had ≥ 1 PsA manifestation when axPsA was investigator defined, of whom 630 (85.9%) had multiple manifestations; the most common presentations were PA + skin (16.2%), PA + skin + nail (12.8%), and enthesitis + PA + nail + skin (7.8%). When using the criteria for elevated spine symptoms, 732 biologic initiators had ≥ 1 disease manifestation, of whom 650 (88.8%) had multiple manifestations; the most common presentations were PA + skin (11.7%), PA + skin + nail (8.5%), and PA + axPsA + skin (6.3%). The prevalence of skin, PA, and dactylitis was higher in those with elevated spine symptoms vs investigator-defined axPsA, whereas the prevalence of enthesitis was higher in those with investigator-defined axPsA (Figure 1B and 2B).

Figure 2. Prevalence of (A) PsA Disease Manifestations and (B) Other Manifestations With Axial Disease in the Biologic Initiator Population

The heat map represents the frequency of any 2 domain combinations by the range of blue shades, with the darkest blue color specifying the highest frequency and the lightest blue specifying the lowest frequency of combinations.

Conclusion: In the Corrona PsA/SpA Registry, there was a higher number of patients with elevated spine symptoms than with investigator-defined axPsA; these patients also had more coexisting manifestations. Although they may have had other reasons for back pain (ie, degenerative spine disease or central sensitization), it is possible that axPsA could be present in some and this warrants further evaluation.

References:

- [1] Goel N, et al. *J Rheumatol*. 2019;95(Suppl):54-7.
- [2] Baraliakos X, et al. *Ann Rheum Dis*. 2019;78:195-6.

Disclosure of Interests: Alexis Ogdie Grant/research support from: Pfizer to Penn, Novartis to Penn, Amgen to Forward/NDB, Consultant of: Abbvie, Amgen, Bristol-Myers Squibb, Celgene, Corrona, Janssen, Eli Lilly, Novartis, Pfizer, Taylor Blachley Employee of: Corrona, LLC, Meghan Glynn Shareholder of: Corrona, LLC – shareholder, Grant/research support from: Pfizer – grant/research support, Employee of: Corrona, LLC – employment, Sabrina Rebello Employee of: Corrona, LLC, Blessing Dube Employee of: Corrona, LLC, Robert McLean Employee of: Corrona, LLC, Peter Hur Employee of: Novartis Pharmaceuticals Corporation, Philip J Mease Grant/research support from: Abbott, Amgen, Biogen Idec, BMS, Celgene Corporation, Eli Lilly, Novartis, Pfizer, Sun Pharmaceutical, UCB – grant/research support, Consultant of: Abbott, Amgen, Biogen Idec, BMS, Celgene Corporation, Eli Lilly, Novartis, Pfizer, Sun Pharmaceutical, UCB – consultant, Speakers bureau: Abbott, Amgen, Biogen Idec, BMS, Eli Lilly, Genentech, Janssen, Pfizer, UCB – speakers bureau

DOI: 10.1136/annrheumdis-2020-eular.1072

OP0053

SECUKINUMAB IMPROVES CLINICAL AND IMAGING OUTCOMES IN PATIENTS WITH PSORIATIC ARTHRITIS AND AXIAL MANIFESTATIONS WITH INADEQUATE RESPONSE TO NSAIDS: WEEK 52 RESULTS FROM THE MAXIMISE TRIAL

X. Baraliakos¹, L. Gossec², E. Pournara³, S. Jeka⁴, R. Blanco⁵, S. D'angelo⁶, G. Schett⁷, B. Schulz³, M. Rissler³, K. Nagar³, C. Perella³, L. C. Coates³.

¹Rheumazentrum Ruhrgebiet Herne, Ruhr-University Bochum, Bochum, Germany; ²Sorbonne Universités, Paris, France; ³Novartis Pharma AG, Basel, Switzerland; ⁴2nd University Hospital, CM UMK, Bydgoszcz, Poland; ⁵Hospital

Universitario Marqués de Valdecilla, Santander, Spain; ⁶Rheumatology Department of Lucania and Rheumatology Institute of Lucania (IRel), San Carlo Hospital of Potenza, Potenza, Italy; ⁷University of Erlangen-Nuremberg, Erlangen, Germany; ⁸Novartis Healthcare Pvt. Ltd., Hyderabad, India; ⁹University of Oxford, Oxford, United Kingdom

Background: Although axial disease may affect up to 70% of patients (pts) with Psoriatic Arthritis (PsA), evidence on the efficacy of biologics in the treatment of axial manifestations in such pts is limited,¹ particularly as validated classification criteria for this subtype of PsA are not yet available. MAXIMISE (NCT02721966) is the first randomised controlled trial evaluating the efficacy of a biologic in the management of the axial manifestations of PsA and showed that secukinumab (SEC) 300 and 150 mg provided rapid and significant improvement in ASAS20 responses in these pts through week (Wk) 12.²

Objectives: To present 52 wks efficacy results and imaging data from the MAXIMISE trial.

Methods: This phase 3b, double-blind, placebo (PBO)-controlled, multicentre 52-wk trial included 498 pts (aged ≥ 18 years) with a diagnosis of PsA and classified by CASPAR criteria, spinal pain VAS score $\geq 40/100$ and BASDAI score ≥ 4 despite use of at least two NSAIDs. Pts were randomised to SEC 300 mg (N=167) or SEC 150 mg (N=165) or PBO (N=166) wks for 4 wks and every 4 wks thereafter. At Wk 12, PBO pts were re-randomised to SEC 300/150 mg. The primary endpoint was ASAS20 response with SEC 300 mg at Wk 12. The key secondary endpoint was ASAS20 response with SEC 150 mg at Wk 12. Wk 52 data are presented as observed. Bone marrow oedema of the entire spine and sacroiliac joints were assessed centrally with Berlin MRI scores at Baseline, Wk 12 and Wk 52.

Results: Primary and key secondary endpoints were met; ASAS20 responses were sustained and increased further through Wk 52. 75%/79.7% of the PBO pts re-randomised at Wk 12 to SEC 300/150 mg achieved ASAS20 response at Wk 52 (Figure 1). ASAS40 responses at Wk 52 were 69.1% [SEC 300 mg], 64.5% [SEC 150 mg], 62.5% [PBO-SEC 300 mg], and 54.1% [PBO-SEC 150 mg]. At baseline, 59.5% [SEC 300 mg], 53.5% [SEC 150 mg] and 64.2% [PBO] of the pts had positive MRIs for the sacroiliac joints and/or the spine with Berlin MRI score ≥ 1 . The reductions of Berlin MRI score for entire spine and sacroiliac joints were statistically significant for pts treated with SEC 300/150 mg vs. placebo (Figure 2 a and b). There were no new or unexpected safety findings.

Figure 1. ASAS20 Response over 52 Wks*

Figure 2. Total Berlin MRI score for the Entire Spine and Sacroiliac Joints at Wk 12

Conclusion: Secukinumab improved all evaluated ASAS responses through Wk 52 in PsA pts with axial manifestations and inadequate responses to NSAIDs

and led to significant reduction of inflammatory MRI lesions in the spine and the Sacroiliac Joints. The safety profile of secukinumab through Wk 52 was consistent with previous reports.³⁻⁴

References:

- [1] McInnes IB, et al. *Lancet*. 2015;386(9999):1137–46.
- [2] Baraliakos X, et al. *Arthritis Rheumatol*. 2019;71 (suppl 10).
- [3] Langley RG, et al. *N Engl J Med*. 2014;371:326–38.
- [4] Sieper J, et al. *Ann Rheum Dis*. 2016;0:1–8.

Acknowledgments: The study was sponsored by Novartis Pharma AG, Basel, Switzerland.

Disclosure of Interests: Xenofon Baraliakos Grant/research support from: Grant/research support from: AbbVie, BMS, Celgene, Chugai, Merck, Novartis, Pfizer, UCB and Werfen, Consultant of: AbbVie, BMS, Celgene, Chugai, Merck, Novartis, Pfizer, UCB and Werfen, Speakers bureau: AbbVie, BMS, Celgene, Chugai, Merck, Novartis, Pfizer, UCB and Werfen, Laure Gossec Grant/research support from: Lilly, Mylan, Pfizer, Sandoz, Consultant of: AbbVie, Amgen, Biogen, Celgene, Janssen, Lilly, Novartis, Pfizer, Sandoz, Sanofi-Aventis, UCB, Effie Pour-nara Shareholder of: Novartis, Employee of: Novartis, Sławomir Jeka Grant/research support from: AbbVie, Pfizer, Roche, Novartis, MSD, Sandoz, Eli Lilly, Egis, UCB, Celgene, Speakers bureau: AbbVie, Pfizer, Roche, Novartis, MSD, Sandoz, Eli Lilly, Egis, UCB, Celgene, Ricardo Blanco Grant/research support from: AbbVie, MSD, Roche, Consultant of: AbbVie, Eli Lilly, Pfizer, Roche, Bristol-Myers, Janssen, UCB Pharma and MSD, Speakers bureau: AbbVie, Eli Lilly, Pfizer, Roche, Bristol-Myers, Janssen, UCB Pharma, MSD, Salvatore D'Angelo Consultant of: AbbVie, Biogen, BMS, Celgene, Eli Lilly, MSD, Novartis, and UCB, Speakers bureau: AbbVie, BMS, Celgene, Eli Lilly, Novartis, Pfizer, and Sanofi, Georg Schett Speakers bureau: AbbVie, BMS, Celgene, Janssen, Eli Lilly, Novartis, Roche and UCB, Barbara Schulz Employee of: Novartis, Michael Rissler Shareholder of: Novartis, Employee of: Novartis, Kriti Nagar Employee of: Novartis, Chiara Perella Shareholder of: Novartis, Employee of: Novartis, Laura C Coates: None declared

DOI: 10.1136/annrheumdis-2020-eular.638

OP0054

EFFICACY OF GUSELKUMAB, A MONOCLONAL ANTIBODY THAT SPECIFICALLY BINDS TO THE P19-SUBUNIT OF IL-23, ON ENDPOINTS RELATED TO AXIAL INVOLVEMENT IN PATIENTS WITH ACTIVE PSA WITH IMAGING-CONFIRMED SACROILIITIS: WEEK-24 RESULTS FROM TWO PHASE 3, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDIES

P. Helliwell¹, D. D. Gladman², D. Poddubnyy^{3,4}, P. J. Mease⁵, X. Baraliakos⁶, A. Kollmeier⁷, E. C. Hsia^{7,8}, X. L. Xu⁷, S. Sheng⁷, P. Agarwal⁷, B. Zhou⁷, S. D. Chakravarty^{9,10}, M. Shawi¹¹, C. Karyekar¹¹, A. Deodhar¹², D. Van der Heijde¹³.

¹University of Leeds, Leeds, United Kingdom; ²Toronto Western Hospital and University of Toronto, Ontario, Canada; ³Charité Universitätsmedizin Berlin Campus Benjamin Franklin, Berlin, Germany; ⁴German Rheumatism Research Centre, Berlin, Germany; ⁵Swedish Medical Center/Providence St. Joseph Health and University of Washington, Seattle, United States of America; ⁶Rheumazentrum Ruhrgebiet, Ruhr-University Bochum, Herne, Germany; ⁷Janssen Research & Development, LLC, Spring House, United States of America; ⁸U Penn Med Ctr, Philadelphia, United States of America; ⁹Janssen Scientific Affairs, LLC, Horsham, United States of America; ¹⁰Drexel University College of Medicine, Philadelphia, United States of America; ¹¹Janssen Global Services, LLC, Horsham, United States of America; ¹²Oregon Health & Science University, Portland, United States of America; ¹³Leiden University Medical Center, Leiden, Netherlands

Background: Guselkumab (GUS), an interleukin-23 inhibitor, was efficacious in reducing signs and symptoms of active psoriatic arthritis (PsA) in patients (pts) in two phase 3 trials (DISCOVER-1 and DISCOVER-2).

Objectives: To evaluate the efficacy of GUS in PsA pts with imaging-confirmed axial involvement consistent with sacroiliitis in DISCOVER-1&2.

Methods: In DISCOVER-1, 381 pts with active PsA (≥ 3 swollen joints, ≥ 3 tender joints; C-reactive protein ≥ 0.3mg/dL despite standard therapies) and in DISCOVER-2, 739 pts with active PsA (≥ 5 swollen joints, ≥ 5 tender joints, CRP ≥ 0.6mg/dL despite standard therapies) were randomized 1:1:1 to GUS 100mg Q4W, GUS 100mg Q8W (Wk0, Wk4, then Q8W), or PBO. This analysis included pts with sacroiliitis at baseline who had either documented imaging confirmation of sacroiliitis in the past or pelvic X-ray confirmation of sacroiliitis at screening (pooled data from DISCOVER-1&2) based on investigators' judgment of presence/absence of sacroiliitis. Efficacy was assessed by BASDAI score, BASDAI50, modified BASDAI (mBASDAI; excludes Q#3), spinal pain (BASDAI Q#2), ASDAS-CRP score, and ASDAS responses of inactive disease (<1.3), major improvement (decrease ≥2.0), and clinically important improvement (decrease ≥1.1). Pts with missing data at wk24 were classified as nonresponders.

Results: 312 pts presented with axial involvement (PBO, n= 118; GUS q8w, n = 91; GUS q4w, n = 103). The LS mean changes from baseline to wk24 in BASDAI, spinal pain, mBASDAI, and ASDAS-CRP were greater in the two GUS groups vs PBO (Table). Greater proportions of GUS-treated pts achieved BASDAI50 (Table) and ASDAS responses of inactive disease, major improvement, and clinically important improvement (Figure) at wk24 vs PBO.

Conclusion: GUS improved axial symptoms over 24 weeks in active PsA patients with imaging-confirmed sacroiliitis.

Table. Efficacy of GUS in PsA patients with axial involvement at week 24.^a

	PBO (n=118)	GUS 100mg every 8 weeks (n=91)	GUS100mg every 4 weeks (n=103)
LS Mean change in BASDAI	-1.35	-2.67*	-2.68*
LS Mean change in spinal pain ^b	-1.30	-2.73*	-2.48*
BASDAI50 ^c , %	21/110 (19.1%)	34/84 (40.5%)**	36/95 (37.9%)**
LS Mean change in modified BASDAI ^d	-1.13	-2.16*	-2.18*
LS Mean change in ASDAS-CRP	-0.71	-1.43*	-1.46*

^aPts with axial involvement consistent with sacroiliitis at baseline and either a history of imaging confirmation or pelvic X-ray at screening (pooled data from DISCOVER-1 & 2)

^bQuestion 2 of the BASDAI.

^cPts with BASDAI > 0 at baseline.

^dExcludes question 3 of the BASDAI.

Unadjusted p-values as noted: *p < 0.001, **p < 0.01

*p<0.001; †p<0.01; ‡p<0.05

Acknowledgments: None

Disclosure of Interests: Philip Helliwell: None declared, Dafna D Gladman Grant/research support from: AbbVie, Amgen Inc., BMS, Celgene Corporation, Janssen, Novartis, Pfizer, UCB – grant/research support, Consultant of: AbbVie, Amgen Inc., BMS, Celgene Corporation, Janssen, Novartis, Pfizer, UCB – consultant, Denis Poddubnyy Grant/research support from: AbbVie, MSD, Novartis, and Pfizer, Consultant of: AbbVie, Bristol-Myers Squibb, Eli Lilly, MSD, Novartis, Pfizer, Roche, UCB, Speakers bureau: AbbVie, Bristol-Myers Squibb, Eli Lilly, MSD, Novartis, Pfizer, Roche, UCB, Philip J Mease Grant/research support from: AbbVie, Amgen, Bristol-Myers Squibb, Janssen, Eli Lilly, Novartis, Pfizer, Sun Pharma, UCB Pharma, Consultant of: AbbVie, Amgen, Bristol-Myers Squibb, Celgene, Janssen, Eli Lilly, Galapagos, Gilead, Novartis, Pfizer, Sun Pharma, UCB Pharma, Speakers bureau: AbbVie, Amgen, Bristol-Myers Squibb, Celgene, Genentech, Janssen, Novartis, Pfizer, UCB Pharma, Xenofon Baraliakos Grant/research support from: Grant/research support from: AbbVie, BMS, Celgene, Chugai, Merck, Novartis, Pfizer, UCB and Werfen, Consultant of: AbbVie, BMS, Celgene, Chugai, Merck, Novartis, Pfizer, UCB and Werfen, Speakers bureau: AbbVie, BMS, Celgene, Chugai, Merck, Novartis, Pfizer, UCB and Werfen, Alexia Kollmeier Shareholder of: Johnson & Johnson, Employee of: Janssen Research & Development, LLC, Elizabeth C Hsia Shareholder of: Johnson & Johnson, Employee of: Janssen Research & Development, LLC, Xie L Xu Shareholder of: Johnson & Johnson, Employee of: Janssen Research & Development, LLC, Shihong Sheng Shareholder of: Johnson & Johnson, Employee of: Janssen Research & Development, LLC, Prasheen Agarwal Shareholder of: Johnson & Johnson, Employee of: Janssen Research & Development, LLC, Bei Zhou Shareholder of: Johnson & Johnson, Employee of: Janssen Research & Development, LLC, Soumya D Chakravarty Shareholder of: Johnson & Johnson, Employee of: Janssen Scientific Affairs, LLC, May Shawi Shareholder of: Johnson & Johnson, Employee of: Janssen Research & Development, LLC, Chetan Karyekar Shareholder of: Johnson & Johnson, Consultant of: Janssen, Employee of: Janssen Global Services, LLC. Previously, Novartis, Bristol-Myers Squibb, and Abbott