AB0744

EFFICACY OF IXEKIZUMAB IN ACTIVE PSORIATIC ARTHRITIS (PSA) PATIENTS WITH AXIAL PAIN STARTING BEFORE AGE 45: A SUBGROUP ANALYSIS OF SPIRIT-P1 AND SPIRIT-P2 PHASE 3 CLINICAL TRIALS

Atul Deodhar¹, Alexis Ogdie², Talia Muram³, David Sandoval³, Vladimir Geneus³, Peter Nash⁴, ¹Oregon Health and Science University, Portland, United States of America; ²University of Pennsylvania, Philadelphia, United States of America; ³Eli Lilly and Company, Indianapolis, United States of America; ⁴University of Queensland, Brisbane, Australia

Background: The efficacy and safety of ixekizumab (IXE), an IL-17A antagonist, was investigated in patients with active psoriatic arthritis (PsA) in the SPIRIT-P1 and SPIRIT-P2 clinical trials.

Objectives: To investigate the efficacy of ixekizumab on axial pain, fatigue, stiffness, and physical function in a subset of patients with PsA self-reporting axial pain starting before the age of 45 years at baseline.

Methods: Patients with PsA in the intent-to-treat populations of SPIRIT-P1 (Biologic-naïve; NCT01695239) and SPIRIT-P2 (Inadequate responders or intolerant to 1 or 2 TNF inhibitors; NCT02349295) with baseline patient-reported axial pain (≥ 4 Bath Ankylosing Spondylitis Disease Activity Index [BASDAI] question 2), high-sensitivity C-reactive protein (hsCRP) $>5\text{mg/L}$, and <45 years old were included in this post-hoc integrated analysis. SPIRIT-P1/P2 did not include axial imaging. Patients were treated with placebo (PBO) or ixekizumab 80-mg every 2 weeks (IXEQ2W) or 4 weeks (IXEQ4W) after a 160-mg starting dose for 24 weeks. The efficacy of ixekizumab on axial pain (BASDAI question 2), fatigue (BASDAI question 1), stiffness (mean of BASDAI questions 5/6), total BASDAI, Health Assessment Questionnaire Disability Index (HAQ-DI), and 36-Item Short Form Health Survey Physical Component Summary (SF-36 PCS) was analyzed at Weeks 16 and 24 using mixed model for repeated measures with treatment, region, baseline conventional DMARD experience, visit, and treatment-by-visit interaction as fixed factors, and response value at baseline as a covariate.

Results: Axial pain and stiffness significantly improved at Weeks 16 and 24 in patients with PsA treated with IXEQ4W or IXEQ2W versus PBO ($p<.05$; Table 1). Fatigue significantly improved at Week 16 in patients treated with IXEQ4W or IXEQ2W versus PBO and at Week 24 with IXEQ2W versus PBO ($p<.05$). Total BASDAI scores significantly improved at Weeks 16 and 24 in patients treated with IXEQ4W or IXEQ2W versus PBO ($p<.01$). Physical function significantly improved at Weeks 16 and 24 in patients treated with IXEQ4W or IXEQ2W versus PBO when assessed by HAQ-DI or SF-36 PCS ($p<.05$).

	PBO N=32		IXEQ4W N=36		IXEQ2W N=37	
	Week 16 n=28	Week 24 n=13	Week 16 n=36	Week 24 n=29	Week 16 n=37	Week 24 n=33
BASDAI total	-0.78±0.51	-1.29±0.56	-2.80±0.45†	-3.28±0.45†	-3.32±0.47†	-3.53±0.47†
Question 1 (Fatigue)	-0.53±0.49	-1.07±0.56	-1.84±0.43*	-2.17±0.44	-2.52±0.46†	-2.72±0.46†
Question 2 (Axial Pain)	-1.26±0.55	-1.85±0.61	-3.25±0.48†	-3.53±0.47*	-3.19±0.49†	-3.45±0.48*
Questions 5/6 (Stiffness)	-0.32±0.58	-0.86±0.65	-2.40±0.50†	-3.09±0.52†	-3.01±0.51†	-3.16±0.52†
HAQ-DI	-0.02±0.13	-0.15±0.13	-0.40±0.12†	-0.52±0.12*	-0.52±0.11†	-0.51±0.11*
SF-36 PCS	1.53±5.15	3.64±5.44	15.56±4.73*	22.38±4.71†	18.33±4.77†	17.26±4.71*

* $p<.05$, † $p<.001$, ‡ $p<.0001$, all vs. PBO.

Conclusion: Ixekizumab treatment yielded significantly higher improvements than placebo in axial pain, fatigue, stiffness, and physical function at Weeks 16 and 24 in the integrated PsA subpopulation self-reporting axial pain at baseline. These analyses were limited by a lack of baseline axial imaging.

Disclosure of Interests: Atul Deodhar Grant/research support from: AbbVie, Amgen, Eli Lilly, GSK, Janssen, Novartis, Pfizer, and UCB, Consultant for: AbbVie, Amgen, BMS, Eli Lilly, Janssen, Novartis, Pfizer, and UCB, Alexis Ogdie Grant/research support from: (To my university) Novartis, Pfizer, Grant/research support from: Novartis, Pfizer, Grant/research support from: Novartis, Pfizer, Grant/research support from: Novartis, Pfizer, Consultant for: AbbVie, Bristol-Myers Squibb, Celgene, Corrona, Eli Lilly and Company, Novartis, Pfizer, and Takeda, Consultant for: AbbVie, Amgen, Bristol-Myers Squibb, Celgene, Corrona, Eli Lilly, Novartis, Pfizer Inc, Takeda, Consultant for: AbbVie, Amgen, BMS, Celgene, Corrona, Lilly, Novartis, Pfizer, Takeda, Consultant for: AbbVie, Amgen, BMS, Celgene, Corrona, Lilly, Novartis, Pfizer, Takeda, Talia Muram Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, David Sandoval Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, Vladimir Geneus Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, Peter Nash Grant/research support from: AbbVie, Bristol-Myers Squibb, Eli Lilly, Janssen, Novartis, Pfizer Inc, Roche, Sanofi, UCB, Consultant for: AbbVie, Bristol-Myers Squibb, Eli

Lilly, Janssen, Novartis, Pfizer Inc, Roche, Sanofi, UCB, Speakers bureau: AbbVie, Bristol-Myers Squibb, Eli Lilly, Janssen, Novartis, Pfizer Inc, Roche, Sanofi, UCB
DOI: 10.1136/annrheumdis-2019-eular.1235

AB0745

ASSESSMENT OF DISEASE ACTIVITY USING RAPID3 AND EVALUATION OF TREATMENT EFFECT OF GUSELKUMAB IN PATIENTS WITH PSA: RESULTS FROM A RANDOMIZED PLACEBO-CONTROLLED PHASE 2 CLINICAL TRIAL

Atul Deodhar¹, L Bruce Kirkham², Proton Rahman³, Philip Helliwell⁴, Alice B. Gottlieb⁵, Wolf-Henning Boehncke⁶, Xie L. Xu⁷, Chenglong Han⁷, ¹Oregon Health and Science U, Portland, United States of America; ²Guy's and St. Thomas NHS Foundation Trust, London, United Kingdom; ³Memorial University of Newfoundland, St. John's, Canada; ⁴Leeds Institute of Rheumatic and Musculoskeletal Medicine, University of Leeds, Leeds, United Kingdom; ⁵Icahn School of Medicine at Mt Sinai, Dermatology, New York, United States of America; ⁶Geneva University Hospitals and Department of Pathology and Immunology, University of Geneva, Geneva, Switzerland; ⁷Janssen Research and Development, LLC, Spring House, United States of America

Background:

Objectives: To evaluate the effect of guselkumab (GUS) on Routine Assessment of Patient Index Data 3 (RAPID3) in patients with psoriatic arthritis (PsA).

Methods: In a phase 2 trial, patients with active PsA and $\geq 3\%$ body surface area of plaque psoriasis despite current or previous treatment with standard-of-care therapies, including anti-TNF α agents, were randomized 2:1 to receive GUS 100 mg (n=100) or placebo (PBO, n=49) subcutaneously at wks 0, 4, and every 8 wks (q8w) thereafter through wk44. At wk16, patients from either group with $<5\%$ improvement from baseline in both swollen and tender joint counts were eligible for early escape to open-label ustekinumab. At wk24, all remaining PBO patients crossed-over to receive GUS 100 mg, and then received GUS at wk28 and q8w thereafter through wk44. RAPID3 (0-30) is derived from the Multi-Dimensional Health Assessment Questionnaire (MDHAQ) and numerical rating scales (0-10) for pain and patient global assessment. A change of 5.1 in RAPID3 score was identified as the minimally important difference (MID) in PsA, and RAPID3 ≤ 3.0 was used to define PsA remission. Change in RAPID3 and proportion of patients achieving MID were compared between treatments. Correlations of RAPID3 scores with the PsA Disease Activity Score (PASDAS), GRACE index, Disease Activity in Psoriatic Arthritis (DAPSA), and Modified Composite Psoriatic Disease Activity Index (mCPDAI) were evaluated using Spearman correlation.

Results: The mean (SD) RAPID3 score at baseline was 16.9 (5.19). At wk24, patients in the GUS group (n=100) achieved statistically significantly greater decrease from baseline (improvement) in RAPID3 (-5.81 $\pm$ 6.0) than the PBO group (n=49) (-0.57 $\pm$ 5.1, $p<.001$), and 50% of patients in the GUS group vs. 20.4% in the PBO group achieved an MID ($p<.001$). Higher RAPID3 remission rate in the GUS than the PBO group (14.0% vs. 2.4%, $p=0.022$) was observed. The mean $\pm$ SD decrease from baseline in RAPID3 was -6.36 $\pm$ 6.2 at wk24, and -7.48 $\pm$ 6.3 at wk44 in those who continued Guselkumab (N=86). Among patients who switched from PBO to GUS at wk24 (N=28), mean $\pm$ SD change from baseline (improvement) in RAPID3 was -2.28 $\pm$ 5.2 at wk24 while on placebo and -7.60 $\pm$ 6.6 at wk44 after switching to GUS. The RAPID3 score was highly correlated with PASDAS ($r=0.84$, $p<.001$), GRACE index ($r=0.89$, $p<.001$), DAPSA ($r=0.77$ $p<.001$) and mCPDAI ($r=0.65$, $p<.001$) at wk16.

Conclusion: GUS-treated PsA patients demonstrated significant improvement in RAPID3 compared to PBO. RAPID3 is simple and feasible to use in routine clinical care, and it correlates well with other comprehensive PsA-specific disease activity measures.

Disclosure of Interests: Atul Deodhar Grant/research support from: AbbVie, Amgen, Eli Lilly, GSK, Janssen, Novartis, Pfizer, and UCB, Consultant for: AbbVie, Amgen, BMS, Eli Lilly, Janssen, Novartis, Pfizer, and UCB, L Bruce Kirkham Grant/research support from: Investigator for Janssen Research & Development, LLC, Consultant for: AbbVie, Eli Lilly and Company, Janssen, Novartis, Proton Rahman: None declared, Philip Helliwell Grant/research support from: Paid to charity: from AbbVie, Janssen and Novartis, Consultant for: Paid to charity: from AbbVie, Amgen, Pfizer, and UCB and Celgene. Paid to self: from Celgene and Galapagos, Alice B Gottlieb Grant/research support from: PI: Incyte Corporation, Janssen-Ortho Inc., Lilly ICOS LLC, Novartis, UCB, XBiotech, Consultant for: AbbVie, Dermira, Incyte Corporation, Lilly ICOS LLC, Novartis, Sun Pharmaceutical Industries Ltd., Avotres (unpaid), XBiotech (unpaid), Speakers bureau: AbbVie, Eli Lilly and Company, Janssen Biotech; advisory board:

Bristol-Myers Squibb, Celgene Corporation, Janssen Biotech, Janssen-Ortho Inc., LEO Pharma, Novartis, UCB, Wolf-Henning Boehncke Consultant for: Pfizer Inc, Speakers bureau: Pfizer Inc, Xie L Xu Employee of: Employee of Janssen Research & Development, LLC, Chenglong Han Employee of: Employee of Janssen Research & Development, LLC
DOI: 10.1136/annrheumdis-2019-eular.172

AB0746 WORKING STATUS AND FACTORS ASSOCIATED WITH WORK PRODUCTIVITY AMONG PEOPLE WITH PSORIATIC ARTHRITIS

Didem Erdem, Halise Hande Gezer, Sevtap Acer Kasman, Mehmet Tuncay Duruöz. *Marmara University Faculty of Medicine, Department of Physical Medicine and Rehabilitation, Rheumatology Division, İstanbul, Turkey*

Background: Work disability is an important functional outcome measure in psoriatic arthritis (PsA) and includes unemployment and loss of work productivity.

Objectives: The aim of this study is to investigate the working status and the factors associated with work productivity in patients with PsA.

Methods: Patients with PsA according to Classification Criteria for Psoriatic Arthritis (CASPAR) were included in the study consecutively, without sample selection. Data about age, sex, disease duration (month) were noted. Disease activity was assessed with DAPSA (Disease Activity in Psoriatic Arthritis) and BASDAI (Bath Ankylosing Spondylitis Disease Activity Index). The Health Assessment Questionnaire (HAQ) was used to evaluate physical disability. The Psoriatic Arthritis Quality of Life (PsAQoL) scale was used to assess the quality of life. Fatigue and stiffness were assessed on the Visual Analogue Scale (VAS). Anxiety and depression were evaluated with HAD (Hospital Anxiety and Depression) scale.

Assessing work disability, we asked some questions to the patients including employment status, and early retirement, changing or reducing work due to PsA. We used WPAI: PsA (Work Productivity and Activity Impairment Questionnaire) to evaluate the impact of PsA on work productivity. WPAI: PsA consists of six questions and gives four scores: the percentage of absenteeism (work time missed due to PsA), the percentage of presenteeism (reduced productivity at work due to PsA), an overall work impairment (combines absenteeism and presenteeism) and percentage of impairment in daily activities.

The association between WPAI: PsA scores and HAQ, PsAQoL, HAD, fatigue and stiffness was determined by Spearman's correlation coefficient. The Mann Whitney-U test was used to compare the means of groups. The descriptive analysis was done for demographic data. $P < 0.05$ accepted as significant. SPSS 20.0 (Statistical package for social sciences for Windows 20.0) program was used for the statistical analysis.

Results: The mean age of 60 patients (38 female, 22 male) with PsA was 48.13 (SD: 11.53) years. The median (min-max) duration of disease was 36 (3-384) months.

63.33% of the patients were not working and 57.89% of these patients were housewives, and 23.68% were retired. 11.66% of the patients with PsA were unemployed. There were no patients who were retired early due to the disease. Percentage of the stopping work, changing work or reducing working hours due to PsA was 3.3%, 6.7% and 10%, respectively.

There was no significant difference between the working and not-working groups of patients according to the disease duration, DAPSA, BASDAI and HAQ scores ($p > 0.05$). The mean age was higher in the non-working group ($p < 0.005$).

There was no absenteeism in 63.3% of patients. The mean percentage of the presenteeism was 36 (SD: 30.79) and the mean percentage of the overall work impairment was 41 (SD: 34.06). There were no significant correlations between WPAI: PsA scores and age, disease duration, DAPSA score ($p > 0.05$). Presenteeism and overall work impairment had significant moderate correlations with fatigue (ρ : 0.639, p : 0.001; ρ : 0.607, p : 0.003), morning stiffness (ρ : 0.424, p : 0.049; ρ : 0.484, p : 0.023), HAQ (ρ : 0.532, p : 0.011; ρ : 0.551, p : 0.008), PsAQoL (ρ : 0.481, p : 0.023; ρ : 0.510, p : 0.015), HAD depression (ρ : 0.650, p : 0.001; ρ : 0.634, p : 0.002), and HAD anxiety scores (ρ : 0.486, p : 0.022; ρ : 0.527, p : 0.012), respectively.

Conclusion: Psoriatic arthritis can cause loss of work productivity. The severity of work impairment is associated with fatigue, stiffness, physical disability, depression, anxiety and health-related quality of life. In our study population, the percentage of housewives and retired was high and the rate of unemployment was 11.66%. This is a preliminary study and will continue in larger patient populations.

Disclosure of Interests: Didem Erdem: None declared, Halise Hande Gezer: None declared, Sevtap Acer Kasman: None declared, Mehmet

Tuncay Duruöz Grant/research support from: Abvie, Speakers bureau: Novartis, AMGEN, Abdi İbrahim, İlko

DOI: 10.1136/annrheumdis-2019-eular.6190

AB0747 RESPONSE TO SECUKINUMAB AMONG NAIVE AND BIOLOGICALLY EXPERIENCED PATIENTS IN PSORIATIC ARTHRITIS

Shehla Farrukh, Ann O. Riordan, Muhammad Haroon, Fahd Adeeb. *University Hospital Kerry, rheumatology, tralee, Ireland*

Background: Secukinumab is a recombinant human monoclonal immunoglobulin IgG antibody that selectively targets IL-17A and blocks its interaction with the IL-17 receptor. Inhibition of the downstream effects of this proinflammatory cytokine thereby interferes with key psoriasis disease pathways while promoting normalization of immune function and skin histology.

Objectives: The aim of the study was two-fold; firstly, to compare the response to Secukinumab in psoriatic arthritis (PsA) patients who were biologically naive and experienced, and secondly to compare the response between smokers and non-smokers.

Methods: In collaboration with the National Psoriatic Arthritis Registry of Ireland, patients who were diagnosed and treated as PsA at University Hospital Kerry between March 2017 and October 2018 were included in this population-based cohort study. Patients demographic, clinical characteristics, treatment strategies (including response rates and adverse effects) were captured at baseline and at follow-up outpatient visits.

Results: A total of 96 patients were identified and included in the study (mean age of 56.6 years; male to female ratio of 1:1, 49 males, 47 females). Of these patients, 15 received Secukinumab (7 biologically-naive patients, 8 patients with previous treatment failure to anti-TNF agents (3 patients received one anti-TNF, 5 received two different anti-TNFs). In the biologically-naive group, 5 patients (71%) had complete response to Secukinumab, one patient (14.3%) had complete improvement of joint symptoms but remained fatigued (high BRAF score) while 1 patient (14.3%) had no improvement. All 7 of these patients were exposed to cigarette smoking (6 current smokers, one ex-smoker). In patients who previously failed anti-TNF, five (62.5%) remained symptomatic (tender & swollen joints, PROMs and BRAF score remained high) despite treatment with Secukinumab. Only three patients (37.5%) responded well to treatment. Two of the eight patients never smoked (both did not respond to Secukinumab) while the other 6 patients (3 responded, 3 had no response) were ex-smokers.

Conclusion: In our study, Secukinumab demonstrated better response to the biologically-naive PsA patients, while smoking did not increase the risk of disease activity among PsA patients receiving Secukinumab.

Disclosure of Interests: None declared

DOI: 10.1136/annrheumdis-2019-eular.3842

AB0748 EVOLUTION ON HEALTH-RELATED QUALITY OF LIFE IN PSORIATIC ARTHRITIS PATIENTS

Dalifer Freites Nuñez^{1,2}, Leticia León², Judit Font¹, Alfredo Madrid García², Zulema Rosales¹, Lydia Abasolo^{1,2}, Benjamin Fernandez¹, Luis Rodriguez Rodriguez^{1,2}. ¹Hospital Clínico San Carlos, Rheumatology, Madrid, Spain; ²Instituto de Investigación Sanitaria San Carlos, Rheumatology, Madrid, Spain

Background: Psoriatic arthritis (PsA) is a chronic, progressive and inflammatory arthritis. It is considered a multifaceted disease, with a high impact on patient's psychological and physical well-being, with patients reporting lower health-related quality of life (HRQoL). Data of burden of disease is substantial and even though there are some studies that identify risk factors with longstanding PsA, there exists a need for properly designed studies to learn more about the evolution of HRQoL throughout the follow-up in this condition.

Objectives: To analyze the evolution on HRQoL in patients with PsA and to evaluate factors that may influence this evolution.

Methods: Retrospective longitudinal observational study including incident patients diagnosed with PsA from 2007 to 2016, and followed-up until loss of follow-up or December 2017; with at least two registered visits; having received any ICD9/ICD10 diagnosis code of PsA; and with symptoms onset after 16 years of age. Patients were collected from the rheumatology outpatient clinic of a tertiary hospital (Hospital Clínico San Carlos, Madrid, Spain). Clinical information was collected from a departmental electronic health record, including demographic, clinical, comorbidities, treatment, and HRQoL related variables (measured with the Rosser