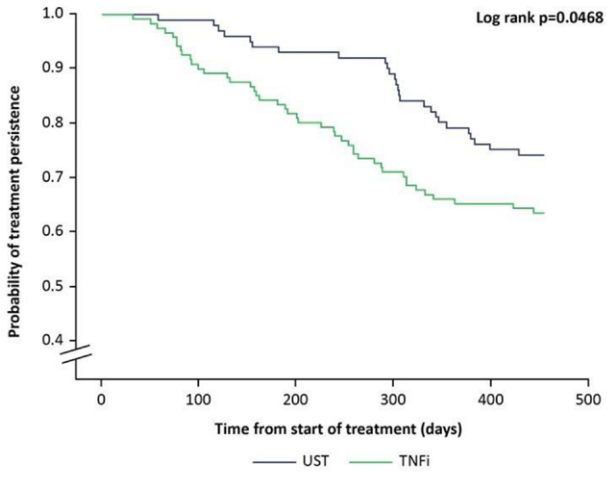
Kaplan–Meier estimates of treatment persistence for ustekinumab and TNFi in the overall PsABio Italian cohort



TNFi, tumour necrosis factor inhibitor

was 26.3 (15.4) for UST and 23.5 (12.3) for TNFi; at 1-year follow-up, 43.5% of UST- and 43.6% of TNFi-treated patients reached cDAPSA LDA/remission. MDA was reached in 24.2% of UST- and 28.0% of TNFi-treated patients, and VLDA in 12.5% of UST- and 10.2% of TNFi-treated patients. After PS adjustment (stoppers/switchers as non-responders), odds ratios (95% CI) at 1 year did not differ significantly between UST and TNFi groups for reaching cDAPSA LDA/remission (1.08 [0.54; 2.15]), MDA (0.96 [0.45; 2.05]) or VLDA (0.98 [0.35; 2.76]). In total, 23 (20.4%) patients reported ≥1 treatment emergent adverse event with UST and 30 (22.2%) with TNFi; 6 (5.3%) and 10 (7.4%) patients, respectively, discontinued treatment because of an adverse event.

Conclusion: In the Italian PsABio cohort, UST had better overall persistence compared with TNFi, as well as in specific subgroups: females, patients on monotherapy without methotrexate, with BMI <25 or >30 kg/m^2, and patients receiving UST as 2nd-line treatment. At 1 year, both treatments showed similar effectiveness, as measured by cDAPSA responses and MDA/VLDA achievement.

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POS1022

BIMEKIZUMAB SAFETY AND EFFICACY IN PATIENTS WITH PSORIATIC ARTHRITIS: 3-YEAR RESULTS FROM A PHASE 2B OPEN-LABEL EXTENSION STUDY

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Background: Bimekizumab (BKZ), a monoclonal antibody inhibitor of interleukin (IL)-17A and IL-17F, demonstrated clinical improvements in joint and skin outcomes up to 108 weeks (wks) in patients (pts) with active psoriatic arthritis (PsA).[1,2]

Objectives: To report up to 3-year safety and efficacy of BKZ in pts with active PsA from a 48-week phase 2b dose-ranging study (BE ACTIVE; NCT02969525) and its open-label extension (OLE; NCT03347110).

Methods: BE ACTIVE and OLE study design has been described previously.[1] All OLE pts received BKZ 160 mg Q4W, irrespective of prior dosing regimen. Treatment-emergent adverse events (TEAEs) are reported for the safety set (SS; pts who received ≥1 dose BKZ in the dose-ranging study). Data are presented from dose-ranging study baseline (BL) to Wk 152. Efficacy outcomes are reported for the full analysis set (FAS): ACR50, minimal or very low disease activity (MDA/VLDA), Psoriasis Area and Severity Index (PASI) 90/100, body surface area affected by psoriasis (BSA) 0% and dactylitis/enthesitis resolution.

Results: Over 152 wks, the exposure-adjusted incidence rate (EAIR) per 100 patient-years (PY) was 126.4 for all TEAEs, 4.1 for serious TEAEs, 0.7 for serious infections and 4.6 for *Candida* infections (Table 1). One event was adjudicated by an independent committee as inflammatory bowel disease (microscopic colitis). All *Candida* infections were localised, mild/moderate, and resolved with appropriate anti-fungal therapy. Overall, the proportions of patients with ACR50 response were sustained through Wk 152 (52.9%, non-responder imputation [NRI]; Figure 1). Response rates were also sustained through Wk 152 for MDA (51.5%), VLDA (30.1%), PASI90 (64.2%), PASI100 (57.7%) and resolution of dactylitis (71.2%) and enthesitis (62.6%) (NRI; Table 1).

Table 1. Safety and efficacy outcomes up to 3 years

Safety (SS) n (%) [EAIR/100 PY]	BKZ 160 mg [a] (n=126)		BKZ 320 mg [b] (n=78)		Total (N=206)	
Any TEAE	114 (90.5) [136.1]		70 (89.7) [113.3]		184 (89.3) [126.4]	
Serious TEAEs	17 (13.5) [5.2]		5 (6.4) [2.3]		22 (10.7) [4.1]	
Key TEAEs of special monitoring						
Serious infections	3 (2.4) [0.9]		1 (1.3) [0.5]		4 (1.9) [0.7]	
Candida infections	15 (11.9) [4.7]		9 (11.5) [4.4]		24 (11.7) [4.6]	
Inflammatory bowel disease [c]	1 (0.8) [0.3]		0		1 (0.5) [0.2]	
Malignancies [d]	1 (0.8) [0.3]		0		1 (0.5) [0.2]	
Injection site reactions	0		3 (3.8) [1.4]		3 (1.5) [0.5]	
Suicidal ideation	1 (0.8) [0.3]		0		1 (0.5) [0.2]	
Liver function analyses	13 (10.3) [4.1]		11 (14.1) [5.3]		24 (11.7) [4.6]	
Study discontinuation due to TEAEs	12 (9.5) [3.5]		4 (5.1) [1.8]		16 (7.8) [2.8]	
Efficacy (FAS)	BKZ 160 mg [a]		BKZ 320 mg [b]		Total (N=206)	
n (%)	(n=124)		(n=82)			
	OC	NRI, %	OC	NRI, %	OC	NRI, %
MDA, Wk 152	64/95 (67.4)	51.6	42/62 (67.7)	51.2	106/157 (67.5)	51.5
VLDA, Wk 152	41/95 (43.2)	33.1	21/62 (33.9)	25.6	62/157 (39.5)	30.1
PASI90 [e] Wk 152	51/61 (83.6)	64.6	37/46 (80.4)	63.8	88/107 (82.2)	64.2
PASI100 [e] Wk 152	47/61 (77.0)	59.5	32/46 (69.6)	55.2	79/107 (73.8)	57.7
BSA 0% [e] Wk 48	48/72 (66.7)	60.8	38/55 (69.1)	65.5	86/127 (67.7)	62.8
Wk 152	46/61 (75.4)	58.2	31/45 (68.9)	53.4	77/106 (72.6)	56.2
Dactylitis [f]/Enthesitis [g] resolution, Wk 48	–	70.6/56.9	–	84.0/57.1	–	76.3/57.0
Wk 152	–	67.6/63.1	–	76.0/61.9	–	71.2/62.6

No anaphylactic reactions or major adverse cardiac events were reported. [a] Includes pts within the indicated analysis set originally assigned to all arms who were subsequently re-randomized to 160 mg, or [b] 320 mg, after double-blind period; [c] Microscopic colitis; [d] Malignant melanoma in situ; [e] Pts with BL BSA ≥3%, NRI: n=79, 58, 137 respectively; [f] Pts with BL LDI >0, NRI: n=34, 25, 59 respectively; [g] Pts with BL MASES >0, NRI: n=65, 42, 107 respectively. LDI: Leeds Dactylitis Index; MASES: Maastricht AS Enthesitis Score; OC: observed case.

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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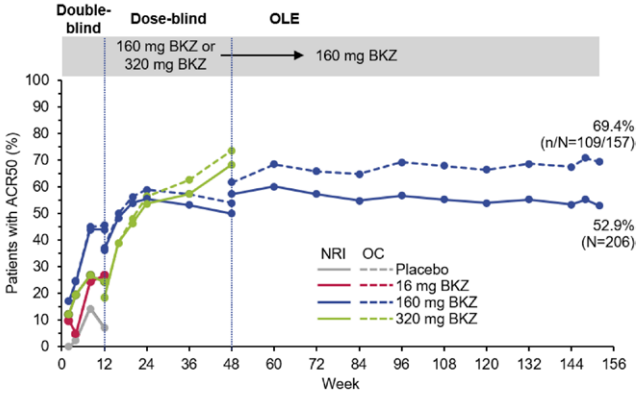
Figure. ACR50 responders up to 3 years



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 medication[1]. 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-bsDMARDs).

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-bsDMARD	299 (56.3)	477 (63.9)

*variables given as mean (SD)

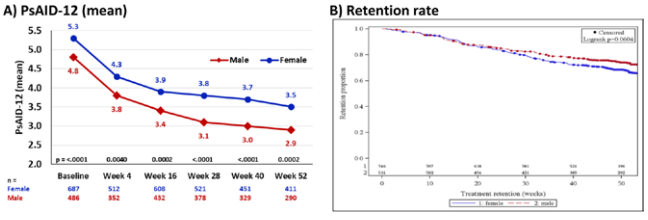

Figure 1. Impact of disease and treatment retention in PsA patients stratified by gender A) PsAID-12 (mean) B) Retention rate
Note: P-values are of exploratory nature