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Sustained Improvements with Bimekizumab in Patient-Reported Symptoms of Axial Spondyloarthritis: 2-Year Results from Two Phase 3 Studies

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Objective

To assess the impact of bimekizumab (BKZ) on spinal pain, morning stiffness, and fatigue over 2 years in patients across the full disease spectrum of axial spondyloarthritis (axSpA).

Background

- Spinal pain, morning stiffness and fatigue are major contributors to disease burden in patients with axSpA.[1]
- BKZ is a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.
- BKZ demonstrated sustained efficacy and was well tolerated across the full disease spectrum of axSpA up to 2 years in the phase 3 studies, BE MOBILE 1 and 2, and their combined open-label extension (OLE) study, BE MOVING.[2,3]
- As previously reported, BKZ treatment also led to sustained improvements in spinal pain, morning stiffness and fatigue to Week 52.[4] Here we report data to 2 years.

Methods

- BE MOBILE 1 (NCT03928704) and 2 (NCT03928743) both comprised a 16-week double-blind period followed by a 36-week maintenance period.
- At Week 52, all patients who completed either study without meeting any withdrawal criteria were eligible to be enrolled into the OLE, BE MOVING (NCT04436640).
- We report pooled data to Week 104 across all patients with non-radiographic (nr-) axSpA and radiographic (r-) axSpA randomized in BE MOBILE 1 and 2 (N=586).
  - Mean scores are presented for total and nocturnal spinal pain, morning stiffness (mean of Bath Ankylosing Spondylitis Disease Activity Index [BASDAI] questions [Q]5 and Q6) and fatigue (BASDAI Q1 and Functional Assessment of Chronic Illness Therapy [FACIT]-Fatigue scores) using multiple imputation (MI).
  - The proportion of patients achieving thresholds for low total and nocturnal spinal pain (<4 or <2) or FACIT-Fatigue response (≥8-point increase from baseline) are reported using non-responder imputation (NRI) and observed case (OC).
  - We also report the distribution of patients across severity levels of BASDAI Q1 (using severity thresholds derived in a recent psychometric analysis[5]) using MI data.

Results

Patients

- Of the randomized patients in BE MOBILE 1 and 2, 208/254 (81.9%) patients with nr-axSpA and 286/332 (86.1%) patients with r-axSpA entered BE MOVING at Week 52.
  - 189/208 (90.9%) patients with nr-axSpA and 267/286 (93.4%) patients with r-axSpA completed Week 104.
- Baseline symptoms were similar between patients randomized to BKZ from baseline to Week 104 and those switched from placebo to BKZ at Week 16 (**Figure 1–3**).

Spinal Pain and Morning Stiffness

- Improvements from baseline to Week 52,[4] were sustained to Week 104 for total spinal pain, nocturnal spinal pain (**Figure 1A–B**) and morning stiffness scores (**Figure 2**).
- At Week 104, 53.9% and 57.3% of patients achieved total and nocturnal spinal pain scores <4, and 29.7% and 37.7% achieved total and nocturnal spinal pain scores <2, respectively (**Figure 1C–D**).

Fatigue

- Improvements from baseline to Week 52 in fatigue were sustained to Week 104, as measured by FACIT-Fatigue (**Figure 3A**).
- More than 50% of patients were considered FACIT-Fatigue responders at Week 52 and Week 104 (**Figure 3B**).
- According to BASDAI Q1, >50% of patients had severe fatigue at baseline but by Week 52 most patients (56.7%) were considered to have no more than mild fatigue. This proportion increased to 64.7% at Week 104 (**Figure 4**).

Although the data presented are pooled for all patients, results were similar across patients with nr-axSpA and r-axSpA.

Conclusions

Results from 2 years of treatment with bimekizumab demonstrated sustained improvements in spinal pain, morning stiffness, and fatigue across the full disease spectrum of axSpA. These long-term benefits in clinically important, patient-reported symptoms underscore the potential of bimekizumab to substantially improve patients' daily lives.

Summary

In patients across the full disease spectrum of axial spondyloarthritis, bimekizumab treatment resulted in sustained improvements over two years in spinal pain, morning stiffness and fatigue

Over half of patients (NRI) achieved thresholds for:

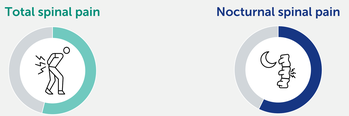
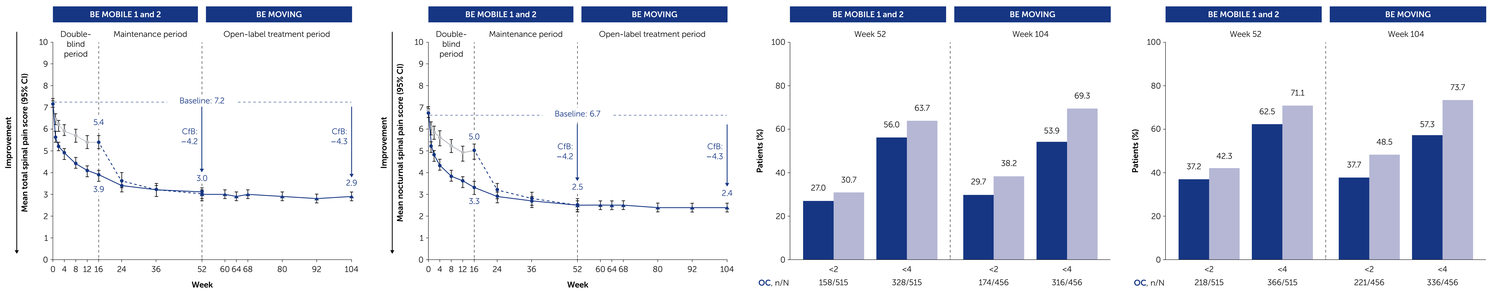
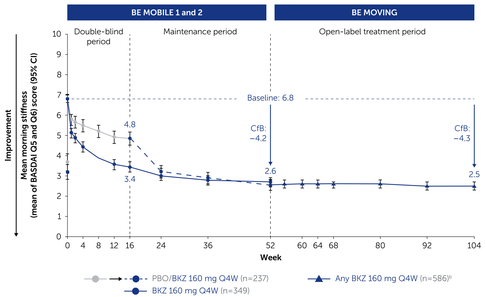


Figure 1 Mean score and change from baseline in spinal pain, and proportion of patients achieving spinal pain scores <2 or <4



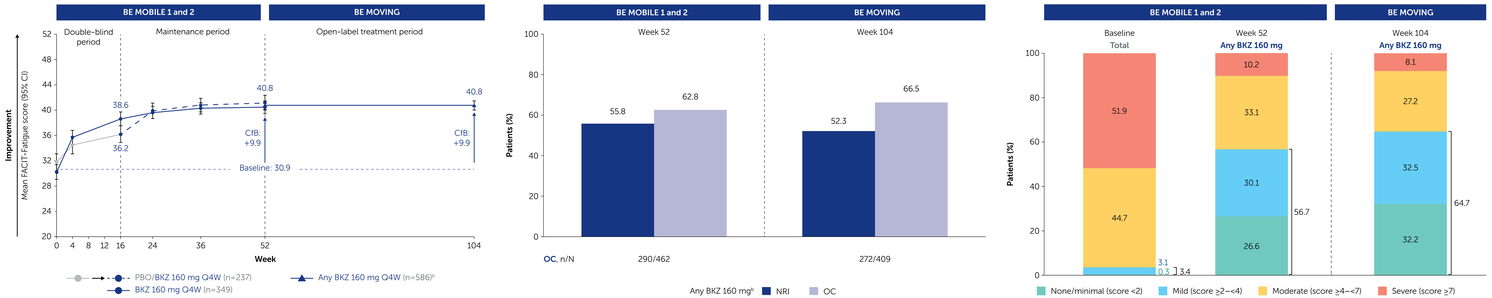
Pooled randomized set (N=586). Baseline scores are from Week 0 of feeder study. Error bars represent 95% CI. Total score range: 0–10. Improvement indicated by reduced scores. Thresholds for low spinal pain scores were defined as follows: scores <2, indicating minimal (score=1) or no (score=0) spinal pain; scores <4, based on the BE MOBILE 1 and 2 study inclusion criteria of spinal pain ≥4 according to BASDAI Q2. **[a]** Study participants with missing data at the given timepoint preceded by an intercurrent event are imputed using MI. **[b]** Includes patients originally randomized to placebo in BE MOBILE 1 or 2.

Figure 2 Mean score and change from baseline in morning stiffness to Week 104 (MI)[a]



Pooled randomized set (N=586). BE MOBILE 1 and 2 included patients with BASDAI total score ≥4. Morning stiffness assessed as the mean of BASDAI Q5 and Q6 scores (total score range: 0–10). Improvement indicated by reduced scores. **[a]** Study participants with missing data at the given timepoint which are preceded by an intercurrent event are imputed using MI. **[b]** Includes patients originally randomized to placebo in BE MOBILE 1 or 2.

Figure 3 Mean score and change from baseline in FACIT-Fatigue, and proportion of FACIT-Fatigue responders (≥8-point increase from baseline) to Week 104



Pooled randomized set (N=586). For NRI data, patients not entering BE MOVING were imputed as non-responders. Improvement indicated by increased scores (score range 0–52). **[a]** Study participants with missing data at the given timepoint which are preceded by an intercurrent event are imputed using MI. **[b]** Includes patients originally randomized to placebo in BE MOBILE 1 or 2. **[c]** ≥8-point increase from baseline in patients with FACIT-Fatigue score ≤44 at baseline (N=520).

Figure 4 Proportion of patients achieving thresholds for BASDAI Q1 severity bands to Week 104 (MI)

Pooled randomized set (N=586), includes patients originally randomized to placebo in BE MOBILE 1 or 2. BASDAI Q1 score range: 0–10 (improvement indicated by decrease in score).

axSpA: axial spondyloarthritis; **BASDAI:** Bath Ankylosing Spondylitis Disease Activity Index; **BKZ:** bimekizumab; **CI:** confidence interval; **CfB:** change from baseline; **FACIT:** Functional Assessment of Chronic Illness Therapy; **IL:** interleukin; **MI:** multiple imputation; **NRI:** non-responder imputation; **nr-axSpA:** non-radiographic axSpA; **OC:** observed case; **OLE:** open-label extension; **PBO:** placebo; **Q4W:** every 4 weeks; **r-axSpA:** radiographic axSpA.

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