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 400mg at Weeks 0/2/4, then 200mg 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.

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POS0899

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

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Background: Current studies suggest that the phenotype of spondyloarthritis differs between genders and that this may influence the subsequent diagnostic approach and therapeutic decisions¹. 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-bDMARDs).

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.

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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-bDMARD	249 (61.0)	190 (69.1)

*variables given as mean (SD)

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

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POS0900

SECUKINUMAB 150 MG PROVIDES SUSTAINED IMPROVEMENT IN SIGNS AND SYMPTOMS OF NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS: 2-YEAR RESULTS FROM THE PREVENT STUDY

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Background: Axial spondyloarthritis (axSpA) is an inflammatory disease characterised by chronic back pain, and it comprises radiographic axSpA and non-radiographic axSpA (nr-axSpA).¹ Secukinumab (SEC) 150 mg, with (LD) or without loading (NL), dose significantly improved the signs and symptoms of patients with nr-axSpA in the PREVENT (NCT02696031) study through Week 52.²

Objectives: To report the long-term clinical efficacy and safety of secukinumab from the PREVENT study through 2 years.

Methods: A detailed study design, key primary and secondary endpoints have been reported previously.² In total, 555 patients fulfilling ASAS criteria for axSpA plus abnormal C-reactive protein (CRP) and/or MRI, without evidence of radiographic changes in sacroiliac (SI) joints according to modified New York Criteria for AS were randomised (1:1:1) to receive SEC 150 mg with LD, NL, or placebo (PBO) at baseline. LD patients received SEC 150 mg at Weeks 1, 2, 3, and 4, and then every 4 weeks (q4wk) starting at Week 4. NL patients received SEC 150 mg at baseline and PBO at weeks 1, 2, and 3, and then 150 mg q4wk. 90% patients were anti-tumour necrosis factor (anti-TNF) naïve, 57% had elevated CRP and 73% had evidence of SI joint inflammation on MRI. All images were assessed centrally before inclusion. All patients continued to receive open-label SEC 150 mg treatment after Week 52. Efficacy assessments through Week 104 included ASAS40 in anti-TNF-naïve patients, ASAS40, BASDAI change from baseline, BASDAI50, ASAS partial remission, and ASDAS-CRP inactive disease in the overall population. The safety analyses included all patients who received ≥1 dose of study treatment for the entire treatment period up to Week 104. Data are presented as observed.

Results: Overall, 438 patients completed 104 weeks of study: 78.9% (146/185; LD), 77.7% (143/184; NL) and 80.1% (149/186; PBO). Efficacy results at Week 52 were sustained through Week 104 and are reported in the Table 1. The safety profile was consistent with the previous reports with no deaths reported during the entire treatment period up to Week 104.²

Conclusion: Secukinumab 150 mg demonstrated sustained improvement in the signs and symptoms of patients with nr-axSpA through 2 years. Secukinumab was well tolerated with no new or unexpected safety signals.

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§p<0.01 and †p<0.05 vs placebo (unadjusted p-values at Week 16). Data presented as non-responder imputation till week 16 and as observed from Week 24 to Week 104. At Week 52 all patients remaining on blinded treatment switched to open-label secukinumab.

ASAS, Assessment of SpondyloArthritis International Society; N, total number of patients randomised; n, number of evaluable patients including those who switched to open label secukinumab or standard of care after Week 20. After Week 52, only patients who continued to receive open-label secukinumab are presented; s.c., subcutaneous

Figure 1. ASAS40 response was maintained through Week 104 in the overall population

Table 1. Summary of clinical efficacy (Observed data)

Endpoints	Week	SEC 150 mg LD (N=185)	SEC 150 mg NL (N=184)	PBO-SEC 150 mg (N=186)
*ASAS40 in anti-TNF-naïve patients, n/M (%)	52 ^a	90/137 (65.7)	95/145 (65.5)	85/151 (56.3)
	104	78/123 (63.4)	83/123 (67.5)	83/134 (61.9)
BASDAI change from baseline, mean±SD	52 ^a	-3.7±2.8	-3.7±2.6	-3.3±2.4
	104	-4.1±2.6	-3.9±2.6	-3.7±2.5
BASDAI50, n/M (%)	52 ^a	90/153 (58.8)	92/163 (56.4)	90/161 (55.9)
	104	88/137 (64.2)	84/136 (61.8)	87/142 (61.3)
ASAS partial remission, n/M (%)	52 ^a	46/152 (30.3)	56/163 (34.4)	46/161 (28.6)
	104	51/137 (37.2)	50/135 (37.0)	50/142 (35.2)
ASDAS CRP inactive disease, n/M (%)	52 ^a	49/152 (32.2)	58/163 (35.6)	48/160 (30.0)
	104	50/132 (37.9)	53/133 (39.8)	53/142 (37.3)

*For anti-TNF-naïve patients, N=164, LD; 166, NL; 171, PBO-SEC.^a total number of evaluable patients including open-label SEC and standard of care (SOC; 2 patients in LD, 1 patient in NL continued on SOC). After Week 52, only patients who continued to receive open-label SEC are presented. ASAS, Assessment of SpondyloArthritis International Society; ASDAS, Ankylosing Spondylitis Disease Activity Score; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; M, number of patients with evaluation; N, total randomised patients; n, number of patients who are responders; SD, standard deviation

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POS0901

IXEKIZUMAB SHOWS A DISTINCT PATTERN OF PAIN IMPROVEMENT BEYOND INFLAMMATION IN RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

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Background: The efficacy of ixekizumab (IXE) in biologic-naïve patients with radiographic axial spondyloarthritis (r-axSpA) has been previously presented using traditional axSpA outcome measures, such as BASDAI and ASAS.