 2 and 3 trials of tildrakizumab (TIL), a high-affinity, humanized, IgG1κ monoclonal antibody against IL-23p19 under development for moderate to severe chronic plaque psoriasis.

Methods: Patients (Pts) were randomized in P05495 (phase 2: NCT01225731), reSURFACE 1 (phase 3: NCT01722331), and reSURFACE 2 (phase 3: NCT01729754) [1,2]. In Part 1 (Week ([W])1–16) of P05495, pts received subcutaneous (SC) TIL 5, 25, 100, or 200 mg or placebo (PBO) at W0 and W4 and were randomized to various TIL doses in Part 2 (W16–52). In Part 1 (W1–12) of reSURFACE 1 and 2, pts received SC TIL 200 mg, TIL 100 mg, or PBO at W0 and W4. Pts were randomized in Part 2 (W12–28) and Part 3 (W28–64 or W28–52 in reSURFACE 1 and 2, respectively). Etanercept (ETN) 50 mg was an active control in Parts 1–2 of reSURFACE 2. Treatment-emergent adverse event data pools (n = 2081) for the PBO-controlled and full trial periods (52 weeks for P05495; reSURFACE 2; 64 weeks for reSURFACE 1) were analyzed. Severe infections met the regulatory definition of a serious adverse event or required intravenous antibiotics.

Results: In the PBO-controlled period, incidences of infections were comparable for TIL 100 mg and 200 mg (23% and 22%, respectively) and PBO (23%); all were comparable with ETN (24%). Incidences of severe infections were low for all treatment groups (range, 0.0%–0.3%; TIL P ≥ 0.6 vs PBO). In the full trial period, exposure-adjusted rates (pts/100 pt-years) for infections with TIL 100 mg and 200 mg were lower than with PBO and ETN (79.5 and 86.0, respectively). Exposure-adjusted rates for severe infections were 1.10, 1.61, 1.96, and 0.91 for TIL 100 mg, TIL 200 mg, ETN, and PBO, respectively. In all, 33 severe infections were identified (respiratory: TIL 100 mg, 4 events; TIL 200 mg, 2 events; ETN and PBO, 0 events; skin: TIL 100 mg, 3 events; TIL 200 mg, 6 events; ETN, 2 events; PBO, 3 events; gastrointestinal: TIL 100 mg, 4 events; TIL 200 mg, 5 events; ETN and PBO, 0 events; urinary tract: TIL 200 mg, 1 event; ETN, 1 event; TIL 100 mg and PBO, 0 events). One pt had bone tuberculosis (TIL 200 mg; original purified protein derivative test was negative); 1 sepsis event (TIL 200 mg) occurred months after ending TIL treatment.

Conclusion: Infection rates with TIL treatment were low and comparable to PBO and ETN during the PBO-controlled period. By W52/64, exposure-adjusted rates remained low for all groups.


Acknowledgements: The studies were funded by Merck Sharp & Dohme, Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA. Analyses were presented at the American Academy of Dermatology Annual Meeting, February 16-20, 2018, San Diego, CA, USA.

P062 EFFICACY AND SAFETY OF RISANKIZUMAB: RESULTS FROM TWO DOUBLE-BLIND, PLACEBO- AND USTEKINUMAB-CONTROLLED, PHASE 3 TRIALS IN MODERATE-TO-SEVERE PLAQUE PSORIASIS
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Introduction: Interleukin-23 is a key cytokine in the development and maintenance of psoriatic lesions. Risankizumab is a humanized IgG1 monoclonal antibody that binds to IL-23-p19 subunit, selectively inhibiting this critical cytokine and its role in psoriatic inflammation.

Methods: UltiMMa-1 (n = 506) and UltiMMa-2 (n = 491) were replicate, randomized, double-blind, placebo- and active comparator-controlled studies that evaluated efficacy and safety of risankizumab in adult patients with moderate-to-severe plaque psoriasis. Patients were stratified by weight and prior TNFi-exposure and randomized 3:1:1 to receive 150 mg risankizumab, 45/90 mg ustekinumab (weight-based per label) or matching placebo. Patients were dosed at weeks 0, 4, 16, 28, and 40, with placebo crossover to risankizumab at week 16. Co-primary endpoints were PASI 90 and sPGA0/1 at week 16 versus placebo with comparisons between risankizumab and ustekinumab as ranked secondary endpoints. Missing data were imputed as non-response.

Results: All primary and ranked secondary endpoints were met for both trials (p < 0.001). At week 16 of UltiMMa-1 & 2 trials, risankizumab-treated patients achieved significantly higher PASI 90 (75.3%/74.8%) and sPGA0 (87.8%/83.7%) response rates versus placebo (4.9%/2.0%; 7.8%/5.1%) or ustekinumab-treated
patients (42.0%/47.5%; 63.0%/61.6%). At week 52, risankizumab-treated patients achieved significantly higher response rates versus ustekinumab. In both trials, treatment-emergent adverse event (TEAE) rates were comparable across treatment groups throughout the study duration. The most frequently reported TEAE was upper respiratory tract infection.

**Conclusion:** Risankizumab was consistently superior to both placebo and ustekinumab in the treatment of moderate-to-severe plaque psoriasis. TEAE profiles were similar between risankizumab and ustekinumab, and there were no unexpected safety findings.

**P063 Efficacy and Safety of Guselkumab Administered with a Novel Self-injection Device for the Treatment of Moderate-to-severe Psoriasis: Results from the Phase III Orion Self-dose Study Through Week 16**

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**Objective:** To evaluate the efficacy and safety of guselkumab (GUS) administered using a novel, self-injection device in adult patients with moderate-to-severe plaque psoriasis (PsO).

**Methods:** ORION is a Phase 3, multicenter, randomized, double-blind, PBO-controlled study evaluating GUS administered using a self-SC injection device that delivers the contents of a pre-filled syringe. Patients of age ≥18 years with moderate-severe PsO for at least 6 months, IGA score ≥3, PASI score ≥12, and BSA ≥10%, were candidates for/or may have previously received systemic therapy or phototherapy, were eligible for the study. At baseline, 78 patients were randomized to PBO (n = 16) at wks 0, 4, and 12 with crossover to GUS 100 mg at wks 16, 20, and 28 or GUS (n = 62) at wks 0, 4, 12, 20, and 28. The co-primary endpoints were the proportions of patients achieving 1) an IGA score of cleared (0) or minimal (1) and 2) a PASI 90 response at wk16 (GUS vs PBO). Major secondary endpoints were the proportions of patients achieving an IGA score of 0 and a PASI 100 response at wk16. Results through wk16 are presented.

**Results:** Baseline demographics and PsO disease characteristics were generally similar between the PBO and GUS-treatment groups. At wk16, significantly higher proportions of GUS vs PBO patients achieved an IGA score of 0/1 (80.6% vs. 0.0%, p < 0.001) and a PASI 90 response (75.8% vs. 0.0%, p < 0.001). In addition, significantly higher proportions of GUS vs PBO patients achieved an IGA score of 0 (56.5% vs 0.0, p < 0.001) and a PASI 100 response (50.0% vs 0.0, p < 0.001) at wk16. Through wk16, the proportions of patients with ≥1 AE were comparable between the treatment groups (GUS: 62.9%, PBO: 68.8%; respectively). Discontinuation rates due to AEs were 1.6% for GUS patients and 6.3% for PBO patients. Two patients in the GUS group had SAEs (1 chest discomfort and 1 atypical chest pain). There were no serious infections, malignancies, or deaths. **Conclusion:** Guselkumab administered using a novel self-injection device was efficacious and well-tolerated in patients with moderate-severe PsO. The efficacy and safety profile of GUS administered with this device was consistent with previously reported findings from the pivotal phase 3 studies in which GUS was administered using a different self-injection device.

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**Introduction:** Etanercept (ETN) is an anti-tumor necrosis factor-α medication that was among the first biologics approved for psoriasis. Additional medications have been developed or are in development for psoriasis, and patients who do not adequately respond to ETN may benefit from these more recent biologics.

**Objectives:** To evaluate the efficacy of tildrakizumab (TIL), a high-affinity, humanized, anti-interleukin-23p19 antibody in patients (pts) with moderate to severe chronic plaque psoriasis who were partial responders (Psoriasis Area and Severity Index [PASI] ≥50–< 75) or nonresponders (PASI < 50) to ETN and were subsequently rerandomized to TIL in a phase 3 trial.

**Methods:** Pts with psoriasis (≥10% body surface area, Physician’s Global Assessment [PGA] ≥3, and PASI score ≥12) participated in a 3-part, 52-week, randomized controlled trial (reSURFACE 2; NCT01729754) [1]. In Part 1 (Week [W] 0–W12), pts were randomized to subcutaneous TIL 200 mg, TIL 100 mg, or placebo (PBO) administered at W0 and W4, or ETN 50 mg administered 2x/week. In Part 2 (W12–W28), TIL- and ETN-treated pts remained on the same treatment (TIL administered at W16; ETN 1x/week), whereas PBO-treated pts were rerandomized to TIL 100 or 200 mg. In Part 3 (W28–W52), ETN responders (PASI ≥75) were discontinued, partial and nonresponders were switched to TIL 200 mg (administered at W32, W36, W48). For this post hoc analysis, the percentages of pts (±SD) with PASI responses and PGA response (score of 0 [clear] or 1 [minimal] with at least a 2-grade score reduction from baseline) were determined at W52. Primary results from the trial have been previously reported.

**Results:** In all, 1090 pts were randomized. Of the 313 pts randomized to ETN, by W28 there were 83 partial responders and 39 nonresponders. At W52 (after 20 weeks of TIL treatment) for ETN partial responders, 75%/±5%, 34%/±5%, 15%/±4%, and 58%/±5% had achieved PASI 75, 90, 100, and PGA responses, respectively, with TIL 200-mg treatment. At W52 for ETN nonresponders, 54%/±6%, 31%/±5%, 10%/±3%, and 56%/±5% had achieved PASI 75, 90, 100, and PGA responses, respectively, with TIL 200-mg treatment. Adverse events were similar in pts switched from ETN to TIL at W28, compared with the pts who were maintained on TIL through W52.

**Conclusions:** A substantial portion of patients with moderate to severe chronic plaque psoriasis who were partial responders or nonresponders to ETN may respond after switching to treatment with TIL 200 mg. TIL may be a reasonable option for those who do not achieve adequate response to ETN.

Reference:

**Acknowledgments:** This study was funded by Merck Sharp & Dohme, Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA. Analyses were presented at the American Academy of Dermatology Annual Meeting, February 16–20, 2018, San Diego, CA, USA.

**P065 Efficacy of Tildrakizumab in Moderate to Severe Psoriasis Patients with Prior Exposure to Apremilast**

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Objective: We assessed a subgroup of patients with chronic plaque psoriasis who reported prior treatment with apremilast (APT), a phosphodiesterase 4 inhibitor, to evaluate its potential influence on efficacy in 2 large phase 3 clinical studies of tildrakizumab.

Methods: The reSURFACE studies were 3-part, double-blind, randomized controlled studies in patients (≥18 years of age) with moderate to severe chronic plaque psoriasis [1]. TIL 100 and 200 mg were evaluated for 64 weeks (reSURFACE 1; NCT01722331) and 52 weeks (reSURFACE 2; NCT01729754). Part 1 (0–12 weeks) was placebo (PBO)-controlled, whereas Part 2 (12–28 weeks) was randomized PBO patients to TIL. The washout period for discontinuation of APT before randomization in these studies was 4 weeks. In this post hoc analysis, we analyzed the efficacy responses to TIL in patients who reported prior exposure to APT. Physicians’ Global Assessment (PGA) (0 or 1) and Psoriasis Area and Severity Index (PASI) 75, 90, and 100 responses were assessed at Weeks 12 and 28 in this cohort. One patient with missing data at Weeks 12 and 28 was considered to be a nonresponder at these visits. The TIL groups were pooled owing to the small numbers reporting prior APT exposure.

Results: The pooled reSURFACE 1 and 2 dataset includes 1238 patients randomized to TIL; of these, prior APT exposure was reported by 35 patients (n = 21 for 100 mg and n = 14 for 200 mg). In the overall pooled population of TIL-treated patients, PASI 75, PASI 90, PASI 100, and PGA (0.1) responses were achieved by 783 (63%), 450 (36%), 161 (13%), and 715 (58%) at Week 12 and 898 (73%), 647 (52%), 303 (25%), and 784 (63%) at Week 28, respectively. In the population of TIL-treated patients with prior APT exposure, PASI 75, PASI 90, PASI 100, and PGA (0.1) responses were achieved by 21 (60%), 9 (26%), 5 (14%), and 22 (63%) at Week 12 and 21 (77%), 16 (46%), 7 (20%), and 22 (63%) at Week 28, respectively. There were no discontinuations due to adverse events (AEs) among patients with prior APT exposure.

Conclusions: Efficacy responses with TIL were similar for the small sample of patients with prior exposure to APT and the overall pooled population from reSURFACE 1 and reSURFACE 2. These results were consistent with the notion that no adverse effect on efficacy or discontinuations due to AEs are expected when initiating treatment with TIL among patients with prior exposure to APT.

Reference:

Acknowledgements: The studies were funded by Merck Sharp & Dohme, Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA. Analyses were presented at the American Academy of Dermatology Annual Meeting, February 16–20, 2018, San Diego, CA, USA.

P067 DISEASE SEVERITY AND EFFICACY INSIGHTS: PATIENT-LEVEL PASI SCORES IN TILDRAKIZUMAB PSORIASIS TRIALS

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Introduction: Tildrakizumab (TIL) is a high-affinity anti-IL-23p19 antibody that showed efficacy in 2 phase 3 chronic plaque psoriasis studies (reSURFACE 1 [NCT01722331] and 2 [NCT01729754]) [1]. Some dichotomous efficacy measures, eg, proportions of patients achieving a 75% Psoriasis Area and Severity Index (PASI) response, provide limited efficacy and disease severity information at a patient level. Analysis of patient-level PASI data could address these limitations.

Objective: To identify potential insights into efficacy assessment

References:
and disease severity using a post hoc analysis of patient-level PASI data.

Methods: ReSURFACE 1 and 2 methods have been described previously [1]. Patients who participated in either TIL phase 3 study received TIL 100 mg or TIL 200 mg at Week (W)0 and W4, and every 12 weeks thereafter, or placebo (PBO) at W0 and W4 then TIL 100 mg or 200 mg at W12 and W16. PASI score distributions were analyzed using descriptive statistics.

Results: Numbers of patients and mean and median PASI scores are shown in the Table. By W4 (1 dose), 55% of patients in both TIL arms had PASI <12, and would no longer meet clinical trial entry criteria. The percentage of patients with PASI <12 increased during TIL treatment: 87% at W12, 93% at W28 (100 mg); 90% at W12, 97% at W28 (200 mg). At W12, 32% (TIL 100 mg), 29% (TIL 200 mg), and 2% (PBO) of patients had PASI ≤1.0. By W28, 48% (TIL 100 mg) and 52% (TIL 200 mg) of patients had PASI ≤1.0. Median PASI scores at W28 were 2.0 (TIL 100 mg) and 1.0 (TIL 200 mg).

Conclusions: These results suggest that PASI scores may provide additional information about disease severity, and resolution with treatment, that might not otherwise be available using dichotomous PASI assessments. Most TIL-treated patients had clinical improvement by W4, and >50% had nominal disease severity (PASI ≤1.0) by W28.

Reference:

Table. PASI Scores

<table>
<thead>
<tr>
<th></th>
<th>TIL 100 mg</th>
<th>TIL 200 mg</th>
<th>PBO</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n = 616)</td>
<td>(n = 622)</td>
<td>(n = 309)</td>
</tr>
<tr>
<td>W0</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Patients with PASI≤12, n (%)</td>
<td>559</td>
<td>602</td>
<td>288</td>
</tr>
<tr>
<td>Mean (95% CI)</td>
<td>5.2 (4.7, 5.7)</td>
<td>4.6 (4.2, 5.1)</td>
<td>16.6 (15.6, 17.7)</td>
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<tr>
<td>Median (range)</td>
<td>3.0 (0–38.0)</td>
<td>3.0 (0–36.0)</td>
<td>15.5 (0–57.0)</td>
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<tr>
<td>PASI &lt;12, n (%)</td>
<td>521 (87%)</td>
<td>539 (90%)</td>
<td>73 (25)</td>
</tr>
<tr>
<td>PASI &lt;1.0, n (%)</td>
<td>189 (32)</td>
<td>175 (29)</td>
<td>5 (2)</td>
</tr>
<tr>
<td>W12</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients with PASI≤12, n (%)</td>
<td>575</td>
<td>581</td>
<td>-</td>
</tr>
<tr>
<td>Mean (95% CI)</td>
<td>3.4 (3.0, 3.8)</td>
<td>2.7 (2.4, 3.0)</td>
<td>-</td>
</tr>
<tr>
<td>Median (range)</td>
<td>2.0 (0–26.0)</td>
<td>1.0 (0–24.0)</td>
<td>-</td>
</tr>
<tr>
<td>PASI &lt;12, n (%)</td>
<td>533 (93)</td>
<td>561 (97)</td>
<td>-</td>
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<tr>
<td>PASI &lt;1.0, n (%)</td>
<td>278 (48)</td>
<td>303 (52)</td>
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P068 SUSTAINED AND IMPROVED EFFICACY OF TILDRAKIZUMAB FROM WEEK 28 TO WEEK 52 IN TREATING MODERATE-TO-SEVERE PLACER PSORIASIS

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Introduction: Two phase-3, double-blind, randomized controlled trials (reSURFACE 1: NCT01722331; reSURFACE 2: NCT01729754) have demonstrated the efficacy and safety of tildrakizumab, a high affinity, humanized, IgG1 K anti-interleukin-23 monoclonal antibody, in the treatment of adult patients with moderate-to-severe plaque psoriasis over 28 weeks.

Objective: This analysis evaluated whether the efficacy is sustained or improved from week 28 through week 52.

Methods: Both trials randomized adult patients with moderate-to-severe plaque psoriasis to receive tildrakizumab 100 mg or 200 mg at weeks 0, 4, then every 12 weeks. At week 28, patients with PASI Area and Severity Index (PASI) response ≥50% were re-randomized, based on their week-28 PASI response, to receive the same, a higher or a lower dose of tildrakizumab or placebo (randomized withdrawal in reSURFACE 1 per the trial designs). The current analysis evaluated only patients treated with the same dose of tildrakizumab (100 mg or 200 mg) throughout the first 52 weeks. Four mutually exclusive groups were created based on week-28 PASI response: PASI 100, PASI 90–99, PASI 75–89 and PASI 50–74. PASI responses at week 52 (observed data) were analyzed for each week-28 PASI-response group.

Results: This analysis included 352 patients on tildrakizumab 100 mg (male: 69.9%; mean baseline age: 44-9 years) and 313 on tildrakizumab 200 mg (male: 67.1%; mean baseline age: 46.4 years). The proportions of patients achieving PASI 75–89 and PASI 50–74 at week 28 were 25.9%, 38.4%, 25.3% and 10.5% respectively for those on the 100 mg dose, and 24.6%, 24.3%, 19.5% and 31.6% respectively for those on the 200 mg dose. Among patients who achieved week-28 PASI<90 with either dose of tildrakizumab, 88.9–89.4% maintained PASI≥75 at week 52. Overall, 91.1% patients on the 100 mg dose and 93.9% on the 200 mg dose with week-28 PASI≥75 maintained PASI≥75 at week 52. In addition, 39.3–40.4% of patients with week-28 PASI 75–89 remained PASI 75–89 at week 52 and 33.7%-41.0% improved to PASI≥70. Among patients with week-28 PASI 50–74, 20.2–29.7% achieved PASI<90 and 52.5–64.9% achieved PASI≥75 at week 52. Overall, only 2.6% of patients on the 100 mg (9 out of 352) or 200 mg (8 out of 313) dose had week-52 PASI<50.

Conclusions: Among patients with moderate-to-severe plaque psoriasis treated with tildrakizumab 100 or 200 mg at weeks 0, 4, then every 12 weeks, those who achieved week-28 PASI≥50 and continued on the same dose had sustained or improved efficacy from week 28 through week 52. The majority patients who achieved week-28 PASI≥75 or PASI≥90 maintained PASI≥75 or PASI≥90 at week 52. More than half of partial responders (PASI 50–74) at week 28 eventually achieved PASI≥75 and at least 1 in 5 achieved PASI≥90 at week 52.


This abstract was presented at 2018 Winter Clinical Dermatology Conference-Hawaii.
cy and safety in patients with moderate-to-severe plaque psoriasis in two phase 3, double-blinded, randomized controlled trials (re-SURFACE 1: NCT01722331; reSURFACE 2: NCT01729754).

Objective: The analysis examined the association between quality-of-life improvements and the degree of skin clearance in patients enrolled in the two phase 3 trials and treated with tildrakizumab 100 mg or 200 mg at weeks 0, 4, then every 12 weeks.

Methods: Both trials used a three-part design: Part 1 (weeks 0–12) was placebo-controlled; Part 2 (weeks 12–28) re-randomized placebo patients to receive tildrakizumab 100 or 200 mg; Part 3 (weeks 28–64, reSURFACE 1; weeks 28–52, reSURFACE 2) re-randomized patients from the tildrakizumab arms with Psoriasis Area and Severity Index (PASI) response ≥50 at week 28 to receive the same, a higher, or a lower dose of tildrakizumab, or placebo (randomized withdrawal in reSURFACE 1). The Dermatology Life Quality Index (DLQI) questionnaire was administrated at weeks 0, 12, 28, 40, and 52. Tildrakizumab-treated patients were pooled in the same, a higher, or a lower dose of tildrakizumab, or placebo patients to receive tildrakizumab 100 or 200 mg; Part 1 (weeks 28–64, reSURFACE 1; weeks 28–52, reSURFACE 2) re-randomized patients from the tildrakizumab arms with Psoriasis Area and Severity Index (PASI) response ≥50 at week 28 to receive the same, a higher, or a lower dose of tildrakizumab, or placebo (randomized withdrawal in reSURFACE 1). The Dermatology Life Quality Index (DLQI) questionnaire was administrated at weeks 0, 12, 28, 40, and 52. Tildrakizumab-treated patients were pooled in the two trials and classified into 5 mutually exclusive groups based on their week-28 PASI response: PASI < 50, PASI 50–74, PASI 75–89, PASI 90–99, and PASI 100. Baseline characteristics, the proportion of patients with DLQI 0/1, and mean DLQI changes from baseline were examined for each PASI response group. Results: Overall, 575 patients on tildrakizumab 100 mg (male: 69.6%; mean baseline age: 45.6 years) and 581 on tildrakizumab 200 mg (male: 73.0%; mean baseline age: 45.9 years) were included. At week 28, 8.3%, 22.0%, 40.9%, 66.3%, and 86.5% (8.7%, 35.2%, 43.9%, 70.4%, and 85.9%) of patients with PASI < 50, 50–74, 75–89, 90–99, and 100 achieved DLQI 0/1 for those on 100 mg (200 mg), respectively. Patients with higher week-28 PASI response also had greater mean DLQI reductions from baseline at week 28 (100 mg: 5.7–13.4; 200 mg: 5.4–12.9). Similar patterns were observed among patients continuously treated with tildrakizumab 100 mg or 200 mg from baseline to week 52, with better PASI-response patients having greater proportions achieving DLQI 0/1 and greater DLQI reductions sustained from week 28 through week 52.

Conclusion: Tildrakizumab-treated patients with higher levels of PASI response also demonstrated better quality-of-life improvements. Achieving PASI 100 was not necessarily associated with achieving DLQI 0/1, therefore both efficacy and quality-of-life improvements need to be evaluated separately to provide a complete picture of treatment success.


P071

STATISTICAL REVIEW OF PSORIASIS SYSTEMATIC THERAPIES IN NORTH GREECE

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Introduction: Psoriasis is a chronic disease that can have a significant effect on quality of life. Therefore, management of psoriasis involves both psychosocial and physical aspects of this disease, lately generally admitted as systemic. Numerous topical and systemic therapies are available for the treatment of the cutaneous manifestations of psoriasis. In our daily clinical practice, treatment modalities are chosen on the basis of disease severity estimated with PASI and DLQI, relevant comorbidities, and patient preference.

Objective: To assess the frequencies of each systemic drug, classical or biological, used for the treatment of mild, moderate to severe psoriasis in our hospital care unit from January 2016 since December 2016.

Methods: Moderate to severe psoriasis was defined by PASI > 10 and/or DLQI > 10 and/or any PASI in a patient with psoriatic arthritis.

Results: Most of our patients with mild to moderate psoriasis are using topical and classical therapies. A significant number of patients with severe psoriasis are using biological therapies and about a half of them were already used a classical or other biologic drug.

Conclusion: Despite the fact that new biological drugs are available for psoriasis treatment, it seems that the patients with mild psoriasis are still treating with topical products. At least as far as it concerns our Mediterranean country, it seems that our patients difficult accept the biological therapies as first choice line treatment.

P073

PHARMACOVIGILANCE OF SYSTEMIC ANTIPSORITIC DRUGS: AN UPDATE FROM ROUTINE CARE

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Introduction & Objectives: The spectrum of antipsoriatic systemic therapies is constantly changing. The short-term efficacy and safety of the various therapies are demonstrated in controlled clinical studies. The German Psoriasis Registry PsoBest aims to gain long-term evidence of safety and effectiveness in routine care. Updated interim data of long-term safety of biological and non-biological treatment of psoriasis is presented.

Materials & Methods: The non-interventional German Psoriasis Registry PsoBest observes adult patients with moderate to severe psoriasis and/or psoriatic arthritis. Patients are registered at naïve systemic treatment start and are observed for 10 years in routine care. The registry aims to gain long-term evidence of safety and effectiveness of systemic antipsoriatic drugs. Data is collected in dermatological practices and walk-in clinics. Presented are standardised patient rates per 100 patient years (py) of exposure classified by system organ classes of MedDRA® (SOC, Medical Dictionary for Regulatory Activities).

Results: Until June 2017, 5 825 patients were registered and sufficient for analyses. They were predominantly male (58.8%), had a mean age of 47.7 years (SD 14.5) and 30.0% of patients suffered psoriatic arthritis. 4 729 patient years (py) were observed on biologic treatments and 6 583 py on other systemic treatments. For the purpose of calculating standardised patient rates per 100 patient years (py) of exposure classified by system organ classes of MedDRA® (SOC, Medical Dictionary for Regulatory Activities).

Conclusion: Most of our patients with mild to moderate psoriasis are using topical and classical therapies. A significant number of patients with severe psoriasis are using biological therapies and about a half of them were already used a classical or other biologic drug.

Conclusion: Despite the fact that new biological drugs are available for psoriasis treatment, it seems that the patients with mild psoriasis are still treating with topical products. At least as far as it concerns our Mediterranean country, it seems that our patients difficult accept the biological therapies as first choice line treatment.

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analyses. For robust data on recently authorised therapeutics, more observation time is needed, especially with a constantly changing spectrum of treatments.

**P074**

THE IMPACT OF PATIENT REQUESTS ON PSORIATIC ARTHRITIS TREATMENT

**Lynn Price**, Jennifer Robinson, Gianna Melendez

Sphero Global Insights

**Introduction:** As a result of direct to consumer advertising, patients frequently request well-known brands for the treatment of psoriatic arthritis, and these patients tend to be highly involved in their therapy decisions. Patient requests commonly relate to formulation preferences, and in an indication dominated by biologics administered either subcutaneously or intravenously, oral small molecules are in high demand.

**Objectives:** One of the objectives of this study was to gain further insight into patient requests as a main driver for switching to and from biologics/apremilast.

**Methods:** An independent market analytics firm collaborated with US rheumatologists (n = 200) to conduct a retrospective chart review of patients diagnosed with psoriatic arthritis (PsA) (n = 1,008), who had switched from one biologic therapy or apremilast to another in the prior twelve weeks. Rheumatologists were able to submit up to seven PsA patient charts. Data were collected in April 2017 and included clinical and non-clinical patient demographics, as well as physician demographics and attitudinal survey responses.

**Results:** PsA patients tend to be very involved when it comes to treatment decisions as 60 percent of patients had significant input or were the primary driver behind the recent decision to switch agents. Of those patients driven switches, only 36 percent of treating rheumatologists felt there was strong clinical rationale behind the switch; despite this, nearly half of rheumatologists state they tend to approve specific patient requests.

Two-thirds of collaborating rheumatologists believe patients would choose an oral agent over one that administered subcutaneously, thus switching to apremilast is particularly common when patients are involved in the decision. Patient requests were the primary driver behind 24 percent of all switches to apremilast, compared to just 12 percent when switching to a biologic. Furthermore, for rheumatologists who are not in favor of an “apremilast before biologics” treatment approach, patient requests are significantly more of a driver for the brand than those who have adopted an “apremilast before biologics” approach.

**Conclusion:** PsA patients are highly involved in the decision to initiate and switch biologic/apremilast therapies, and treating rheumatologists tend to be open to granting such requests, regardless of clinical rationale. When patient requests are a primary driver for switching, apremilast benefits the most; largely due to the oral formulation. With the new approval of the first JAK inhibitor and second oral option in the PsA market, tofacitinib will likely fill a gap for both physicians and patients by introducing a high efficacy oral option, warranting follow-up analysis on the evolution and impact of patient requests in PsA.

**P075**

THE RISK OF KC IN PSORIASIS PATIENTS RECEIVING BIOLOGICS COMPARED TO CONVENTIONAL SYSTEMIC THERAPIES

Kayleigh Mason

The University of Manchester, Manchester, UK

**Introduction:** Whether psoriasis patients exposed to biologic therapies have an elevated risk of keratinocyte carcinoma (KC), including basal cell carcinoma (BCC) or cutaneous squamous cell carcinoma (cSCC) remains uncertain.

**Objective:** The aim of the present study was to determine whether such patients were at higher risk of developing a KC compared to those on conventional therapy.

**Methods:** The British Association of Dermatologists Biologic Interventions Register (BADBIR), a pharmacovigilance register of psoriasis patients, explores the long-term safety of systemic therapies. Patients with chronic plaque psoriasis registering to BADBIR on their first biologic or a conventional therapy, who had at least one follow-up completed were included in analyses if they were of white ethnicity, Fitzpatrick skin types 1–4 and reported no previous cancers. Confounding factors included: age; sex; smoking; and previous exposure to acitretin, psoralen ultraviolet-A (PUVA), ciclosporin, and/or PUVA and ciclosporin. Propensity score-weighted Cox-proportional hazard models estimated the hazard ratio (HR) for developing a first KC or separately, first BCC or cSCC.

**Results:** In total, 5672 patients initiating biologic therapy and 3188 patients on conventional therapy who met the entry criteria were identified with 20558 and 7829 person-years of follow-up, respectively. During follow-up, 74 (1.3%) patients initiating a biologic therapy were diagnosed with their first KC (43 BCC; 34 cSCC first) and 22 (0.7%) patients receiving conventional therapy with their first KC (15 BCC; 10 cSCC first). No significant difference in risk was observed for developing a KC (adjusted HR 1.05; 95% CI 0.64, 1.73), BCC (0.84; 95% CI 0.45, 1.54) or cSCC (1.20; 95% CI 0.57, 2.50) on biologic compared to conventional therapy.

**Conclusion:** Biologic therapy does not appear to confer a higher risk of developing a first KC as compared to conventional therapy in psoriasis patients. These data will help inform clinical decision making in psoriasis patients at risk of KC in whom biologic or conventional therapy is being considered.

On behalf of the BADBIR Study Group, British Association of Dermatologists, London, UK
**P077**

**PATIENT EXPECTATIONS AND SATISFACTION IN PSORIASIS TREATMENT: A SURVEY FROM EUROPE AND CANADA**

Jonathan Barker, Robert McKenzie, Daniel Saure, Stefan Wilhelm, Kunal Gulati, Ronald Vender

**Introduction:** Psoriasis is a chronic immune-mediated disease that negatively affects the quality of life of patients. Despite recent advancements in treatment, patient expectations may differ from the treatment outcome, potentially leading to dissatisfaction.

**Objective:** To evaluate patient expectations on psoriasis treatment outcomes and to what extent these were met by the treatment.

**Methods:** Data were collected from patients with moderate-to-severe psoriasis with ≥3% skin involvement. Patients were included from 17 European countries and Canada through a structured, web-based interview in their local language. Patients were on topical, PUVA/phototherapy, conventional systemic or biological treatment. Descriptive statistical analyses were conducted.

**Results:** Overall, 1946 patients (mean [SD] age: 42 [13] years, 43% male) with psoriasis were surveyed between 6 July 2016 and 5 May 2017. The vast majority of patients currently on treatment reported reduced itchiness (69%), reduced flaking (62%), and clearer skin/skin that looked better generally (61%) as the main expectations of their treatment. In addition, these patients reported duration of effect (41%), extent of overall skin clearance (36%), and speed of onset (34%) as the main influences for changing their current treatment. Furthermore, patients were asked whether their achieved results matched with their initial treatment expectations. Patients reported that the convenience of dosing (68%) and administration method (68%) completely met, or even exceeded their initial expectations for the treatment. Conversely, expectations for reduced itchiness (62%), reduced flaking (62%), clearer skin/skin that looked better generally (63%) were only partially met or not met at all. Approximately, two-thirds of patients were dissatisfied or only partially satisfied with the extent of their skin clearance and improvement in at least one specific area. Specifically, scalp (48%), legs (42%), and arms (41%) were the highest rated areas if asked for insufficient satisfaction for clearance.

**Conclusion:** Data from this international survey indicate that efficacy and maintenance of response are the patients’ primary expectations of psoriasis treatment whereas, insufficient response to therapy in difficult-to-treat areas appears to be a major reason for patient dissatisfaction.

**Reference:**

**This survey was sponsored by Eli Lilly and Company, Indianapolis, USA.**

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**P078**

**SOCIOECONOMIC DETERMINANTS OF PAEDIATRIC PSORIASIS**

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**Introduction:** Psoriatic comorbidities have been shown to be inversely associated with socioeconomic position (SEP). We hypothesized that the social patterning of paediatric psoriasis would be similar to that observed for several psoriatic comorbidities, such as cardiovascular disease and type 2 diabetes mellitus.

**Objectives:** Our aim was to investigate whether maternal SEP is a determinant of paediatric psoriasis.

**Methods:** Data on paediatric psoriasis from 36,003 offspring of a national birth cohort were cross-linked with nation-wide registry data on maternal educational attainment, maternal labour market attachment and equivalised household income. We performed logistic regression analyses to test for associations between measures of maternal SEP and paediatic psoriasis. Cohort analyses were conducted, estimating the odds ratios (OR) and 95% confidence intervals (CI) of offspring psoriasis. We included maternal age at birth and maternal psoriasis as covariates in adjusted analyses.

**Results:** Maternal educational attainment and equivalised household income were inversely associated with offspring psoriasis. Offspring of mothers with a low educational attainment had an OR 1.62 (95% CI: 1.20–2.18; p < 0.01) of paediatric psoriasis, after adjusting for maternal psoriasis and age, compared to offspring of mothers with a medium educational attainment. Offspring of mothers in the highest quartile compared to mothers in the lowest quartile of equivalised maternal household income had an OR 0.59 (95% CI: 0.44–0.80; p = 0.001) of paediatric psoriasis, after adjusting for maternal psoriasis and age.

**Conclusion:** Lifetime prevalence of paediatric psoriasis was inversely associated with maternal SEP in our study population. Early life exposure to modifiable risk factors associated with SEP may play an important role in the development of paediatric psoriasis. Future studies are warranted to clarify the role of mediating factors.

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**P079**

**OBESITY AND THE RISK OF PSORIASIS: A KOREAN NATIONWIDE, POPULATION-BASED STUDY**

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**Introduction:** Psoriasis is a T-helper-1 and -17 cell-mediated, chronic, inflammatory skin disease affecting approximately 1–3% of the general population. Psoriasis is currently considered as a chronic low-grade inflammatory condition that plays an active role in the development of the pathophysiologic phenomena responsible for metabolic syndrome and cardiovascular disease. Obesity, as a component of the metabolic syndrome, represents a major comorbidity and possibly contributes to reduced treatment response.

**Objective:** This nationwide, population-based study investigated the impact of body mass index (BMI) and waist circumference (WC) on the psoriasis in the Korean population.

**Methods:** We used the health check-up database, which is sub-
Psoriasis in 67.7%. Median PASI was 5.4 (1.5, 16.4). Axial pre-
to the activity of PsO the most frequent presentation was plaque

Conclusion: showed highest risk of psoriasis (HR 1.305, 95% CI 1.261–1.349)
increased in proportion to WC. Subjects with WC over 105 cm
of psoriasis (HR 1.118, 95% CI 1.1–1.137). The risk of psoriasis
adjustment, the presence of a severe DAS 28 is associated with

an increase in the risk of deterioration in quality of life, with OR
of 6.24 (1.74, 22.2). The presence of BMI > 27 is associated with
an increase in the risk of deterioration in quality of life with OR
of 6.53 (1.59, 26.8). When performing the adjusted multivariate
model, the only variables that were associated with severe de-
terioration of quality of life were the presence of BMI > 27 and
on the other side, pain, with BMI > 27 is the factor that mostly
impairs the quality of life.

Conclusions: Prevalence of PsA in this series of patients with skin
or nail psoriasis was 58.3%. The 45.2% of patients showed severe
activity and 51.6% severe deterioration in their quality of life, that
leads to disability and limitation performing daily activities. An
early diagnosis provides the possibility of appropriate treatment
to improve function, quality of life and decrease the progression
and complications of the disease.

P080 CLINICAL CHARACTERIZATION OF PSORIATIC ARTHRITIS IN A MULTIDISCIPLINARY CARE MODEL OF PATIENTS WITH PSORIASIS
Dalila Alejandra Lopez-Rodriguez
Dermatologico Country

Introduction: Psoriatic arthritis (PsA) is an inflammatory arthro-
pathy that occurs in patients with Psoriasis (PsO). The frequency of
PsA in patients with PsO has been estimated between 10–40%.
The presentation and clinical course are variable, therefore, it is
necessary to understand the clinical behavior, severity and as-

Objectives: To describe the clinical features of the PsA,
in a multi-
disciplinary PsO clinic.
Methods: Prospective study, August 2016–February 2018, patients
attending to Multidisciplinary Clinic for psoriasis in Dermatolo-

gico Country were included.
Results: A total of 53 participants were included, finding a preva-

ence of psoriatic arthropathy of 58.5%.
The median age was 42 years and 71% were female. Patients with
PsA have higher frequency of DM2, metabolic syndrome and
hepatic steatosis. However, the differences are not statistically
significant, which could be a result of the sample size. According
to the activity of PsO the most frequent presentation was plaque
psoriasis in 67.7%. Median PASI was 5.4 (1.5, 16.4). Axial pre-

sentation of PsA was observed in 51.6% and peripheral disease in
71%, enthesisitis was found in 54.8% and dactylitis 16.1%.
To determine the severity of PsA according DAS 28 score, we
found 45.2% of patients presented severe activity. One hundred
percent of the subjects with peripheral disease did not achieve
low activity criteria of the disease measured by MDA. When
calculating the tertiles of the HAQ instrument, it is possible to
observe that 51.6% of patients presented severe deterioration
in the quality of life. In the logistic regression model without
adjustment, the presence of a severe DAS 28 is associated with
an increase in the risk of deterioration in quality of life, with OR
of 6.24 (1.74, 22.2). The presence of BMI > 27 is associated with
an increase in the risk of deterioration in quality of life with OR
of 6.53 (1.59, 26.8). When performing the adjusted multivariate

P081 TRIGGERING FACTORS IN CHILDHOOD PSORIASIS
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Introduction: Psoriasis is a chronic multisystem, inflammatory di-
sease that occurs at any age. It represents about 4% of all dermatol-
sis observed in children. Approximately one third of all patients
have onset of the disease under the age of 16. The most common

Objectives: The aim of this study was to assess the most common
triggering and precipitating factors of psoriasis among Bulgarien
children.

Materials and Methods: This study included 42 consecutively
diagnosed children with psoriasis who presented in the Department
of Dermatology and Venereology at Alexandrovska University
Hospital, in Sofia, Bulgaria. The inclusion criteria were a clinical
diagnosis of psoriasis and age under 18 years.

Results: A total of 42 children with psoriasis were examined, 18
(42.85%) males and 24 (57.15%) females. The most frequent fac-
tors precipitating psoriasis in our group of children were psycho-
emotional stress in 16 (38.09%) cases. Koebner’s phenomenon
was observed in 3 (7.14%) patients. In only two (4.76%) children

triggering factors associated with psoriasis were infections. In 17
(40.47%) cases aggravating factors could not be identified. The

influence of the season on disease activity could be determined
in 25 (59.52%) patients. All of them showed worsening in winter
and improvement in summer.

Conclusion: The most frequent factors precipitating psoriasis in
children revealed in this study, were stressful life events, Koebner
phenomenon and infectious disease. Among patients who reported
triggering factors, stress was the most common cause. The study
showed that psoriasis in children relapses and worsens mainly in
winter season.

P082 QUALITY OF CARE FOR PSORIASIS IN THE PAST 12 YEARS – RESULTS FROM A SERIES OF NATIONWIDE HEALTH CARE STUDIES IN GERMANY
Matthias Augustin
Institute for Health Services Research in Dermatology

Introduction: In Germany, the quality of health care for psoriasis
was very critical in 2005. Most patients lacked of sufficient care
and there was only a minor proportion receiving systemic drugs.
In the mean time, there has been conducted a national psoriasis
program in order to improve the quality of psoriasis care, includ-
ing development of an evidence-based guideline, a consensus of
treatment goals, the invention of a “culture of measurement” and
consented national goals for psoriasis care. These measures were
supported by the establishment of 30 regional psoriasis networks
involving more than 800 dermatologists.

Objectives: (1) Presentation of the very recent results on the health
care situation of patients with psoriasis vulgaris in dermatological

Acta Derm Venereol 2018

Methods: Nationwide, non-interventional, cross-sectional studies. In each survey between 71 and 130 centers included patients and data from patients and dermatologists were obtained from a minimum of 1500 patients per survey. Quality of care indicators were severity of the psoriasis (PASI and proportion of patients with PASI > 20, indicating high severity), quality of life (DLQI and proportion of patients with DLQI > 10, indicating strong impairments in quality of life), previous systemic therapy and inpatient treatment in the last five years.

Results: Between January 2016 and December 2017 n = 1827 patients from 93 dermatological centers were included in the recent survey (mean age 51 years, 45.2% female). 7.5% had severe psoriasis (PASI> 20) compared to 9.2% in 2013/14, 11.6% in 2007 and 17.8% in 2004/05. The mean PASI was 7.3 compared to 8.1 in 2013/14, 10.1 in 2007 and 11.4 in 2005. The mean DLQI was 6.1 compared to 5.9 in 2013/14, 7.5 in 2007 and 8.6 in 2005. 21.4% reported a strongly impaired quality of life (DLQI > 10) compared to 21.3% in 2013/14, 28.2% in 2007 and 34.0% in 2005. 59.5% of all participants stated that they had received systemic therapy at least once within the last five years compared to 59.5% in 2013/14, 47.3% in 2007 and 32.9% in 2005. 18% received inpatient hospital treatment within the last five years at least once, compared to 20.1% in 2013/14, 20.1% in 2007 and 26.9% in 2005.

Conclusions: It can be assumed that health care quality for psoriasis patients in Germany has improved within the last 12 years.

P083
GLOBAL PSORIASIS ATLAS – WORK STREAM 2
Matthias Augustin, Niroshshath Suthaharan
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Introduction: Psoriasis is a common, chronic and non-communicable skin disease with an immensely negative impact on people’s lives. There is a lack of standardized case-definition or methodology leading to a wide variation in the prevalence estimate between 0.99% and 11.43%. To tackle this knowledge deficit and in response to the WHO Global report on Psoriasis (2016), the Global Psoriasis Atlas (GPA) will be a first-ever online leading epidemiological database on psoriasis. It will inform research, public and health care provision worldwide. GPA provides a detailed disease prevalence and incidence as well as information on access to treatment, comorbidities and cost to society which will enable extensive comparisons between countries over time. Furthermore, it will provide accurate health data for decision makers, stakeholders and patients worldwide.

Objectives: The GPA includes two Work Streams (WS) Teams. WS1 is conducting extensive literature review on psoriasis. In this paper the WS2 is explaining the development of methodology to serve the framework for compiling the GPA data. Methods: Currently, data sources are being collected in two phases and to serve the framework for compiling the GPA data. Methods: A systematic literature review was performed to answer the research questions. Comprehensive search of eligible scientific and grey publication in English, from 2007 to 2017, were conducted in PubMed and EMBASE (Ovid). The studies included were based on 16 skin condition and other diseases indicating a re-estimation, alternative approach (also besides DALY) to DWs. 20 relevant studies were included and have been elaborated in the review based on a ‘conceptual model of assessing DWs and its design choices’ by Haagsma et al., 2014. The health state description, panel composition and valuation methods used to derive DWs in these studies is discussed in detail.

Results: There was scarce literature available for skin diseases in particular. DW value depends on and can vary with the panel composition: general public, health experts or patients. The health state description whether disease specific or generic, with or without label, describing the course of condition over a period or only temporarily, can all influence the panel members’ decision. The valuation methods paired comparison, population health equivalence, visual analogue scale, standard gambling or person/time trade-off can alter the results to a great extent. The contextual differences across the countries can also make a difference in the calculation. The inclusion of certain skin conditions/health states under other medical specialties can be a major factor leading to underestimation of overall skin disease burden worldwide.

P085
MIR-499 POLYMORPHISM IS ASSOCIATED WITH SUSCEPTIBILITY TO PSORIATIC ARTHRITIS – PRELIMINARY STUDY
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**Introduction:** Polymorphism within the miR-499 has been reported to be associated with susceptibility to rheumatoid arthritis (RA) in various populations.

**Objectives:** Our study aimed to find out whether similar association could be observed also in Polish population in both RA and psoriatic arthritis (PsA) patients.

**Methods:** For this purpose 359 individuals were studied, including 111 RA patients, 86 patients with PsA and 162 healthy blood donors that served as a control group. Genotyping for miR-499 rs3746444 T/C was performed using a LightSNiP assay.

**Results:** Distribution of the miRNA-499 alleles and genotypes was similar in RA patients and controls. Among RA patients those carrying the CC homozygous genotype presented with lower DAS28 at diagnosis (p = 0.027) but higher CRP levels after 12 weeks of anti-TNF treatment (p = 0.042). Interestingly, the TT genotype (rs3746444) was overexpressed in patients with PsA as compared to controls (OR = 1.85, p = 0.034) but its frequency was not significantly different when compared to RA cases. This polymorphism was also not found to be associated with clinical parameters in PsA patients.

**Conclusions:** These results show that miR-499 rs3746444 T/C polymorphism may constitute a risk factor for psoriatic arthritis development.

**P086**

**ASSOCIATION BETWEEN INFLAMMASOME-RELATED POLYMORPHISMS AND CLINICAL PHENOTYPES OF PSORIATIC ARTHRITIS**

Kristina Janeblad, Gerd-Marie Alenius
Department of Public Health and Clinical Medicine, Rheumatology, University Hospital, Umeå

**Introduction:** Psoriatic Arthritis (PsA) disease expression can vary from mild mono- to oligoarthritis to severe erosive polyarthritis comparable with Rheumatoid Arthritis (RA), with or without axial involvement, and manifestations such as dactylitis and enthesitis are common. Markers of systemic inflammation (ESR or CRP) are generally unhelpful as markers of disease severity since elevated in only 50% of cases.

In recent years, research on the interleukin 1β (IL1 β)–regulating protein complex, called the inflammasome, has shown interesting associations with various inflammatory diseases. E.g. for RA (1) and psoriasis (2,3) associations with genetic polymorphisms in genes related to the inflammasome has been discovered. So far, no studies investigating genetic polymorphisms in inflammasome genes in patients with Psoriatic Arthritis (PsA) have been published.

**Aim:** To analyse different single nucleotide polymorphisms (SNP:s) in genes related to the inflammasome in relation to different disease phenotypes of Psoriatic Arthritis (PsA).

**Methods:** DNA from 771 PsA patients from Northern Sweden were analyzed for different single nucleotide polymorphisms (SNPs) in NLRP1 (rs35829419 (NLRP3-Q705K), rs10733113, rs4335135), CARD8 (CARD8-C10X, rs 2043211) and NLRP1 (rs8079034, rs878329) in relation to different phenotypes of PsA.

**Results:** A significant association was seen with NLRP1 rs878329C and patients with axial involvement of disease. When different genotypes were compared, significantly higher frequency of genotype CC were detected in the subgroup with axial involvement of disease. In addition, NLRP1 rs8079034T was significantly associated with prescription of a csDMARD. Also, the NLRP3 rs10733113 showed association with the G-allele in patients with a skin disease with an early onset (PsO type 1, onset <40 years) and in the subgroup of PsA with destructive-/deforming disease significant association was found with the major allele, C, of NLRP3 Q705K rs35829419. (Table 1)

**Conclusions:** In the study, we found association with different phenotypes of PsA and different polymorphisms in inflammasome genes. The results could indicate a possible role of inflammasomes in different disease phenotypes of PsA and make further studies in the area of interest.

**References:**

**Table 1. Genotype and allele frequencies in different PsA disease expressions**

<table>
<thead>
<tr>
<th>Genotype</th>
<th>n</th>
<th>G/G (n %)</th>
<th>G/C (n %)</th>
<th>C/C (n %)</th>
<th>C allele OR (95% CI)* p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Axial disease</td>
<td>107</td>
<td>30 (28)</td>
<td>51 (48)</td>
<td>26 (24)</td>
<td>4.44 (1.37) 0.035</td>
</tr>
<tr>
<td>Peripheral disease</td>
<td>539</td>
<td>184 (34)</td>
<td>275 (51)</td>
<td>80 (15)</td>
<td>41%</td>
</tr>
<tr>
<td>NLRP1 rs705K C/C</td>
<td>314</td>
<td>282 (90)</td>
<td>32 (10)</td>
<td>0 (0)</td>
<td>95% 4.7 1.61 0.03</td>
</tr>
<tr>
<td>NLRP3 Q705K C/C</td>
<td>360</td>
<td>304 (84)</td>
<td>54 (15)</td>
<td>2 (0.6)</td>
<td>92%</td>
</tr>
<tr>
<td>Pso type 1</td>
<td>439</td>
<td>347 (79)</td>
<td>87 (20)</td>
<td>5 (1)</td>
<td>89% 7.4 1.58 0.007</td>
</tr>
<tr>
<td>Neur psO</td>
<td>210</td>
<td>149 (71)</td>
<td>53 (25)</td>
<td>8 (4)</td>
<td>84%</td>
</tr>
<tr>
<td>csDMARD ever</td>
<td>499</td>
<td>320 (64)</td>
<td>169 (33)</td>
<td>80 (15)</td>
<td>41%</td>
</tr>
</tbody>
</table>

*Calculated with test comparing variant allele frequencies between patients and controls.

**P088**

**FREQUENCY OF INADEQUATE RESPONSE TO TREATMENT AMONG PSORIASIS PATIENTS ON FIRST-LINE BIOLOGICS**

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**Introduction:** Studies describing the occurrence of inadequate response (IR) to biologic treatments in psoriasis (PSO) in the real-world setting are currently lacking. Thus an understanding of IR, due to the lack of treatment durability, persistence, or access, to 1st line biologics in PSO may help to identify and address unmet treatment needs.

**Objectives:** To assess the frequency of IR in the year after initiation of 1st line biologic treatment for PSO. IR was defined as biologic dose increase, biologic discontinuation, or add-on treatment.

**Methods:** Retrospective analysis of commercial US healthcare claims (2012–2016) was conducted. Patients initiating a biologic (PSO approved anti-TNF, secukinumab, ustekinumab, apremilast) with ≥ 1 year of database enrolment before and after biologic initiation (index date) who had a qualifying PSO ICD 9/10 code and no previous biologic exposure in the year prior to the index date were included. Patients experiencing any of the following were classified as experiencing an IR event: 1) ≥ 1 claim with a biologic dose > 110% of the label-recommended dose for ≥ 30 days, 2) cessation of 1st line biologic (> 2 months with no treatment) (‘non-switch discontinuation’), 3) cessation of first line biologic followed by initiation of a new biologic within 2 months, or 4) addition of a corticosteroid, immunosuppressant, or biologic (‘add-on treatment’) with any days’ supply overlap.

**Results:** Of the 13,995 patients meeting inclusion criteria, 9,520 (68.0%) experienced an IR event in the 12-month follow-up period (53.2% female; mean age: 46.2 yrs) and 4,475 (32.0%) did not experience an IR event (45.2% female; mean age: 46.9 yrs). The most frequently used 1st line biologics were adalimumab (42.5%) and etanercept (26.5%); the proportion of IR patients was 60.4% in adalimumab and 75.8% in etanercept. Among all IR patients, 20% were csDMARD ever.
non-switch discontinuation was experienced by 63.8% of patients, switch to another biologic by 15.1%, above label dosing by 11.5%, and add-on treatment by 9.7%. Overall, the mean time from initiation of 1st line treatment to IR event was 4.7 months, ranging from 4.3 months to add-on therapy and 5.7 months for patients switching to another biologic. Among patients switching to another biologic, 70.3% of patients were persistent on the new biologic after three months versus 54.0% after 6 months. The most frequent add-on therapies were immunosuppressive drugs (63.8%) followed by systemic corticosteroids (20.6%), and biologics (15.5%).

Conclusions: IR in 1st line PSO biologic treatment is common with non-switch discontinuation being the most frequent. This highlights an opportunity to optimize treatment options currently available and better understand patients’ needs for successful therapy. Therapeutic options with improved durability may provide a clinically meaningful path to optimizing psoriasis management. Further analysis is necessary to identify underlying causes of IR and to guide more effective approaches to treatment.

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P089 BARRIERS OF GUIDELINE-COMPLIANT CARE FOR PSORIASIS IN GERMANY – RESULTS OF THE EUROPEAN STUDY PSOBARRIER
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Introduction & Objectives: A series of nation-wide studies in Germany over the last years has focused on the quality of psoriasis care. It was found that a significant proportion of psoriasis patients is not treated according to the national guideline. Similar under-provision of care has been identified in other countries as well, reflected by patients’ dissatisfaction with the management of their disease. This study aims to identify these barriers of guideline-compliant healthcare for psoriasis in Europe.

Materials & Methods: The study assesses barriers and quality of health care in a multi-centre, cross-sectional study design. Participating centres in five European countries (Denmark, Poland, Spain, United Kingdom, and Germany) aim to represent the range of dermatological health care-providing outpatient facilities of the respective country. The current analysis includes the data collected in Germany from January 2016 to May 2017.

Results: Data of n = 497 patients were analysed. Mean age was 49.7 years, 41.4% were female. Mean PASI was 7.2 ± 9.2, 20.9% had a PASI > 10. The mean DLQI was 6.2 ± 6.7, 27.0% were currently treated with systemic treatments (excluding biologics), 22.3% with biologics. Since the diagnosis of psoriasis, the participants consulted on average 3.0 ± 2.3 different dermatologists (min 0/max 27) and had 3.5 ± 3.7 therapy changes. For 32.0% of the patients the time between the first skin changes and the first diagnosis of psoriasis was one year or longer. 7.6% stated that their health insurance turned down a therapy, treatment or referral that was recommended by a physician at least once.

Conclusions: The quite high numbers of consultations of different dermatologists, therapy changes and therapies turned down indicate that there might be barriers in psoriasis care. The generated data facilitate measures for an improved patient access to systemic drugs and biologics. The European comparison will allow for the first time the direct description of psoriasis care in a wide variety of European countries. The matching of patient-reported outcomes with data of the health care system and barriers from the physician’s perspective is a novelty worldwide and the results will contribute to developing strategies to overcome these barriers.

References:

P090 INDIVIDUALISED THERAPY FOR PSORIASIS - CASE SERIES
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tional Academy of Classical Homeopathy

Introduction: Psoriasis and its complications are still a challenge to clinicians. The autoimmune disorder though targeting the skin, involves the immune system as a whole. The inflammatory component in the pathogenesis of psoriasis has further established the role of aberrant immune system in the process [1, 2, 3]. Homeopathy addresses every individual’s peculiar combination of genetic and epigenetic causative factors in the development of such auto immune diseases [4, 5]. Therefore it may be considered as a therapy where integrated approach is indicated.

Case series: 5 cases of psoriasis were presented, two of which were in erythrodermic state [one also with sepsis superimposed]. Through monitoring of blood markers and documenting on photos and videos the effect of individualised homeopathic therapy on psoriasis and its complications is demonstrated.

The theory of Levels of Health can explain the variety in the presentation of psoriasis and response to treatment in terms of the time taken and number of remedies required. The same theory also helps to assess the prognosis and comprehend the response to treatment [LOH]. With the help of the evidence of these cases we may formulate a larger study to ascertain the extent to which classical homeopathy may be employed in psoriasis.

Conclusions: These cases depict the potential for homeopathy in alleviating the suffering of patients with psoriasis if applied as individualised therapy and give grounds to further conduct controlled studies to confirm the role of homeopathy in psoriatic therapy.

References:

P091 A UNIQUE CLINICAL CASE OF PSORIATIC ARTHRITIS AND RELAPSING POLYCHONDRITIS
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Introduction: Relapsing polychondritis (RP) is a rare systemic autoimmune disorder affecting the cartilaginous structures of the body and resulting in their destruction. In the literature available we didn’t find any references to RP occurring together with psoriatic arthritis (PsA).

Objective: to demonstrate a rare clinical case of RP and PsA.

Methods: Patient (pt) (female), 29 y.o., complained of pain, swelling, and hyperemia of both ears, pain in the joints, in heels and toes and pain in cervical spine. Scalp psoriasis (Ps) and Ps in the external ear canal occurred in April, 2017, nail Ps and dactilitiis in October, 2017; in November, asymmetrical polyarthritis, pain in heels, pain and limitation of movement in cervical spine developed. Besides the pt noticed redness, swelling and pain in pinnas of both ears and impairment of hearing; conjunctivitis, stomatitis and subfebrile temperature developed.

www.medicaljournals.se/acta
At presentation: plaque Ps on the face and scalp, nail Ps, palmoplantar feet pustulosis (BSA–4%, PASI –2.1); both pinnae of the ears were swollen, painful and red; ear lobes were not involved. The pt suffered from conjunctivitis. The pt had bilateral auricular chondritis, nonerosive seronegative arthritis, nasal septum chondritis, ocular inflammation, respiratory tract chondritis, and cochlear disorder. Our pt had bilateral auricular chondritis, conjunctivitis, cochlear disorder. The diagnosis was confirmed by ear-auricles biopsy which showed perichondrial inflammation and granulocyte infiltration. The therapy delivered: methotrexate s/c 10 mg pw; Solu-Medrol i/v (750 mg cumulatively); methylprednisolone per os 16 mg per day. Within days, there was normalization of temperature, ear-auricle swelling, redness and pain had regressed; hearing was restored. Conjunctivitis passed, the intensity of arthritises, dactylitis and cochlear disorder had decreased; the reduction in ESR, CRP was to 14 mm/h, to 7.0 mg/l accordingly.

**Conclusion:** As is known, when a pt has PsO, he is twice as likely to develop additional autoimmune diseases. It is of great importance to properly diagnose and treat cross autoimmune diseases. Early diagnosis (within 3 months) and adequate treatment resulted in rapidly decreased inflammatory process and in escaping nonreversible changes in cartilage tissues.

**P092**

**SPINY FOLLICULAR HYPERKERATOSIS IN A PSORIASIS PATIENT TREATED WITH USTEKINUMAB**

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**Introduction:** We present a psoriasis patient developing asymptomatic white spiny follicular hyperkeratoses (SFH) after being treated with ustekinumab for 3 months.

**Objectives:** This type of eruption has been described under several names including spiny follicular keratoderma, hyperkeratotic spicules, filiform hyperkeratoses, parakeratotic horns, and follicular hyperkeratoses (1). Facial hyperkeratotic spicule eruption was reported in association with monoclonal gammopathy. Drug-induced filiform hyperkeratosis has been reported with cyclosporine, with Braf inhibitors ( vemurafenib), with acitretin and with vismodegib and sorafenib.

**Methods:** Our patient started ustekinumab treatment in June 2015. At the same time he was treated with methotrexate, folic acid, metformin and lisinopril/hydrochlorothiazide. Three months after ustekinumab introduction patient noticed growth of tiny skin projections located on the face, scalp, upper trunk and upper arms. Each spiny lesion was approximately 0.5 to 1 mm in diameter and up to 5 mm high. A biopsy of a white spiny keratotic projection showed orthokeratosis, acanthosis and mild spongiosis in epidermis, inflammatory infiltrate in stratum and dilatated acrotrichia. Condition resolved in several weeks without any treatment and without ustekinumab cessation.

**Results:** A similar condition viral-associated trichodysplasia (TS) was originally described in 1999 as a folliculocentric viral infection in a patient who was receiving cyclosporine after kidney and pancreas transplantation. Trichodysplasia spinulosa associated polyomavirus (TSPyV) was identified in TS lesions and shown to be the probable cause of this disease (2). Pathogenesis both of viral-associated TS and Braf inhibitor-induced SFH is based on the paradoxical activation of MAPK (mitogen-activated protein kinase) pathway, which regulates a variety of cellular processes including cell division, differentiation and apoptosis.

**Conclusions:** Our patient developed SFH possibly due to use of ustekinumab, IL-12 and IL-23 inhibitor. The latter has a role in differentiation process of the skin (12), suggesting that inhibition of IL-23 might explain the imperfect keratinization process observed in SFH. Considering that in our patient drug was not stopped and the condition resolved in several weeks without any treatment, possible cause could be ustekinumab-induced immunosupression and consequent viral infection.

**References:**

**P093**

**COMBINATION THERAPY OF APREMILAST AND BIOLOGICAL PRODUCT IN A PATIENT WITH PSORIASIS**

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Apremilast was approved in March 2017 in Japan for the treatment of psoriasis and psoriatic arthritis. Apremilast appears to have lower efficacy than biological product. However, its ease of administration as an oral agent coupled with a mild side effect profile makes it an attractive option for psoriasis treatment. While monotherapy with biological products is effective for many patients with psoriasis, some patients are not satisfied by the outcome. There are few data or reports about the safety and efficacy of apremilast in combination of biological product in the treatment of psoriasis. We report a 46-year-old man with about a twenty-year history of plaque psoriasis and psoriatic arthritis who failed several therapies including topical therapy, phototherapy and etretinate. At the time of presentation, the patient was using secukinumab for 9 months, which had controlled his arthritis. However, the patient noted plaque remained mainly on his lower legs. Apremilast was added and up-titrated to 30 mg twice per day along with his secukinumab therapy. After two months of combination therapy, the patient’s disease has improved and stabilized with only a few scattered erythematous mildly scaly plaques on his lower legs. The patient denied side effects of nausea, diarrhea or headache. Laboratory work was within normal limits. However, we also experienced two other cases who failed apremilast add on therapy to biological product because of efficacy or side effects. So, this method may be useful for uncontrolled patient for psoriasis, more studies are needed to determine the safety and efficacy of using these drugs together.

**P094**

**PSORIASIS WORST-CASE SCENARIOS: A SERIES OF 3 CASE REPORTS**

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**Introduction:** Psoriasis is a chronic, immune, inflammatory disease, that can occur at any time and it is most common in the age group 50-69. The reported prevalence of psoriasis in countries ranges between 0.09% and 11.4%, making psoriasis a serious global problem.

**Objectives:** We present a series of 3 case reports that stand for some of the worst-case scenarios a Psoriasis patient could end up in.
We won’t be insisting on the treatment nor the outcomes of these patients whereas the aim of this presentation is to emphasize the importance of patient’s education, prevention, but also of an early and correct treatment.

**Materials And Methods:**

Case report no.1:

- **Patient characteristics:** 49-years-old white Caucasian male;
- **Clinical presentation:** widespread, confluent erythema of the skin, large scales, malaise, intense joint pain, shivers, oliguria, marked onychodystrophy of fingernails and toenails with an evolution of about 1 week;
- **Physical examination:** fever, tachycardia, generalized nontender adenopathy;
- **Patients history:** Psoriasis vulgaris and Psoriatic arthritis since 2003 treated with 8 months Methotrexate switched (due to digestive symptoms) to oral Acitretinum for about 2 months prior the current presentation;
- **Possible cause of the flare-up:** lack of compliance to treatment, but mostly because of disorderly lifestyle.

Case report no.2:

- **Patient characteristics:** 64-years-old white Caucasian male;
- **Clinical presentation:** widespread, confluent erythema of the skin, large scales, malaise, loss of appetite, marked onychodystrophy of fingernails and toenails with an evolution of about 2 weeks;
- **Physical examination:** fever, tachycardia;
- **Patients history:** Psoriasis vulgaris since 1992 treated with Adalimumumb (discontinued after 2 years) and Methotrexate;
- **Possible cause of the flare-up:** voluntarily discontinuation of the treatment (Methotrexate) 3 weeks prior to current presentation.

Case report no.3:

- **Patient characteristics:** 38-years-old white Caucasian female;
- **Clinical presentation:** pustular lesions spread throughout an erythematous background intercalated with skin atrophies and subepidermal pseudocysts disseminated throughout the body, erythematous, scaly plaque on the scalp;
- **Physical examination:** vital signs within normal limits;
- **Patients history:** Pustular Psoriasis from the age of 7 treated with Prednisone, Acitretinum and topical steroids;
- **Possible cause of the flare-up:** voluntarily discontinuation of the treatment (Acitretinum) 7 months prior to current presenta- tion (the patient wishes to conceive) and long-term use of potent topical steroids.

**Results:** All three cases were treated considering the Psoriasis type, clinical presentation and symptoms, each of them having a positive evolution during the hospitalization and follow-up visits.

**P095**

**SUCCESSFUL SWITCHING TO BIOSIMILAR IN PSORIATIC PATIENT WITH SEVERE DRUG REACTION TO INFlixIMAB. A CASE REPORT**

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**Introduction:** Biosimilar medicines are drugs which are highly similar to other biological medicines already licensed and that do not have any clinically meaningful difference to the originator drug in structure, pharmacokinetics, quality, safety or efficacy.

**Objectives:** Many clinical and observational studies involving a switch between reference infliximab and its biosimilars have been conducted or are ongoing. Switching between reference biologics and biosimilars should be performed by the prescriber for clinical reasons such as optimizing efficacy or minimizing AES. Efficacy and clinical measures of safety were similar in the switched and not switched groups at studies end. Differences in the type of AES upon switching must also be considered. Because biosimilars are structurally distinct from innovator biologic, they may produce significantly different side effects. Although, data in the literature suggest that if a patient experience a severe allergic reaction to the originator drug it is most possible the same reaction to happen with the biosimilar this may not always be the case.

**Methods/Results:** We present a case of a 60 years old female patient with severe plaque psoriasis from 25 years treated with infiximab every eight weeks for the last five years with great therapeutic efficacy. During the last five infusions she presented mild reaction with itching and facial redness which was treated successfully with antihistamines without the need of interrupting the infusion. Patient was also administered pretreatment therapy with a three day course of corticosteroids to minimize these reactions. During the last infusion patient presented severe body rash and hypotension which led to the discontinuation of the infusion. Due to the great therapeutic response and because patient had undergone several therapies in the past which either hadn’t tolerated or hadn’t responded to, she was reluctant to change therapy so we decided to switch to a biosimilar. Patient is currently through the eight month of treatment with the biosimilar with no sign of reaction and with maintenance of the therapeutic response.

**Conclusion:** Biologics are much more complex than conventional chemical drugs because they are larger and have more complicated structures, so it is impossible to produce biosimilars that are identical to the originator drug. As a result, the therapeutic efficacy and safety of a biosimilar could vary from the originator because the end product is highly dependent on a proprietary manufacturing process that differs for each manufacturer. Our case suggests that we may try a switch between reference biologic and its biosimilar even when an allergic reaction to the originator drug had occurred, especially when we have a great therapeutic efficacy. However, more data is needed.

**P096**

**SAFETY OF APREMILAST IN THE TREATMENT OF A PSORIASIS PATIENT WITH CHRONIC HEPATITIS B**

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**Introduction:** The treatment of patients with moderate-to-severe psoriasis in an everyday clinical setting, sometimes, poses serious challenges. The presence of hepatitis B Virus Infection (HBV) in these patients complicates the therapeutic choices.

**Objectives:** We report the case of a female patient, 52 years old, suffering from moderate-to-severe plaque psoriasis and chronic hepatitis B.

**Methods:** She was referred to our outpatient psoriasis clinic with a Psoriasis Area and Severity Index (PASI) score of 13.2. The patient’s condition has deteriorated the past year but she had not received any kind of systemic treatment. During our pre-treatment screening tests she was found HBsAg positive although the liver function tests were within normal rates. The HBV serological status of the patient (HBsAg, HBeAg, anti-HBs, anti-HBs and anti-HBe) was estimated. HBV DNA load was measured with the Polymerase Chain Reaction (PCR) method, in order to confirm that the disease was not active, and it was undetectable.

**Results:** At that point it was decided to treat the patient with Apremilast using the standard titration dosing schedule (10mg on day one and increasing the dose by 10 mg daily) until reaching the maintenance dose of 30mg twice daily on day 6. Antiviral treatment was not given to the patient but liver function tests were performed at a monthly basis and HBV load every three months during treatment. All these test from the baseline until last observation (12 months after) were within normal rates. The patient exhibited an amelioration of her condition from the beginning which was confirmed by the significant reduction of her PASI score.
which reached PSI75 at week 12 and PASI90 at week 24. At the
time of this writing, one year after the initiation of treatment, the
patient remains almost clear from her psoriatic lesions. Apremilast
was well-tolerated by the patient.

Conclusions: The treatment of moderate-to-severe psoriasis in the
background of chronic HBV limits the therapeutic options due
to the possibility of HBV reactivation when the psoriasis patient is
affected by immunosuppressive or even immunomodulatory
drugs. Apremilast is an oral small-molecule PDE-inhibitor, approved
by the Food and Drug Administration for the treatment of
moderate-to-severe plaque psoriasis in 2014. It does not target
any one cytokine but restores a balance of pro-inflammatory and
anti-inflammatory mediators. The pharmacokinetics of Apre-
milast is not affected by hepatic impairment and the drug is not
hepatotoxic. Moreover, it is not contraindicated in patients with
active infection. To our knowledge, this is the first reported case of
Apremilast psoriasis patient with chronic inactive Hepatitis B. It
proved to be both safe and efficacious but large, well-organized
studies are needed in order to confirm this conclusion.

P098
IL-22 INDUCES KERATINOCYTES
HYPERPROLIFERATION IN PSORIASIS VIA MIR-21
AND MIR-31 UPREGULATION
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Psoriasis is a chronic inflammatory skin disease that affects
people of all ages with an estimated 3% prevalence worldwide. It manifests as thick red irritated skin lesions due to imbalanced keratinocytes hyperproliferation and differentiation caused mainly
by increased activation of IL-22 pathway in keratinocytes. Emerging studies showed a specific psoriatic miRs signature where
miR-21 and miR-31 are one of the most upregulated miRs. The
latter acts by favoring cellular proliferation and inflammation.
Hence, re-conciliating the microRNAs and the immunopathogenic
occasions responsible for psoriasis development can be a new
approach for developing effective mechanism and target-based
agents to treat psoriasis.

The common hyper-proliferation effect of IL-22, miR-21 and
miR-31 prompted us to look at a potential interaction between
these actors. The expression levels of those 2 microRNAs and that
of their targets were evaluated both in vitro and in vivo studies in
presence or absence of IL-22.

We first exploited different skin models to investigate a potential
connection between IL-22 and miR-21 or miR-31. The qPCR
analysis showed a significant increase in the relative expression
(Re) of both miRs in the different models upon IL-22 stimulation during 24h compared to untreated cells. These observations
indicate the implication of miR-21 and miR-31 in proliferation-
differentiation processes in the different layers of the epidermis.
We also examined the miR-21 target RE PTEN involved in cell
growth and apoptosis control and the miR-31 target RE ppp6c
involved in G1 to S phase transition restriction. In line with the
upregulation of miR-21 and miR-31, IL-22 stimulation resulted in
significant downregulation of both targets at the genomic and
proteomic levels.

We next investigated the in vivo correlation between IL-22 and
miR-21 or miR-31 respectively in the development of psoriatic
lesion. We used the imiquimod-induced psoriasisform skin inflam-
mation in Wild type and IL-22 deficient mice (known to be almost
protected from IMQ). Mice displaying a less severe disease form
had less miR-21 expression. By contrast, WT mice treated with
IMQ exhibited significantly higher miR-21 RE than IL-22/-/- mice.
Furthermore, miR-31 expression in IL-22/-/- mice was identical to
miR-31 expression in WT control mice. These results suggest a
direct correlation between IL-22 pathway and miR-31 epidermal
expression. In line with these observations, the miR targets (PTEN
and pp6c) were contrariwise proportional to miRs expression
confirming by that the specificity of the IL-22/miR-21 and IL-22/
miR-31 correlation.

These findings identify IL-22 as a key regulator of miRs implica-
ted in multiple signaling pathways that coordinate keratinocytes
proliferation activity

P099
SERUM CONCENTRACION OF IFN-GAMMA IN
PATIENTS WITH Psoriasis: Correlation with
CLINICAL TYPE AND SEVERITY OF Disease
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Introduction: Psoriasis is a multifactorial chronic inflammatory
disease. The etiopathogenesis of the disease is still unclear but
there is evidence that many of cytokines released by keratinocytes
and inflammatory leukocytes may contribute to the induction or
persistence of the inflammatory process in psoriasis.

Objectives: The aim of the study was to evaluate serum concentrations of IFN-gamma in patients with psoriasis and the healthy
subjects and also to assess a possible association between IFN-
gamma, clinical type and severity of disease.

Methods: The study included a total of 60 patients with psoriasis,
both genders and all of ages. There were 20 healthy subjects in the
control group. According to the clinical type of disease, patients
with psoriasis were divided into four groups: psoriasis vulgaris,
psoriasis pustulosa, psoriasis erythrodermica and psoriasis arthrop-
atica. Blood samples were collected from all psoriasis patients
and from healthy control subjects. Serum IFN-gamma levels were
measured by an enzyme-linked immunosorbent assay (ELISA)
technique. The severity of psoriasis vulgaris was assessed by
Psoriasis Area and Severity Index (PASI) score.

Results: Of the total number of patients suffering from psoriasis
42 (70%) had psoriasis vulgaris. The second most frequent was
psoriasis erythrodermica 9 (15%), while 5 (10%) patients had
psoriasis pustulosa and 3 (5%) psoriasis arthropatica. The severity
concentration of IFN-gamma in patients with psoriasis was sig-
ificantly higher than that in the control group (1.91±1.79 pg/ml
vs 0.91±0.38 pg/ml, respectively). Significantly elevated serum
IFN-gamma concentrations were noticed in patients with psoriasis
vulgaris (2.15±0.30 pg/ml), compared with patients suffering from
psoriasis erythrodermica (1.57±0.68 pg/ml), psoriasis arthropa-
tica (1.33±0.53 pg/ml), and in particular patients suffering from
psoriasis pustulosa (1.08±0.21 pg/ml) who had the lowest mean
serum concentration of IFN-gamma. There was no statistically
significant difference between the mean values of IFN-gamma
compared to the clinical type of psoriasis (p > 0.05). In the group of
patients with psoriasis vulgaris 36 (85.71%) patients had mild form
disease with PASI < 50, and 6 (14.29%) patients had severe
disease with PASI > 50. It was not found statistically significant
correlation between IFN-gamma and PASI score.

Conclusions: The results of this study showed that psoriasis is
associated with significant changes in serum concentration of IFN-
gamma. There was no statistically significant correlation between
serum IFN-gamma concentrations, clinical type of psoriasis, and
also severity of psoriasis vulgaris evaluated by PASI score.

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IMMUNOLOGICAL MEMORY EXISTS IN THE RECURRENT LESION AND NONRECURRENT SKIN AFTER REMISSION IN PSORIATIC PATIENTS

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Introduction: Psoriasis usually recurs in previously affected areas, so a pathogenic memory has been proposed, but the nature of such site-specific recurrent memory is not completely known. Tissue-resident memory T (TRM) cells are non-recirculating memory T cells that persist long-term in epithelial tissues, including the skin. Because they can localize in the skin for many months, we speculate that TRM may contribute to recurrent pathology of psoriasis.

Objectives: The aim of the present study is to compare the differences of quantity proportion and secretion ability of cytokines of the TRM cells between recurrent and nonrecurrent lesions following remission, as well as to explicit the possible survival signal for these TRM cells in psoriatic lesion.

Methods: RNA-Seq, Gene Ontology and KEGG analysis, real-time PCR, flow cytometer analysis/sorting, cell stimulation assay, and western blot were used to explore the immunological memory.

Results: Compared with normal skin, there are common shared genes significantly upregulated ( > 2 folds, p < 0.001) by recurrent and nonrecurrent lesions, including CD69. CD69 mRNA transcription level in nonrecurrent lesions after remission remains as high as in neighboring recurrent lesions. CD8+CD69+ TRM cells exist in both lesions, and they can secret almost same amount of IL-17A and IL-22 after stimulation. Levels of IL-15, secreted by keratinocytes in psoriasis epidermis, in nonrecurrent lesions remain as high as in neighboring recurrent lesions, and recombiant human IL-15 can induce CD69 on TRM cells.

Conclusions: Our preliminary study shows that CD8+CD69+ TRM cells persist in clinically resolved psoriatic lesions whether it recur or not, and they can produce IL-17A and IL-22 with critical effect on psoriatic recurrence and development. Furthermore, we have indicated the IL-15 may play crucial role in the survival of CD8+CD69+ TRM cells in psoriatic lesions.

References:

THE IMMUNE-PHENOTYPE OF SMALL PLAQUE PSORIASIS

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Introduction: Small plaque psoriasis (SPP) is a subtype of psoriasis first described by Griffiths et al (2007). It resembles guttate psoriasis but lesions are larger, are chronic, and are not associated with streptococcal infection. We have observed SPP develop in four different population groups; patients under TNFα-inhibitor therapy, patients under immune checkpoint inhibitor (ICI) therapy, and patients with concurrent SLE or ANA positivity and psoriasis. Subtypes of psoriasis develop on a spectrum between autoimmune and auto-inflammatory responses and an interplay between three signalling pathways are involved in their distinct pathogenesis. Chronic plaque psoriasis lesions are on the autoimmune spectrum, dominated by a T-cell mediated TNFα/IL-23-IL-17/IL-22 axis. Pustular psoriasis is a neutrophilic infiltrative inflammatory skin disease resulting from dysregulation of the IL-36/IL-1 axis. Lastly, TNFα-inhibitor (TNFi) induced lesions have a SPP morphology and demonstrate increased expression of LL-37 by keratinocytes, activated plasmacytoid dendritic cells and upregulated type-1 interferons (IFN). These lesions express fewer epidermal CD8 T cells.

Objectives: Our aim is to characterize the immune-phenotype of SPP in multiple clinical scenarios. We hypothesize that SPP develops as a result of increased expression of cytokines and antimicrobial peptides involved in the type-1 IFN pathway.

Methods: Skin biopsies were obtained from three patients with
The evidence is strong that immunological mechanisms in patients without psoriatic arthritis (p < 0.001). Serum SGK-1 levels were significantly high in patients with psoriasis compared with healthy controls (p < 0.001). Serum SGK-1 levels were significantly high in patients with psoriatic arthritis compared with in patients without psoriatic arthritis (p < 0.001).

Conclusions: The evidence is strong that immunological mechanisms are involved in the pathogenesis of psoriasis. In this study, we demonstrated that serum SGK-1 levels were significantly elevated in patients with psoriasis and psoriatic arthritis.

P105 DIFFERENTIAL NH2-TERMINAL AUTOANTIGEN TRIMMING MAY EXPLAIN EPITISIS BETWEEN HLA-C*06:02 AND ERAP1 VARIANTS IN PSORIASIS RISK

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Introduction: NH2-terminal trimming by endoplasmic reticulum aminopeptidase 1 (ERAP1) generates the appropriate length of antigenic peptides for binding to and presentation by HLA-class I molecules. Genetic interaction between ERAP1 variants and HLA-class I alleles determines the genetic risk for various HLA-class I-associated inflammatory diseases. Epitasis between HLA-C*06:02 and ERAP1 variants affects also psoriasis risk but the mechanisms of these gene interactions remained unknown. Using a pathogenic Vu3S1/Vβ13S1-TCR from a psoriatic CD8+ T-cell clone, we had shown that in psoriasis, HLA-C*06:02 mediates an autoimmune response against melanocytes through autoantigen presentation and we had identified a peptide from ADAMTS-like protein 5 (ADAMTSL5) as HLA-C*06:02-presented melanocye autoantigen.

Objectives: To determine the role of ERAP1 variants in psoriasis pathogenesis.

Methods: We established ERAP1 knockout cells using CRISPR/Cas9 system. ERAP1 knockout cells transfected with plasmids coding for HLA-C*06:02, ERAP1 variants, and antigenic peptides were co-cultured with the TCR hybridoma to determine the levels of TCR ligation which reflect the generation of the antigenic ADAMTSL5 peptide and other Vu3S1/Vβ13S1-TCR ligands from precursors.

Results: Our data show that NH2-terminal trimming by ERAP1 is required to generate the actual antigenic ADAMTSL5 peptide from NH2-terminally elongated precursors. An ERAP1 variant protecting from psoriasis reduced the immunogenicity of the antigenic ADAMTSL5 peptide presumably through overtrimming and peptide destruction, whereas a psoriasis risk variant of ERAP1 highly kept the antigenicity of the autoantigen. This effect was specific for ADAMTSL5. Precursors of other Vu3S1/Vβ13S1-TCR self-ligands were not substrates of ERAP1.

Conclusions: Using a proven psoriatic autoantigen and a cognate psoriatic TCR, these experiments provide direct evidence that gene-gene interaction between ERAP1 and HLA-C*06:02 affects the risk for psoriasis through differential autoantigen trimming from precursors. These data furthermore propose a model where ERAP1 function essentially controls the autoantigenic potential of self-peptides in HLA-class I associated CD8+ T-cell mediated autoimmune diseases.

P106 ENVIRONMENTAL TRIGGERS OF AN HLA-C*06:02-RESTRICTED AUTOIMMUNE RESPONSE IN PSORIASIS

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Introduction: Psoriasis vulgaris is a multifactorial disease. While the major psoriasis risk gene HLA-C*06:02 accounts for up to 50% of disease onset, environmental factors are considered to contribute to approximately 30% of disease risk. Psoriatic skin inflammation is driven by an HLA-C*06:02-mediated autoimmune response against melanocytes. A pathogenic Vu3S1/Vβ13S1 T-cell receptor (TCR), which we had reconstituted from a lesional epidermal CD8+ T-cell clone of an HLA-C*06:02–positive psoriasis patient in a mouse reporter hybridoma cell line, specifically reacts against melanocytes through HLA-C*06:02 restricted recognition of a psoriatic melanocyte autoantigen, ADAMTS-like protein 5 (ADAMTSL5). However, it is unknown whether and how environ-
mental factors may contribute to autoimmunity in psoriasis. TCRs are known to be polyspecific, recognizing multiple peptide ligands which share a conserved amino acid pattern specific for each TCR. **Objectives:** To examine the potential role of environmental factors in the psoriatic autoimmune response.

**Methods:** We first determined the particular amino acid motif which is recognized by the psoriatic Va3S1/Vp13S1 TCR in the context of HLA-C*06:02. By homology searches using this conserved amino acid pattern, we selected 57 peptides from food, bacterial, fungal and viral pathogens and from the skin and intestinal microbiomes as candidate environmental antigens that may trigger the psoriatic autoimmune response. We cloned the peptides into expression plasmids, co-transfected them with HLA-C*06:02 into Cos7 cells and used them to stimulate the Va3S1/Vp13S1 TCR. TCR ligation was determined by GFP induction of TCR hybridoma in FACS analysis. We then stimulated blood lymphocytes with the candidate peptides that had ligated the Va3S1/Vp13S1 TCR. Lymphocyte activation was assessed by induction of activation markers and proliferation assays using thymidine incorporation.

**Results:** We identified a variety of peptides contained in proteins from food (wheat, coffee, apple, and spinach), microbiota of human skin and gut-derived pathogens including *Chlamydia trachomatis*, which ligated the psoriatic TCR in a polyspecific manner. Stimulation of blood lymphocytes with particular candidate antigens resulted in significant activation in psoriasis patients, as compared to healthy individuals. Interindividual-correlation analyses demonstrated cross-reactive immune responses between environmental antigens and the melanocyte autotigen presented by HLA-C*06:02 in psoriasis patients. Among the candidate antigens, wheat peptides induced most robust lymphocyte activations in psoriasis patients. Moreover, psoriasis was significantly improved by wheat-free diet in several patients with lymphocytes responding to wheat, indicating potential pathogenic contribution of wheat antigens in psoriasis.

**Conclusions:** Our results provide unbiased evidence that several environmental antigens may trigger the melanocyte-specific autoimmune response in psoriasis. By identifying and avoiding those triggers at the molecular level which translate the genetic predisposition into disease manifestation, we may develop strategies to prevent disease onset and exacerbation.

**P107**

A SKEWED POOL OF RESIDENT T CELLS TRIGGERS DISEASE-ASSOCIATED TISSUE RESPONSES IN NEVER-LESIONAL PSORIASIS

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**Background:** Psoriasis lesions evolve as a result of cytokine driven interactions between intraleisional immune cells and keratinocytes in genetically predisposed individuals. Skin resident T cells are implicated in maintenance and recurrence of psoriasis plaques but their composition and function in never-lesional psoriasis skin is less known.

**Objective:** Characterisation of T cell driven tissue responses and subsets of resident T cells in never-lesional psoriasis.

**Methods:** T cell driven tissue responses were assessed in explanted skin biopsies using Nanostring and Multiplex analysis. Epidermal and dermal T cells were characterised using flow cytometry in never-lesional skin from patients with mild disease.

**Results:** T cell activation induced epidermal psoriasiform and type-I interferon tissue responses in explants from never-lesional skin. Skin resident T cells were skewed with enrichment of epidermal IL-17 and IL-22 producing CD4+CCR6+ and CD8+CD103+CD49a+ T cells and IFN-γ producing CD4 T cells in never-lesional skin compared to healthy skin. Keratinocytes from never-lesional psoriasis responded to IFN-γ activation with IFN-α secretion and MX1 upregulation and skin explants exposed to common fungal antigens produced the CCR6-attractant CCL20.

**Conclusion:** Resident T cells poised to induce psoriasiform tissue responses accumulate in never-lesional skin of psoriasis-affected individuals. Additionally our data suggest that microbial interplay with genetically predisposed keratinocytes may shape the local pool of resident T cells.

**References:**


**P108**

NAIL INVOLVEMENT IN PSORIASIS; IS IT A PREDICTOR OF PSORIATIC ARTHRITIS?

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**Introduction:** Psoriatic Arthritis (PsA) arises in an increased burden of psoriasis and impairments in both quality of life and functional capacity. The relationship between nail involvement and PsA in psoriasis is not fully characterized.

**Objective:** To evaluate the frequency and characteristics of nail involvement in psoriatic patients and to assess the relationship with joint involvement.

**Methods:** A total of 197 patients with moderate-to-severe psoriasis, were consecutively selected to participate in this cross-sectional study. The patients divided into two groups; with and without psoriatic arthritis.

**Results:** 69.5% of psoriatic (137 out of 197) patients had nail involvement. The most common nail abnormality was onycholysis, followed by pitting and oil drop. Nail changes were more common in patients with psoriatic arthritis (82.1% vs. 57.8%).

**Limitations:** Our study had certain limitations. One of them was lack of information about the subtypes of PsA. Also, we have not recorded the severity of nail involvements. Furthermore, previous medications may have interfered with the degree of nail changes in our patients.

**Conclusion:** Nail involvement is associated with PsA. Onycholysis, splinter hemorrhage, and oil drop were significantly more common in PsA group. In general, psoriatic patients with arthritis had the more severe disease.

**References:**


**P109**

ABSOLUTE AND RELATIVE PASI IMPROVEMENTS WITH INEKIZUMAB TREATMENT: RESULTS AT WEEK 12 FROM IXORA-P

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12 FROM IXORA­P WITH IXEKIZUMAB TREATMENT: RESULTS AT WEEK
**Introduction and Objectives:** Ixekizumab (IXE), an interleukin-17A antagonist, has shown superior efficacy in psoriasis compared to placebo,1 etanercept,1 and ustekinumab.2 This post hoc analysis intended to evaluate absolute and relative Psoriasis Area and Severity Index (PASI) improvements with IXE treatment in a phase 3 trial (IXORAP).

**Methods:** In IXORA-P, patients with moderate-to-severe psoriasis were randomized (2:1:1) to receive any of the 3 dosing regimens of IXE 80 mg: every 2 weeks (Q2W; n = 611), every 4 weeks (Q4W; n = 310), or Q4W/Q2W step-up (n = 306), for 52 weeks. Randomization was stratified by country and weight (<80 kg, ≥80 to <100 kg, or ≥100 kg). The percentage of patients achieving a 75%, 90%, or 100% improvement from baseline in PASI (PASI 75, 90, and 100) was evaluated using logistic regression with dosing regimen, country, and baseline weight as factors. Fisher’s exact test with nonresponder imputation was used to compare the response rates between treatment groups. Here, we present results at 12 weeks for Q2W (label dose) and Q4W groups; results from Q4W/Q2W group will be discussed separately.

**Results:** Mean (standard deviation) PASI score at baseline was 20.3 (8.25). Response rates were significantly higher (p < 0.001) for Q2W group compared to Q4W group across all cut-off points for absolute PASI: absolute PASI ≤1, 2, 3, and 5 response rates at Week 12 were 61.4%, 76.1%, 84.5%, and 89.4%, respectively, for Q2W group, and 49.7%, 64.5%, 72.6%, and 83.9%, respectively, for Q4W group. At Week 12, PASI 75 response rates in Q2W and Q4W groups were 89.2% and 83.2%, respectively (p = 0.012). For Q2W and Q4W groups, PASI 90 response rates were 75.3% and 63.2%, respectively (p < 0.001), and PASI 100 response rates were 46.0% and 32.6%, respectively (p < 0.001).

**Conclusion:** As reported in psoriasis registration trials, induction with IXE Q2W, the labeled dosing regimen, provides better clinical outcomes at Week 12.

**References:**


**PI10**

**PREVALENCE AND SEX DIFFERENCES OF PSORIATIC ARTHRITIS IN PATIENTS WITH SEVERE PLACQUE PSORIASIS.**

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**Background:** Prevalence of psoriatic arthritis in patients with psoriasis has conflicting data in different population. But no study has been performed in Russian population of prevalence and sex differences of psoriatic arthritis in patients with severe plaque psoriasis.

**Objectives:** to evaluate the prevalence PsA in patients (pts) with PsO in a dermatological hospital cohort.

**Methods:** 890 pts (Male-516/Female-374) with severe plaque PsO, mean age 50.4 ± 17.6 years, mean PsO duration 21.5 ± 14.7, mean PASI 49.4 ± 0.5 were included. 374 female were divided into groups by age. 113 young F. pts with age less than 49 years (mean age 36.1 ± 11.0 years), 261 old F. pts with age more than 50 years (mean age 63.7 ± 9.6 years). 516 male were divided into groups by age. 304 young M. pts with age less than 54 years (mean age 38.5 ± 11.3 years), 212 old M. pts with age more than 55 years (mean age 38.5 ± 11.3 years) were included. PsO and PsA pts were identified in hospital Database reporting and coding by International Statistical Classification of Disease and Related Health Problems (ICD-10) between 2010 - 2015 years. PSA was diagnosed after appointment with a rheumatologist and an X-ray examination. Diagnosis was carried out according to the criteria of CASPAR. M+m, t-test, x2, (%) were calculated. All p < 0.05 were considered to indicate statistical significance.

**Results:** 303 out of 890 pts (34.0%) had psoriatic arthritis (PsA). PsA pts were older than PsO pts without arthritis – 55.3 ± 13.7 years and 50.4 ± 17.6 years accordingly (p < 0.001). PsA was found significantly often in F. pts compared to M. pts – in 143 out of 374 pts (38.2%) and in 129 out of 516 pts (25.0%) accordingly (p < 0.05). PsA was found significantly often in F. pts over 50 years old (y.o.) compared to F. pts under 50 y.o. – in 134 out of 261 pts (51.3%) and in 9 out of 113 pts (7.9%) accordingly (p < 0.05). In old M. and young M. PsA was found in the same cases - in 58 out of 212 pts (27.3%) and in 71 out of 304 pts (23.3%) accordingly (p < 0.05).

**Conclusions:** PsA was detected in more than a third of patients with severe plaque psoriasis. PsA was found predominantly often in F. pts over 50 years of age with severe plaque psoriasis. Future investigation in this field is needed to determine the causes of high risks PSA in this age group.

**PI11**

**SKIN LESION SEVERITY IN EARLY AXIAL AND PERIPHERAL PSORIATIC ARTHRITIS PATIENTS**

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**Introduction:** Comparative analysis of skin lesion severity in early PsA patients with and without axial involvement hadn’t been sufficiently studied.

**Objective:** to compare skin lesion severity of two early peripheral PsA patient populations – with and without axial involvement.

**Methods:** 95 patients (pts) (M/F–47/48) with early PsA according to CASPAR criteria were included; all pts had peripheral arthritis for ≤2 years; no inflammatory back pain (IBP) pts were specially selected. Mean age 36.5 ± 10.7 yrs, disease duration 12.2 ± 10.3 mo, disease activity indexes DAS = 4.0 ± 1.4, DAS28 = 4.2 ± 1.1, BASDAI = 4.5 ± 1.6. Skin lesion severity was evaluated in terms of body surface area (BSA) affected and Psoriasis Area Severity Index (PASI). When BSA was ≥3%, PASI was calculated. PASI ≥11 indicates moderate and severe psoriasis.

All pts were evaluated for the presence of inflammatory back pain (IBP) by ASAS criteria. IBP was observed in 63 (66.3%) cases. Magnetic resonance imaging (MRI) of SIJs was performed in 79 pts, regardless of the presence of IBP, on Sigma Ovation 0,35T. MRI results were evaluated by an independent reader. Bone marrow edema on MRI (STIR) was considered as active MRI sacroiliitis (MRI-SI). MRI-SI was detected in 28 of 79 (35.4%) examined cases. The examination also included X-ray of sacroiliac joints (SIJs) (pelvic radiographs). Radiographic sacroiliitis (R-SI) was considered according to New York criteria (unilateral grade ≥2 or bilateral grade ≥2). R-SI was found in 29 (30.5%) cases. Pts were split into two groups: those with axial involvement (axPsA), that is with IBP and/or MRI-SI and/or R-SI; and those without axial involvement (having only peripheral PsA [pPsA]). The axPsA group included 65 (68.4%) cases, the pPsA one 30 (31.6%) cases.

**Results:** skin lesions’ severity was higher in the axPsA group than in the pPsA group: in axPsA pts BSA median was 3.0 [1.0 – 9.0] and in pPsA pts it was 1.0 [0.2 – 3.0] (p < 0.007); in the axPsA group PASI median was 15.6 [6.6 – 55.2] and in the pPsA group it was 6.0 [0.0 – 7.2] (p = 0.006).

**Conclusion:** Axial involvement in early PsA patients is associated with skin lesions’ severity. These findings may have a positive impact on the selection of the best therapeutic strategy.
PI112 GASTROINTESTINAL SYMPTOMS ARE COMMON IN U.S. PATIENTS WITH MODERATE-TO-SEVERE PSORIASIS

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Background/Objective: Patients with moderate-to-severe plaque psoriasis (PsO) are at increased risk of developing inflammatory bowel disease (IBD). A survey was conducted to evaluate the prevalence of gastrointestinal symptoms in PsO patients.

Methods: An electronic survey was available to U.S. PsO patients with data collected from Jan-Feb. 2017. Patients with moderate-to-severe plaque PsO and healthy controls (HC), with common comorbidities allowed in both groups qualified for inclusion in the survey. Psoriasis patients were further categorized as those without recent exposure to biologic therapy (PsO-) vs those with recent (within 4 months) biologic exposure (PsO+). GI symptoms and signs, including frequency and severity, were compared across groups. CalproQuest (CPQ) scores, which have recently been proposed as a tool to identify patients with elevated fecal calprotectin levels and increased risk for IBD, were also calculated. Patients with inflammatory bowel disease (IBD), inflammatory bowel syndrome (IBS), or other gastrointestinal (GI) diagnoses with symptoms that overlap with IBD were excluded.

Results: Overall, 915 patients with self-reported moderate-severe PsO and 1,411 healthy controls participated. Demographics were generally comparable between groups. GI symptoms and signs were significantly more prevalent in the PsO- and PsO+ groups vs the HC group, respectively; pain- 20.6% and 36.9% vs 10.5%; fullness/bloating- 37.2% and 48.4% vs 25.3%; and diarrhea (16.3% and 29.3% vs 12.2% (all p-values = 0.002 except diarrhea for PsO- vs HC, p = 0.023). Mucous and blood in the stool followed a similar pattern. A significantly greater percentage of PsO- and PsO+ patients had positive CPQ scores vs HCs, with the greatest percentage of positive CPQ scores in the PsO+ group.

Conclusion: GI symptoms and signs are common in patients with moderate-to-severe PsO, more so than in healthy controls. This suggests that physicians caring for patients with PsO may consider assessing for GI symptoms and signs, and monitoring for their progression with treatment of PsO to identify patients potentially at risk for developing IBD.

PI113 SECUKINUMAB’S LONG-TERM SAFETY REMAINS FAVORABLE UP TO 5 YEARS OF TREATMENT

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Introduction and Objectives: Secukinumab (IXE) treatment of patients with psoriasis is a condition typically requiring long-term treatment, thus longitudinal data establishing the safety of approved therapies are required. We report exposure adjusted incidence rates (IRs per 100 patient years) for treatment-emergent adverse events (AEs) per year of treatment from a pooled analysis of all secukinumab psoriasis trials to date (19 studies, 4,674 patients, 10,061 patient-years exposure; secukinumab exposure up to 5 years).

Methods: AE IRs were examined per year for subjects receiving secukinumab, and for 52 weeks only for those receiving etanercept (ETN), ustekinumab (UST), or placebo (PBO).

Results: Duration of exposure through 52 weeks of secukinumab treatment 300 mg, ETN 50 mg, UST 45/90 mg, and PBO was 1467.4, 296.9, 318.1, and 301 patient-years, respectively. Exposure duration through 2, 3, 4, and 5 years of secukinumab 300 mg treatment was 859.6, 423, 377.5, and 90 patient-years. Over 52 weeks for secukinumab, ETN, UST, and PBO, respectively, exposure adjusted IRs were overall comparable across treatments: total AEs (275.6, 245.7, 252.2, 355.8); nasopharyngitis (28.4, 35.9, 31.2, 35.9); headache (12.6, 15, 14.6, 23.7); upper respiratory infections [URI] (9.1, 5.9, 9.9, 8.8); opportunistic infections (0.2, 0.3, 0.3); Candida infections (4.7, 1.4, 1.6, 1.7); neutropenia (0.5, 1.4, 0.0); major adverse cardiovascular events [MACE] (0.5, 0.3, 0.3, 1.3); Crohn’s disease (0.1, 0.3, 0.0); and malignant or unspecified tumors [excluding non-melanoma skin cancer [NMSC]] (0.4, 0.3, 0.3, 0.3).

Conclusion: Secukinumab 300 mg pooled safety remained favorable over time with no increases in AEs (exposure adjusted IRs for up to Year 1 to Year 5, respectively): total AEs (275.6, 168.1, 160.2, 111.9, 13.9); nasopharyngitis (28.4, 21.2, 24.1, 11.8, 3.4); headache (12.6, 5.4, 4.3, 4.9, 0.0); URI (9.1, 7.3, 6.1, 5.5, 0.0); opportunistic infections (0.2, 0.1, 0.0, 0.0); Candida infections (4.7, 3.6, 1.9, 1.3, 1.1); neutropenia (0.5, 0.1, 0.0, 0.0); MACE (0.5, 0.1, 0.5, 0.0); Crohn’s disease (0.1, 0.0, 0.0, 0.0); ulcerative colitis (0.1, 0.4, 0.2, 0.3, 0.0); and malignant or unspecified tumors [excluding NMSC] (0.4, 0.4, 0.2, 0.0, 0.0).

Conclusions: This comprehensive pooled analysis supports the favorable long-term safety profile of secukinumab in patients with psoriasis; no new safety signals were identified for up to 5 years of treatment and secukinumab’s safety profile was consistent with that established in a large Phase 3 program.

Findings previously published at the AAD Annual Meeting, February 16–20, 2018, San-Diego, California.

PI114 IMPACT OF IMPROVEMENT IN SKIN AND JOINT ON QUALITY OF LIFE IN ACTIVE PSORIATIC ARTHRITIS PATIENTS

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Introduction: Psoriatic arthritis (PsA) is a chronic immune-mediated inflammatory disease affecting peripheral and axial joints. For patients with active psoriasis, the added burden of skin disease can further reduce health-related quality of life (HRQoL) of patients with joint disease.

Objective: To determine the contribution of joint and skin improvements in HRQoL of patients with active PsA during Phase 3 clinical trials investigating ixekizumab (IXE) treatment.

Methods: The double-blind Phase 3 trials (SPIRIT) investigated the treatment of IXE, a high-affinity monoclonal antibody selectively targeting interleukin-17A, for patients with active PsA. The integrated database of 2 SPIRIT trials consisted of biologic disease-modifying antirheumatic drug (DMARD)-naïve patients (SPIRIT-P1, NCT01695239) or inadequate responders to tumor necrosis factor (TNF)-inhibitors (SPIRIT-P2, NCT02349295). Patients were randomized to 80mg IXE every 4 weeks (Q4W, 16–20, 2018, San-Diego, California.
n = 229) or 2 weeks (Q2W, n = 226) after a 160mg starting dose or placebo (PBO, n = 224). At baseline and Week 24, joint and skin diseases were measured by the Disease Activity index for Psoriatic Arthritis (DAPSA; calculated post-hoc) and Psoriasis Area and Severity Index (PASI), respectively. HRQoL was measured by EuroQoL. 5 Dimensions Visual Analog Scale (EQ-5D VAS), Short Form-36 Health Survey (SF-36), and Work Productivity and Activity Impairment-Specific Health Problem (WPAI). The synergistic contribution of skin and joint improvements to HRQoL was modeled using smoothing spline method and depicted with response surface. Missing data were imputed using last observation carried forward.

**Results:** Of 679 PBO- and IXE-treated patients in the SPIRIT trials, 402 (65%) and 224 (36%) patients had ≥3% body surface area (BSA) and ≥10% BSA psoriasis at baseline, respectively. In these patients, we applied response surface modeling to investigate the relationship among DAPSA, PASI, and change from baseline in EQ-5D VAS at Week 24. The greatest improvement in EQ-5D VAS was associated with the largest percent improvements in both DAPSA and PASI alone. Similar improvements, regardless of ≥3% or ≥10% BSA baseline psoriasis, were made in domains of SF-36 (General Health, Physical Functioning, Social Functioning, and Vitality; data not shown) and WPAI (Activity Impairment; data not shown).

**Conclusion:** For PsA patients with psoriasis, optimal improvements in patients’ HRQoL, as measured by select domains of patient-reported outcomes, were dependent on successful treatment of both joint and skin symptoms.


**PI15 SECUKINUMAB SHOWS HIGH AND SUSTAINED EFFICACY IN SUBJECTS WITH MODERATE TO SEVERE PALMOPLANTAR PSORIASIS: 2.5-YEAR RESULTS FROM THE GESTURE STUDY**

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**Introduction:** Palmpoplantar psoriasis (ppPsO) occurs in up to 40% of plaque psoriasis subjects and is often resistant to treatment. It is associated with pain, functional limitations, and greater impairment of health related quality of life compared with plaque psoriasis on other parts of the body (1). Secukinumab, a fully human monoclonal antibody that selectively neutralises IL-17A, has shown long lasting efficacy and safety in the complete spectrum of psoriasis manifestations, including nails, scalp, palms and soles and psoriatic arthritis.

**Objectives:** Here we report, the long-term follow-up efficacy and safety results from the GESTURE study, the first robust (2.5-year) data reported in subjects with moderate to severe ppPsO treated with secukinumab.

**Methods:** GESTURE is a double blind, randomised, placebo-controlled, parallel-group, multicentre phase 3b study to investigate safety and efficacy of secukinumab 150 and 300 mg s.c. in 205 subjects with moderate to severe ppPsO.

**Results:** As previously reported, after 16 weeks placebo-controlled treatment, the primary endpoint palmpoplantar Investigator’s Global Assessment (ppIGA) 0/1 and all secondary endpoints of this study were met, demonstrating superiority of secukinumab to placebo at week 16 (2). An interim analysis at week 80 established the continuation improvement of palmpoplantar disease for all efficacy parameters. The effect was sustained through 2.5 years with 59.2% and 52.5% of subjects in secukinumab 300 and 150 mg groups, respectively [multiple imputation (MI)] achieving clear or almost clear palms and soles (ppIGA 0/1). Consistent with this observation, the mean palmpoplantar Psoriasis Area and Severity Index % change from baseline reached –74.7% and –61.6% for secukinumab 300 and 150 mg, respectively, at 2.5 years (MI).

The Dermatology Life Quality Index 0/1 response, was achieved in 45.5% vs. 23.9% of subjects for secukinumab 300 and 150 mg groups respectively (LOCF). Pain and function of palms and soles was markedly improved with secukinumab; as reflected by the Palmpoplantar Quality of Life Instrument overall scores with 16.7% and 17.9% subjects experiencing no difficulty in hand and feet functionality in secukinumab 300 mg and 150 mg groups respectively (LOCF). The safety profile was consistent with that seen in secukinumab phase 3 trials. The most common adverse events across all treatment arms were nasopharyngitis, upper respiratory tract infection and headache.

**Conclusions:** GESTURE, the largest and longest duration randomised controlled trial to date, revealed that secukinumab provides a novel treatment option for the challenging and infrequently studied ppPsO population by providing a strong and sustained response through 2.5 years.

**References:**

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**PI16 SECUKINUMAB SHOWS HIGH AND SUSTAINED EFFICACY IN NAIL PSORIASIS: 2.5-YEAR TRANSFIGURE STUDY RESULTS**

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**Introduction:** Nail psoriasis is associated with decreased finger mobility, functional impairment, pain and reduced quality of life (QoL) and is often challenging to treat. It correlates with more severe psoriatic disease and is an important predictor of psoriatic arthritis (PsA). Nails are affected in up to 50% of psoriasis patients, with a lifetime incidence as high as 90% (1). Secukinumab, a fully human monoclonal antibody that selectively neutralises IL-17A, has shown long lasting efficacy and safety in the complete spectrum of psoriasis manifestations, including nails, scalp, palms and soles and psoriatic arthritis.

**Objectives:** Here, we report the long-term follow-up efficacy and safety results from the TRANSFIGURE study, the first robust (2.5-year) data reported in subjects with nail psoriasis treated with secukinumab.

**Methods:** TRANSFIGURE is a double blind, randomised, placebo-controlled, parallel group, multi-centre phase 3b study, to investigate safety and efficacy of secukinumab 150 and 300 mg s.c. in moderate to severe nail psoriasis, involving 198 subjects.

**Results:** As previously reported, at week 16 the primary endpoint NAPSI (NAI Psoriasis Severity Index) and all secondary endpoints of this study were met, demonstrating superiority of secukinumab to placebo after 16 weeks placebo-controlled treat-
ment. An interim analysis at week 80 demonstrated the continuation of improvement in nail psoriasis for all efficacy endpoints. The effect was sustained through 2.5 years with a mean NAPSI improvement from baseline (BL) of −73.3% and −63.6% with secukinumab 300 and 150 mg, respectively (as observed). Secukinumab demonstrated sustained reductions (improvements) in total mean NAPPA (Nail Assessment in Psoriasis and Psoriatic Arthritis) QoL scores from BL to 2.5 years by −52.4% and −18.1%, and 70.2% and 71.0% of subjects achieved a weighted NAPPA-PBI (Patient Benefit Index) global score of ≥2 (at least moderate benefits) with secukinumab 300 and 150 mg, respectively (LOCF). Subjects showed considerable improvements in EQ-5D (EuroQOL 5-Dimension Health Status Questionnaire) compared with BL reporting decreased pain and discomfort. The safety profile was consistent with that observed in previous phase 3 trials of psoriasis and PsA.

Conclusions: TRANSFIGURE is the first large, randomised controlled trial to report long-term results in subjects with nail psoriasis. Secukinumab demonstrated strong sustainability of clinically meaningful efficacy, large QoL improvement and a favourable safety profile up to 2.5 years in this challenging form of psoriasis. This investigation was sponsored by Novartis Pharma AG, Basel, Switzerland.

References:


PI117
THE OBESITY AND PREVALENCE PSORIATIC ARTHRITIS IN PATIENTS WITH PLAQUE PSORIASIS: DERMATOLOGICAL REAL-SETTING DATA
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Background: Psoriasis (PsO) is a chronic inflammatory disease, which can be associated with the obesity. A link between body mass index (BMI) and psoriatic arthritis (PsA) has been found recently. But there is limited data about this association in Russian population and from real-world data.

Objective: To study the incidence of PsA in PsO patients (pts) with/without obesity.

Methods: 103 pts (male-47/female-56) with different forms of plaque PsO, mean age 44±13.69 years (yrs.), mean PsO duration 10.7±10.2 yrs., mean PASI 15.39±12.51 were included. 61 out of 103 pts with PsO (59.2%) had psoriatic arthritis (PsA) by CASPAR criteria. In all pts BMI was calculated. If the BMI was more than 30–35 (obesity 1 degree). Thus, it was more than 4 times higher the pts with PsA, compared with pts without PsA - 19 and 4 pts (31.2% vs. 9.5%) respectively (p = 0.06).

Conclusion: There is a higher incidence of PsA in PsO pts with obesity. It should be taken into account during choice of treatment and evaluation of efficiency of therapy in real-world dermatological setting. Russian population – based studies are needed.

PI118
DIAGNOSIS OF PSORIATIC ARTHRITIS IN PATIENTS WITH MODERATE TO SEVERE CHRONIC PLAQUE PSORIASIS TREATED WITH SECUKINUMAB VS. OTHER TREATMENTS IN THE PURE REGISTRY: INDICATION OF SELECTION PREFERENCES AND UNDERDIAGNOSIS

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Introduction: Secukinumab (SEC) is a fully human monoclonal antibody that selectively neutralizes IL-17A, a key cytokine involved in the development of psoriasis (PsO). SEC has shown long lasting efficacy and safety in the complete spectrum of PsO manifestations, including nails, scalp, palms and soles and psoriatic arthritis (PsA). PURE is an international registry of adult patients (pts) from Canada and Latin America with moderate to severe PsO treated with SEC vs other approved therapies (other Tx).

Objectives: To describe and compare the baseline demographic, disease, and clinical characteristics – specifically, the history of PsA diagnosis among PsO pts treated with SEC vs other Tx.

Methods: Approximately 2,500 adult pts (1:1 ratio, SEC: other Tx) will be recruited. A decision regarding treatment must have been reached prior to enrollment. The independent-samples and Chi-square tests were used for continuous and categorical variables, respectively, for treatment group comparison.

Results: As of Nov 27, 2017, 1032 pts (397 SEC vs 635 other Tx) had been enrolled. Mean age (50.5 vs 49.4 years), time since diagnosis (18.5 vs 16.9 years), duration since symptom onset (20.5 vs 19 years), and race (78.6% vs 83.8% Caucasian) were comparable between groups. The percentage of females was lower in the SEC group (38.0%) vs other Tx (45.5%; p = 0.037). At baseline, the majority of SEC-treated pts (66.2%) were employed, and 23.7% vs 34.8% vs 34.3% had public vs private vs combined coverage, respectively. There was no difference between cohorts. A higher proportion of SEC pts had a history of PsA (23.2% vs 15.0%; p = 0.001) or diabetes (18.1% vs 13.4%; p = 0.072) compared to pts on other Tx. About 87.9% pts with PsA history and 34.1% pts without had a Psoriasis Epidemiology Screening Tool (P EST) score ≥3 at baseline; however, the diagnosis of PsA in these pts needs to be confirmed. In terms of prior PsO treatments, 52.4% vs 29.9% (p < 0.001) of SEC vs other Tx pts had been previously treated with methotrexate, and 50.6% vs 18.0% (p < 0.001) with a biologic. Prior to enrollment, 4.7%, 13.2% and 4.7% pts in the other Tx group received anti-IL-12/23, anti-TNF-a, and anti-IL-17A, respectively. Pts treated with SEC had a higher historical Psoriasis Area and Severity Index (PASI) score (16.5 vs 14.2; p = 0.005), baseline PASI (13.6 vs 12.0; p = 0.001) and Investigator’s Global Assessment score (severe disease [score = 4]: 25.4% vs 20.1%) at enrollment compared to pts on other Tx.

Conclusions: Pts with moderate to severe PsO selected for treatment with SEC were more likely to have been previously exposed to another biologic, have comorbid PsA and had more severe skin disease, compared to pts treated with other Tx. A significant proportion of PsO pts may have their PsA undiagnosed in routine clinical care.

References:

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Introduction/Objective: To evaluate the efficacy, safety & tolerability of guselkumab (GUS) in patients (pts) w/ PsA.

Methods: In this double-blind, PBO-controlled study, pts w/ active PsA & ≥3% BSA of PsO despite treatment were randomized 2:1 to SC GUS 100mg or PBO at wk0, 4, & q8w thereafter through wk44. At wk16, pts w/ <5% improvement from baseline (BL) in swollen & tender joint counts were eligible for early escape (EE) to open-label ustekinumab. At wk24, PBO pts crossed-over to GUS 100mg (PBO to GUS). The primary endpoint was ACR 20 at wk24. Major secondary endpoints were PASI 75 & ACR 50 responses, change from BL in HAQ-DI, & improvement in enthesitis (Leeds enthesitis index [LEI]) & dactylitis score (by a 0–3 scoring system) at wk24; & ACR 20 response at wk16. Through wk24, efficacy analyses were performed in a modified Intent-to-Treat (mITT) pop. Pts who met treatment failure criteria, EE or had missing data at wk24 were considered non-responders for ACR/MDA endpoints at wk24. Efficacy post wk24 was evaluated in pts who did not EE & continued treatment at wk24 based on observed data.

Results: Of 1149 pts (PBO:49, GUS:100), BL demographics & ACR component measures were generally similar between the 2 groups. 4 PBO & 9 GUS pts were previously exposed to anti-TNFα agents. At wk24, significantly more GUS pts achieved ACR 20 (58.0% vs 18.4%, p < 0.001), PASI 75 (78.6% vs 12.5%, p < 0.001), & ACR 50 (34.0% vs 10.2%, p = 0.002) responses vs PBO. At wk24, mean decrease in HAQ-DI score from BL (-0.42 vs -0.06, p < 0.001), & median percent improvement in enthesitis (100% vs 33.33%, p = 0.009) & dactylitis (100% vs 33.33%, p < 0.001) scores (among pts w/ BL enthesitis and dactylitis) were significantly greater in GUS group vs. PBO. Significantly more GUS pts achieved ACR 20 at wk16 (60.0% vs 16.3%, p < 0.001) and MDA at wk24 (23.0% vs. 2.0%, p < 0.001) vs. PBO. Post wk24, efficacy improved in PBO to GUS crossover pts as expected and were well-maintained in GUS pts through wk56. Through wk24, the frequencies of AEs & infections were comparable (AEs: PBO 32.7%; GUS 36.0%; infections: PBO: 20.4%; GUS: 16.0%). Post wk24, there was no disproportional increase in AE frequency or infections among GUS pts w/ longer exposure. GUS: 16.0%). Post wk24, there was no disproportional increase in AE frequency or infections among GUS pts w/ longer exposure. Similar results were observed for TIL 200 mg as well as a subgroup analysis with bio-naive and bio-experienced patients respectively. Conclusions: GUS demonstrated significant improvement on joint symptoms, physical function, PsO, enthesitis, dactylitis & quality of life; efficacy was well-maintained through wk56. GUS was well tolerated in this population after ~1 year of exposure. Data has been previously presented at EULAR 2017 & ACR 2017

PI20
TILDRAKIZUMAB EFFICACY OVER TIME BY WEEK 28 RESPONSE LEVELS IN TWO PHASE 3 CLINICAL TRIALS IN PATIENTS WITH CHRONIC PLAQUE PSORIASIS

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Introduction: Tildrakizumab (TIL), a humanized, IgG1κ monoclonal antibody for IL-23p19, recently demonstrated its efficacy in subjects with chronic plaque psoriasis in two, phase 3 clinical studies.1

Objective: In this analysis, we examined efficacy from baseline to week 52 among TIL patients achieving various Psoriasis Area and Severity Index (PASI) responses at week 28.

Methods: ReSURFACE 1 (NCT01722331) and reSURFACE 2 (NCT01729754) were double-blind, randomized controlled studies in subjects with moderate-to-severe chronic plaque psoriasis. Part 1 (0–12 weeks) was placebo controlled; Part 2 (12–28 weeks) re-randomized placebo patients to TIL; Part 3 (28–64 weeks, reSURFACE 1; 28–52 weeks, reSURFACE 2) re-randomized patients with ≥PASI 50 to continue or increase TIL dose or to placebo based on their PASI response at week 28. In this post-hoc pooled analysis, patients consistently on TIL 100 mg and 200 mg from baseline to week 52 were classified in 5 mutually exclusive groups based on their week-28 PASI response: PASI < 50, PASI 50–74, PASI 75–89, PASI 90–99, and PASI 100. Baseline characteristics and % PASI improvement from baseline up to week 52 (observed data) were examined for each group.

Results: This analysis included 575 (TIL 100 mg) and 581 (TIL 200 mg) patients; the proportions of patients with week-28 PASI 75/90/100 responses were 77%/54%/23% (TIL 100 mg) and 78%/58%/29% (TIL 200 mg). At week 28, 133 (23.1%), 175 (30.4%), 137 (23.8%), 82 (14.3%), and 48 (8.3%) TIL 100 mg patients and 170 (29.3%), 169 (29.1%), 114 (19.6%), 105 (18.1%), and 23 (4.0%) TIL 200 mg achieved PASI 100, PASI 90–99, PASI 75–89, PASI 50–74, and PASI < 50, respectively. On average, PASI 100 patients were younger, lighter, and had shorter disease duration at baseline compared to other response groups. For TIL 100 mg, % PASI improvement was highest for PASI 100 and least for PASI < 50 patients on all visits up to week 28 (week 4: 53%, 46%, 38%, 30%, and 16%; week 28: 100%, 95%, 83%, 64%, and 33% for PASI 100, PASI 90–99, PASI 75–89, PASI 50–74, and PASI < 50 categories, respectively). Among patients achieving PASI > 90 at wk 28 and continued up to 52 weeks, % PASI improvement maintained or improved from week 28 to week 52. Similar results were observed for TIL 200 mg as well as a subgroup analysis with bio-naive and bio-experienced patients respectively.

Conclusions: The majority of TIL 100 and 200 mg patients achieved PASI > 50 response at week 28, and PASI improvement was maintained from week 28 to week 52. Among patients achieving PASI > 90 at week 28, TIL 100 and 200 mg were associated with a rapid PASI improvement by week 4.

Reference:

This abstract was presented at 2018 Annual Meeting of American Academy of Dermatology. Note: This abstract was presented at 2018 Annual Meeting of American Academy of Dermatology.
At the time of dermatologist referral, rheumatologists state that they refer their PsO patients to a rheumatologist at the worsening disease. Furthermore, only 35 percent of dermatologists report they refer only severe arthritis/patients with improving on their current systemic regimen, while an additional 35 percent report they refer only severe arthritis/patients with worsening disease. Only 6 percent having controlled PsO and joint pain. However, 31 percent of dermatologists report they do not refer PsO patients to rheumatologists until patients have failed biologics or are not improving on their current systemic regimen, while an additional 35 percent report they refer only severe arthritis/patients with worsening disease. Furthermore, only 35 percent of dermatologists agree that they refer their PsO patients to a rheumatologist at the first sign of joint involvement.

At the time of dermatologist referral, rheumatologists state that two-thirds of referred patients are biologic/apremilast naïve, with only 6 percent having controlled PsO and joint pain. However, dermatologists state that 40 percent the patients that they referred to rheumatologists were treated with biologics and 15 percent of said referred patients were treated with apremilast. Indeed, 76 percent of dermatologists agree with the statement, “I believe that starting my PSO patients earlier on biologic therapy will slow the development and progression of the arthritic component of the disease (PsA),” while 57 percent of dermatologists agree “I prefer to use biologics that are indicated in both PSO and PsA.”

Conclusion: With many patients diagnosed with both PSO and PsA, co-management between dermatologists and rheumatologists is common. While rheumatologists appear to be under the impression that they are receiving the majority of dermatologist-treated patients with PsA at the first sign of joint involvement, dermatologists largely report that they are managing and treating PsA patients. Furthermore, most dermatologists believe early aggressive use of biologic treatments will mitigate the development and/or progression of joint involvement, implying their willingness to manage their patients with PsA, particularly at early stages.

**P123**
**THE USE OF TUMOR NECROSIS FACTOR INHIBITORS (TNF) IN THE SECOND-LINE BIOLOGIC/SMALL MOLECULE SETTING: A CROSS-SPECIALTY COMPARISON**

Lynn Price, Jennifer Robinson, Gianna Melendez

Spherix Global Insights

TNF therapy has been the standard of care for adult patients diagnosed with autoimmune conditions, resulting in familiarity, comfort, and satisfaction among physicians. TNFs are typically used as a first-line biologic/small molecule in the treatment of psoriasis (PSO) and psoriatic arthritis (PsA). However, the adoption of agents with alternate mechanisms of action (AMOA) has increased in recent years across indications and the practice of sequential TNF prescribing after an initial TNF is less common. Though TNFs are still the preferred first-line agent, there are discrepancies between specialists on the use of AMOA agents in the second-line setting. This research sought to understand the extent to which AMOA agents are prescribed after an initial TNF, and how this varies across PSO and PsA.

An independent market analytics firm collaborated with US dermatologists (n = 201) and US rheumatologists (n = 200) to conduct a retrospective chart review of patients diagnosed with PSO (n = 950) and PsA (n = 1,008) who had switched from one biologic/apremilast to another agent in the prior 12 weeks. Physicians were able to submit up to 7 patient charts. PSO data was collected in September 2017 and PsA data was collected in April 2017.

Analysis of patients recently switched from one biologic/apremilast to a different brand revealed the majority of patients were treated with a TNF in the first-line biologic/small molecule setting, though this varies by indication. Rheumatologists prescribe first-line TNFs significantly more than dermatologists. 83% of PsA patients are prescribed TNF first-line compared to just 69% of PSO patients. Furthermore, rheumatologists are significantly more likely to practice TNF-sequencing than dermatologists. 51% of rheumatologists prescribed a second TNF, compared to 6% of PsO patients. Additionally, certain TNF brands have experienced recent declines in first-line use, though this varies by indication as well. For rheumatologists, use of first-line etanercept has declined, 38% of PsA patients were initiated on etanercept at least 24 months prior to the study, compared to just 28% initiated on etanercept within 12 months of the study. For dermatologists, there were significantly more PSO patients initiated on etanercept in the first-line setting 24 months or more prior to the study compared to those initiated within 12 months of the study, (45% vs 31%). This pattern also held true for adalimumab, where 42% of first-line PSO patients initiated more than 24 months prior to the study were prescribed adalimumab, a figure that drops to just 27% for patients initiated within 12 months.

Though the position of TNFs as first-line agents remains dominant, the treating specialist and indication influence how widespread and continuous TNF use is. Specifically, dermatologists are less likely to prescribe TNFs as first-line agents and are also significantly less likely to partake in the sequencing of TNFs in the first- and second-line setting than rheumatologists. The introduction of several agents in PSO reporting substantially higher rates of skin clearance compared to TNFs could potentially be the source of increased switching to AMOAs compared to other specialties; whereas superior efficacy of AMOA agents over TNFs in PsA may be less apparent.

**P124**
**IMPACT OF GUSELKUMAB VERSUS PLACEBO AND ADALIMUMAB ON PATIENT REPORTED OUTCOMES IN PATIENTS WITH AND WITHOUT PSORIATIC ARTHRITIS IN VOYAGE 2**

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Introduction/Objective: VOYAGE 2 is a phase 3 double-blind, placebo/active comparator-controlled trial comparing guselkumab (GUS) with placebo (PBO) and adalimumab (ADA) in patients (pts) with moderate-to-severe PsO. The impact of treatment on patient-reported outcomes (PROs) was evaluated.

Methods: Pts were randomized to GUS 100mg (wks 0 & 4, then...
n = characterized by chronic inflammation of the joints, spine, and the entheses. PsA, which belongs to the seronegative spondyloarthritis group, affects a younger age of patients with skin manifestations PsO was 54.0 ± 14.2 years (n = 50). The group of patients with PsA was older than the group PsO patients by age. PASI > 10. The quality of life was assessed using the Dermatology Life Quality Index (DLQI) questionnaire. The results were evaluated: from 0 to 1 score - cutaneous disease does not affect the patient's life, from 2 to 5 scores - the disease has a minor effect on the patient's life, from 6 to 10 scores - the disease has a moderate effect on the patient's life, from 11 to 20 scores - the disease has a strong effect on the patient's life, from 21 to 30 scores - the disease has an extremely strong effect on the patient's life. Statistical processing of the data was carried out using the Excel analysis package. All p < 0.05 were considered to indicate statistical significance. Results: 120 (100%) patients suffering from PsO were taken for analysis. The duration of PsO was: for more than 15 years - 25 people (35.7%), 10–15 years - 18 people (25.7%); 3–10 years - 15 people (21.4%), 1–3 years - 12 people (17.1%). The duration of PsA was: for more than 15 years – 5 people (10.0%), 10–15 years – 7 people (14.0%); 3–10 years – 20 people (40.0%), 1–3 years – 18 people (36.0%). Heredity was aggravated in 35 (29.1%) out of 120 patients. Comorbidity was presented in 112 (93.3%) out of 120 patients. Gastrointestinal and liver diseases were found in 48 (42.8%) out of 120 patients. Type 2 diabetes was observed in 45 (40.1%) out of 120 patients, cardiovascular diseases - in 100 (89.2%) out of 120 patients, diseases of the nervous system - in 59 (52.6%) out of 120 patients, and diseases of the urinary system - in 20 (17.8%) out of 120 patients. The total score DLQI in the psoriasis group was 15.8 ± 5.2. The score DLQI in PsO patients was 12.5 ± 3.4 and in PsA patients was 20.4 ± 3.7. The total score DLQI in PsO patients with comorbidity was 16.1 ± 5.3. Conclusions: The total score DLQI was significantly higher in patients with PsA compare to PsO patients. This result revealed the existence of an inferior quality of life for the PsO patients with comorbidity disease, compared with pts without comorbidity disease. The score of DLQI is affected the development and progress of the psoriasis and comorbidity pathology. Then higher DLQI value, the more it affects experience considerable physical and/or psychological discomfort, difficulties in social and professional adaptation, which subsequently cause significant distress and even social phobia. All these conditions psoriasis are interrelated by genetic and immunopathogenetic mechanisms. Thus, patients with psoriasis require an integrated approach and dynamic observation by dermatologists and doctors of related specialties.

P126
EFFECTS OF MINDFULNESS-BASED COGNITIVE THERAPY ON SELF-REPORTED PSORIASIS AND PSORIATIC SYMPTOMS
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Introduction: Psoriasis can have a profound impact on a patient’s life, with the prevalence of anxiety, depression, poor wellbeing and quality of life generally found to be high in psoriasis populations. Mindfulness based interventions have been shown to have positive impacts on anxiety, depression, wellbeing and quality of life in various populations.
Objectives: The aim of the present study was to investigate the effect of mindfulness-based cognitive therapy (MBCT) on psoriasis symptoms and psychological symptoms associated with psoriasis including anxiety, depression, reduced wellbeing and QoL. The study also aimed to investigate if MBCT significantly impacted the potential mediating variables of a new theory of mindfulness mechanisms the ‘Clinically Modified Buddhist Psychological Model (CBPM)’, these variables being acceptance, mindfulness, self-compassion, aversion, non-attachment, attention, rumination and worry.

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PI25
THE DERMATOLOGY LIFE QUALITY INDEX IN RUSSIAN PATIENTS WITH PSORIASIS AND PSORIATIC ARTHRITIS.
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Introduction: The most severe form of psoriasis is psoriatic arthritis (PsA), which belongs to the seronegative spondyloarthropathy group, characterized by chronic inflammation of the joints, spine, entheses. The frequency of PsA in the population is 0.06—1.4%. PsA is comparable to rheumatoid arthritis (RA) in terms of progression, disability and quality of life (QOL) in patients.
Objectives: Compare the quality of life index of patients with severe forms of psoriasis (PsO) with psoriatic arthropathies' index.
Methods: 120 (100%) patients suffering from PsO and PsA (Male-87/female - 33) were analyzed. 70 (54.2%) patients were diagnosed PsO, 50 (41.7%) were diagnosed PsA. The average age of patients with skin manifestations PsO was 54.0 ± 14.2 years (n = 70). The average age of patients with PsA was 49.1 ± 15.9 years.
Methods: 101 participants were randomly allocated to a treatment arm (MBCT) or a TAU arm. Participants were measured pre, post-treatment and after a 3-month follow up period. Data were analysed using intention-to-treat analysis and the ANCOVA method with baseline scores entered as covariates.

Results: There was a significant group x time (pre vs. post) interaction on all variables except QoL, indicating a significant reduction of each variable except QoL over time in the MBCT group, but not in the control group. When baseline variables were controlled for, the participants in the MBCT group achieved small statistically significant changes across all variables post intervention versus the TAU group.

Conclusions: The results suggest that MBCT may be a useful adjunct therapy for those suffering from psoriasis and the associated psychological symptoms relating to the condition. The results also indicate that each of the mechanisms outlined in the CBPM change significantly for patients who engage in the intervention.

**PI27**

**A MIXED METHODS STUDY EXPLORING THE IMPACT OF MINDFULNESS ON PSORIASIS, ANXIETY, DEPRESSION AND QOL**

**Alan Maddock, David Hevey**

School of Psychology, Trinity College Dublin

**Introduction:** Psoriasis is a common condition with recognised psychological comorbidity. Psoriasis can have a profound impact on a patient’s life, with the prevalence of anxiety, depression, poor wellbeing and quality of life generally found to be high in psoriasis populations. Based on Buddhist psychology, mindfulness based interventions have been shown to have positive impacts on anxiety, depression, wellbeing and quality of life in various populations.

**Methods:** Mixed methods explored the impact of a mindfulness based cognitive therapy (MBCT) intervention on 10 psoriasis patients using a Buddhist Psychological Model (BPM) as a theoretical framework to understand changes in these variables. Quantitative measures of acceptance, attention regulation, attachment, aversion, self-compassion, mindfulness, rumination, worry, wellbeing, anxiety, depression and psoriasis symptoms were completed pre and post intervention, and participants were interviewed about their experiences of MBCT.

**Results:** Statistically significant changes in attention, mindfulness, attachment, aversion, rumination, quality of life, anxiety and psoriasis were found. The qualitative data provided support for the BPM as a theoretical lens with which to understand the way in which mindfulness impacts on patient quality of life, anxiety and psoriasis symptoms.

**Conclusions:** This study gives support to the promising potential of mindfulness interventions being implemented by mental health care professionals with psoriasis patients.

**PI28**

**A LINK BETWEEN QUALITY OF PATIENT-PHYSICIAN COMMUNICATION AND PATIENT HEALTHCARE NEEDS IN PSA**

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**Introduction:** Patient(pt)-physician(HCP) communication may influence symptom reporting and disease control.

**Objectives:** To evaluate psoriatic arthritis (PsA) symptoms, life impact and treatment satisfaction in pts who report good communication with their HCP vs suboptimal communication.

**Methods:** An online pt-based survey was conducted in the US from 2 Nov–1 Dec 2017. Pts had reported having PsA for >1 year, taken >1 synthetic(s) or biologic(s) DMARD for PsA. Pts reported overall health, PsA severity/symptoms/life impact, treatment satisfaction and communication experience. We evaluated differences by pt-HCP communication status.

**Results:** Overall, 301 pts with PsA responded, mean age 45 years, 61% female, 89% self-reported moderate/severe PsA. Current PsA treatments included bDMARD (52%), sDMARD (25%), combination b/sDMARD (15%). Overall, 256 (85%) of PsA pts were managed by a rheumatologist and 15% by a dermatologist. Of the 256, >40% reported suboptimal pt-HCP communication. Pts in the suboptimal vs good communication subgroups were typically younger, more likely to be Hispanic and reported greater life impact and lower satisfaction with pt-HCP communication (Table).

**Table.** Pts with PsA managed by a rheumatologist (n=256)

<table>
<thead>
<tr>
<th>Symptom/Impact</th>
<th>Agree</th>
<th>Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (years)</td>
<td>41.9</td>
<td>46.5*</td>
</tr>
<tr>
<td>White</td>
<td>66</td>
<td>73</td>
</tr>
<tr>
<td>Hispanic</td>
<td>20</td>
<td>25</td>
</tr>
<tr>
<td>Black</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>Symptoms in past 12 months</td>
<td>85</td>
<td>90</td>
</tr>
<tr>
<td>Joint pain</td>
<td>83</td>
<td>84</td>
</tr>
<tr>
<td>Skin/nail symptoms</td>
<td>74</td>
<td>79</td>
</tr>
<tr>
<td>Stiffness</td>
<td>70</td>
<td>72</td>
</tr>
<tr>
<td>Joint swelling</td>
<td>70*</td>
<td>55</td>
</tr>
<tr>
<td>Moderate PsA</td>
<td>23</td>
<td>32</td>
</tr>
<tr>
<td>Severe PsA</td>
<td>36*</td>
<td>59</td>
</tr>
<tr>
<td>Very satisfied with HCP communication</td>
<td>43</td>
<td>39</td>
</tr>
<tr>
<td>Very satisfied with treatment</td>
<td>29</td>
<td>45*</td>
</tr>
<tr>
<td>Stopped taking treatment</td>
<td>22*</td>
<td>8</td>
</tr>
</tbody>
</table>

*p<0.05

**Conclusions:** Pts who reported suboptimal communication with their HCP may have greater healthcare needs for their PsA vs other pts.

**PI29**

**PSORIASIS PATIENTS POINT OF VIEW: WHAT ARE WE MISSING WHEN MANAGING THEM?**

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**Introduction:** Psoriasis is a skin disease that can occur at any time and it is most common in the age group 50–69. The reported prevalence of Psoriasis in countries ranges between 0.09% and 11.4%, making it a serious global problem. Psoriasis affects the quality of life and it is associated with many comorbidities such as depression, diabetes, cardiovascular disease and psoriatic arthrits.

To evaluate the severity and the efficiency of the treatment applied to patients with Psoriasis, in practice it is used PASI (Psoriasis Area and Severity Index). The value may vary, for example, in this study, PASI 75 represents the percentage (or number) of patients that have achieved a 75% or more reduction in their PASI score in 12 weeks from baseline.

**Objectives:** Aim of this study is to gain a better perspective on the Psoriasis patient’s point of view when seeking a physician’s...
help, therefore, to try and minimize the gaps that exist when managing them.

Methods: This study was based on a custom questionnaire which included 14 questions for each patient. The responses were gathered from 20 patients (and it is still ongoing) diagnosed in our Department of Dermatology and Venereology Timisoara, each in different stages of disease. All the answers are confidential and anonymous. An informed consent was signed prior to any taken actions. To achieve meaningful results, we asked patients to be honest and to present the situation in a real way. The most important question on the questionnaire was “Which of the three options represents the PASI score you would like to achieve? 50/75/90?” In addition to this question, we provided the patients with three pictures each of them showing a different PASI score, so they can choose the proper answer much easier.

Results: 80% of the patients chose PASI 90, 15% chose PASI 75 and only 5% chose PASI 50.

In addition to this, the gender distribution showed us that 100% of the female patients chose PASI 90, proving how important appearance is for them, and how much of a weight is for them to have disease that is in the limelight. On the other hand, the male patients were divided into three groups. 69% said that the efficiency of the therapy is very good, choosing PASI 90. Only 23% of male patients consider PASI 75 satisfying and the last 8% represents PASI 50.

Conclusions: Psoriasis is a chronic inflammatory disease, which is intensively studied at the cellular and molecular level. What is considered a good response to a treatment is sometimes different from the perception of a patient vs. a physician, therefore we must always keep a balance between aiming high (and maybe risking to over-treat some patients) and meeting the patient’s expectations.

P130
THE IMPACT OF PSORIASIS AND PSORIATIC ARTHRITIS ON QUALITY OF LIFE AND CAREER IN SCANDINAVIA

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Introduction: Patients’ perspectives on the effects of psoriasis (PsO) and psoriatic arthritis (PsA) on health-related quality of life (HRQoL) are important in establishing better approaches to their care and treatment.

Objectives: To better understand the impact of PsO and PsA on daily life, education and work in Scandinavian countries. Methods: The NORdic PaTient survey of PsOriasis and Psoriatic arthritis (NORPAPP) was an on-line survey carried out in November 2015 using YouGov panels in Sweden, Denmark, and Norway. Adults (18–74 years old), with physician-diagnosed PsO or PsA (n = 1221), answered questions about the impact of disease on 10 aspects of daily activity/mood and on work/education; 5-point Likert scale responses were dichotomised into “no/minor impact” (1–3 or “don’t know”) and “strong impact” (4–5).

Results: For the 10 aspects of activity/mood a “strong impact” was reported for ≥4, 1–3 or 0 aspects by 22.8%, 24.2%, and 61.9% of respondents with PsO alone and 44.5%, 63.0%, and 27.0% of those with PsA:PsO. The most commonly reported strong impacts were limitations on dressing (22.6%), sleep disorders (16.3%) and depression and/or anxiety (16.2%) for respondents with PsO alone; and, daily routine (45.1%), leisure/sports (44.0%), sleeping disorders (44.5%), and limitations on clothing (41.8%) for respondents with PsA:PsO. Regarding the impacts on work/career or education since development of symptoms, 6.4% of respondents with PsO alone and 30.3% of those with PsA:PsO reported a strong negative impact. Of the 82.2% of respondents who were working or studying, frequency of absences in the previous 12 months were significantly higher (Bonferroni corrected z-tests, total α = 0.05) among those who: had PsA:PsO vs PsO alone; perceived their symptoms to be severe vs non-severe; used systemic vs only topical treatments; were aged 18–44 years vs 45–74; were members of patient groups vs non-members; saw a dermatologist or rheumatologist at least annually vs those who did not.

Conclusion: PsO has a profound impact on the HRQoL and career/education of individuals with these conditions in Scandinavia. The impact is greater among individuals with PsA:PsO.
P132 MIRIKIZUMAB SIGNIFICANTLY IMPROVES SELF-REPORTED DISEASE SEVERITY AND GENERAL HEALTH STATUS IN PATIENTS WITH MODERATE-TO-SEVERE PSORIASIS

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1SKIn Centre for Dermatology, ‘Eli Lilly & Company, 2Windsor Dermatology

Introduction: In a randomized, placebo-controlled, phase 2 trial (NCT02899988), mirikizumab met its primary efficacy endpoint at Week 16.

Objective: To determine if mirikizumab improves patient-reported disease severity and general health status in psoriasis patients at Week 16.

Methods: Adults with moderate-to-severe psoriasis were randomized 1:1:1:1 to receive placebo (n=52), mirikizumab 30 mg (n=51), 100 mg (n=51), or 300 mg (n=51) at Weeks 0 and 8. At baseline and Weeks 2, 4, 8, 12, and 16, patients completed the Patient Global Assessment of psoriasis (PtGA) (0=clear, 5=severe). At baseline and Week 16, patients completed the Patient Outcomes Study 36-Item Short Form Health Survey (SF-36; [range 0–100]) which measures 8 general health status domains that can be scored as mental component and physical component summaries. For continuous measures, comparisons were made by a mixed-effects for repeated measures model (PtGA) or an analysis of covariance model (SF-36). Comparisons of categorical efficacy variables were conducted by logistic regression analysis with non-responder imputation (NRI).

Results: At Week 16, mirikizumab-treated patients reported greater improvements in psoriasis severity and aspects of physical functioning versus placebo (Table).

Conclusion: Mirikizumab treatment at various doses significantly improved psoriatic disease severity and physical health status.

Reference:
1. Reich K et al. Programme and abstracts of Psoriasis from Gene to Clinic; Nov. 30-Dec. 2, 2017; Abstract FC31.

Table. Patient-Reported Outcomes (Week 16)

<table>
<thead>
<tr>
<th>PtGA, least squares mean(SE)</th>
<th>30 mg</th>
<th>100 mg</th>
<th>300 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical functioning</td>
<td>2.8 (1.9)</td>
<td>7.2 (2.0)</td>
<td>8.2 (1.9)*</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>1.2 (2.4)</td>
<td>11.2 (2.5)**</td>
<td>11.5 (2.5)**</td>
</tr>
<tr>
<td>General health</td>
<td>1.4 (1.9)</td>
<td>5.8 (2.0)</td>
<td>3.2 (1.9)</td>
</tr>
<tr>
<td>Vitality</td>
<td>1.0 (2.0)</td>
<td>6.9 (2.1)*</td>
<td>4.7 (2.0)</td>
</tr>
<tr>
<td>Social functioning</td>
<td>-0.2 (2.4)</td>
<td>10.5 (2.4)*</td>
<td>13.4 (2.4)**</td>
</tr>
<tr>
<td>Role-emotional</td>
<td>1.3 (2.0)</td>
<td>5.2 (2.1)</td>
<td>6.1 (2.0)</td>
</tr>
<tr>
<td>Mental health</td>
<td>1.7 (1.8)</td>
<td>5.5 (1.8)</td>
<td>6.6 (1.8)</td>
</tr>
</tbody>
</table>

Change from Baseline in SF-36 Domains, LSM (SE)

<table>
<thead>
<tr>
<th>MCS, % (NRI)</th>
<th>30 mg</th>
<th>100 mg</th>
<th>300 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥2.5 point improvement in SF-36</td>
<td>36.5</td>
<td>37.3</td>
<td>45.1</td>
</tr>
<tr>
<td>MCSI, % (NRI)</td>
<td>42.3</td>
<td>52.9</td>
<td>56.9</td>
</tr>
</tbody>
</table>

MCSI, mental component summary; PtGA, Patient Global Assessment; PCS, physical component summary; SE, standard error; SF-36, 36-Item Short Form Health Survey.

P134 PRURITUS SEVERITY ASSESSMENT AND CORRELATION WITH BASELINE CHARACTERISTICS OF PATIENTS WITH PSORIASIS VULGARIS: AN EXPLORATORY ANALYSIS OF THE PHASE IIIB, PSORITUS STUDY

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Introduction: Chronic pruritus lasts for at least 6 weeks and is a most common symptom in patients with psoriasis. Pruritus is a highly prevalent and troublesome symptom and has a negative impact upon patients’ health-related quality of life (QoL). The ItchyQoL is a pruritus-specific QoL questionnaire that can be applied to patients with pruritus independent of the underlying disease.

Objective: To assess the impact of pruritus on QoL in patients with psoriasis by an exploratory analysis of baseline characteristics of subjects from the PSORITUS study.

Methods: PSORITUS was an exploratory, randomized, double-blind, placebo-controlled 16-week drug withdrawal study with a 16-week open-label run-in phase, to assess the kinetics of psoriasis symptoms, pruritus intensity, and lesional biomarkers. Subjects...
≥18 years of age with chronic moderate-to-severe psoriasis at least 6 months prior to baseline, with a Psoriasis Area and Severity Index (PASI) score > 10 at baseline, and pruritus intensity ≥30 on a 100-point Visual Analogue Scale (VAS, the worst itching within a recall period of 24 hours), were included. In an exploratory baseline analysis, correlation coefficients were calculated between ItchyQoL outputs and individual baseline characteristics based on Spearman’s (r) and Kendall rank correlations (τ). A multiple linear regression model was performed to assess the effect of exploratory variables correlating with the ItchyQoL score and achieving statistical significance (p-value < 0.05).

Results: The study included 130 subjects with psoriasis. The subjects had a mean age of 46.8 years (standard deviation [SD], 12.30) and majority (71.5%) were in the age group of 35–64 years. The mean (SD) time since first diagnosis of psoriasis and psoriatic arthritis (PsA) was 19.5 (13.81) and 17.2 (18.30) years, respectively; 13.8% of subjects had PsA. The mean (SD) baseline PASI, patient benefit index (PBI), and ItchyQoL scores were 23.9 (10.85), 84.2 (24.17), and 78.7 (17.42) respectively, indicating severe disease activity and pruritus. The baseline ItchyQoL score showed moderate correlation with baseline VAS scores for average and worst pruritus (r: 0.542 [95% CI: 0.41, 0.65] and 0.547 [95% CI: 0.41, 0.66]; t: 0.381 [95% CI: 0.22, 0.52] and 0.383, 95% CI: 0.23, 0.52)) and a strong correlation with baseline dermatology life quality index (DLQI) scores (r: 0.803 [95% CI: 0.73, 0.86]; t: 0.622 [95% CI: 0.50, 0.72]). Furthermore the multiple linear regression analysis showed substantial dependency of QoL measured by ItchyQoL for VAS (average pruritus last 24 h), duration of psoriasis and health-related patient needs as measured by patient benefit index.

Conclusions: ItchyQoL assessment demonstrated that subjects with psoriasis are highly burdened by pruritus and show severely impaired quality of life. The correlation between pruritus intensity, ItchyQoL- and DLQI questionnaire results suggests the need for routine assessment of pruritus in clinical practice.

P135 QUALITY OF LIFE AND PSYCHOSOCIAL IMPLICATIONS IN PATIENTS WITH PSORIASIS

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Introduction: Psoriasis is a common, long-term skin disease that affects approximately 1.5–3% of the population. The burden of living with psoriasis is equivalent to or greater than that seen in other long-term conditions, such as cardiac failure and chronic lung disease. The stigma provoked by the disease, often lead to the discontinuation of daily activities and social withdrawal. Nevertheless, these effects of psoriasis are seldom recognized and often undertreated.

Objectives: The aim of the study is to evaluate the quality of life, anxiety and depression, self-esteem and loneliness in patients with psoriasis.

Methods: Ninety-eight patients with psoriasis were enrolled in the study. The quality of life, depression and anxiety, loneliness and self-esteem of the patient were assessed using the Dermatology Life Quality Index, Hospital Anxiety and Depression Scale, the UCLA loneliness Scale (UCLA-Version 3) and Rosenberg’s Self-esteem Scale, respectively.

Results: The Dermatology Quality of Life Index score among psoriasis patients was 3.52 ± 4.88. They had statistically significantly higher scores for the Hospital Anxiety and Depression Scale -anxiety subscale (p = 0.031) compared with healthy volunteers. Moreover, a statistically significant difference was found between the two groups concerning the UCLA-scale (p = 0.032) and RSES-scale (p = 0.0001). Female patients presented with lower self-esteem than male patients.

P136 SWEDISH PSORIATIC PATIENTS’ PERSPECTIVE OF THEIR DISEASE, RESULTS FROM AN OBSERVATIONAL PATIENT SURVEY

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Introduction: A global patient survey was adapted and implemented in Sweden, in order to explore and understand the patients’ view on their disease, as well as the personal and emotional impact of their psoriasis. The focus of the survey was the patient’s perception of the possibility to achieve clear skin, and how having clear skin could affect their quality of life. A publication based on earlier data is under review.

Methods: The Swedish “Clear about Psoriasis” survey was conducted from June 16 2017 to August 8 2017. Recruitment was made via online panels and patient organizations. Validated methods were used to assess severity of disease and health-related quality of life. The survey consisted of multiple-choice questions, no definition of clear skin was given, and spontaneous feelings/perceptions were reported. Respondents (≥18 years old) were required to have current plaque psoriasis, for which they had received a medical diagnosis and should not have participated in an online survey about psoriasis in the preceding four weeks. The analysis included only patients with moderate-to-severe plaque psoriasis, defined as a Psoriasis Area Severity Index (PASI) score ≥10, or a PASI score 5.0–9.9 with plaques in visible and/or in sensitive areas, such as the face and genitals.

Results: In total, 54 patient responses were completed and analyzed. Mean age was 45 years and 80% were female. The average self-assessed PASI score was 16.0, 26% had PASI 5.0–9.9, 74% PASI > 10 and 54% reported to have psoriatic arthritis. Current treatment allowed 44% of patients to achieve clear or almost clear skin. Clear or almost clear skin was believed to be achievable by 30% of the patients. Of patients reaching clear or almost clear skin, 71% had talked to their physician about their aim for clear skin. Among patients who have not achieved clear or almost clear skin, 47% had spoken to their physician about their aim. 57% of the patients were satisfied with their current treatment. The most important reasons for treatment satisfaction were less itching (81%), and the achievement of less pain and soreness (55%). Not achieving clear skin was the major reason for dissatisfaction. Discrimination or humiliation has been experienced by 98%. About 69% have been asked if they are contagious. Relationships were affected and 52% avoided to have sex. Worklife was affected by 65% of the respondents. For 58% of patients it took more than 5 years to get a treatment that resulted in clear or almost clear skin. During the last 6 months, 24% of employed patients had taken at least one day off work due to their disease whilst 5% took more than 14 days.

Conclusions: This survey shows that a majority of patients do not believe achieving clear or almost clear skin is possible and they are not comfortable to talk to their physician about it. Furthermore, patients encounter a stigmatizing environment. Better treatment as well as improved patient information is needed.

Novartis is grateful to Psoriasis förbundet for facilitating the survey.

P137 IXEKIZUMAB PROVIDES GREATER CUMULATIVE BENEFITS VERSUS USTEKINUMAB OVER 24 WEEKS FOR PATIENTS WITH MODERATE-TO-SEVERE PSORIASIS IN A RANDOMIZED, DOUBLE-BLIND PHASE 3B CLINICAL TRIAL

Andrew Blauvelt1, Mark Lomaga2, Russel Burg4, Baojin Zhu3, Carsten Henneges4, Wei Shen4, David Shrom5, Martin Dossenbach1, Andreas Pinter4

1Oregon Medical Research Center, 2DermEdge Research, 3Eli Lilly and Company, 4University Hospital Frankfurt

Acta Derm Venereol 2018
Introduction: Ixekizumab, a high-affinity monoclonal antibody that selectively targets IL-17A, was shown to be superior to ustekinumab, an IL-12/23 inhibitor, with respect to skin clearance and quality of life up to 24 wks in patients with moderate-to-severe psoriasis in IXORA-S1.

Objectives: The objective of this analysis was to compare the cumulative benefits of ixekizumab versus ustekinumab at 12 and 24 weeks of treatment in IXORA-S, with respect to skin clearance, itching, health-related quality of life (HRQoL), and pain.

Methods: In the IXORA-S trial, patients were randomized (1:1) to receive either IXE (160-mg starting dose, then 80-mg every 2 wks for 12 wks followed by 80-mg every 4 wks; n = 136) or UST (45–mg/90-mg weight-based dosing per label; n = 166) through 52 wks. Data at week 12 and week 24 were used in this post-hoc analysis. At wks 2, 4, and every 4 wks thereafter, clinical benefits were measured using percentage improvements in Psoriasis Area and Severity Index (PASI 75/90/100), the Itch Numeric Rating Scale (NRS; 0 = no itch, 10 = worst itch imaginable); and Skin Pain VAS (0 = no pain, 100 = maximum pain). Health-related quality of life (HRQoL) benefit was measured at wks 2, 4, 12, and 24 using the Dermatology Life Quality Index (DLQI) [DLQI score = 0 = no effect on patient’s life]. Total benefits - PASI 75/90/100; itch NRS = 0; DLQI = 0; Pain VAS 0 – were used to determine the area-under-the-curve (AUC) of responders for each outcome at 12 and 24 weeks. Missing values were imputed using non-responder imputation (NRI). AUC results, capturing the rapid and sustained treatment response, were normalized as a percentage of maximum possible (0–100%) AUC. The clinical benefit ratios between IXE vs UST were calculated for each outcome to show relative cumulative benefit.

Results: At 12 wks, the normalized cumulative clinical benefit with IXE vs UST, respectively, was 58.2% and 32.9% (PASI75); 36.7% and 15.6% (PASI90); 14.2% and 4.0% (PASI100); 25.3% and 14.3% (itch); 36.0% and 23.7% (pain); and 44.9% and 25.2% (DLQI). Cumulative clinical benefits at week 24 for IXE and UST, respectively, were 74.3% and 54.3% (PASI75), 58.1% and 32.3% (PASI90), 29.0% and 12.2% (PASI100); 33.5% and 22.1% (itch); 42.7% and 30.6% (pain); and 54.3% and 37.0% (DLQI). At 12 wks, clinical benefit ratios (IXE/UST) for PASI 75/90/100 were 1.77, 2.36, and 3.52; 1.51 for pain; and 1.78 for both itch and DLQI. At 24 wks, the ratios were 1.37, 1.80, 2.38 (PASI 75/90/100), 1.52 (itch), 1.39 (pain) and 1.47 (DLQI).

Conclusions: Cumulative benefits measured by PASI, itch, pain, and DLQI responders were greater for IXE vs UST following 12 and 24 wks of treatment. Long-term cumulative benefits will be addressed upon publication of Week 52 results from the IXORA-S trial.


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Coach@home: A support program for patients treated with certolizumab pegol (CZP)-treated patients (pts) with rheumatic diseases, including psoriatic arthritis (PsA). Eight coaching calls are offered over one year, scheduled around critical milestones on the therapeutic journey. These are made by trained nurses, who offer support and information about both the pt’s disease and its treatment with CZP.

Objectives: To assess the baseline characteristics of PsA pts subscribed to c@h, and the level of pt satisfaction with the program across indications (Sep 2017 data cut).

Methods: c@h was launched in Jun 2014, and is available to pts who are prescribed CZP according to the local product label. Pts must be CZP-naive when subscribed to the program, and pt consent is required prior to subscription by the treating physician. There are no additional criteria for enrolment, although the program must be recommended to the pt by the treating physician. Pt satisfaction across indications (PsA, rheumatoid arthritis and axial spondylo-arthritis) was measured at program completion or discontinuation using the net promoter score (NPS), which has previously been used for this purpose. The NPS is derived by asking pts to state the likelihood that they would recommend c@h to others (on a 0–10 scale). Rankings of 9–10 are considered ‘promoters’, 7–8 ‘passives’, and 0–6 ‘detractors’. Subtracting the percentage of detractors from that of promoters yields the NPS.

Results: A cumulative total of 136 PsA pts had been registered to c@h by Sep 2017. Mean age at baseline was 52 years; the majority were female (69%). Prior biological DMARD exposure was 24%. The most common topics discussed on calls were treatment adherence (290 calls), CZP maintenance dose (284 calls) and synringe disposal (201 calls). The average length per call was 15.7 min (SD: 5.33) at the end of Week 0 (total: 135 calls), and 14.6 min (SD: 6.59) at the end of Week 52 (45 calls). Across indications, a cumulative total of 272/655 pts had either completed the coaching period (n = 70) or discontinued (n = 202) by 28 Sep 2017, of whom 106 rated the program. Of these, 87.5% gave promoter scores, 10.4% passive, and 3.8% detractor, yielding an NPS of 83.7. The program was still ongoing at the time of this data cut.

Conclusions: c@h offers support and guidance to CZP-treated pts in Germany. Feedback from pts willing to provide a rating (39%) indicates a high level of satisfaction with the program.

References:

Acknowledgements: c@h is performed by Healthcare@home Deutschland GmbH, funded by UCB Pharma, led by Elke Zeise and managed by Karen Thiel and Manh Dan Nguyen. We thank the patients and their caregivers in addition to the investigators and their teams who contributed to this program. Editorial services were provided by Costello Medical.

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A comprehensive survey assessing the family planning needs of women with psoriasis

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Introduction: Psoriasis (PS) in women often overlaps with their peak reproductive years. Data on the family planning (FP) experience of patients (pts) are therefore needed to optimize PS management.

Objectives: To report the results of a survey evaluating the FP needs of women with PS.

Methods: Women of childbearing potential (WoCP; aged 18–45) diagnosed with PS (including pts with psoriatic arthritis), were recruited to complete a 96-question web-based survey on SurveyGizmo®. The survey included questions on pts’ experience, concerns and educational needs, and was disseminated using eblasts (the National Psoriasis Foundation, Advance E-News, and TalkPsoriasis.org mailing lists) and social media (Facebook and Twitter). Responses were collected Dec 2017–Feb 2018.

Results: Of 141 pts completing the survey, 91 (65%) were planning to conceive (PTC), and 66 (47%) had experienced pregnancy (EP) within the last 5 years. Prescribed systemic medications were
being used by 40% of pts PTC and 12% of pts who had EP. Only 41% pts who had EP informed the healthcare provider (HCP) treating their PS of their pregnancy right away, while 21% did not notify them at all.

While PTC, most pts who had not EP (88%), sought FP advice from the internet; only 21% had consulted the HCP treating their PS, compared to 55% of pts who had EP. Of the 96 pts who discussed FP with the HCP treating their PS, just 7% said this was initiated by the HCP. Pts PTC were most influenced by their personal network (e.g. family), but of pts who had EP, 41% said the HCP treating their PS was one of the most influential types of support in their FP decisions. Pts reported wanting information on the impact of PS and treatments on their baby, the heritability of PS, and flare management during pregnancy. During pregnancy, 65% pts who had EP stopped treatment (of any type), 79% of whom did so out of fear of harming their baby. In 40% cases where pts had stopped all and any treatment for PSO, the decision was initiated by the pt, and in 47%, by their PS treatment provider. Of pts who stopped treatment, 44% experienced a worsening in the severity of their PS, yet most pts do/did not have a plan for flare management during pregnancy (PTC: 69%; EP: 65%). Many pts stopping all treatment had not been advised on restarting treatment post-partum (PTC: 42%; EP: 23%).

Conclusions: Many WoCP with PS take systemic medications but many do not discuss FP with their PS treatment provider, and if they do, the discussion is rarely initiated by the HCP. PS treatment providers should prioritize discussing FP, and plan treatment around and during pregnancy. The educational needs of WoCP with PS include the impact of treatment on their baby, flare management during pregnancy, and restarting treatment post-partum.

Acknowledgements: This study was funded by UCB Pharma. The survey was conducted by the National Psoriasis Foundation. We thank the patients who contributed to this study. Editorial services were provided by Costello Medical.

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THE PSYCHOSOCIAL IMPACT OF PSORIASIS: DIFFERENTIAL EXPERIENCES OF MEN AND WOMEN IN EARLY ADULTHOOD

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2UCB Pharma, Brussels, Belgium.

Introduction: Plaque psoriasis (PSO) can have a profound impact on patients’ (pts’) psychosocial wellbeing, leading to self-consciousness, embarrassment, depression, social isolation and stigmatization. However, little is known of how the impact of disease differs between genders.

Objective: To evaluate differences in the psychosocial impact of PSO on quality of life in men and women in early adulthood.

Methods: Pts aged ≥18 in the US, Canada, France, Germany and Italy without a diagnosis of psoriatic arthritis were invited to complete a postal survey (Oct 2016–Jan 2017), in the ratio 3:1. Week 16 CZP-treated PASI 50 responders continued initial blinded treatment to Week 48 (PBO-treated PASI 50 responders are not included). PASI 50 non-responders at Weeks 32, 40 and 48 were discontinued.

Mean change from baseline (CFB) in DLQI was 4.9 (P = 0.002) in CZP-treated pts vs 1.2 (P = 0.30) in PBO-treated pts at Week 48. A higher proportion of women than men were concerned by their appearance (73% vs 63%), and always/usually tried to cover their skin (27% vs 16%).

Conclusion: Despite similar clinical manifestations of PSO, women in early adulthood tended to report a greater impact of their disease on their lives, both physically, in terms of pain, and psychosocially, in terms of effects on relationships and impact on their daily lives.

Reference:

P141
CERTOLIZUMAB PEGOL IMPROVES PATIENT-REPORTED OUTCOMES IN CHRONIC PLAQUE PSORIASIS OVER 1 YEAR

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Introduction: Certolizumab pegol (CZP) is an Fc-free, PEGylated, anti-TNF biologic. Here we present patient (pt)-reported quality of life (QoL), work productivity and social activities over 48 weeks of CZP treatment.

Materials/Methods: Data were pooled from CIMPASI-1 (NCT02326298) and CIMPASI-2 (NCT02326272) phase 3 trials of adults with PSO ≥6 months (psoriasis area and severity index [PASI] ≥12, affected body surface area [BSA] ≥10%, physician’s global assessment [PGA] ≥3/5). Pts were randomized to CZP 400 mg every 2 weeks (Q2W), CZP 200 mg Q2W (following 400 mg loading dose at Weeks 0, 2, 4), or placebo (PBO) Q2W for 16 weeks. Week 16 CZP-treated PASI 50 responders continued initial blinded treatment to Week 48 (PBO-treated PASI 50 responders are not included). PASI 50 non-responders at Weeks 32, 40 and 48 were discontinued.

Mean change from baseline (CFB) in Dermatology Life Quality Index (DLQI), rates for DLQI minimally clinically important difference (MCID; ≥4-point improvement) and DLQI remission (score of 0/1), and CFB in Work Productivity and Activity Impairment (WPAI) PSO-specific at Weeks 16 and 48 were assessed. Negative CFB for DLQI and WPAI signifies improvement. CFB DLQI analyses used last observation carried forward (LOCF) imputation for missing data, DLQI MCID and remission analyses used non-responder imputation, WPAI analyses used last observation carried forward imputation at Week 16 and observed data at Week 48.

Results: At Week 16, CZP pts showed greater improvements in DLQI vs PBO, and higher proportions achieved DLQI MCID and DLQI remission (Table). Improvements were maintained to Week 48 in CZP-treated pts who continued treatment (Table). Improve-
ments in work productivity and reductions in activity impairment were seen with both CZP doses vs PBO; and were maintained to Week 48 in patients remaining in the trial. (Table).

Conclusions: Treatment with CZP was associated with improvements in QoL, work productivity and social activities vs PBO at Week 16, which was maintained to Week 48 in patients remaining in the trials.

Table. Improvements in DLQI and WPAI at Weeks 16 and 48

<table>
<thead>
<tr>
<th></th>
<th>PBO (n = 100)</th>
<th>CZP 400 mg Q2W (n = 175)</th>
<th>CZP 200 mg Q2W (n = 186)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Week 16</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DLQI</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean CFB (SD)</td>
<td>-3.1 (6.7)</td>
<td>-9.8 (7.0)</td>
<td>-10.3 (7.5)</td>
</tr>
<tr>
<td>MCID, n (%)</td>
<td>41 (41.0)</td>
<td>135 (77.5)</td>
<td>121 (69.1)</td>
</tr>
<tr>
<td>DLQI 0/1, n (%)</td>
<td>7 (7.0)</td>
<td>84 (48.0)</td>
<td>90 (51.4)</td>
</tr>
<tr>
<td>WPAI Domains, mean change from baseline (SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Absenteeism</td>
<td>-0.1 (17.5)</td>
<td>0.7 (21.7)</td>
<td>2.6 (15.6)</td>
</tr>
<tr>
<td>Presenteeism</td>
<td>0.7 (21.8)</td>
<td>-12.9 (25.2)</td>
<td>-17.0 (26.1)</td>
</tr>
<tr>
<td>Work productivity loss</td>
<td>4.8 (28.5)</td>
<td>-9.0 (32.7)</td>
<td>-16.4 (28.9)</td>
</tr>
<tr>
<td>Activity impairment</td>
<td>-1.5 (25.3)</td>
<td>-23.9 (28.3)</td>
<td>-28.6 (28.9)</td>
</tr>
</tbody>
</table>

First outcomes will be a comprehensive review of papers derived from the systematic literature search in May 2018.

P143
THE GLOBAL RESEARCH ON THE IMPACT OF DERMATOLOGICAL DISEASES (GRIDD)

Matthias Augustin,1 Nirohshah Suthakharan,2 Christine Janus3, Jennifer Austin1, Christine Bundy1, Rachael Pattinson1

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Introduction: The Global Research on the Impact of Dermatological Diseases (GRIDD) project will be the first global patient-initiated and patient-led impact research study in dermatology. By including the patient perspective stringently into the burden metrics, this will be the first program to systematically challenge the current Global Burden of Disease concept, which markedly underestimates the patient burden of skin diseases.

Objective: The objective of the GRIDD research project is to develop a comprehensive measure of the impact of living with skin diseases instruments by country, regionally and worldwide. The global instrument, developed with patient organisations, will capture patient experiences, including the extent of disease impact and burden for patients and their families, for generic (i.e. all dermatological diseases) and specific dermatological disease including psoriasis assessment worldwide.

Materials + Methods: Development of the comprehensive measure of impact of disease will be based on a novel methodology with several phases. Phase 1 will systematically review existing measures of the life impact of skin diseases and conduct a patient-centered item identification exercise. Phase 2 will be informed by Phase 1 data and will focus on instrument development: develop the wording for items (i.e. impact categories) and appropriate item scaling. This measure will describe the impact on life which may include economic; psychological and social impacts. Phase 3 describes the acquisition of real world data to further test the validity and acceptability of the new measure. Lastly, phase 4 and 5 include dissemination and launch of data, the new measure and an implementation strategy to increase uptake of the measure.

Results: GRIDD has assembled a scientific advisory board representing different regions worldwide. Currently, we are collaborating with over 100 patient associations in 32 countries worldwide, with more than 26 disease areas. Industry funding has been secured from five different companies for the first phase and a portion of phase 2. The GRIDD research team, including researcher from the University Medical Center in Hamburg and University of Cardiff, met in 2017 to start phases 1 and 2. The systematic literature review on “Existing patient-centred outcome measures currently used in dermatology” is currently underway.

Conclusion: This novel patient-centric methodology will complement existing concepts of evaluating patient perspective in dermatology. GRIDD will provide an extended patient view for better decision making in dermatology on a global and country level. It supports local, regional and international attempts to create awareness, better position psoriasis and other skin diseases and encourage decision-makers and stakeholders to include dermatological diseases in their policies.

P144
TREATMENT OF NAIL PSORIASIS WITH DIFFERENT PULSE DURATIONS OF PULSED DYE LASER

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Background: There are different treatment modalities for nail psoriasis but the treatment of choice is still controversial. Laser
therapy opened new windows for treatment of nail psoriasis (1, 2).

Objective: The aim of this study was to evaluate the efficacy of different pulse durations in the treatment of nail psoriasis with the 595-nm PDL to determine the optimal pulse duration.

Methods: In this clinical trial study, 120 patients with bilateral fingernail or toenail psoriasis were evaluated. PDL was applied on the proximal and lateral nailfolds based on random assignment. 240 nails were treated with 6-millisecond pulse duration and 9 J/cm² whereas 240 nails were treated with 0.45-millisecond pulse duration and 6 J/cm². Nail Psoriasis Severity Index (NAPSI) was used to assess the clinical outcome from pretreatment and posttreatment photographs.

Results: After 6 months of first treatment, there was a significant reduction in overall NAPSI, nail matrix NAPSI, and nail bed NAPSI scores from baseline in both groups; however, no significant difference was found between the two pulse duration groups. Side effects were mild including transient petechiae and hyperpigmentation.

Conclusion: PDL was found to be an effective and well-tolerated option in the treatment of nail psoriasis. This study demonstrated that both the longer 6-millisecond and shorter 0.45-millisecond pulses of PDL (595 nm) have been clinically proven to be effective for the treatment of nail matrix and nail bed psoriasis.

References:

P145
NEUTROPENIA IN A PSORIASIS PATIENT: SECUKINUMAB OR MICRONUTRITION DEFICIENCY?
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We report a case of severe neutropenia in a psoriasis patient, which developed three months after discontinuation of secukinumab. She had gastric bypass surgery a few years ago and was intermittently treated due to iron deficiency anemia. According to the suggested approach to the adult with unexplained neutropenia (1) a range of diagnostic tests were performed and no abnormalities were noticed. Neutropenia still persists, however the patient hasn’t had any complications. Neutropenia was reported infrequently in subjects with moderate to severe psoriasis receiving secukinumab in a pooled analysis of 10 phase II and III clinical studies (2). Most were grades 1 or 2. Grade 3 neutropenia was uncommon and not associated with serious infections, and no grade 4 neutropenia was recorded. Deficiencies of dietary vitamins and minerals typically cause neutropenia in association with other cytopenias. Patients who have undergone bariatric surgery require lifelong vitamin and mineral supplementation. Severe neutropenia in our patient could be due to combination of secukinumab and micronutrient deficiency, however exact etiology remains unclear.


P146
ESTABLISHMENT OF A PSORIATIC SKIN MODEL FOR α-IRRADIATION
Julia Wiedemann1, Valeria Grönebaum1, Claudius Witzler1, Maximilian Dornhecker1, Sylvie Lerchl, Claudia Fournier1,2

Poster abstracts 59

1GSI Helmholtzzentrum für Schwerionenforschung, Darmstadt, Germany, 2University of Applied Sciences, Darmstadt, Germany

Introduction: Psoriasis is on the indication list for therapy in radon galleries (1). Radon is a radioactive noble gas evaporating from rocks. It is absorbed through skin or lung epithelium during inhalation. Radon decays in the tissue under emission of α-particles. The estimated dose received during a radon therapy is in the order of 1.2 mSv which corresponds to the annual background irradiation caused by radon. Chronic inflammatory diseases such as rheumatoid arthritis are treated with radon and pain reduction and improvement of mobility are reported (2). Positive effects are also reported for psoriasis, but sparsely documented. However, for both diseases the mechanisms underlying the clinical benefit are unknown.

Objectives: To investigate effects of radon treatment we have established a cellular model for psoriasis which can be used for irradiation with α-particles. The requirements in using α-particles are specific due to their short range.

Methods: Special rings stringed with a 2 µm oxygen plasma treated boPET foil are used to facilitate α-irradiation and growth of NHEK (normal human epidermal keratinocytes). Cells were cultured in rings or culture dishes for 24 hours and induced with IL-17, IL-22 and TNF-α. Supernatants and cells for protein and mRNA extraction were collected 24 hours after induction. ELISA, qPCR and Western Blot analysis was performed.

Results: We could show that it is possible to culture primary keratinocytes on plasma treated boPET foil with a similar morphology to cells cultured in cell culture dishes. Furthermore, the selected cytokines are able to significantly induce psoriasis-related markers like IL-19 and BDE2F2 on mRNA level and the release of the cytokine IL-6. Testing if culturing of NHEK on the treated boPET foil alone has an inflammatory effect revealed no significant differences in the expression or release of markers compared to cells cultured in cell culture dishes.

Conclusion: We conclude that the plasma treated boPET foil is a promising tool for a setup, which enables α-irradiation of monolayer cell cultures. The induction of a psoriasis-like phenotype with cytokines leads to an enhancement of relevant markers.

References:
Gasteiner Kur- Reha- und Heilstollen-Betriebsges.m.b.H. www.gasteiner-heilstollen.com
Cucu et al; Front Immunol. 2017; 8: 882.; doi: 10.3389/fimmu.2017.00882 This work is supported by the Forschungsinstitut Bad Gastein (FOI-15/08-031WIE), EURADON, the Radon Gallery of Bad Gastein and GREWIS (02NUK017A)

P147
THE HISTORY OF PSORIASIS
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Many ancient texts, including the Bible, mention people afflicted with diseases and symptoms very much like psoriasis. Ancient Egyptians wrote about a salve made with various herbs that would be spread on the skin, after which the afflicted person would be instructed to sit in the sun to bring relief to symptoms that seem to point to psoriasis. The Arabian physicians perhaps first distinguished psoriasis from other skin diseases already in the 8th century A.D., but the first written description of psoriasis appears during the Roman Empire in the 1st century AD in the books of A. Cornelius Celsus » De re medica libri octo«, Galen (131–201 AD) of Pergamon, physician of some Roman emperors, was the first who used the term psoriasis, but only for an itchy, scaly eruption of the eyelids and scrotum, that was probably seborrheic dermatitis. Unfortunately, little was known about the origin of the disease for hundreds of years, in the darkness of the Middle Age - a period of stagnation, and many psoriasis sufferers were thought at the time to have leprosy. Because so little was known about contraction
and treatment, psoriasis patients were often separated from the general population for fear of them contaminating others. People with psoriasis – thousands in medieval Europe – were forced to warn others of their arrival by ringing a clapper.

It wasn’t until the early 1800’s that psoriasis was determined to be a condition separate from leprosy. In the cultural movement of Renaissance some authors mentioned the diseases psora and lepra in their books. In the 18th century hospitals or dispensaries were opened only for treatment of skin or venereal diseases giving to the physicians the opportunity to study more cases of skin diseases and psoriasis as well, while the end of the 19th century psoriatic micro morphology was already described. In 20th century many authors studied the genetic alteration, and today there is undisputed evidence that the disease is multifactorial.

Psoriasis, as a common disease, has a significant socio-economic impact on the individual and on the society. Last decades numerous immunological researches accumulate evidence of presence of alteration of the innate and adaptive immune response in psoriatic patients. This imply a primary disregulation of the immune system and permits a better understanding and new insight in the pathogenesis and as well new possibilities in the management of psoriasis. This article shows a retrospective view of development of our knowledge on psoriasis through history.

P148
COMORBIDITIES AND TREATMENTS IN PATIENTS WITH INVERSE PSORIASIS
Mia Schneeweiss, Joseph Merola
Brigham and Women’s Hospital

Introduction: Inverse (intertriginous) psoriasis is an underdiagnosed, often untreated phenotype of psoriasis (PsO) with a high burden of illness. Inverse PsO may occur in up to 23% of subjects with psoriasis, higher than previously reported.

Objectives: To characterize the frequency of inverse PsO and patient characteristics and their treatment in a large commercial insurance claims database.

Methods: We used longitudinal claims data from commercially insured patients in the US between 10/2015 and 12/2016 to identify adults with a diagnosis of flexural psoriasis (ICD-10-CM: L40.8, “other psoriasis” which is “recommended to be used for flexural PsO”) associated with an outpatient or inpatient encounter. A 180-day enrollment period was required before the first diagnosis of an. A composite endpoint was defined as the risk of initiating immunomodulating medications during the following 6 months.

All analyses were conducted using the Action Evidence Platform.

Results: Of 1.5 million patients with at least one code for PsO, after excluding patients with concomitant other autoimmune conditions, we identified 5,310 patients with an ICD-10 code of L40.8 used for inverse PsO (4/1,000) with a median age of 52 years and an equal gender distribution. Half of the patients were 41–60 years old. Of those, 0.3% generalized pustular, 0.5% guttate, and 0.2% pustulosis palmaris et plantaris. Prevalent comorbidities included depression (7%), anxiety (6.5%), and cardiovascular conditions (5%). 20% received antidepressants. Within 180 days after the diagnosis of flexural PsO, 81% were using high-potency topical corticosteroids, 66% phototherapy, 8.6% calcipotriene, 5.6% ustekinumab, 7.2% methotrexate, 7.3% adalimumab, 3.3% etanercept, 1.3% acitretin, 0.8% infliximab, 0.9% Cyclosporine, 0.1% Sulfasalazine, 0.02% topical tacrolimus, 0.5% topical pimecrolimus. In patients 60+, 83% used high-potency topical corticosteroids, 7.8% phototherapy, 8.8% calcipotriene, 3.1% ustekinumab, 6.9% methotrexate, 4.8% adalimumab, 2.9% etanercept, 1.5% acitretin, 0.5% infliximab, 0.9% Cyclosporine, 0.6% topical pimecrolimus.

Limitations: Although the ICD-10-CM code L40.8 is recommended for flexural PsO, its sensitivity/specificity for validating cases of flexural PsO has not been established, it may not encompass all aspects of inverse/intertiginous disease and the code may be highly underutilized.

Conclusions: Using the code ICD-10-CM L40.8, which is recommended to be used for inverse “flexural” PsO leads to lower prevalence estimates of inverse PsO than previously reported; this underscores the known underreporting and underdiagnosis of this condition. Among those patients diagnosed and coded, most received topical corticosteroids and/or phototherapy; others received calcipotriene, ustekinumab, methotrexate, adalimumab, etanercept, and acitretin. Further work is needed to understand how best to capture inverse (intertriginous) / flexural psoriasis for clinical research work.

P150
DEVELOPMENT OF THE “PSO SLEEPY-Q” AND THE “PSA SLEEPY-Q”: TWO QUESTIONNAIRES TO CHARACTERIZE SLEEP IN PATIENTS WITH PSORIATIC DISEASE
Lourdes Perez-Chuda
Harvard Medical School - Brigham and Women’s Hospital

Introduction: Substantial evidence suggests that psoriasis (PsO) and psoriatic arthritis (PsA) are independently associated with sleep disturbance, which may result in serious health consequences including cardiovascular events and mortality. However, the validity of the sleep measures used in these studies is unknown as they have not been validated in patients with psoriatic disease or included psoriatic patients during their development process. There is a need for validated disease-specific Patient-Reported Outcome Measures (PROMs) to accurately characterize sleep in this population and to measure the effect of psoriatic therapies on sleep disturbance.

Objectives: This study aimed to develop and establish the content validity of 2 new sleep PROMs: the “PsO Sleepy-Q” and the “PsA Sleepy-Q”.

Methods: Following FDA PROM-development guidance, our study: (i) hypothesized a conceptual framework and identified domains through literature review and patient semi-structured interviews using a saturation model (n = 30); (ii) rated domains for importance by patients (n = 42) and an international expert panel including dermatologists, rheumatologists and sleep experts (n = 45); (iii) selected final domains based on the patients’ preference; (iv) generated item pools and the preliminary versions of the instruments.

Results: Psoriatic patients reported that sleep maintenance, adequacy, quantity and quality were the most important aspects of disordered sleep. Regarding causes of disturbed sleep: itch, skin and joint pain, stiffness, taking care of psoriatic lesions before bedtime, worsening of psoriatic symptoms at night, feeling uncomfortable in bed due to PsA and sleep apnea were the most outstanding factors selected. Finally, patients reported that disturbed sleep may increase psoriatic signs and symptoms as well as fatigue, cognitive impairment and psychological stress. Overall, patients with PsA expressed a higher burden of sleep disturbance compared to patients with PsO. Preliminary versions of the “PsO Sleepy-Q” and “PsA Sleepy-Q” including 18 and 24 items, respectively, were created. These questionnaires intend to measure the degree of sleep disturbance, the potential causes of sleep disturbance and the impairment related to sleep disturbance.

Conclusion: This study establishes the content validity of the “PsO Sleepy-Q” and “PsA Sleepy-Q”, two patient-derived PROMs to characterize sleep in patients with psoriatic disease in research and clinical settings. These questionnaires will undergo cognitive debriefing and further psychometric testing to define the final instrument forms.
P151
UNSTABLE FORMS OF PSORIASIS – INDICATOR OF AN INTERMEDIATE STATE OF SYSTEMIC DISEASE
Florentina-Silvia Delli
State Hospital for Skin and Venerable Diseases - Hippokratia General Hospital, Thessaloniki, Greece

Introduction: Erythrodermic psoriasis, inverse psoriasis and generalized pustular psoriasis are considered three particular clinical forms of psoriasis.

Objectives: We present two clinical cases in which it is discussed the possibility of considering these clinical pictures as a manifestation of the immunological switch of psoriasis from an organ-target (skin or joint) disease, to a systemic form of psoriasis.

Methods: A 22-year-old-man with erythrodemic psoriasis and a history of inverse psoriasis since childhood was successfully treated with 60 mg acitretin, until the diagnosis of psoriatic arthritis at the age of 26. The presence of arthritis determined us to change the therapy. Secukinumab at the classic therapeutic scheme is keeping the patient’s skin clean of psoriatic lesions, except from the armpits, and without any arthritic symptoms. A 75-year-old-woman with psoriatic arthritis and hyperkeratotic palms and soles non-specific lesions, under infliximab therapy presented generalized pustular psoriasis. After 3 months of acitretin 40mg and etanercept at the classic dose, the patient remains free of any symptoms.

Conclusions: The majority of psoriasis studies focus on chronic plaque psoriasis. We sustain the opinion that the above unstable forms of psoriasis, usually impossible to diagnose by other specialties than Dermatology, should be consider the main step in multidisciplinary approach of psoriasis as a systemic disease.

References:

P152
COULD BIOLOGICAL AGENTS FOSTER SUICIDE THROUGH ITS POTENTIAL ANTIDEPRESSANT MECHANISM? A PSYCHODERMATOLOGICAL APPROACH
Estela M Malatesta
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Introduction: Depression and Psoriasis are associated in up to 60% of the cases, with an increased risk of attempted and completed suicide in patients with severe forms of the disease. Bipolar Disorder is a biological condition that affects between 2 and 5% of the population, being an important cause of disability in the world. In spite of this, Bipolar Disorder is often underdiagnosed as Unipolar Depression, which increases the possibility of prescribing errors, as it occurs when administering only antidepressant agents without accompanying them with mood stabilizers, fostering the appearance of episodes of inverse polarity (SWITCHING) which, in turn, raises the risk of suicide.

Objectives: The “Cytokine Hypothesis” as a cause of depression suggests the association between the immune system and depression through the induction of the indolamine 2, 3- dioxygenase enzyme. The objectives of the poster are:

• To deepen the criteria for patient selection for both scientific and therapeutic protocols.

Methods: This poster reviews the literature for evidence that while biological agents could improve the mood of patients with psoriasis treated with these drugs, this same favourable antidepressant effect on humor may trigger a switch of mood into mania, favouring attempted and completed suicide in undiagnosed bipolar patients treated for psoriasis with IL17-TNF alpha cytokine blockers.

Results: Evidence gathered so far suggests that common inflammatory processes could underpin both bipolar and psoriasis. The current literature is lacking of longitudinal and mechanistic studies, as well as comparison studies to explore the magnitude of this relation.

Conclusion: Considering both bipolar disorder and psoriasis as a multi-system disorder should help us understand the common physiopathology of this comorbidity so as not to see them as separated disorders. Consequently, it is vital to emphasize the importance of the initial psychiatric evaluation for a correct psychiatric/ clinical diagnosis for patients with Psoriasis to be both admitted to a strict control protocol and treated with biological agents.

P153
TREATING THE PAIN, NOT THE PROBLEM? RESULTS FROM A SWEDISH ONLINE SURVEY ON PSORIATIC ARTHRITIS AND PSORIASIS WITH JOINT PAIN
T Norgren, B Bohannan
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Introduction: Psoriatic arthritis (PsA) is a chronic inflammatory disease associated with psoriasis, that can cause pain, swelling and, if untreated, severe joint destruction and disability. The knowledge about PsA among both the public and healthcare providers is limited, leading to both underdiagnosis and undertreatment. To raise awareness of PsA and gather relevant data, the Swedish Psoriasis Association (Psoriasisförbundet) and the Swedish Rheumatism Association (Reumatikerförbundet) initiated an educational awareness campaign on a well-visited online health information platform, which also featured a survey on healthcare experiences and Quality of Life.

Objectives: The purpose of the survey was to identify gaps or discrepancies in the healthcare provided for individuals diagnosed with PsA and for individuals with psoriasis and joint pain consistent with a PsA diagnosis, as well as understanding the impact on QoL for both groups.

Methods: The survey consisted of two questionnaires, one for individuals diagnosed with PsA, group A, and one for individuals diagnosed with psoriasis who have joint pain consistent with a PsA diagnosis (using CASPAR criteria as reference), group B. The survey was open from April 6 2017 to March 31 2018. The total number of respondents in group A was 5 201, and in group B 11 272. It was not mandatory to answer all questions in the survey. One section of the survey focussed on prescribed medication, to specifically identify discrepancies in the treatment of the diagnosed (A) and undiagnosed (B) groups. Limitations: self-reported diagnosis, possible to take survey multiple times using different devices.

Results: In response to the question “Which medication has been prescribed for your joint pain during the past year?” 23.91% of group B (214 of 895) answered that they had been prescribed opioid pain medication for their joint pain. In group A only 4.61% of the respondents (73 out of 1 582) were prescribed opioid pain medication for their PsA.

Conclusions: The results show a large discrepancy between the groups in the prescription of opioid pain medication. The results suggest that individuals with psoriasis that have joint pain consistent with a PsA diagnosis are being over-prescribed potentially addictive pain medication rather than receiving treatment for their underlying condition or inflammatory symptoms apart from pain.
As early diagnosis and effective treatment is vital to slow down disease progression, individuals with psoriasis as well as healthcare providers need to be educated on symptoms and diagnosis criteria of PsA to prevent undertreatment or treatment that may even be harmful.

Disclosure: Project platform and consultancy services were provided by health portal company Netdoktor. The project received funding from Novartis.

P154
AN INTERNATIONAL DELPHI SURVEY TO DEFINE SCREENING FOR PSORIATIC ARTHRITIS AND MEASUREMENT OF PSORIATIC ARTHRITIS SYMPTOMS IN PSORIASIS CLINICAL TRIALS
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Introduction: The International Dermatology Outcome Measures (IDEOM) group was established to standardize patient-centered outcome measures to improve the assessment of treatment response and disease course in dermatology. To define the measurement set for psoriasis, IDEOM has initially defined a set of domains to be measured in all psoriasis clinical trials representing a “Core Domain Set”. “Psoriatic arthritis (PsA) Symptoms” is part of this set.

Objectives: To achieve consensus on whether patients enrolling in a psoriasis clinical trial should first be screened for PsA and then with which measure their PsA symptoms should be assessed.

Methods: Following the OMERACT (Outcome Measures in Rheumatology) Filter 2.0, the COSMIN guidelines, and based upon the feedback from a consensus meeting held at the IDEOM 2017 Annual Meeting, we conducted an international, multidisciplinary and multi-stakeholder on-line Delphi survey. The survey was organized into 3 parts in which participants were asked to (1) vote on the role of PsA screening in psoriasis trials, (2) vote on the quality (measurement properties) of 4 patient-reported instruments: Patient Global (PG)-arthritis associated to a pain assessment tool, PG-Psoriatic Arthritis (PG-PsA) associated to a pain assessment tool, Routine Assessment of Patient Index Data-3 (RAPID3), and Psoriatic Arthritis Impact of Disease 9 (PsAID9), and (3) rank these instruments in order of importance. Additionally, respondents were invited to provide feedback on the survey.

Results: A total of \( n = 293 \), \( n = 233 \) and \( n = 218 \) subjects completed the PsA screening, instrument quality assessment, and ranking sections of the survey, respectively. The group was comprised of rheumatologists (44.5%), dermatologists (26%), patients (7.5%), industry partners (8.9%), dermatologist-rheumatologists (5.1%), and patient association representatives (3.4%). Results showed that 90% of participants agreed that all patients enrolling in a psoriasis trial should be screened for PsA. Regarding the quality of the instruments, only the PsAID9 reached the pre-specified endpoint of >70% with agreement that the instrument has good-to-excellent validity, feasibility, reliability and responsiveness; <15% agreed that the quality of the instrument is poor or that there is not enough information to make an informed decision. In the ranking exercise, PsAID9 was the first choice (voted by 48% of respondents) and RAPID3 represented an acceptable alternative second choice (voted by 33% of respondents).

Conclusion: In this Delphi study, most participants agreed that all psoriasis trial participants should be screened for PsA. Regarding the measurement set for “PsA Symptoms”, PsAID9 was selected as the most appropriate measure, while RAPID3 could be an acceptable alternative to PsAID9. This will be followed by a workshop at the IDEOM and GRAPPA 2018 annual meetings to review discussion points as well as any need for a second Delphi round.

P155
THE IMPACT OF A DIAGNOSIS ON THE PATIENT’S PERCEPTION OF TREATMENT AND CARE. RESULTS FROM AN ONLINE SURVEY ON PSORIATIC ARTHRITIS AND PSORIASIS WITH JOINT PAIN
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Introduction: Psoriatic arthritis (PsA) is a chronic inflammatory joint disease that, if untreated, can cause joint destruction and disability. The knowledge about PsA among both public and healthcare providers is limited, leading to under diagnosis and undertreatment.

To raise awareness of PsA and gather relevant data, the Swedish Psoriasis Association and the Swedish Rheumatism Association initiated a web-based educational campaign which also featured a survey on healthcare experiences and Quality of Life.

Objectives: The purpose of the survey was to identify the gaps in the healthcare provided for individuals diagnosed with PsA and individuals with psoriasis and joint pain consistent with a PsA diagnosis, as well as understanding the impact on QoL for both groups.

Method: The survey consisted of two questionnaires, one for individuals diagnosed with PsA, group A, and one for individuals diagnosed with psoriasis who have joint pain consistent with a PsA diagnosis (using CASPAR criteria), group B. The survey was open from April 6 2017 to March 31 2018. One section of the survey focused on time to diagnosis and perception of healthcare. Limitations: self-reported diagnosis, possible to take survey multiple times using different devices.

Results: Both groups had seen multiple doctors for their joint pain. In group A 60% (\( n = 1 132 \)) had seen >4 doctors, with 11% reporting having seen >10. In group B 52.5% (\( n = 824 \)) had seen >4 doctors, with 8% having seen >10. In group A nearly 51% (\( n = 1 211 \)) reported having had joint pain/symptoms for at least 1 year before receiving a diagnosis, with 12% waiting >10 years. In group B 91% (\( n = 1 872 \)) reported having had joint pain/symptoms for at least 1 year, with 35% at >10 years.

Perception of healthcare differed greatly between the groups. In group A over half (\( n = 1 273 \)) reported that their perception of healthcare improved or improved greatly after receiving their PsA diagnosis. In group B nearly 78% (\( n = 1 227 \)) reported be- ing dissatisfied or very dissatisfied with the care they receive.

Conclusions: The results show that the group with a PsA diagnosis have a much more positive perception of the treatment and care they receive than the group without a diagnosis. Interestingly, in another part of the survey group B reported their psoriasis having a low to medium impact on their lives, indicating that their psoriasis may be mild enough to be treated in a primary care setting only. In the past few years there have been extensive efforts put into educating Swedish dermatologists on recognizing early signs of PsA, but steps should also be taken to raise awareness of psoriasis-associated joint pain among general practitioners to ensure timely referral to specialist care.

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