study design is reported elsewhere.[2] Multivariate stepwise logistic regression analysis was used to identify predictors of response for the primary efficacy variable (Ankylosing Spondylitis Disease Activity Score – major improvement [ASDAS-MI] at Week 52) and the main secondary efficacy variable (Assessment of SpondyloArthritis international Society 40% [ASAS40] at Week 52) in patients randomised to CZP 200 mg every 2 weeks (Q2W). Predictive factors used in the model included demographic and baseline characteristics, and clinical outcomes at Week 12. A p value ≤0.05 was required for forward selection into the model and p=0.1 for backward elimination from the model. Non-responder imputation was used to account for missing data or values collected after switching to open-label treatment. A sensitivity analysis was conducted to account for patients who had changes in their non-biologic background medication during the 52-week placebo-controlled period.

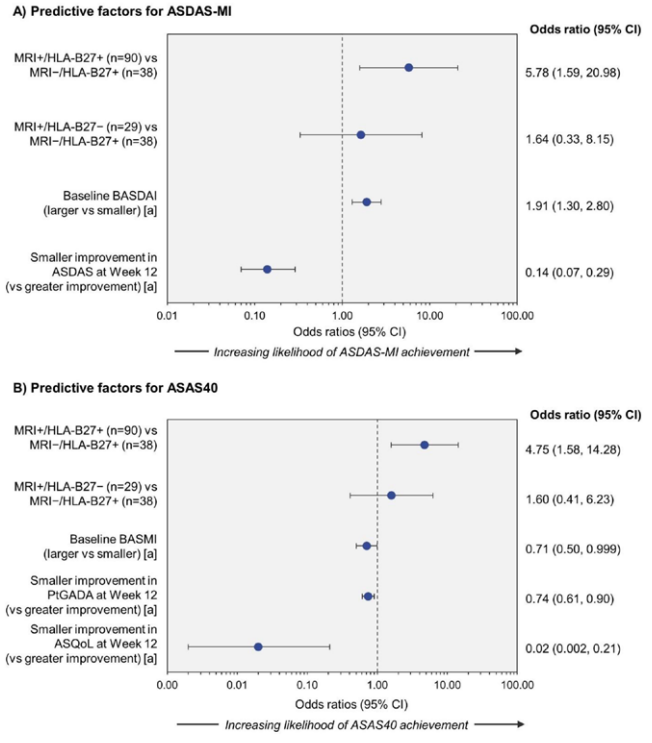
Results: A total of 159/317 patients were randomised to CZP 200 mg Q2W and 158/317 to placebo. Predictive factors identified for Week 52 ASDAS-MI in the CZP-treated patients included being positive for both presence of sacroiliitis on MRI (MRI+) and human leukocyte antigen (HLA)-B27 (HLA-B27+), having a higher Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) at baseline, and having a larger Week 12 improvement in ASDAS (Figure 1A). For ASAS40 response, MRI+/HLA-B27+ was also identified as a predictor of Week 52 response, along with a lower baseline Bath AS Metrology Index (BASMI) and larger Week 12 improvements in Patient Global Assessment of Disease Activity (PtGADA) and AS Quality of Life (ASQoL; Figure 1B). Sensitivity analysis identified the same predictors for ASDAS-MI and ASAS40, with the exception of change from baseline in PtGADA as a predictor of ASAS40. Sensitivity analysis also identified achievement of Week 12 ASAS40 as a predictor of Week 52 ASAS40. In placebo-treated patients, no meaningful predictors of response at Week 52 were identified.

Conclusion: Presence of sacroiliitis on MRI and HLA-B27 positivity were identified as consistent predictors of Week 52 response (ASDAS-MI and ASAS40) in nr-axSpA patients treated with CZP. To our knowledge, this is the first report from an interventional 52-week placebo-controlled study in nr-axSpA to identify objective clinical features, particularly the presence of sacroiliac joint inflammation, as being predictive of response.

REFERENCES:

[1] Ashrafi M. Curr Opin Rheumatol 2020;32:321–9.
[2] Deodhar A. Arthritis Rheumatol 2019;71:1101–11.

Figure. Predictive factors of Week 52 response in CZP-treated patients



[a] Included in the predictive model as continuous variables; for these factors, an odds ratio >1 indicates a higher probability of larger values being predictive of a response. For Week 12 change from baseline measures, a lower (negative) value is indicative of improvement, while larger (positive) values indicate worsening. ASAS40: Assessment of SpondyloArthritis international Society 40%; ASDAS-MI: Ankylosing Spondylitis Disease Activity Score – major improvement; ASQoL: Ankylosing Spondylitis Quality of Life; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BASMI: Bath Ankylosing Spondylitis Metrology Index; CI: confidence interval; HLA: human leukocyte antigen; MRI+/−: presence/absence of sacroiliitis on magnetic resonance imaging; PtGADA: Patient Global Assessment of Disease Activity; vs: versus.

Acknowledgements: This study was funded by UCB Pharma. Editorial services were provided by Costello Medical.

Disclosure of Interests: Walter P Maksymowych Speakers bureau: AbbVie, Janssen, Novartis, Pfizer, UCB Pharma, Consultant of: AbbVie, BMS, Boehringer, Eli Lilly, Novartis, Pfizer, UCB Pharma, Grant/research support from: AbbVie, Novartis, Pfizer, Thomas Kumke Shareholder of: UCB Pharma, Employee of: UCB Pharma, Simone Auteri Shareholder of: UCB Pharma, Employee of: UCB Pharma, Bengt Hoepken Shareholder of: UCB Pharma, Employee of: UCB Pharma, Lars Bauer Shareholder of: UCB Pharma, Employee of: UCB Pharma, Martin Rudwaleit Speakers bureau: AbbVie, Eli Lilly, Novartis, UCB Pharma, Consultant of: AbbVie, Celgene, Eli Lilly, Janssen, Novartis, UCB Pharma

DOI: 10.1136/annrheumdis-2021-eular.108

POS0897 REDUCTION OF ANTERIOR UVEITIS FLARES IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS DURING CERTOLIZUMAB PEGOL TREAT MENT: 96-WEEK RESULTS FROM THE C-VIEW STUDY

I. Van der Horst-Bruinsma[1], R. Van Bentum[1], F. Verbraak[2], T. Rath[3], B. Hoepken[4], O. Irvin-Sellers[5], T. Kumke[4], L. Bauer[4], M. Rudwaleit[6,7]. *[1]Amsterdam University Medical Centre, Location VUmc, Department of Rheumatology, Amsterdam, Netherlands*; *[2]Academic Medical Centre, University of Amsterdam, Department of Ophthalmology, Amsterdam, Netherlands*; *[3]St Franziskus-Hospital, Department of Ophthalmology, Münster, Germany*; *[4]UCB Pharma, N/A, Monheim am Rhein, Germany*; *[5]UCB Pharma, N/A, Slough, United Kingdom*; *[6]Klinikum Bielefeld, Clinic for Internal Medicine and Rheumatology, Bielefeld, Germany*; *[7]Charité – Universitätsmedizin Berlin, Department of Gastroenterology, Infectiology and Rheumatology, Berlin, Germany*

Background: Acute anterior uveitis (AAU) is the most common extra-articular manifestation in axial spondyloarthritis (axSpA), affecting up to 40% of patients and causing significant burden.[1] Previous studies have shown that tumour necrosis factor inhibitors (TNFi) can reduce the incidence of AAU flares in patients with radiographic axSpA (ankylosing spondylitis),[2-4] but few have focused on patients across the full axSpA spectrum.[1]

Objectives: To report 2-year outcomes from the phase 4, open-label C-VIEW study (NCT03020992), which investigated the impact of certolizumab pegol (CZP) treatment on AAU in patients with active axSpA and a recent history of AAU.

Methods: C-VIEW prospectively investigated patients with active axSpA who were HLA-B27 positive and had recurrent AAU, with a history of ≥1 AAU flare in the year prior to baseline (additional study criteria and study design are described elsewhere[5]). The primary efficacy variable was the incidence of AAU flares during 96 weeks of CZP treatment versus the 2-year pre-baseline period. AAU incidence was evaluated using Poisson regression adjusted for duration of time in each period, with period (pre- and post-baseline) and axSpA disease duration as covariates. Secondary efficacy variables were Assessment of SpondyloArthritis international Society 20%/40% (ASAS20/40) response rates, as well as mean Ankylosing Spondylitis Disease Activity Score (ASDAS) and mean Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) to Week 96.

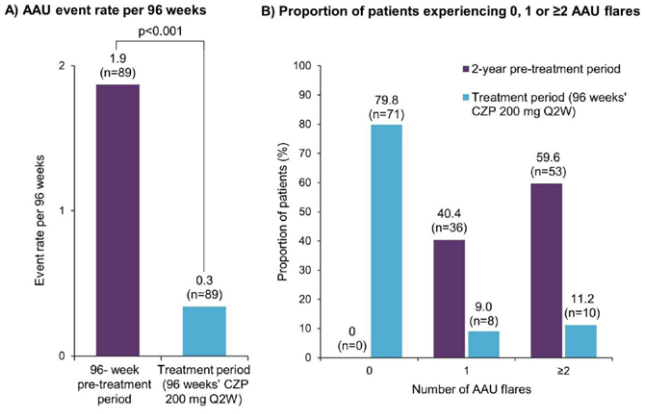
Results: Of 115 enrolled patients, 89 initiated CZP treatment; 83 completed Week 96. The primary analysis revealed an 82% reduction in the incidence of AAU flares during CZP treatment compared with pre-baseline (Figure 1A; rate ratio [95% CI]: 0.18 [0.12, 0.28], p<0.001). The percentage of patients experiencing ≥1 and ≥2 AAU flares reduced from 100% and 59.6% pre-baseline to 20.2% and 11.2% during treatment (Figure 1B). There were also improvements in axSpA disease activity (Table 1): by Week 96, 75.6% and 58.5% of patients had achieved ASAS20 and ASAS40 responses, respectively. ASDAS and BASDAI also improved substantially over the 96-week treatment period. No new safety signal was identified, compared to previous reports.[5]

Conclusion: These data support the use of CZP for the treatment of patients with axSpA and a history of recurrent AAU. During 96 weeks' CZP treatment, there was a significant reduction of 82% in the AAU flare rate compared to pre-baseline. There were also substantial improvements in patients' axSpA disease activity.

REFERENCES:

[1] Martin TM. Curr Opin Rheumatol 2002;14:337–41.
[2] van der Heijde D. Rheumatology (Oxford) 2017;56:1498–509.
[3] van Bentum RE. J Rheumatol 2019;46:153–9.
[4] van Denderen JC. J Rheumatol 2014;41:1843–8.
[5] van der Horst-Bruinsma I. RMD Open 2020;6:e001161.

Figure. Summary of AAU flares (observed data)



Treatment period: after start of study medication until Week 96 or discontinuation visit. Pre-treatment period: 24 months prior to treatment start. Flares on the same eye are combined and counted as one flare if the time interval between two subsequent flares is <3 months (90 days). Patients received CZP 400 mg at Weeks 0/2/4, then 200 mg Q2W through 96 weeks. a) Poisson regression analysis, with period (pre-/post-baseline) and axSpA disease duration as covariates and adjusting for the length of time in the pre- and post-baseline periods. AAU: acute anterior uveitis; CZP: certolizumab pegol; Q2W: every 2 weeks.

Table 1. Changes in axSpA disease activity to Week 96

Disease activity measure	Week 0 (n=89)	Week 48 (n=86)	Week 96 (n=82)
ASAS responder rates, n (%)			
ASAS20	N/A	65 (75.6)	62 (75.6)
ASAS40	N/A	46 (53.5)	48 (58.5)
ASDAS, mean (SD)	3.5 (1.0)	2.0 (0.9)	1.9 (1.0)
BASDAI, mean (SD)	6.5 (1.5)	3.3 (2.1)	3.0 (2.1)

Observed data are shown. Patients received CZP 400 mg at Weeks 0/2/4, then 200 mg Q2W through 96 weeks. ASAS20/40: Assessment of SpondyloArthritis international Society 20%/40%; ASDAS: Ankylosing Spondylitis Disease Activity Score; axSpA: axial spondyloarthritis; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; CZP: certolizumab pegol; Q2W: every 2 weeks; SD: standard deviation.

Acknowledgements: This study was funded by UCB Pharma. Editorial services were provided by Costello Medical.

Disclosure of Interests: Irene van der Horst-Bruinsma Speakers bureau: AbbVie, BMS, MSD, Pfizer, UCB Pharma, Consultant of: AbbVie, Eli Lilly, MSD, Novartis, UCB Pharma, Grant/research support from: AbbVie, MSD, Pfizer, Rianne van Bentum: None declared, Frank Verbraak Speakers bureau: Bayer, IDxDR, Novartis, UMC, Consultant of: Bayer, Novartis, Grant/research support from: Bayer, Thomas Rath Speakers bureau: AbbVie, BMS, Chugai, Eli Lilly, MSD, Novartis, Pfizer, Roche, UCB Pharma, Consultant of: AbbVie, BMS, Chugai, Eli Lilly, MSD, Novartis, Pfizer, Roche, UCB Pharma, Bengt Hoepken Shareholder of: UBC Pharma, Employee of: UCB Pharma, Oscar Irvin-Sellers Shareholder of: UCB Pharma, Employee of: UCB Pharma, Thomas Kumke Shareholder of: UCB Pharma, Employee of: UCB Pharma, Lars Bauer Shareholder of: UCB Pharma, Employee of: UCB Pharma, Martin Rudwaleit Speakers bureau: AbbVie, Eli Lilly, Novartis, UCB Pharma, Consultant of: AbbVie, Celgene, Eli Lilly, Janssen, Novartis, UCB Pharma

DOI: 10.1136/annrheumdis-2021-eular.115

POS0899

HOW DOES GENDER AFFECT SECUKINUMAB TREATMENT OUTCOMES AND RETENTION RATES IN PATIENTS WITH ANKYLOSING SPONDYLITIS? - REAL WORLD DATA FROM THE GERMAN AQUILA STUDY

U. Kiltz[1], J. Brandt-Juergens[2], P. Kästner[3], E. Riechers[4], D. Peterlik[5], H. P. Tony[6]. *[1]Rheumazentrum Ruhrgebiet / Ruhr-Universität Bochum, Rheumazentrum Ruhrgebiet, Herne, Germany*; *[2]Rheumatologische Schwerpunktpraxis, Rheumatologische Schwerpunktpraxis, Berlin, Germany*; *[3]Ambulantes Rheumazentrum, Ambulantes Rheumazentrum, Erfurt, Germany*; *[4]Medizinische Hochschule Hannover, Klinik für Immunologie und Rheumatologie, Hannover, Germany*; *[5]Novartis Pharma GmbH, Immunology, Hepatology & Dermatology, Nuremberg, Germany*; *[6]Medizinische Klinik II, Universitätsklinik, Rheumatology/ Immunology, Würzburg, Germany*

Background: Current studies suggest that the phenotype of spondyloarthritis differs between genders and that this may influence the subsequent diagnostic approach and therapeutic decisions[1]. The German non-interventional study AQUILA provides real-world data on the influence of gender on therapeutic effectiveness and retention rate under treatment with secukinumab, a fully human monoclonal antibody that selectively inhibits interleukin-17A.

Objectives: The aim of this interim analysis is to describe selected baseline (BL) demographics, to evaluate secukinumab treatment outcomes on disease activity, global functioning and health and retention rate depending on the gender of AS patients.

Methods: AQUILA is an ongoing, multi-center, non-interventional study including more than 3000 patients with active AS or psoriatic arthritis. Patients were observed from BL up to week (w) 52 according to clinical routine. Real-world data was assessed prospectively and analyzed as observed. Validated questionnaires were used to collect data on disease activity (Bath Ankylosing Spondylitis Disease Activity Index, BASDAI), global functioning and health (Assessment of SpondyloArthritis-Health Index, ASAS-HI) and severity of depressive mood (Beck´s Depression Inventory version II, BDI-II). Patient reported outcomes were reported using patient´s global assessment (PGA). In addition, retention rates (time from study inclusion until premature secukinumab treatment discontinuation) were assessed through Kaplan-Meier plots. This interim analysis focuses on the subgroups of male and female AS patients.

Results: At BL, 683 AS patients were included: 59.7% (n=408) male and 40.3% (n=275) female. Demographic data (Table 1) of male and female AS patients differed numerically in the following parameters: proportion of obese patients, smokers, pretreatment with disease-modifying antirheumatic drugs (csDMARDs), and biologicals/biosimilars (b-bsDMARDs).

Mean BASDAI and PGA were comparable between male and female AS patients over time (♂: 5.2 at BL to 3.8 at w52, ♀: 5.3 at BL to 4.1 at w52 and ♂: 5.9 at BL to 4.1 at w52, ♀: 5.6 at BL to 4.3 at w52, respectively). Mean ASAS-HI over time was higher in women; nevertheless, improvements in global functioning were comparable for both genders from BL to week 52 (Fig. 1A). Severity of depressive mood was numerically lower in male patients; nevertheless, BDI-II reductions were comparable across the genders (♂: 11.2 at BL to 10.0 at w52, ♀: 13.1 at BL to 11.0 at w52). Secukinumab treatment retention rate for men was (not significantly) higher than for women (Fig. 1B).

Conclusion: In a real-world setting, secukinumab improved disease activity, global functioning and severity of depressive mood in AS patients in both men and women. Women showed overall higher disease burden. Altogether, real-world data of this interim analysis are in line with those of Phase 3 studies and show that secukinumab is an effective treatment up to 52 weeks with high treatment retention rates, irrespective of gender.

REFERENCES:

[1] Landi, M., *et al. Medicine (Baltimore)* **95**, e5652 (2016).

Table 1. Overview of baseline characteristics in AS patients depending on gender

Demographics*	Male (N=408)	Female (N=275)
Age, years	45.6 (12.1)	47.8 (12.2)
BMI, kg/m^2	27.4 (4.5)	27.6 (5.7)
BMI >25 to ≤30 kg/m^2, n (%)	178 (45.1)	88 (32.4)
BMI >30 kg/m^2, n (%)	94 (23.8)	83 (30.5)
Smoker, n (%)	150 (36.8)	67 (24.4)
BASDAI	5.2 (1.9)	5.3 (1.9)
PGA	5.8 (4.9)	5.6 (5.6)
ASAS-HI	7.4 (3.5)	8.2 (3.5)
BDI-II	11.2 (10.2)	13.1 (13.0)
Medication prior to secukinumab initiation, n (%):		
NSAID	330 (80.9)	222 (80.7)
csDMARD	145 (35.5)	137 (49.8)
b-bsDMARD	249 (61.0)	190 (69.1)

*variables given as mean (SD)

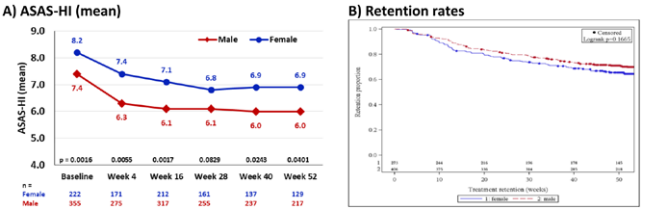


Figure 1. Global functioning and secukinumab treatment retention in AS patients stratified by genderNote: P-values are of exploratory nature

Disclosure of Interests: Uta Kiltz Consultant of: AbbVie, Biocad, Chugai, Eli Lilly, Gruenenthal, Janssen, MSD, Novartis, Pfizer, Roche, UCB, Grant/research support from: AbbVie, Biogen, Novartis, Pfizer, Jan Brandt-Juergens Consultant of: Abbvie, Affibody, BMS, Gilead, Janssen, Lilly, Medac, MSD, Novartis, Pfizer, Roche, Sanofi-Aventis, UCB, Peter Kästner Consultant of: Chugai, Novartis, Elke Riechers Consultant of: AbbVie, Chugai, Novartis, UCB, Grant/research support from: AbbVie, Chugai, Lilly, Janssen, Novartis, Pfizer, Roche, UCB, Daniel Peterlik