Figure. a) CFB in DSS^a and b) dactylitic digits count^b in patients with DSS >0 at BL, stratified by location of dactylitis, and the proportion of patients with dactylitis^c in patients with DSS^a >0 at BL, stratified by c) right-hand fingers, d) left-hand fingers, e) right-foot toes, and f) left-foot toes (pooled from OPAL, Braden and OPAL, Beyond)

^aA blinded assessor squeezed each digit of the hands and feet with moderate pressure, and assigned a score for each digit on a scale of 0-3, where 0 = no tenderness, 1 = tender, 2 = tender and swollen, and 3 = tender and erythematous. DSS is calculated as the sum of those scores, ranging from 0-60, with a score of 60 being the highest dactylitis severity.
^bDactylitis was defined as swelling of an entire digit.
^cIt ranged from 121-127 at BL, 115-122 at M1, 115-122 at M3 and 113-120 at M6 for all digits.
 CFB, change from baseline; N, total number of patients with DSS >0 at BL; n, total number of patients with dactylitis in that particular location; SE, standard error

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POS1021

THE PSABio STUDY IN ITALY: A REAL-WORLD COMPARISON OF THE PERSISTENCE, EFFECTIVENESS AND SAFETY OF USTEKINUMAB AND TUMOUR NECROSIS FACTOR INHIBITORS IN PATIENTS WITH PSORIATIC ARTHRITIS

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Background: There are still unmet needs in the treatment of psoriatic arthritis (PsA), including in terms of treatment persistence, which is a function of effectiveness, safety and patient satisfaction. Ustekinumab (UST) was the first new biologic drug to be developed for the treatment of PsA after tumour necrosis factor inhibitors (TNFi).

Objectives: To compare treatment persistence, effectiveness and safety of UST and TNFi in Italian patients within the PsABio cohort.

Methods: PsABio (NCT02627768) is an observational study of 1st/2nd/3rd-line UST or TNFi treatment in PsA in 8 European countries. The current analysis set includes 222 eligible patients treated in 15 Italian centres, followed to Month 12 (±3 months). Treatment persistence/risk of stopping was analysed using Kaplan-Meier (KM) and Cox regression analysis. Proportions of patients reaching minimal disease activity (MDA)/very low disease activity (VLDA) and clinical Disease Activity Index for PsA (cDAPSA) low disease activity (LDA)/remission were analysed using logistic regression, including propensity score (PS) adjustment for imbalanced baseline covariates, and non-response imputation of effectiveness endpoints if treatment was stopped/switched before 1 year. Last observation carried forward data are reported.

Results: Of patients starting UST and TNFi, 75/101 (74.3%) and 77/121 (63.6%), respectively, persisted with treatment at 1 year. The observed mean persistence was 410 days for UST and 363 days for TNFi. KM curves and PS-adjusted hazard ratios confirmed significantly higher persistence (hazard ratio [95% confidence interval (CI)] for UST versus TNFi overall (0.46 [0.26; 0.82]; Figure 1). Persistence was also higher for UST than TNFi in patients receiving monotherapy without methotrexate (0.31 [0.15; 0.63]), in females (0.41 [0.20; 0.83]), and in patients with body mass index (BMI) <25 kg/m² (0.34 [0.14; 0.87]) or >30 kg/m² (0.19 [0.06; 0.54]). There was no significant difference in persistence between treatments in patients with BMI 25–30 kg/m². While patients receiving 1st- and 3rd-line UST or TNFi showed similar risk of discontinuation (0.60 [0.27; 1.29] and 0.36 [0.10; 1.25], respectively), patients receiving 2nd-line UST showed better persistence than those receiving 2nd-line TNFi (0.33 [0.13; 0.87]). Other factors added to the PS-adjusted Cox model did not show significant effects. In patients with available follow-up data, the mean (standard deviation) baseline cDAPSA

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 (stop-pers/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/m², 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 2a 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)	BKZ		BKZ		Total	
n (%) [EAIR/100 PY]	160 mg [a]		320 mg [b]		(N=206)	
	(n=126)		(n=78)			
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		BKZ		Total	
n (%)	160 mg [a]		320 mg [b]		(N=206)	
	(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	—	70.6/56.9	—	84.0/57.1	—	76.3/57.0
[g] resolution, Wk 48						
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 $\geq 3\%$, 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.