Bimekizumab Maintained Efficacy Responses Through 52 Weeks in Patients with Active Psoriatic Arthritis: Results from Two Phase 3 Studies

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Objective

To report the proportion of Week 16 responders maintaining their response at Week 52 and patients who demonstrated no loss of response (i.e. maintained their response at all visits) to Week 52, for joint and skin efficacy outcomes in bimekizumab (BKZ)-treated patients with active psoriatic arthritis (PsA) who were biologic disease-modifying antirheumatic drug (bDMARD)-naïve or had prior inadequate response or intolerance to tumour necrosis factor inhibitors (TNFi-IR).

Background

- BKZ, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, achieved significantly greater improvements in efficacy outcomes at Week 16, that were sustained to Week 52, in patients with PsA in two phase 3 studies.[1–4]
- Given the chronic, long term nature of PsA, sustaining high levels of disease control with treatment is important.

Methods

- BE OPTIMAL (NCT03895203) and BE COMPLETE (NCT03896581) assessed subcutaneous BKZ 160 mg every 4 weeks (Q4W) in patients with active PsA.
- Maintenance of response is reported here, defined as the proportion of Week 52 responders among Week 16 responders. Among Week 16 responders, no loss of response is defined as patients who achieved a response at all subsequent visits to Week 52.
- Data reported for patients randomised to BKZ at baseline, using non-responder imputation (NRI): ≥20/50/70% improvement from baseline in American College of Rheumatology response criteria (ACR20/50/70) and ≥75/90/100% improvement from baseline in Psoriasis Area and Severity Index (PASI75/90/100).
- Number of visits after Week 16 varied by study and outcome (7 for ACR and 4 for PASI in BE OPTIMAL; 3 for ACR and PASI in BE COMPLETE; **Figure 1**); data for no loss of response may appear higher for outcomes with fewer visits.

Results

- Of the patients randomised to BKZ, 388/431 (90.0%) bDMARD-naïve and 236/267 (88.4%) TNFi-IR patients completed Week 52.
- At Week 16, ACR50 and ACR70 were achieved by 189 (43.9%) and 105 (24.4%) bDMARD-naïve patients; 116 (43.4%) and 71 (26.6%) TNFi-IR patients. A high proportion of Week 16 responders maintained their response at Week 52 (**Figure 2**).
- The proportions of Week 16 ACR50 and ACR70 responders that did not lose response at any visit to Week 52 were 110 (58.2%) and 51 (48.6%) bDMARD-naïve patients, and 74 (63.8%) and 41 (57.7%) TNFi-IR patients, respectively (**Figure 2**).
  - Of the Week 16 ACR50 responders, 33 (17.5%), 13 (6.9%) and 33 (17.5%) bDMARD-naïve patients, and 23 (19.8%), 6 (5.2%) and 13 (11.2%) TNFi-IR patients, lost response at 1 visit, 2 visits or >2 visits through to Week 52.
- Of the 217 bDMARD-naïve and 176 TNFi-IR patients with baseline psoriasis affecting ≥3% body surface area, PASI90 and PASI100 were achieved at Week 16 by 133 (61.3%) and 103 (47.5%) bDMARD-naïve; 121 (68.8%) and 103 (58.5%) TNFi-IR patients. A high proportion of Week 16 responders maintained their response at Week 52 (**Figure 3**).
- The proportions of Week 16 PASI90 and PASI100 responders that never lost response at any visit to Week 52 were 97 (72.9%) and 63 (61.2%) bDMARD-naïve patients, and 96 (79.3%) and 76 (73.8%) TNFi-IR patients, respectively (**Figure 3**).
  - Of the Week 16 PASI90 responders, 17 (12.8%), 11 (8.3%) and 8 (6.0%) bDMARD-naïve patients, and 15 (12.4%), 4 (3.3%) and 6 (5.0%) TNFi-IR patients, lost response at 1 visit, 2 visits or >2 visits through to Week 52.

Conclusions

With bimekizumab treatment, high proportions of Week 16 responders maintained robust efficacy responses at Week 52 or did not lose response at any time point to Week 52 across joint and skin outcomes, demonstrating durable improvement irrespective of prior TNFi use.

Summary

Maintenance of response at **Week 52** was assessed in **bimekizumab-treated** patients who achieved a response at **Week 16** of **BE OPTIMAL (bDMARD-naïve)** and **BE COMPLETE (TNFi-IR)**.

Most patients who responded to treatment with bimekizumab at Week 16 **maintained their response** at Week 52 across joint and skin outcomes[a,b]

ACR50

80.2–86.8% patients maintained ACR50 at Week 52

PASI100[c]

79.6–84.5% patients maintained PASI100[c] at Week 52

A **high proportion of patients** who responded at Week 16 **never lost response at any visit** to Week 52[a,b]

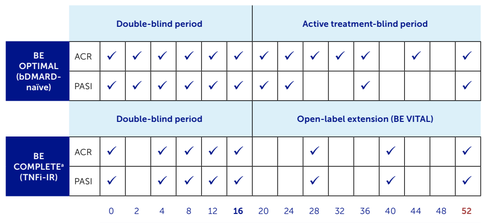
58.2–63.8% patients maintained ACR50 or greater at all visits to Week 52

61.2–73.8% patients maintained PASI100[c] at all visits to Week 52

With bimekizumab treatment, **most** Week 16 responders **maintained their response** through Week 52 across **joint** and **skin** outcomes.

[a] Values shown here are NRI; [b] Data are reported for bimekizumab-randomised patients, ranges indicate proportions in bDMARD-naïve and TNFi-IR populations; [c] In patients with psoriasis affecting ≥3% body surface area at baseline.

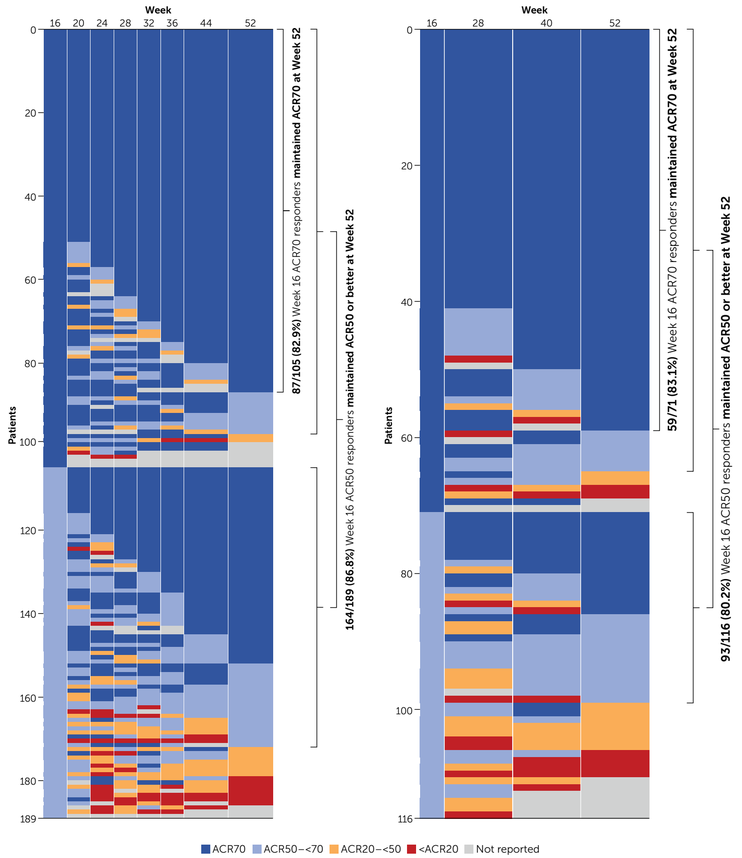
Figure 1 Schedule of ACR and PASI assessments



✓ Study visit at which endpoint was assessed

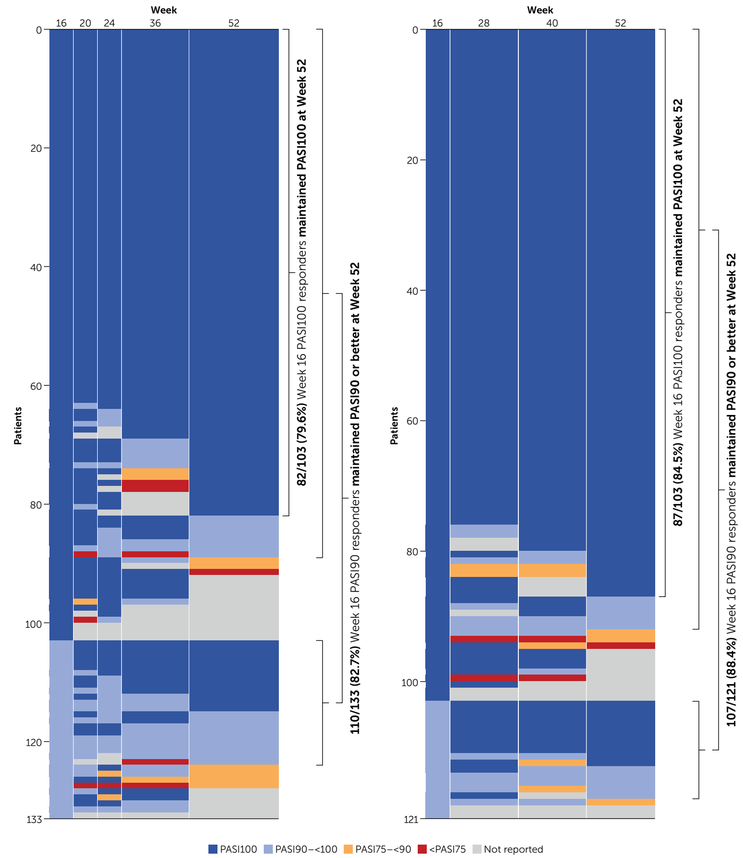
In BE OPTIMAL, patients were randomised 3:2:1 to BKZ 160 mg Q4W:PBO:reference arm (adalimumab 40 mg Q2W). In BE COMPLETE, patients were randomised 2:1 to BKZ 160 mg Q4W:PBO. In both studies, patients on PBO switched to BKZ 160 mg Q4W at Week 16.
In BE OPTIMAL, the adalimumab 40 mg Q2W treatment arm served as an active reference; the BE OPTIMAL study was not powered for statistical comparisons of adalimumab to BKZ or PBO. In both studies, ACR50 at Week 16 was the primary endpoint. Results reported here are for patients receiving BKZ from baseline in both studies. [a] Patients who completed Week 16 of BE COMPLETE were eligible to enrol in the open-label extension BE VITAL (NCT04009499).[4]

Figure 2 ACR responses up to Week 52, in Week 16 ACR50 responders (NRI)



Randomised set. BKZ-randomised patients who achieved ACR50 or ACR70 responses at Week 16.

Figure 3 PASI responses up to Week 52, in Week 16 PASI90 responders (NRI)



Randomised set. BKZ-randomised patients with psoriasis affecting ≥3% body surface area at baseline who achieved PASI90 or PASI100 responses at Week 16.

ACR20/50/70: ≥20/50/70% improvement from baseline in American College of Rheumatology response criteria; **bDMARD:** biologic disease-modifying antirheumatic drug; **BKZ:** bimekizumab; **IL:** interleukin; **NRI:** non-responder imputation; **OLE:** open-label extension; **PASI75/90/100:** ≥75/90/100% improvement from baseline in Psoriasis Area and Severity Index; **PBO:** placebo; **PsA:** psoriatic arthritis; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks; **TNFi-IR:** prior inadequate response or intolerance to tumour necrosis factor inhibitors.

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