Disclosure of Interests: Maria Rato: None declared, Filipe Pinheiro: None declared, Salomé Garcia: None declared, Bruno Miguel Fernandes: None declared, Sara Ganhão: None declared, Rita Gaio: None declared, Miguel Bernardes Speakers bureau: Abbvie, Amgen, Biogen, Eli-Lilly, Glaxo-Smith-Kline, Pfizer, Janssen, Novartis, Alexandra Bernardo: None declared, Lúcia Costa: None declared

DOI: 10.1136/annrheumdis-2020-eular.3948

AB0826

PROBABILITY OF SURVIVAL OF USTEKINUMAB IN PSORIATIC ARTHRITIS: A REAL CLINICAL PRACTICE COHORT COMPOSED OF 64 PATIENTS

E. Raya¹, P. Morales-Garrido¹, I. Jiménez-Moleón¹. ¹San Cecilio Clinic University Hospital, Rheumatology, Granada, Spain

Background: Psoriatic arthritis (PsA) is an inflammatory disorder of unknown etiology. Several domains are affected as peripheral or axial joints, enthesitis, dactylitis, nails as well as skin. Diverse cytokines have been described in the pathology of PsA as TNF α , IL-17 and IL-23. Ustekinumab (UST) is a fully human IgG1 κ monoclonal antibody to interleukin 12/23. Its efficacy and safety have been tested in several clinical trials and registries. Nevertheless data from real word evidence studies is needed to understand the effectiveness, safety and behavior of UST in a different population of patients from randomized controlled trials

Objectives: Analyze the persistence of UST 45 and 90mg along 52 weeks of treatment

Methods: Drug survival, effectiveness and security of UST were studied in a population of 64 PsA patients treated in the period between August 2014 to October 2019. Drug survival was defined as the time from initiation to discontinuation (stop/switch) of bDMARDs. For the determination of drug survival, Kaplan-Meier survival curves and Cox-regression analyses were used. Effectiveness was described as a reduction in the use of corticosteroids and in the levels of CRP along the study. All adverse events were recorded during the study

Results: 64 patients were included with a mean follow-up of 57,2 weeks. At baseline the mean age was 47,8 years (8,9). 54,7% of patients were women and 45,3% were male. 31,3% were obese. Mean disease duration was 7,9 (5,0) years. 45,3% presented peripheric arthritis; 32,8% axial involvement; 31,3% enthesitis; 80% psoriasis. Patients were 45% bDMARDs-naïve; had a previous bDMARDs in 20,3% and $\geq$ than two bDMARDs in 34,4%. 30% of the patients had co-therapy with methotrexate and 29,7% of patients received corticosteroid therapy. Mean CRP was 7,9 (12,7) mg/L. The global probability of survival for UST was 96%, 83,9% and 60% at week 12, 24 and 52 respectively. High UST dosage was associated with favorable drug survival (at 52W: UST 45 mg=40,1%; UST 90 mg=75,8%; UST 45 to 90 mg*=88,9%) ($p=0,008$). The bDMARDs-naïve population also correlated with favorable UST survival (at 52W: bDMARDs-naïve=66,1% vs bDMARDs-experienced=56,7%), however no statistical significance was found ($p=0,196$). No difference in survival was observed among patients with or without axial involvement (W52: axial=58,2% vs non-axial=61,6; $p=0,869$). UST produced a reduction in the use of corticosteroids (30% vs 16%) and CRP levels (8,7 vs 7,7). Differences were greater in patients treated more than 28 weeks (maximum efficiency described for UST) (corticosteroids: 26% vs 16%; CRP levels: 8,5 vs 4,4). 4,9% of the patients suffered an AE. Most of them were non-serious AE: infections (3,3%) or headache (1,6%). The main cause of treatment discontinuation was lack of efficacy (30%), followed by primary failure (9,4%) and just a 3% due to AE

Conclusion: The persistence of UST was dose-dependent and greater for the UST 90mg dosage and for the population of bDMARD-naïve patients. Drug survival of UST in the population of patients with axial involvement seems similar to the population of patients without axial affection which provide evidence of the efficacy of the IL23 inhibition in the axial domain of PsA. UST decreased the use of corticosteroids and CRP levels along treatment. The security profile of UST was to the drug. Only few non-serious AE reported during this study

*UST 45 to 90mg, patients who change from UST 45 to UST 90mg dosage

References:

- [1] Ritchlin C. Efficacy and safety of the anti-IL-12/23 p40 monoclonal antibody, ustekinumab, in patients with active psoriatic arthritis despite conventional non-biological and biological anti-tumour necrosis factor therapy: 6-month and 1-year results of the phase 3. *Ann Rheum Dis* 2014;73:990–9
- [2] McInnes IB. Efficacy and safety of ustekinumab in patients with active psoriatic arthritis: 1 year results of the phase 3, multicentre, double-blind, placebo-controlled PSUMMIT 1 trial. *Lancet* 2013;382:780–9

Disclosure of Interests: None declared

DOI: 10.1136/annrheumdis-2020-eular.4922

AB0827

IMPACT OF BASELINE BODY MASS INDEX ON THE EFFICACY AND SAFETY OF TOFACITINIB IN PATIENTS WITH PSORIATIC ARTHRITIS

C.T. Ritchlin¹, A. Ogdie², J.T. Giles³, J.J. Gomez-Reino⁴, P. Helliwell⁵, L. Stockert⁶, P. Young⁶, W. Joseph⁶, R. Mundayat⁷, D. Graham⁷, J. Woolcott⁷, A. B. Romero⁸. ¹University of Rochester Medical Center, Rochester, United States of America; ²University of Pennsylvania, Philadelphia, United States of America; ³Columbia University, New York, United States of America; ⁴Hospital Clínico Universitario, Santiago de Compostela, Spain; ⁵University of Leeds, Leeds, United Kingdom; ⁶Pfizer Inc, Collegeville, United States of America; ⁷Pfizer Inc, Groton, United States of America; ⁸Pfizer Inc, Barcelona, Spain

Background: Obesity is highly prevalent in PsA (~45%)¹ and is associated with a reduced response to TNF inhibitors.² Tofacitinib is an oral Janus kinase inhibitor for the treatment of PsA.

Objectives: This post hoc analysis assessed tofacitinib efficacy and safety in patients (pts) with PsA by baseline (BL) body mass index (BMI) category.

Methods: Data were pooled from two placebo (PBO)-controlled, double-blind, Phase 3 studies in pts with active PsA and an inadequate response to $\geq$ 1 conventional synthetic DMARD (OPAL Broaden [12 months; NCT01877668]) or to $\geq$ 1 TNF inhibitor (OPAL Beyond [6 months; NCT01882439]).^{3,4} This analysis included pts randomised to tofacitinib 5 mg twice daily (BID), tofacitinib 10 mg BID or PBO, stratified by BL BMI: <25 kg/m², ≥ 25 – <30 kg/m², ≥ 30 – <35 kg/m², or ≥ 35 kg/m². Efficacy and safety were reported to Month (M)3. M3 efficacy outcomes included ACR20/50/70 and HAQ-DI responses, dactylitis and enthesitis resolution rates and changes from BL in HAQ-DI, Short Form-36 Version 2 (SF-36v2) Physical (PCS) and Mental Component Summary (MCS) scores, and Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) scores. Safety outcomes included adverse events (AEs), such as cardiovascular (CV) events and changes in lipid levels and liver function tests (LFTs).

Results: This analysis included 710 pts; 43.8% were obese (BMI ≥ 30). At BL, 161 (22.7%) pts had a BMI <25 , 238 (33.5%) had a BMI ≥ 25 – <30 , 186 (26.2%) had a BMI ≥ 30 – <35 and 125 (17.6%) had a BMI ≥ 35 . Most pts were white (92.5–96.8%), middle-aged (mean: 44.5–51.2 yrs) and female (49.5–65.6%). Greater proportions of obese pts were from Russia/Eastern Europe (35.0%) and USA/Canada (31.8%), vs the rest of world. At BL, higher BMI correlated with an increased prevalence of metabolic syndrome (4.3% in BMI <25 to 76.0% in BMI ≥ 35) and CRP levels >2.87 mg/L (49.1% in BMI <25 to 84.0% in BMI ≥ 35). Higher proportions of pts (42.5–47.9%) in BL BMI categories <35 reported no prior biologic DMARD use, vs pts with a BL BMI ≥ 35 (33.6%). At M3, efficacy improvements were greater in tofacitinib-treated pts vs PBO-treated pts (Figure 1). In pts with a BL BMI ≥ 35 , a trend towards fewer pts responding was observed (Figure 1) and mean changes from baseline in SF-36v2 PCS and MCS and FACIT-F generally appeared lower (Figure 2) vs pts in lower BL BMI categories. Up to M3, the proportions of pts with AEs, and percentage change from BL in lipid levels and LFTs, were generally similar across all BL BMI categories. Three CV events were reported: non-fatal cerebrovascular accident, transient ischemic attack (both tofacitinib 5 mg BID, BMI ≥ 30 – <35) and coronary artery revascularisation (PBO; BMI ≥ 35). Limitations include the 3-month observation time, particularly for safety findings, thus longer observation times are warranted.

Conclusion: Regardless of BL BMI, tofacitinib demonstrated greater efficacy than PBO at M3 in pts with PsA. Similar to other advanced therapies,² reduced efficacy was generally observed in tofacitinib and PBO pts with a BL BMI ≥ 35 . Tofacitinib safety appeared consistent across all BL BMI categories.

References:

- [1] Labitigan et al. *Arthritis Care Res (Hoboken)* 2014;66:600-07.
- [2] Singh et al. *PLoS One* 2018;13:e0195123.
- [3] Mease et al. *NEJM* 2017;377:1537-50.
- [4] Gladman et al. *NEJM* 2017;377:1525-36.

Figure 1. a) ACR20, b) ACR50, c) ACR70 and d) HAQ-DI responses, e) dactylitis resolution rates, f) enthesitis resolution rates and g) LS mean change from baseline in BMI at M3 by baseline BMI and treatment group (pooled data from OPAL Broaden and OPAL Beyond)

*ACR20/50/70 are calculated as a ≥50%/70% improvement from baseline in tender and swollen joint counts and ≥50%/70% improvement from baseline in 3 of the 5 remaining ACR core measures.
 †HAQ-DI response was defined as the number of patients achieving a reduction from baseline ≥0.25 in HAQ-DI, considered the minimal clinically important difference.
 ‡Dactylitis resolution rates, defined as the absence of dactylitis in all of the 20 assessed digits, and enthesitis resolution rates, defined as the absence of enthesitis in all of the 6 assessed sites, were only assessed in patients who reported a baseline value of DSI or LEI <0, respectively.
 §Δ change from baseline: ACR, American College of Rheumatology; BID, twice daily; BMI, Body Mass Index; DSI, dactylitis severity score; HAQ-DI, Health Assessment Questionnaire Disability Index; LEI, Leeds Enthesitis Index; LS mean, least squares mean; M3, Month 3; N, number of patients with a non-missing BMI evaluable at M3; n, number of patients in each category; PBO, placebo; SE, standard error.

Figure 2. LS mean (SE) changes from baseline in a) SF-36v2 PCS, b) SF-36v2 MCS and c) FACIT-F at M3 by baseline BMI and treatment groups (pooled data from OPAL Broaden and OPAL Beyond)

Δ, change from baseline; BID, twice daily; BMI, Body Mass Index; FACIT-F, Functional Assessment of Chronic Illness Therapy-Fatigue; LS, least squares; M, month; MCS, Mental Component Summary; N, total number of unique patients; PBO, placebo; PCS, Physical Component Summary; SE, standard error; SF-36v2, Short-Form 36 Version 2.

Acknowledgments: Medical writing support was provided by Mark Bennett of CMC Connect, McCann Health Medical Communications, and funded by Pfizer Inc.

Disclosure of Interests: Christopher T. Ritchlin Grant/research support from: UCB Pharma, AbbVie, Amgen, Consultant of: UCB Pharma, Amgen, AbbVie, Lilly,

Pfizer, Novartis, Gilead, Janssen, Alexis Ogdie Shareholder of: Amgen, Novartis, Pfizer Inc, Grant/research support from: Novartis, Consultant of: AbbVie, Amgen, Bristol-Myers Squibb, Celgene, Corrona, Eli Lilly, Novartis, Pfizer Inc, Jon T Giles Grant/research support from: Pfizer Inc, Juan Jesus Gomez-Reino Grant/research support from: AbbVie, Novartis, Pfizer Inc, Roche, UCB, Consultant of: Pfizer Inc, Speakers bureau: AbbVie, Bristol-Myers Squibb, Janssen, MSD, Pfizer Inc, Roche, UCB, Philip Helliwell: None declared, Lori Stockert Shareholder of: Pfizer Inc, Employee of: Pfizer Inc, Pamela Young Shareholder of: Pfizer Inc, Employee of: Pfizer Inc, Wael Joseph Shareholder of: Pfizer Inc, Employee of: Pfizer Inc, Rajiv Mundayat Shareholder of: Pfizer Inc, Employee of: Pfizer Inc, Daniela Graham Shareholder of: Pfizer Inc, Employee of: Pfizer Inc, John Woolcott Shareholder of: Pfizer Inc, Employee of: Pfizer Inc, Ana Belen Romero Shareholder of: Pfizer Inc, Employee of: Pfizer Inc

DOI: 10.1136/annrheumdis-2020-eular.993

AB0828

IS PSORIATIC ARTHROPATHY DIFFERENT WHEN IS ACCOMPANIED BY AXIAL INVOLVEMENT?

S. M. Rojas Herrera¹, J. Malave Calzada¹, I. Braña Abascal¹, M. Priego Fernandez-Martos¹, D. Fernandez Lozano¹, R. Veroz Gonzalez¹, J. J. Aznar Sanchez¹, L. M. Chaves Chaparro¹, E. Chamizo Carmona¹. ¹Rheumatology, Hospital of Mérida, Mérida, Spain

Background: Axial involvement in patients diagnosed of Psoriatic arthritis (PsA) in variable in previous studies. Axial involvement (according GRAPPA criteria) is based upon inflammatory spinal symptoms pain with loss of lumbar mobility and the presence of radiological sacroiliitis and other radiographic signs of spondylitis in patients with PsA.

Objectives: Evaluate the prevalence of axial involvement in PsA an their clinical features.

Methods: All patients included in the monographic PsA consultation database of our second level hospital were analyzed. Demographic, clinical and analytical variables were collected. Statistical analysis was performed using SPSS v.25

Results: We included 145 patients with PsA (fulfilling CASPAR criteria) with a mean age at diagnosis of 45,4 (±13) years and time of evolution of the disease 9,3 (±6,2) years. The proportion of the affection types were: peripheral 94 (64,8%), mixta 31 (21,4%) and axial 20 (13,8%). Therefore, 51 (35,2%) patients meet criteria for axial involvement, of with 31 (21,4%) also had associated peripheral involvement. Table 1 shows the differences between patients with and without axial disease. Axial involvement was higher in males than women [OR=2,3 (1,1-4,7), p=0,023]. HLAB27, determined in 106 patients, was more prevalent in axial PsA than in exclusive peripheral patients, 35% and 4,5% respectively [OR=11,3 (3,0-42,7), p<0,0001]. We didn't find any differences in other domains of psoriatic disease or gender. Age at diagnosis was lower in patients with HLA B27 positive [35,6 (±12,3) vs 46,2 (±12,1) years, p=0,0001] and in the patients with dactylitis [40,2 (11,8) vs 46,7 (13) años, p=0,018] or uveitis [28,7 (8,5) vs 45,8 (12,8) years, p=0,02], respect patients who did not present them, regardless of HLAB27. No differences were found in age between patients with axial o peripheral disease [44,6 (±13,3) vs 45,9 (±12,8) years, p=0,56], neither other domains like skin psoriasis, onicopathy or enthesitis. Patients with axial involvement had overweight (BMI >25) less frequently than peripheral disease [OR=0,4 (0,2-0,8), p=0,01]. We didn't find any differences in other comorbidities (arterial hypertension, diabetes, hyperlipemia, hyperuricemia, ischemic heart disease, depression) between patines with axial or peripheral disease.

Table 1. Differences between axial and peripheral patterns

	With axial involve- ment, n=51	Without axial involvement, n=94	OR (IC 95%)	p value
Age at diagnosis, years (SD)	44,6 (±13,3)	45,9 (±12,8)		0,6
Time of evolution, years (SD)	10 (±6,8)	8,9 (±5,8)		0,3
Men, n (%)	36 (42,9%)	48 (57,1%)	2,3 (1,1-4,7)	0,02
HLAB27, n (%)	14 (82,4%)	3 (17,6%)	11,3 (3,0-42,7)	<0,0001
Skin Psoriasis, n (%)	47 (36,4%)	82 (63,6%)	1,7 (0,5-5,6)	0,4
Onicopathy, n (%)	11 (26,2%)	31 (73,8%)	0,6 (0,2-1,2)	0,1
Dactylitis, n (%)	9 (32,1%)	19 (67,9%)	0,8 (0,3-2,0)	0,7
Enthesitis, n (%)	13 (44,8%)	16 (55,2%)	1,7 (0,7-3,8)	0,2
Uveitis, n (%)	2 (66,7%)	1 (33,3%)	3,8 (0,3-42,9)	0,2
Inflammatory bowel disease, n (%)	2 (66,7%)	1 (33,3%)	3,8 (0,3-42,9)	0,2
Hyperlipemia, n (%)	27 (31%)	60 (69%)	0,6 (0,3-1,3)	0,2
BMI >25, n (%)	22 (26,5%)	61 (73,5%)	0,4 (0,2-0,8)	0,01
Hypertension, n (%)	18 (39,1%)	28 (60,9%)	1,3 (0,6-2,6)	0,5
Hyperuricemia, n (%)	16 (39%)	25 (61%)	1,3 (0,6-2,7)	0,5
Smokers, n (%)	13 (50%)	13 (50%)	2,1 (0,9-5,0)	0,08
Ischemic heart disease, n (%)	8 (53,3%)	7 (46,7%)	2,3 (0,8-6,8)	0,1
Depression, n (%)	7 (30,4%)	16 (69,6%)	0,8 (0,3-2,0)	0,6
Diabetes, n (%)	7 (30,4%)	20 (74,1%)	0,6 (0,2-1,5)	0,3