Bimekizumab efficacy and safety in patients with psoriatic arthritis who had skin and nail psoriasis at baseline: Up to 2-year results from two phase 3 studies

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Supplementary Table 1 Baseline characteristics in patients with baseline skin and nail psoriasis

	BE OPTIMAL (bDMARD-naïve)			BE COMPLETE (TNFi-IR)	
	PBO n=88	BKZ 160 mg Q4W n=133	ADA 40 mg Q2W[a] n=42	PBO n=54	BKZ 160 mg Q4W n=105
Patient characteristics					
Age (years), mean (SD)	48.9 (10.4)	46.3 (11.6)	49.8 (11.8)	49.6 (13.6)	48.8 (11.9)
Sex, male, n (%)	42 (47.7)	70 (52.6)	23 (54.8)	30 (55.6)	60 (57.1)
BMI (kg/m^2), mean (SD)	29.6 (5.8)	29.8 (6.1)	29.2 (6.1)	28.4 (5.3)	29.9 (5.6)
Time since PsA diagnosis (years), mean (SD)	7.0 (7.6)	7.8 (9.2)[b]	6.5 (7.1)	8.5 (7.4)[c]	10.5 (10.0)
Disease activity					
PASI score, mean (SD)	9.0 (6.0)	9.2 (7.8)	9.2 (8.4)	9.3 (7.4)	11.8 (10.2)
DAPSA score, mean (SD)	40.7 (19.5)	41.5 (20.9)	40.7 (19.1)	46.3 (26.1)	44.2 (23.8)
TJC (of 68 joints), mean (SD)	17.3 (11.6)	18.5 (12.9)	19.0 (11.7)	19.9 (14.9)	18.8 (14.2)
SJC (of 66 joints), mean (SD)	9.7 (7.9)	10.4 (7.1)	9.2 (6.0)	11.9 (10.1)	11.3 (9.3)
Enthesitis (LEI >0), n (%)	24 (27.3)	43 (32.3)	10 (23.8)	13 (24.1)	39 (37.1)
LEI score,[d] mean (SD)	2.5 (1.4)	2.5 (1.5)	2.5 (1.7)	3.0 (1.3)	2.3 (1.5)
Dactylitis (LDI >0), n (%)	7 (8.0)	25 (18.8)	5 (11.9)	5 (9.3)	17 (16.2)
LDI score,[e] mean (SD)	64.0 (51.4)	61.7 (74.9)	64.3 (38.0)	43.8 (30.8)	73.1 (93.6)
mNAPSI score, mean (SD)	4.5 (2.2)	4.4 (2.5)	4.0 (2.0)	5.1 (2.6)	4.8 (2.9)
hs-CRP ≥6mg/L, n (%)	45 (51.1)	72 (54.1)	19 (45.2)	30 (55.6)	52 (49.5)
HAQ-DI, mean (SD)	0.92 (0.61)	0.87 (0.58)	0.96 (0.54)	1.08 (0.70)	1.05 (0.56)
PsAID-12 total score, mean (SD)	4.3 (1.8)	4.3 (1.8)	4.6 (1.7)	4.8 (1.8)	4.9 (2.0)
Pain VAS, mean (SD)	60.9 (21.5)	56.9 (24.7)	59.1 (24.8)	66.0 (22.6)	62.0 (23.4)

Randomized set, in patients with baseline skin psoriasis ≥3% BSA and mNAPSI >0. (a) Reference arm; study not powered for statistical comparisons of ADA to BKZ or PBO; (b) Data missing for 2 patients; (c) Data missing for 1 patient; (d) In patients with enthesitis at baseline; (e) In patients with dactylitis at baseline.

Supplementary Table 2 Additional efficacy outcomes at Week 104/100 for patients with baseline skin and nail psoriasis (MI, NRI, WCI)

	BE OPTIMAL (bDMARD-naïve) Week 104			BE COMPLETE (TNFi-IR) Week 100	
Data are NRI unless otherwise stated	PBO → BKZ 160 mg Q4W n=88	BKZ 160 mg Q4W n=133	ADA 40 mg Q2W[a] → BKZ 160 mg Q4W n=42	PBO → BKZ 160 mg Q4W n=54	BKZ 160 mg Q4W n=105
ACR20 responders, n (%)	62 (70.5)	97 (72.9)	29 (69.0)	40 (74.1)	80 (76.2)
ACR70 responders, n (%)	36 (40.9)	56 (42.1)	19 (45.2)	22 (40.7)	45 (42.9)
PASI90 responders, n (%)	66 (75.0)	92 (69.2)	32 (76.2)	39 (72.2)	79 (75.2)
ACR50 + PASI100 responders, n (%)	37 (42.0)	56 (42.1)	21 (50.0)	25 (46.3)	47 (44.8)
VLDA responders, n (%)	24 (27.3)	47 (35.3)	16 (38.1)	11 (20.4)	31 (29.5)
DAPSA disease state [WCI],[b] n (%)					
LDA+REM	59 (67.0)	94 (70.7)	29 (69.0)	37 (68.5)	71 (67.6)
REM	27 (30.7)	52 (39.1)	19 (45.2)	16 (29.6)	36 (34.3)
TJC=0 (of 68 joints), n (%)	29 (33.0)	50 (37.6)	19 (45.2)	15 (27.8)	35 (33.3)
SJC=0 (of 66 joints), n (%)	60 (68.2)	90 (67.7)	27 (64.3)	35 (64.8)	68 (64.8)
Enthesitis resolution (LEI=0),[c] n/N (%)	18/24 (75.0)	28/43 (65.1)	5/10 (50.0)	7/13 (53.8)	28/39 (71.8)
Dactylitis resolution (LDI=0),[d] n/N (%)	7/7 (100.0)	19/25 (76.0)	4/5 (80.0)	2/5 (40.0)	15/17 (88.2)
Nail psoriasis resolution (mNAPSI=0), n (%)	63 (71.6)	91 (68.4)	32 (76.2)	34 (63.0)	72 (68.6)
HAQ-DI CfB [MI], mean (SE)	−0.40 (0.06)	−0.40 (0.05)	−0.51 (0.11)	−0.51 (0.09)	−0.51 (0.05)
HAQ-DI MCID,[e] n/N (%)	41/70 (58.6)	62/105 (59.0)	22/37 (59.5)	30/47 (63.8)	58/93 (62.4)
PsAID-12 total score MCID,[f] n/N (%)	34/68 (50.0)	50/102 (49.0)	22/35 (62.9)	22/45 (48.9)	52/87 (59.8)
Pain VAS ≥50% improvement,[g] n (%)	53 (60.2)	77 (57.9)	25 (59.5)	31 (57.4)	68 (64.8)

Randomized set, in patients with baseline skin psoriasis ≥3% BSA and mNAPSI >0. (a) Reference arm; study not powered for statistical comparisons of ADA to BKZ or PBO; (b) Missing data were imputed using the WCI method. Any missing data or data recorded after discontinuation of the study treatment were categorized as HDA, which is the worst category out of the four DAPSA categories (REM ≤4, LDA 4<DAPSA≤14, MDA 14<DAPSA≤28, and HDA DAPSA >28). DAPSA REM+LDA defined as a DAPSA score of ≤14. (c) In patients with baseline enthesitis (LEI >0). (d) In patients with baseline dactylitis (LDI >0). (e) Decrease of ≥0.35 points from baseline in patients with HAQ-DI ≥0.35 at baseline; (f) Clinically meaningful within-patient improvement referred to here as MCID: decrease of ≥3 points from baseline in patients with PsAID-12 total score ≥3 at baseline. PsAID-12 MCID data reported to Week 88 for BE COMPLETE as PsAID-12 not collected at Week 100 in BE COMPLETE; (g) Pain VAS assessed using the Patient's Assessment of Arthritis Pain 100mm visual analog scale which ranges from 0 to 100, 0 representing 'no pain' and 100 'most severe pain'. Pain VAS ≥50% improvement represents a substantial improvement in patient-reported pain.[1]

ACR20/50/70: ≥20%/50%/70% improvement from baseline in American College of Rheumatology response criteria; **ADA:** adalimumab; **bDMARD:** biologic disease-modifying antirheumatic drug; **BKZ:** bimekizumab; **BMI:** body mass index; **BSA:** body surface area; **CfB:** change from baseline; **DAPSA:** Disease Activity Index for Psoriatic Arthritis; **HAQ-DI:** Health Assessment Questionnaire-Disability Index; **HDA:** high disease activity; **hs-CRP:** high-sensitivity C-reactive protein; **LDA:** low disease activity; **LDI:** Leeds Dactylitis Index; **LEI:** Leeds Enthesitis Index; **MCID:** minimal clinically important difference; **MDA:** Minimal Disease Activity; **MI:** multiple imputation; **mNAPSI:** modified Nail Psoriasis Severity Index; **NRI:** non-responder imputation; **PASI:** Psoriasis Area and Severity Index; **PASI90/100:** ≥90%/100% improvement from baseline in Psoriasis Area and Severity Index; **PBO:** placebo; **PsAID-12:** Psoriatic Arthritis Impact of Disease-12 questionnaire; **Q2W:** every two weeks; **Q4W:** every four weeks; **REM:** remission; **SD:** standard deviation; **SE:** standard error; **SJC:** swollen joint count; **TJC:** tender joint count; **TNFi-IR:** prior inadequate response or intolerance to tumor necrosis factor inhibitors; **VAS:** visual analog scale; **VLDA:** Very Low Disease Activity; **WCI:** worst-category imputation.

References: [1]Dworkin et al. J Pain 2008;9:105–21.