Conclusion: The safety profile of BKZ in pts with PsA reflects previous observations^{1,2} for up to 3 years. High threshold disease control was achieved by >50% of BKZ-treated pts up to 3 years, reflected in long-term improvements in joint and skin outcomes.

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Figure. ACR50 responders up to 3 years

NRI and OC data shown for all timepoints from BL to Wk 152; pts randomised to placebo and 16 mg shown through double-blind period; pts re-randomised at start of dose-blind period to either 160 mg or 320 mg BKZ; 190/206 (92.2%) patients randomised at BE ACTIVE study baseline completed Week 48. At Week 48, 181/206 (FAS; 87.9%) patients entered the OLE; 157 patients had an efficacy assessment at Week 152; all OLE pts received 160 mg BKZ regardless of prior dosing regimen.

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POS1023

HOW DOES GENDER AFFECT SECUKINUMAB TREATMENT OUTCOMES AND RETENTION RATES IN PATIENTS WITH PSORIATIC ARTHRITIS? – REAL WORLD DATA FROM THE GERMAN AQUILA STUDY

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Background: Gender disparities in PsA can affect natural course of disease, clinical presentation and response to medication¹. The German non-interventional

study AQUILA provides real-world data on the influence of gender of patients with psoriatic arthritis (PsA) 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, depressive mood and retention rate depending on the gender of PsA patients.

Methods: AQUILA is an ongoing, multi-center study including more than 3000 patients with active PsA or ankylosing spondylitis. Patients were observed from BL up to week (w) 52. Real-world data was assessed prospectively and analyzed as observed. Data was collected on impact of disease (Psoriatic Arthritis Impact of Disease - 12 items, PsAID-12 score), skin disease activity (Psoriasis Area and Severity Index, PASI), joint counts and severity of depressive mood (Beck's Depression Inventory version II, BDI-II), in addition to patient's global assessment (PGA). Moreover, 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 PsA patients.

Results: At BL, 1278 PsA patients were included: 41.5% (n=531) male and 58.5% (n=747) female. Demographic data (Table 1) of male and female PsA patients differed most obviously regarding proportion of overweight patients, smokers, pretreatment with nonsteroidal anti-inflammatory drugs (NSAIDs) and biologicals/biosimilars (b-bDMARDs).

Mean PsAID-12 values over time were higher in women; nevertheless, PsAID-12 improved comparably for both genders from BL to week 52 (♂: 4.8 at BL to 2.9 at w52, ♀: 5.3 at BL to 3.5 at w52, Figure 1A). This was similar to the course of improvements for mean PGA across genders (♂: 4.9 at BL to 3.0 at w52, ♀: 5.6 at BL to 3.5 at w52). In terms of PASI scores, both BL mean values and improvements over time were similar across genders (♂: 6.8 at BL to 1.9 at w52, ♀: 7.0 at BL to 1.0 at w52). Mean joint counts (tender/swollen) also improved similarly (♂: 6.8/3.7 at BL to 3.1/0.9 at w52, ♀: 7.3/3.7 at BL to 2.8/0.9 at w52). Over time, male patients showed overall reduced BDI-II values; nevertheless, BDI-II reductions were comparable across the genders (♂: 10.2 at BL to 8.1 at w52, ♀: 13.0 at BL to 10.6 at w52). Secukinumab treatment retention rate for men was (not significantly) higher than for women (Figure 1B).

Conclusion: In a real-world setting, secukinumab improved disease activity and depressive mood of PsA patients in both men and women. Women showed overall higher burden of disease. Altogether, this interim analysis shows that secukinumab is an effective treatment up to 52 weeks with high treatment retention rates in real-world setting, irrespective of gender.

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

Demographics*	Male (N=531)	Female (N=747)
Age, years	51.9 (11.6)	53.1 (11.2)
BMI, kg/m ²	29.1 (4.9)	29.0 (6.4)
BMI >25 to ≤30 kg/m ² , n (%)	219 (42.8)	211 (29.5)
BMI >30 kg/m ² , n (%)	188 (36.7)	285 (39.8)
Smoker, n (%)	103 (19.4)	196 (26.2)
PsAID-12	4.8 (2.2)	5.3 (2.2)
PGA	4.9 (2.6)	5.6 (2.4)
PASI	6.8 (9.8)	7.0 (11.1)
Tender joint counts	6.8 (7.9)	7.3 (7.4)
Swollen joint counts	3.7 (5.3)	3.7 (5.0)
BDI-II	10.2 (8.8)	13.0 (9.4)
Medication prior to secukinumab initiation, n (%):		
NSAID	290 (54.6)	467 (62.5)
csDMARD	460 (86.6)	678 (90.8)
b-bDMARD	299 (56.3)	477 (63.9)

*variables given as mean (SD)

Figure 1. Impact of disease and treatment retention in PsA patients stratified by gender
A) PsAID-12 (mean) B) Retention rate
 Note: P-values are of exploratory nature

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POS1024

GUSELKUMAB PROVIDES SUSTAINED DOMAIN-SPECIFIC AND COMPREHENSIVE EFFICACY AS ASSESSED USING COMPOSITE ENDPOINTS IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS

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Background: Guselkumab (GUS) is a human monoclonal antibody specific to the p19-subunit of interleukin-23. GUS significantly improved signs and symptoms of PsA through Week24 (Wk24), and improvements were maintained through Wk52 in the Phase 3 DISCOVER-1¹ and DISCOVER-2² studies.

Objectives: Assess GUS efficacy through Wk52 in both studies utilizing composite indices.

Methods: Adult patients (pts) enrolled had active PsA despite standard therapies. Pts in DISCOVER-1 had ≥ 3 swollen and ≥ 3 tender joints and C-reactive protein (CRP) ≥ 0.3 mg/dL; in DISCOVER-2, pts had ≥ 5 swollen and ≥ 5 tender joints and CRP ≥ 0.6 mg/dL. 31% of DISCOVER-1 pts received 1-2 prior tumor necrosis factor inhibitors; DISCOVER-2 pts were biologic-naïve. Pts were randomized 1:1:1 to GUS 100mg every 4 weeks (Q4W); GUS 100mg at Wk0, Wk4, then every 8 weeks (Q8W); or placebo (PBO); PBO pts crossed over to GUS 100mg Q4W at Wk24. Composite endpoints pooled across the two studies were: Disease Activity Index for Psoriatic Arthritis (DAPSA), Psoriatic Arthritis Disease Activity Score (PASDAS), Minimal Disease Activity (MDA), and Very Low Disease Activity (VLDA). GUS vs PBO comparisons through Wk24 employed a Cochran-Mantel-Haenszel test with baseline stratification factors or Fisher's exact test; no treatment group comparisons were performed beyond Wk24. P-values were not adjusted for multiplicity. From Wk24 -Wk52, pts with missing data were considered nonresponders (>90% of pts completed study treatment through Wk52).

Results: In randomized and treated pts from DISCOVER-1 (N=381) and DISCOVER-2 (N=739), pooled baseline characteristics were generally well-balanced across treatment groups and reflected active disease. Differences in response rates between GUS Q4W or Q8W and PBO were seen as early as Wk8 and increased over time through Wk24. In pts continuing GUS Q4W or Q8W, respectively, post-Wk24 response rates associated with these composite indices continued to increase through Wk52, at which time they were 54.2% and 52.5% for DAPSA LDA, 45.3% and 41.9% for PASDAS LDA, 35.9% and 30.7% for MDA, 18.2% and 17.6% for DAPSA remission, and 13.1% and 14.4% for VLDA, with no discernable difference between the GUS Q4W and Q8W dosing regimens (Table 1 and Figure 1). After PBO pts crossed over to GUS Q4W at Wk24, response rates increased through Wk52.

Conclusion: GUS 100mg Q4W and Q8W provided robust and sustained benefits to pts with active PsA across multiple domains, indicating that GUS

may provide an alternative treatment option for the diverse manifestations of PsA.

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Table 1. Pooled response rates for DISCOVER-1 and DISCOVER-2 randomized and treated patients.

	DISCOVER-1&2		
	GUS Q4W	GUS Q8W	PBO → GUS Q4W ¹
Randomized and treated patients, n	373	375	372
PASDAS² LDA			
Wk 24	27.9%**	30.1%**	8.9%
Wk 52	45.3%	41.9%	36.8%
MDA³			
Wk 24	22.8%**	24.3%**	7.8%
Wk 52	35.9%	30.7%	28.2%
DAPSA⁴ Remission			
Wk 24	10.2%**	8.3%**	2.2%
Wk 52	18.2%	17.6%	11.0%
VLDA³			
Wk 24	6.4%**	4.3%*	1.3%
Wk 52	13.1%	14.4%	8.3%

Data reported as proportions of patients, %. Unadjusted p values at Wk24 vs PBO: *p<0.05; **p<0.001.

¹ Pts randomized to PBO crossed over to GUS Q4W at Wk24.

² PASDAS is derived from Pt global assessment of arthritis and psoriasis (0-100), Physician global assessment (0-100), swollen joint count (0-66), tender joint count (0-68), CRP (mg/L), Leeds enthesitis index score, tender dactylitis count, and the 36-item Short-Form Health Survey Physical Component Summary score. PASDAS LDA ≤ 3.2 .

³ MDA is 5/7 criteria met; VLDA is 7/7 criteria met: tender joint count ≤ 1 , swollen joint count ≤ 1 , Psoriasis Activity and Severity Index ≤ 1 , Pt assessment of pain ≤ 15 (0-100), Pt global assessment of disease activity ≤ 20 (0-100), Health Assessment Questionnaire-Disability Index score ≤ 0.5 , Tender entheses points ≤ 1 .

⁴ DAPSA Remission: score ≤ 4 (definition in Figure 1 legend).

Figure. Proportions of Pooled DISCOVER-1 and DISCOVER-2 Patients Achieving DAPSA LDA^a Through Week 52.

Missing data imputed as nonresponse.

*, †, ‡ p < 0.05, 0.01, 0.001, respectively, vs placebo. Unadjusted (nominal) p values are not controlled for multiplicity and are descriptive/supportive only; no statistical significance should be implied.

^a The DAPSA score is derived from tender joint count (0–68), swollen joint count (0–66), CRP (mg/dL), patient assessment of pain (0–10 cm VAS), and patient global assessment of disease activity (arthritis, 0–10 cm VAS). DAPSA LDA: ≤ 4 . DAPSA Remission: ≤ 4 .

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