Bimekizumab Maintained Stringent Clinical Responses Over 2 Years in Patients with Axial Spondyloarthritis: Results from Two Phase 3 Studies

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Objective

To assess the maintenance of stringent clinical responses to bimekizumab (BKZ) over 2 years in patients across the full disease spectrum of axial spondyloarthritis (axSpA).

Background

- AxSpA is a chronic, inflammatory disease mainly affecting the sacroiliac joints and spine.[1] Optimal management and disease control is required to prevent irreversible damage caused by disease progression.[2,3]
- Assessment of SpondyloArthritis international Society ≥40% improvement (ASAS40) and ASAS partial remission (ASAS PR) are stringent outcomes in trials, while in clinical practice the focus is on sustained remission (inactive disease [ID]) or low disease activity (LDA) according to axSpA Disease Activity Score (ASDAS; <1.3 and <2.1, respectively).
- Maintenance of response is an internationally recommended target for patient care.[2]
- BKZ is a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A. It has demonstrated sustained clinical efficacy to 2 years in patients across the full disease spectrum of axSpA in the phase 3 studies BE MOBILE 1 and 2, and their open-label extension (OLE), BE MOVING.[4]
  - Here, we report maintenance of response to BKZ over 2 years in these studies.

Methods

- The study designs of BE MOBILE 1 (non-radiographic axSpA [nr-axSpA]; NCT03928704) and BE MOBILE 2 (radiographic axSpA [r-axSpA]; NCT03928743) have been reported previously.[5]
- Patients were randomized to receive subcutaneous BKZ 160 mg every 4 weeks (Q4W) or placebo (PBO). From Week 16 to Week 52, all patients received BKZ. Eligible patients could then be enrolled into the ongoing OLE (NCT04436640).
- The proportions of patients achieving ASAS40, ASAS PR, ASDAS LDA (<2.1), and ASDAS ID (<1.3) to Week 104 were assessed among BKZ-randomized patients who achieved each respective outcome at Week 16 and were pooled across studies.
- To assess the validity of the results, presented data use three different imputation methods: non-responder imputation (NRI), multiple imputation (MI), and worst category imputation (WCI; ASDAS only). Observed case (OC) data are also reported.
- Treatment-emergent adverse events (TEAEs) to Week 104 are reported for patients who received ≥1 BKZ dose, including patients who switched from PBO to BKZ at Week 16.

Results

- A total of 128 and 221 patients were randomized to BKZ in BE MOBILE 1 and 2, respectively (N=349).
  - Among Week 16 ASAS40 responders, 85.7% maintained this response at Week 104 (MI; **Figure 1**). Similarly, of patients who achieved ASAS PR at Week 16, 76.8% also achieved this outcome at Week 104 (MI; **Figure 2**).
  - Of patients who achieved ASDAS LDA at Week 16, 89.3% also achieved this outcome at Week 104 (MI; **Figure 3**). Among patients who achieved ASDAS ID at Week 16, 76.0% achieved this outcome at Week 104 (MI; **Figure 4**).
  - Results were generally similar across all imputation methods reported.
  - Through Week 104, 514/574 (exposure-adjusted incidence rate per 100 patient-years [EAIR/100 PY]: 141.9) patients had ≥1 TEAE whilst receiving BKZ; 72 (5.4) had serious TEAEs. 39 (2.8) patients discontinued BKZ due to TEAEs (**Table**).

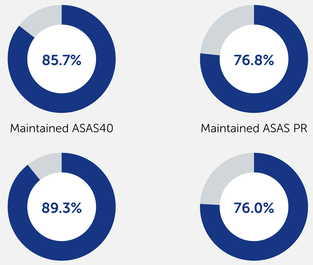
Conclusions

Bimekizumab maintained stringent clinical responses from Week 16 to Week 104 across the full disease spectrum of axSpA, with no new safety signals observed. These findings suggest bimekizumab may provide a valuable long-term treatment option for achieving and maintaining treatment targets in axSpA.

Summary

This analysis examined the **maintenance of stringent clinical responses** through 2 years of treatment with **bimekizumab** in patients with nr-axSpA and r-axSpA, pooled across two phase 3 trials and their open-label extension

Among patients who achieved efficacy outcomes at Week 16, maintenance of each respective outcome at Week 104 was:



Bimekizumab provided **robust maintenance of stringent clinical responses**, including **low levels of disease activity**, from Week 16 to Week 104 across the full disease spectrum of axSpA

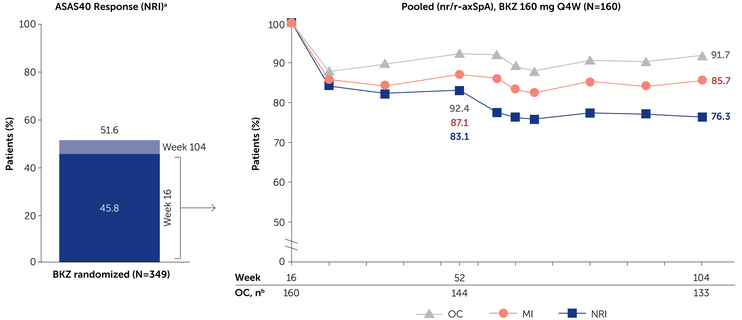
Missing data imputed using MI.

Table Summary of TEAEs reported up to Week 104

n (%) [EAIR/100 PY]	Any BKZ 160 mg Q4W (N=574; 1,430 PY)
Any TEAE	514 (89.5) [141.9]
Severe TEAEs	46 (8.0) [3.4]
TEAEs leading to study discontinuation	34 (5.9) [2.4]
TEAEs leading to BKZ discontinuation	39 (6.8) [2.8]
Drug-related TEAEs	283 (49.3) [30.7]
Serious TEAEs	72 (12.5) [5.4]
TEAEs leading to death	0

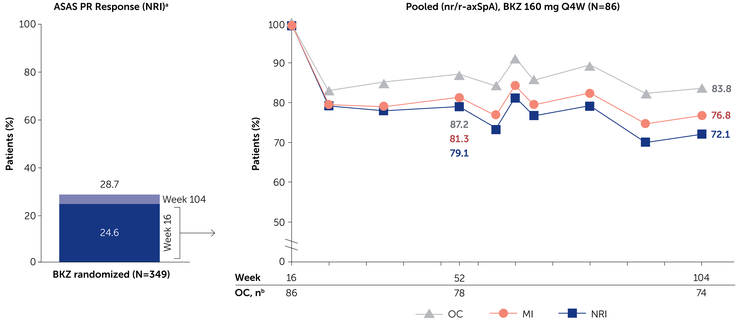
Data to the most recent data-cut (July 2023) shown, including all patients who received ≥1 dose of BKZ 160 mg Q4W in the phase 3 studies and their ongoing OLE.

Figure 1 Maintenance of ASAS40 to Week 104 among patients who achieved ASAS40 at Week 16 (OC, MI, NRI)



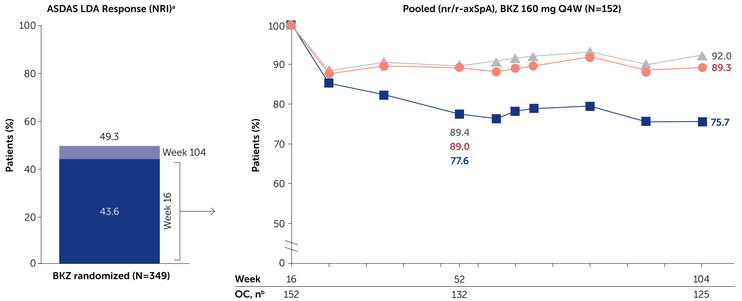
[a] Response at Week 16 and Week 104 in patients randomized to BKZ 160 mg Q4W at baseline; [b] n represents the total number of patients with a non-missing assessment for ASAS40 at the given week.

Figure 2 Maintenance of ASAS PR to Week 104 among patients who achieved ASAS PR at Week 16 (OC, MI, NRI)



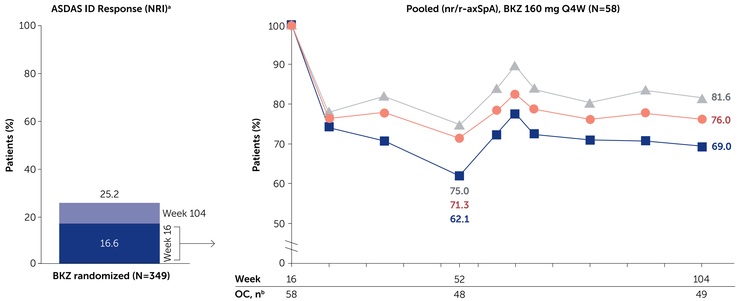
[a] Response at Week 16 and Week 104 in patients randomized to BKZ 160 mg Q4W at baseline; [b] n represents the total number of patients with a non-missing assessment for ASAS PR at the given week.

Figure 3 Maintenance of ASDAS LDA to Week 104 among patients who achieved ASDAS LDA at Week 16 (OC, MI, WCI)



[a] Response at Week 16 and Week 104 in patients randomized to BKZ 160 mg Q4W at baseline; [b] n represents the total number of patients with a non-missing assessment for ASDAS LDA at the given week; [c] For WCI, missing data were assigned to the worst ASDAS state possible (i.e., very high disease activity; ASDAS >3.5).

Figure 4 Maintenance of ASDAS ID to Week 104 among patients who achieved ASDAS ID at Week 16 (OC, MI, WCI)



[a] Response at Week 16 and Week 104 in patients randomized to BKZ 160 mg Q4W at baseline; [b] n represents the total number of patients with a non-missing assessment for ASDAS ID at the given week; [c] For WCI, missing data were assigned to the worst ASDAS state possible (i.e., very high disease activity; ASDAS >3.5).

ASAS40: Assessment of SpondyloArthritis international Society ≥40% improvement; **ASAS PR:** ASAS partial remission; **ASDAS:** Axial Spondyloarthritis Disease Activity Score; **axSpA:** axial spondyloarthritis; **BKZ:** bimekizumab; **EAIR:** exposure-adjusted incidence rate; **ID:** inactive disease (<1.3); **IL:** interleukin; **LDA:** low disease activity (<2.1); **MI:** multiple imputation; **nr-axSpA:** non-radiographic axSpA; **NRI:** non-responder imputation; **OC:** observed case; **OLE:** open-label extension; **PBO:** placebo; **PY:** patient-years; **Q4W:** every 4 weeks; **r-axSpA:** radiographic axSpA; **TEAE:** treatment-emergent adverse event; **WCI:** worst category imputation.

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