Bimekizumab Maintained Efficacy Responses Through 52 Weeks in Patients with Psoriatic Arthritis and Inadequate Response or Intolerance to TNF-α Inhibitors who were Responders at Week 16: Results from a Phase 3, Randomized Study

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Objective

To report maintenance of response in joint, skin, and composite efficacy outcomes to 1 year in bimekizumab (BKZ)-treated patients with psoriatic arthritis (PsA) and inadequate response or intolerance to TNF-α inhibitors (TNFi-IR) who were responders at Week 16 of the BE COMPLETE study.

Background

- PsA is a chronic disease affecting multiple domains; however, patients can experience loss of response with long-term therapy.[1] Maintaining long-term treatment responses in patients with prior TNFi-IR is of clinical interest.[2]
- BKZ, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, demonstrated rapid and clinically meaningful improvements in joint and skin efficacy outcomes that were sustained to Week 52.[3–6]

Methods

- BE COMPLETE (NCT03896581), a 16-week double-blind phase 3 study, included TNFi-IR patients with active PsA. Patients completing Week 16 were eligible to enter an open-label extension, BE VITAL (NCT04009499).
- Maintenance of response is reported as the percentage of BKZ-randomized Week 16 responders who met the response criteria at subsequent study visits for American College of Rheumatology (ACR)20/50/70, Psoriasis Area and Severity Index (PASI)75/90/100, minimal/very low disease activity (MDA/VLDA), Disease Activity Index for Psoriatic Arthritis (DAPSA) remission/low disease activity (REM+LDA; ≤14) and remission (REM; ≤4), and composite ACR50+PASI100 responses.
- Week 16 responders are reported using non-responder imputation (NRI). Week 52 maintenance data are reported as observed case (OC) and using NRI.
- Treatment-emergent adverse events (TEAEs) to Week 52 are reported for patients who received ≥1 dose of BKZ.

Results

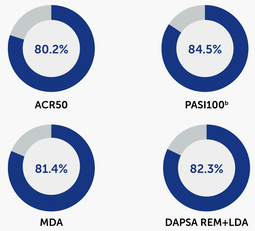
- Overall, 263 (98.5%) patients completed Week 16. Of those patients initially randomized to BKZ, 236/267 (88.4%) completed Week 52.
- Baseline demographics and disease characteristics are reported in **Table 1**.
- At Week 16, 116 (43.4%; NRI) BKZ-treated patients achieved ACR50. Of those responders, 80.2% (NRI) and 86.1% (OC) maintained ACR50 response at Week 52 (**Figure 1**). Similar results were seen across other ACR endpoints: ACR20/70 was achieved by 179 (67.0%) and 71 (26.6%) patients, respectively, at Week 16 (NRI). At Week 52, ACR20/70 was maintained by 81.6%/83.1% (NRI) and 89.6%/85.5% (OC) of patients.
- Of 176 patients with psoriasis affecting ≥3% body surface area (BSA) at baseline, 121 (68.8%) and 103 (58.5%) achieved PASI90/100 at Week 16. Robust maintenance of response was observed in high proportions (>84%) of these patients to Week 52 (**Figure 2**). 145 (82.4%) achieved PASI75; 88.3% maintained response to Week 52.
- A high proportion of Week 16 responders for MDA, DAPSA REM+LDA, and ACR50+PASI100 maintained their responses at Week 52 (**Figures 3–5**).
- Response was maintained to Week 52 for 66.7% (NRI) and 68.6% (OC) of patients that achieved VLDA at Week 16. 66.7% (NRI) of the 24 (9.0%) patients that achieved DAPSA REM at Week 16 maintained response to Week 52.
- To Week 52, 243/388 (62.6%) BKZ-treated patients reported ≥1 TEAE and 23 (5.9%) reported serious TEAEs.

Conclusions

Across all joint, skin, and composite outcomes assessed, bimekizumab demonstrated robust maintenance of response at Week 52 in TNFi-IR patients with PsA who responded to treatment at Week 16. The safety profile was consistent with previous reports.[2,3]

Summary

Maintenance of response, up to 52 weeks, was assessed in BKZ-treated patients who achieved a response at Week 16 of BE COMPLETE[a]



A **high proportion of TNFi-IR patients** who responded to BKZ treatment at Week 16 **maintained their response to Week 52** across multiple domains

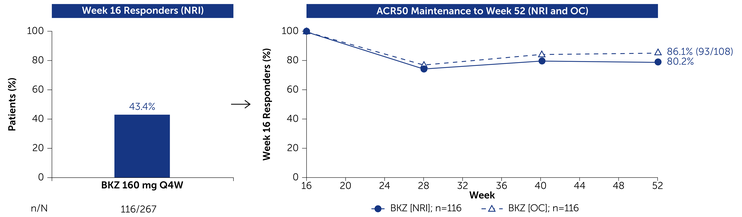
(a) Values shown here are NRI; (b) In patients with psoriasis affecting at least 3% BSA at baseline.

Table 1 Baseline patient demographics and disease characteristics for TNFi-IR patients

	BKZ 160 mg Q4W n=267
Age, years, mean (SD)	50.1 (12.4)
Male, n (%)	130 (48.7)
BMI, kg/m^2, mean (SD)	30.1 (6.5)
Time since first PsA diagnosis,[a] years, mean (SD)	9.6 (9.9)
Concomitant methotrexate, n (%)	119 (44.6)
BSA affected by psoriasis ≥3%, n (%)	176 (65.9)
PASI score,[b] mean (SD)	10.1 (9.1)
TJC (of 68 joints), mean (SD)	18.4 (13.6)
SJC (of 66 joints), mean (SD)	9.7 (7.5)
Enthesitis (LEI >0), n (%)	106 (39.7)
Score,[c] mean (SD)	2.6 (1.5)
Dactylitis (LDI >0), n (%)	34 (12.7)
Score,[d] mean (SD)	72.7 (114.4)
hs-CRP ≥6 mg/L, n (%)	118 (44.2)
HAQ-DI, mean (SD)	0.97 (0.59)
PtAAP,[e] mean (SD)	58.3 (24.2)

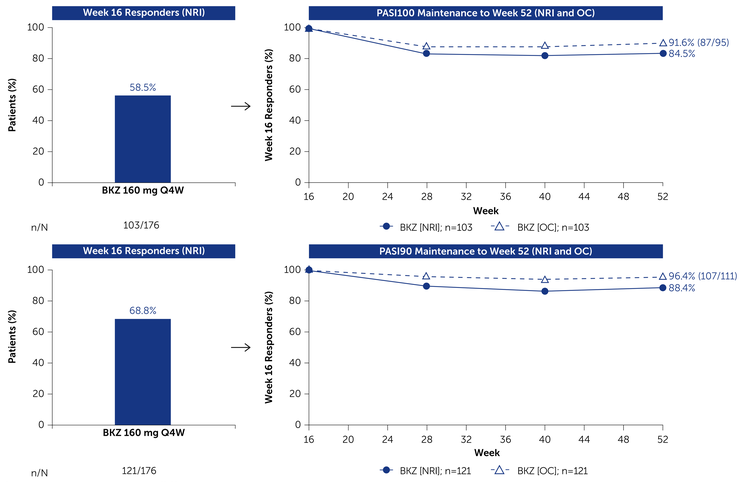
Randomized set. [a] Data missing for 1 patient; [b] In patients with psoriasis involving at least 3% of BSA at baseline; [c] In patients with enthesitis at baseline (LEI >0); [d] In patients with dactylitis at baseline (LDI >0); [e] PtAAP VAS 0 (no symptoms) to 100 (severe symptoms).

Figure 1 Maintenance of ACR50 responses for TNFi-IR patients to Week 52, in Week 16 responders (NRI, OC)



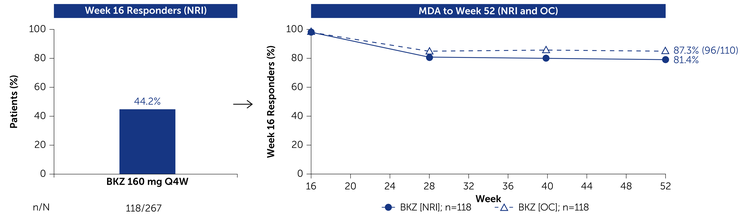
Randomized set.

Figure 2 Maintenance of PASI100 and PASI90 responses for TNFi-IR patients to Week 52, in Week 16 responders (NRI, OC)



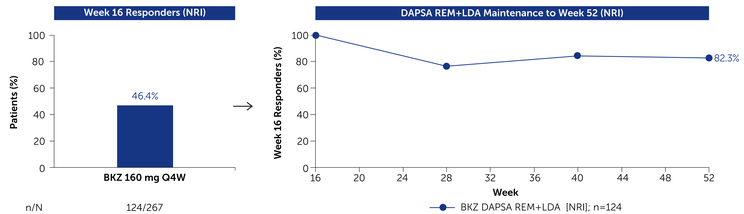
Randomized set. In patients with psoriasis affecting ≥3% BSA at baseline.

Figure 3 Maintenance of MDA for TNFi-IR patients to Week 52, in Week 16 responders (NRI, OC)



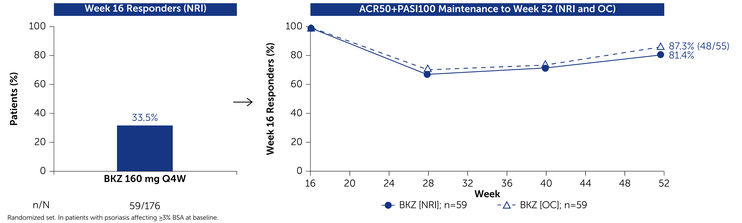
Randomized set. Patients are considered to achieve MDA when they meet 5/7 of the following criteria, respectively: TJC ≤1, SJC ≤1, PASI ≤1 or BSA ≤3%, patient pain (VAS ≤15 mm), patient global assessment (VAS ≤20), HAQ-DI ≤0.5, and tender entheseal points (LEI) ≤1.

Figure 4 Maintenance of DAPSA REM+LDA responses for TNFi-IR patients to Week 52, in Week 16 responders (NRI)



Randomized set. DAPSA score is the sum of SJC (range: 0–66), TJC (range: 0–68); patient pain (VAS 0–10), patient global assessment (VAS 0–10), and C-reactive protein (mg/L). DAPSA REM+LDA is defined as DAPSA total score ≤14; DAPSA REM is defined as DAPSA total score ≤4.

Figure 5 Maintenance of ACR50+PASI100 for TNFi-IR patients to Week 52, in Week 16 responders (NRI, OC)



Randomized set. In patients with psoriasis affecting ≥3% BSA at baseline.

ACR20/50/70: ≥20/50/70% improvements from baseline in American College of Rheumatology response criteria; **BKZ:** bimekizumab; **BMI:** body mass index; **BSA:** body surface area; **DAPSA:** Disease Activity in Psoriatic Arthritis; **HAQ-DI:** Health Assessment Questionnaire-Disability Index; **hs-CRP:** high-sensitivity C-reactive protein; **IL:** interleukin; **LDA:** low disease activity; **LDI:** Leeds Dactylitis Index; **LEI:** Leeds Enthesitis Index; **MDA:** minimal disease activity; **NRI:** non-responder imputation; **OC:** observed case; **PASI75/90/100:** ≥75/90/100% improvement from baseline in Psoriasis Area and Severity Index; **PsA:** psoriatic arthritis; **PtAAP:** Patient's Assessment of Arthritis Pain; **Q4W:** every 4 weeks; **REM:** remission; **SD:** standard deviation; **SJC:** swollen joint count; **TEAE:** treatment-emergent adverse events; **TJC:** tender joint count; **TNFi-IR:** inadequate response/intolerance to tumor necrosis factor-α inhibitors; **VAS:** visual analog scale; **VLDA:** very low disease activity.

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Acknowledgments: We would like to thank the patients and their caregivers in addition to all the investigators and their teams who contributed to this study. The authors acknowledge Heather Edens, PhD, UCB Pharma, Smyrna, Georgia, USA, for publication coordination, Eve Sullivan, MSc, Costello Medical, London, UK and David Morgan, PhD, Costello Medical, Manchester, UK for medical writing and editorial assistance, and the Costello Medical Creative team for design support. This study was funded by UCB Pharma. All costs associated with development of this presentation were funded by UCB Pharma.

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