Bimekizumab Maintained Stringent Clinical Responses Through Week 52 in Patients with Axial Spondyloarthritis: Results from the Phase 3 Studies BE MOBILE 1 and BE MOBILE 2

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Objective

To report the maintenance of stringent clinical responses through one year of treatment with bimekizumab in patients with non-radiographic axial spondyloarthritis and radiographic axial spondyloarthritis (i.e., ankylosing spondylitis)[1] in two phase 3 studies.

Background

- Axial spondyloarthritis (axSpA) is a chronic rheumatic disease which requires optimal management and disease control.
- Long-term maintenance of response is an internationally recommended treatment target.[2]
- Bimekizumab (BKZ) is a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A. BKZ has demonstrated consistent and sustained clinical efficacy to Week 52 in patients across the full disease spectrum of axSpA in the phase 3 studies BE MOBILE 1 and 2.[3]

Methods

- In BE MOBILE 1 (NCT03928704; non-radiographic-axSpA [nr-axSpA]) and BE MOBILE 2 (NCT03928743; radiographic axSpA [r-axSpA]), patients were randomised to receive subcutaneous BKZ 160 mg every 4 weeks (Q4W) or placebo to Week 16. From Weeks 16–52, all patients received BKZ 160 mg Q4W.[4,5]
- Maintenance of Assessment of SpondyloArthritis international Society 40% (ASAS40) response, ASAS partial remission (PR) response, and Ankylosing Spondylitis Disease Activity Score (ASDAS) <2.1 (low disease activity [LDA]) or <1.3 (inactive disease [ID]) to Week 52 were assessed among BKZ-randomised patients who responded/achieved those levels at Week 16.
- Non-responder imputation (NRI) and multiple imputation (MI) were used for missing ASAS and ASDAS data. Observed case (OC) data are also reported. Week 16 and 52 responder rates for all BKZ-randomised patients are included for context (NRI or MI).
- The number of treatment-emergent adverse events (TEAEs) to Week 52 are reported for patients who received ≥1 dose of BKZ, including patients who switched from placebo to BKZ at Week 16.

Results

- A total of 128 and 221 patients were randomised to BKZ 160 mg Q4W in BE MOBILE 1 and 2, respectively, with 112 (87.5%) and 196 (88.7%) patients completing the studies to Week 52.
  - Of BKZ-randomised patients in BE MOBILE 1 and 2 that achieved ASAS40 at Week 16, 82.0% and 83.8% maintained this response at Week 52 (NRI, **Figure 1**). Similarly, of patients that achieved ASAS PR at Week 16, the majority maintained this response at Week 52 (**Figure 2**).
  - Of patients that achieved ASDAS LDA at Week 16, 88.9% and 88.4% maintained this response at Week 52 (MI, **Figure 3**). Among Week 16 ASDAS ID responders, this was maintained by 88.0% and 58.7% at Week 52 (MI, **Figure 4**).
- To Week 52 of BE MOBILE 1 and 2, 183/244 (75.0%) and 249/330 (75.5%) patients reported ≥1 TEAE whilst receiving BKZ, respectively; 9 (3.7%) and 20 (6.1%) reported serious TEAEs.

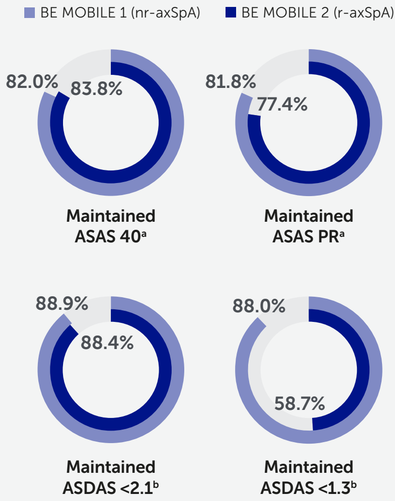
Conclusions

Bimekizumab provided robust maintenance of stringent clinical responses and low levels of disease activity from Week 16 to Week 52 across the full disease spectrum of axSpA. This is consistent with previously reported observations of bimekizumab treatment over three years in patients with r-axSpA in the phase 2b study BE AGILE and its open-label extension.[6]

Summary

This analysis examined the maintenance of stringent clinical responses through one year of treatment with bimekizumab in patients with nr-axSpA and r-axSpA in BE MOBILE 1 and 2

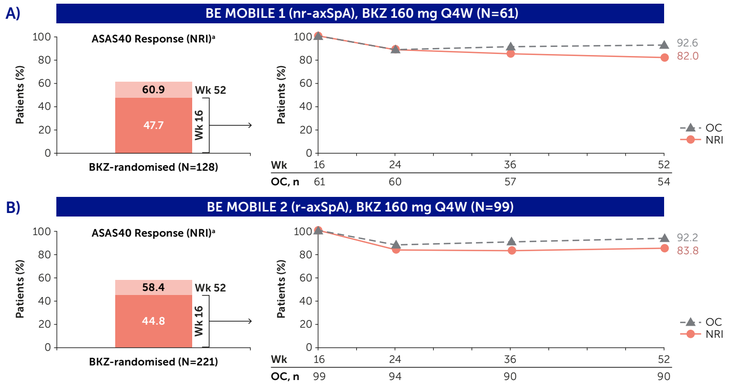
In Week 16 responders, maintenance of efficacy outcomes at Week 52 were:



Bimekizumab provided **robust maintenance of stringent clinical responses and low levels of disease activity** from Week 16 to Week 52 across the full disease spectrum of axSpA

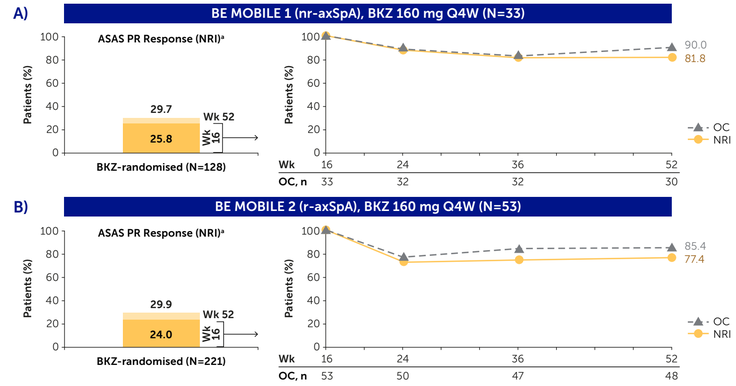
[a]Missing data were imputed using NRI. [b]Missing data were imputed using MI.

Figure 1 Maintenance of ASAS40 response from Week 16 to Week 52 (NRI and OC)



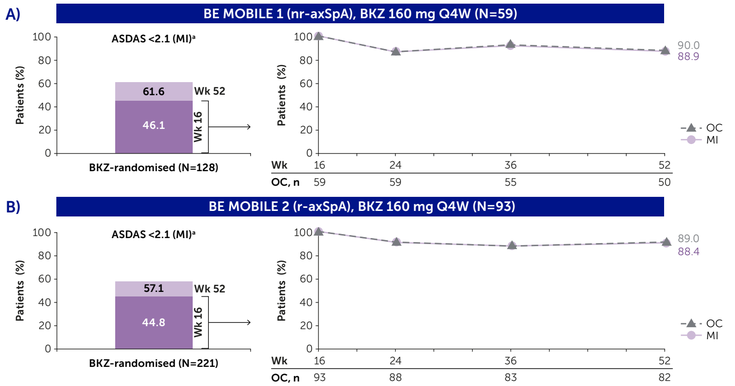
[a]Response at Week 16 and Week 52 in patients randomised to BKZ 160 mg Q4W at baseline.

Figure 2 Maintenance of ASAS PR response from Week 16 to Week 52 (NRI and OC)



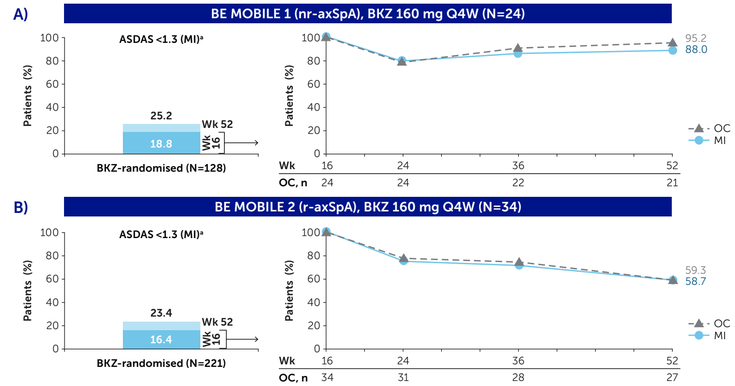
[a]Response at Week 16 and Week 52 in patients randomised to BKZ 160 mg Q4W at baseline.

Figure 3 Maintenance of ASDAS LDA (<2.1) from Week 16 to Week 52 (MI and OC)



[a]Response at Week 16 and Week 52 in patients randomised to BKZ 160 mg Q4W at baseline.

Figure 4 Maintenance of ASDAS ID (<1.3) from Week 16 to Week 52 (MI and OC)



[a]Response at Week 16 and Week 52 in patients randomised to BKZ 160 mg Q4W at baseline.

ASAS40: Assessment of SpondyloArthritis international Society 40%; **ASAS PR:** Assessment of SpondyloArthritis international Society partial remission; **ASDAS <2.1:** Ankylosing Spondylitis Disease Activity Score <2.1; **axSpA:** axial spondyloarthritis; **BKZ:** bimekizumab; **IL:** interleukin; **ID:** inactive disease; **LDA:** low disease activity; **MI:** multiple imputation; **nr-axSpA:** non-radiographic axSpA; **NRI:** non-responder imputation; **OC:** observed case; **Q4W:** every four weeks; **r-axSpA:** radiographic axSpA; **TEAE:** treatment-emergent adverse event; **Wk:** week.

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