Bimekizumab Maintained Efficacy Responses in Patients With Active Psoriatic Arthritis: Up to 2-Year Results from Two Phase 3 Studies

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Objective

To report the proportion of Week 16 responders maintaining their responses up to 2 years in joint, skin, and composite efficacy outcomes, among bimekizumab (BKZ)-treated patients with psoriatic arthritis (PsA) who were biologic disease-modifying antirheumatic drug (bDMARD)-naïve or had inadequate response or intolerance to tumor necrosis factor inhibitors (TNFi-IR).

Background

- PsA is a chronic disease, and patients can experience loss of response with sustained therapy; therefore, assessing long-term maintenance of response in patients achieving early treatment targets is of interest.[1]
- BKZ, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated clinically meaningful improvements in efficacy outcomes that were sustained up to 2 years in patients with active PsA.[2]

Methods

- The phase 3 BE OPTIMAL (NCT03895203; bDMARD-naïve) and BE COMPLETE (NCT03896581; TNFi-IR) studies, both placebo-controlled to Week 16, assessed subcutaneous BKZ 160 mg every 4 weeks (Q4W) in patients with PsA. Complete methodologies have been previously reported.[2]
- BE OPTIMAL Week 52 and BE COMPLETE Week 16 completers were eligible for the open-label extension, BE VITAL (NCT04009499), in which all patients received BKZ 160 mg Q4W.
- Maintenance of response is reported in BKZ-randomized patients, as the proportion of Week 16 responders who achieved a response at subsequent study assessment visits for joint, skin, and composite efficacy outcomes.
- Data are reported to Week 104 in BE OPTIMAL and Week 100 in BE COMPLETE as observed case (OC), and using non-responder (NRI) or worst-category imputation.
- Exposure-adjusted incidence rates per 100 patient-years (EAIR/100 PY) are reported to Week 104 for all bDMARD-naïve and TNFi-IR patients who received at least one dose of BKZ, regardless of initial treatment arm.

Results

- Of patients randomized to BKZ at baseline, 359/431 (83.3%) bDMARD-naïve and 215/267 (80.5%) TNFi-IR patients completed Week 104 of BE OPTIMAL or Week 100 of BE COMPLETE, including patients not on randomized treatment (bDMARD-naive: 4; TNFi-IR: 0).
- Across BKZ-randomized bDMARD-naïve and TNFi-IR patients, approximately half (NRI, OC) achieved each of the following outcomes at Week 16:
  - ≥50% improvement from baseline in ACR response criteria (ACR50), 100% improvement from baseline in Psoriasis Area and Severity Index (PASI100), Minimal Disease Activity (MDA), and resolution of swollen joint count (SJC=0).
- Of these patients who achieved a response at Week 16, 70.9%–80.6% (NRI) and 84.5%–92.2% (OC) maintained their respective responses at Week 104/100 (**Figures 1A–D**, **Table**).
- Similar results were observed for additional joint, skin, and composite efficacy outcomes (**Table**).
- EAIR/100 PY for BKZ-treated patients with ≥1 treatment-emergent adverse event was 179.9 (n=823; 1,333.7 PY) in bDMARD-naïve and 100.3 (n=388; 677.0 PY) in TNFi-IR patients to Week 104.

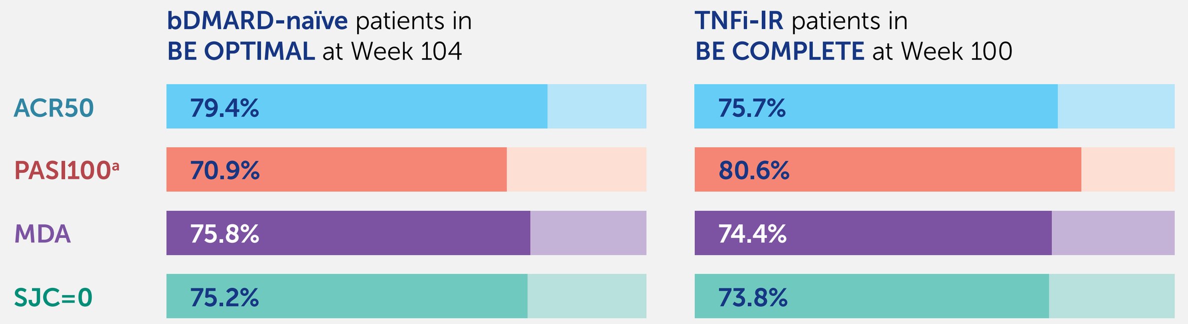
Conclusions

Bimekizumab demonstrated robust maintenance of response at 2 years in both bDMARD-naïve and TNFi-IR patients with PsA who responded to bimekizumab treatment at Week 16. Bimekizumab was well tolerated and the safety profile was consistent with previous reports.[2]

Summary

Maintenance of response up to **2 years** was assessed in **bimekizumab-treated** patients with **PsA** who were responders at Week 16 of **BE OPTIMAL (bDMARD-naïve)** or **BE COMPLETE (TNFi-IR)**.

High proportions of Week 16 responders **maintained their response at Week 104/100** across joint, skin, and composite outcomes (NRI):



Treatment with **bimekizumab** demonstrated **robust maintenance of response at 2 years** in both **bDMARD-naïve** and **TNFi-IR** patients with **PsA** who responded to bimekizumab at Week 16.

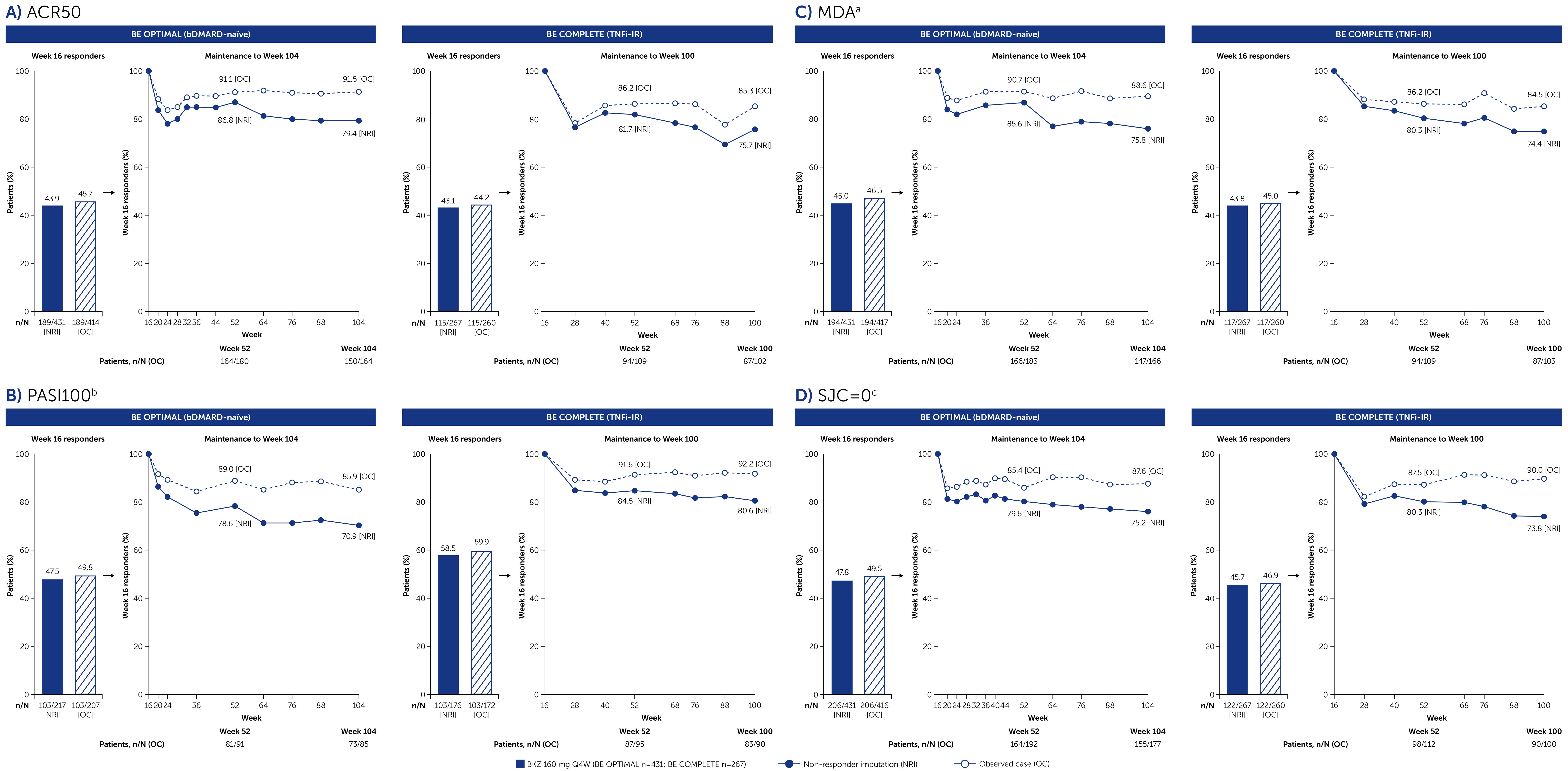
[a] In patients with baseline psoriasis affecting ≥3% BSA.

Table Maintenance of responses at Week 104/100 in Week 16 responders for additional efficacy outcomes (NRI, OC, WCI)

	BE OPTIMAL (bDMARD-naïve) BKZ 160 mg Q4W n=431				BE COMPLETE (TNFi-IR) BKZ 160 mg Q4W n=267			
	Week 16 Responders		Maintenance at Week 104		Week 16 Responders		Maintenance at Week 100	
	NRI, n (%)	OC, n/N (%)	NRI, n (%)	OC, n/N (%)	NRI, n (%)	OC, n/N (%)	NRI, n (%)	OC, n/N (%)
ACR20	268 (62.2)	268/413 (64.9)	210 (78.4)	210/229 (91.7)	178 (66.7)	178/260 (68.5)	142 (79.8)	142/151 (94.0)
ACR50	189 (43.9)	189/414 (45.7)	150 (79.4)	150/164 (91.5)	115 (43.1)	115/260 (44.2)	87 (75.7)	87/102 (85.3)
ACR70	105 (24.4)	105/417 (25.2)	78 (74.3)	78/91 (85.7)	70 (26.2)	70/260 (26.9)	50 (71.4)	50/65 (76.9)
PASI75,[a] n/N (%)	168/217 (77.4)	168/207 (81.2)	133 (79.2)	133/139 (95.7)	144/176 (81.8)	144/172 (83.7)	120 (83.3)	120/124 (96.8)
PASI90,[a] n/N (%)	133/217 (61.3)	133/207 (64.3)	102 (76.7)	102/109 (93.6)	120/176 (68.2)	120/172 (69.8)	99 (82.5)	99/105 (94.3)
PASI100,[a] n/N (%)	103/217 (47.5)	103/207 (49.8)	73 (70.9)	73/85 (85.9)	103/176 (58.5)	103/172 (59.9)	83 (80.6)	83/90 (92.2)
ACR50+PASI100,[a] n/N (%)	60/217 (27.6)	60/206 (29.1)	42 (70.0)	42/53 (79.2)	59/176 (33.5)	59/172 (34.3)	43 (72.9)	43/53 (81.1)
MDA[b]	194 (45.0)	194/417 (46.5)	147 (75.8)	147/166 (88.6)	117 (43.8)	117/260 (45.0)	87 (74.4)	87/103 (84.5)
VLDA[b]	63 (14.6)	63/417 (15.1)	46 (73.0)	46/53 (86.8)	36 (13.5)	36/260 (13.8)	25 (69.4)	25/32 (78.1)
DAPSA disease state[c,d]								
LDA+REM	205 (47.6)	205/413 (49.6)	157 (76.6)	157/178 (88.2)	123 (46.1)	123/260 (47.3)	94 (76.4)	94/103 (91.3)
REM	47 (10.9)	47/413 (11.4)	30 (63.8)	30/36 (83.3)	24 (9.0)	24/260 (9.2)	17 (70.8)	17/21 (81.0)
TJC=0	78 (18.1)	78/416 (18.8)	54 (69.2)	54/64 (84.4)	41 (15.4)	41/260 (15.8)	29 (70.7)	29/33 (87.9)
TJC ≤1	136 (31.6)	136/416 (32.7)	97 (71.3)	97/115 (84.3)	65 (24.3)	65/260 (25.0)	48 (73.8)	48/53 (90.6)
SJC=0	206 (47.8)	206/416 (49.5)	155 (75.2)	155/177 (87.6)	122 (45.7)	122/260 (46.9)	90 (73.8)	90/100 (90.0)
SJC ≤1	260 (60.3)	260/416 (62.5)	204 (78.5)	204/223 (91.5)	160 (59.9)	160/260 (61.5)	120 (75.0)	120/133 (90.2)

Randomized set, in patients randomized to BKZ at baseline. Maintenance data are reported as the proportion of Week 16 responders who also achieved a response at subsequent study assessment visits. **[a]** In patients with baseline psoriasis affecting ≥3% BSA; **[b]** MDA or VLDA response defined as achievement of ≥5/7 or 7/7 of the following criteria, respectively: TJC ≤1, SJC ≤1, PASI ≤1 or BSA ≤3%, patient pain VAS ≤15 mm, PGA-PsA VAS ≤20 mm, HAQ-DI ≤0.5, and tender entheseal points (LEI) ≤1; **[c]** DAPSA score is the sum of SJC (range: 0–66), TJC (range: 0–68), patient pain VAS 0–100 mm, PGA-Arthritis VAS 0–100 mm, and hs-CRP (mg/L). DAPSA LDA+REM is defined as DAPSA total score ≤14; DAPSA REM is defined as DAPSA total score ≤4; **[d]** 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, LDA, MoDA, and HDA).

Figure 1 Maintenance of efficacy responses to Week 104/100 in Week 16 responders (NRI, OC)



Randomized set, in patients randomized to BKZ at baseline. Maintenance data are reported as the proportion of Week 16 responders who also achieved a response at subsequent study assessment visits. **[a]** MDA response defined as achievement of ≥5 of the following 7 criteria: TJC ≤1, SJC ≤1, PASI ≤1 or BSA ≤3%, patient pain VAS ≤15 mm, PGA-PsA VAS ≤20 mm, HAQ-DI ≤0.5, and tender entheseal points (LEI) ≤1; **[b]** In patients who had baseline psoriasis affecting ≥3% BSA; **[c]** SJC ranges from 0–66.

ACR: American College of Rheumatology; **ACR20/50/70:** ≥20%/50%/70% improvement from baseline in American College of Rheumatology response criteria; **bDMARD:** biologic disease-modifying antirheumatic drug; **BKZ:** bimekizumab; **BSA:** body surface area; **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; **LEI:** Leeds Enthesitis Index; **MDA:** Minimal Disease Activity; **MoDA:** medium disease activity; **NRI:** non-responder imputation; **OC:** observed case; **PASI:** Psoriasis Area and Severity Index; **PASI75/90/100:** ≥75%/90%/100% improvement from baseline in Psoriasis Area and Severity Index; **PGA:** Patient's Global Assessment; **PsA:** psoriatic arthritis; **Q4W:** every 4 weeks; **REM:** remission; **SJC:** swollen joint count; **TJC:** tender joint count; **TNFi-IR:** tumor necrosis factor inhibitor inadequate response/intolerance; **VAS:** visual analog scale; **VLDA:** Very Low Disease Activity; **WCI:** worst-category imputation.

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References: [1]Boehncke WH. Am J Clin Dermatol 2013;14:377–88; [2]Mease PJ. Rheumatol Ther 2024;11:1363–82.
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