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

William R. Tillett,[1,2] Joseph F. Merola,[3] Yoshiya Tanaka,[4] Ennio G. Favalli,[5] Dennis McGonagle,[6] Diamant Thaçi,[7] Jessica A. Walsh,[8] Barbara Ink,[9] Rajan Bajracharya,[9] Jason Coarse,[10] Christopher T. Ritchlin[11]

Presented by: Jeffrey Stark[12]

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 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

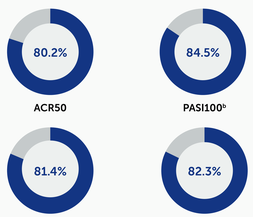
- Overall, 263 (98.5%) patients completed Week 16. Of those patients initially randomized to BKZ, 236/267 (88.4%) completed Week 52.
- Baseline demographics and disease characteristics are reported in **Table 1**.
- At Week 16, 116 (43.4%; NRI) BKZ-treated patients achieved ACR50. Of those responders, 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 (>84.0%) 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.[3,4]

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

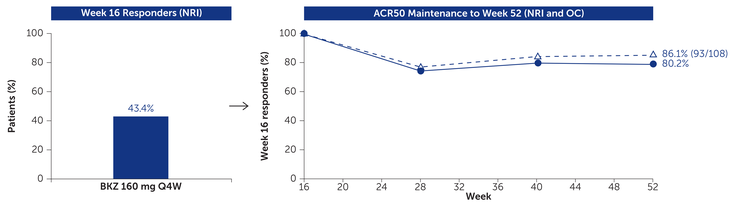
[a] Values shown here are NRI; [b] In patients with psoriasis affecting at least 3% BSA at baseline.

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/m², 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 (13.5)
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)

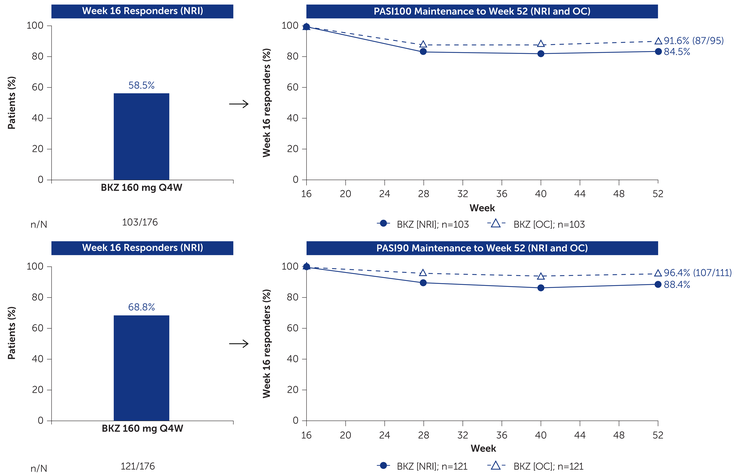
Randomized set. [a] Data missing for 1 patient; [b] In patients with psoriasis involving at least 3% of BSA at baseline; [c] In patients with enthesitis at baseline (LEI >0); [d] In patients with dactylitis at baseline (LDI >0); [e] PtAAP VAS 0 (no symptoms) to 100 (severe symptoms).

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



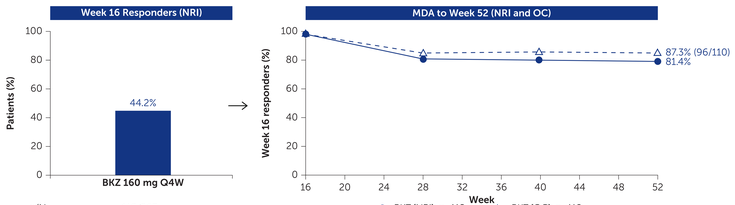
Randomized set.

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



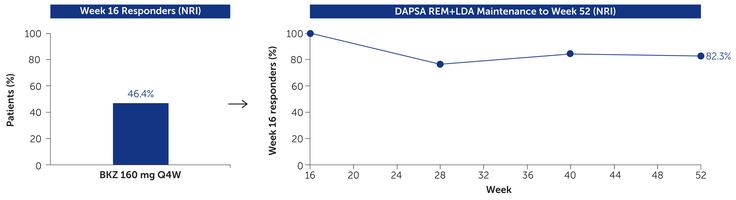
Randomized set. In patients with psoriasis affecting ≥3% BSA at baseline.

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



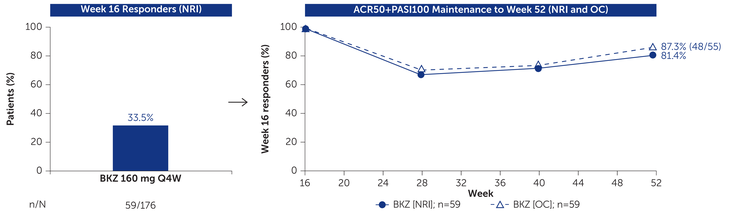
Randomized set. Patients are considered to achieve MDA when they meet 5/7 of the following criteria, respectively: TJC ≤1, SJC ≤1, PASI ≤1 or BSA ≤3%, patient pain (VAS ≤15), patient global assessment (VAS ≤20), HAQ-DI ≤0.5, and tender entheseal points (LEI) ≤1.

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.

Institutions: [1]Royal National Hospital of Rheumatic Diseases, Bath, UK; [2]Department of Life Sciences, Centre for Therapeutic Innovation, University of Bath, Bath, UK; [3]Department of Dermatology and Department of Medicine, Division of Rheumatology, UT Southwestern Medical Center, Dallas, TX, USA; [4]The First Department of Internal Medicine, University of Occupational and Environmental Health, Japan, Kitakyushu, Fukuoka, Japan; [5]Department of Rheumatology, ASST Gaetano Pini-CTO, University of Milan, Milan, Italy; [6]Academic Unit for the Musculoskeletal Diseases, Leeds Teaching Hospitals NHS Trust, Leeds, UK; [7]Institute and Comprehensive Center for Inflammation Medicine, University of Lübeck, Lübeck, Germany; [8]Division of Rheumatology, Salt Lake City Veterans Affairs Health and University of Utah Health, Salt Lake City, UT, USA; [9]UCB Pharma, Slough, UK; [10]UCB Pharma, Morrisville, NC, USA; [11]Allergy, Immunology & Rheumatology Division, University of Rochester Medical School, Rochester, NY, USA; [12]UCB Pharma, Smyrna, GA, USA.

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