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 (**Supplementary Figure 1**: QR code).
- 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 patients with non-radiographic (nr-)axSpA and radiographic (r-)axSpA from BE MOBILE 1 and 2.
  - 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).
  - We also report the proportion of patients achieving thresholds indicating low levels of severity in these key symptoms using non-responder imputation (NRI); patients enrolled in BE MOBILE 1 or 2 who did not enter BE MOVING were imputed as non-responders) and observed case (OC).

Results

Patients

- Of the randomised 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.
  - By July 2023, 189/208 (90.9%) patients with nr-axSpA and 267/286 (93.4%) patients with r-axSpA had completed Week 104.
- Baseline symptoms were comparable between treatment groups (**Figure 1–3**).

Spinal Pain and Morning Stiffness

- Improvements from baseline with BKZ at Week 52, similar to those reported previously for patients with nr- and r-axSpA,[4] were sustained to Week 104 for total spinal pain (**Figure 1A**), nocturnal spinal pain (**Figure 1B**) and morning stiffness scores (**Figure 2A**).
- At Week 52 and Week 104, more than 50% of patients achieved total and nocturnal spinal pain scores <4, and more than 25% and 35% achieved total and nocturnal spinal pain scores <2, respectively (**Figure 1C–D**).
- At the same timepoints, more than 50% of patients achieved morning stiffness scores <4, and more than 30% achieved morning stiffness scores <2 (**Figure 2B**).

Fatigue

- Improvements from baseline to Week 52 in fatigue were sustained to Week 104, as measured by BASDAI Q1 (**Figure 3A**) and FACIT-Fatigue (**Figure 3B**).
- More than 50% of patients were considered FACIT-Fatigue responders at Week 52 and Week 104 (**Figure 3C**).

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 in patients with r-axSpA and nr-axSpA. These findings emphasise the longer-term benefit of bimekizumab on key clinical symptoms, which are important to patients and have a substantial impact on their daily lives.

Summary

In patients across the full disease spectrum of axial spondyloarthritis, bimekizumab resulted in sustained improvements over 2 years in spinal pain, morning stiffness and fatigue

Over half of patients (NRI) achieved thresholds for:

Total spinal pain

53.9% total spinal pain score <4

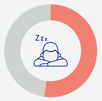
Nocturnal spinal pain

57.3% nocturnal spinal pain score <4

Morning stiffness

55.6% morning stiffness score (mean of BASDAI Q5 and Q6) <4

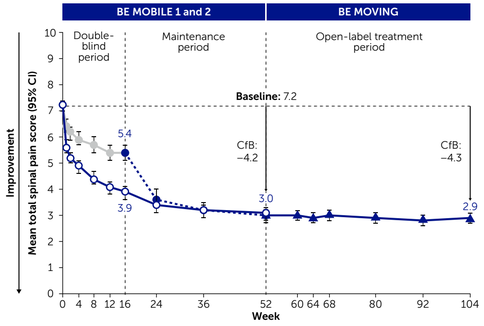
Fatigue



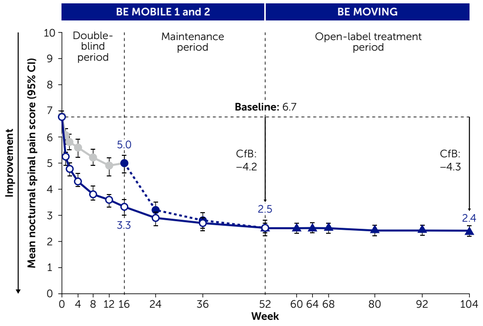
52.3% ≥8-point improvement in FACIT-Fatigue score

Figure 1 Mean score and change from baseline in spinal pain to Week 104, and proportion of patients achieving spinal pain score <4 or <2

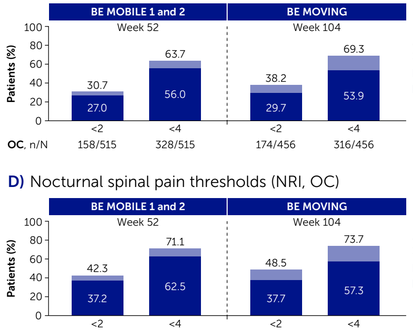
A) Total spinal pain (MI)



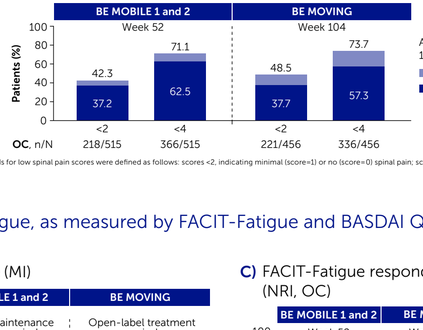
B) Nocturnal spinal pain (MI)

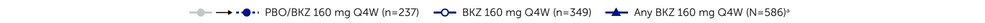


C) Total spinal pain thresholds (NRI, OC)



D) Nocturnal spinal pain thresholds (NRI, OC)

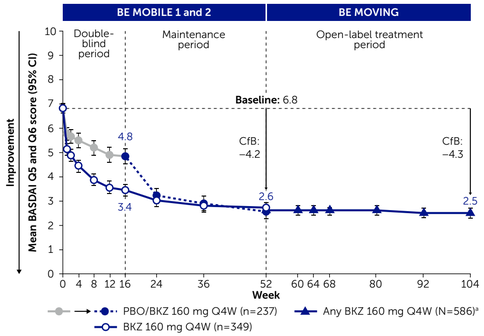




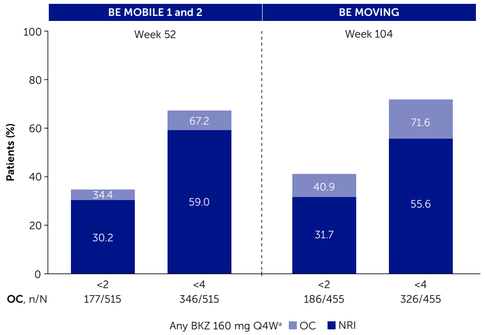
Pooled randomised set (N=586). Baseline scores are from Week 0 of feeder study. Total score range: 0–10. Improvement indicated by reduced scores. Study participants with missing data at the given timepoint which are preceded by an intercurrent event are imputed using MI. Thresholds for low spinal pain 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] Includes patients originally randomised to placebo in BE MOBILE 1 or 2.

Figure 2 Mean score and change from baseline in morning stiffness to Week 104, and proportion of patients achieving morning stiffness score <4 or <2

A) Morning stiffness (MI)



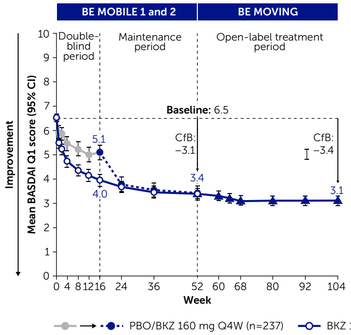
B) Morning stiffness thresholds (NRI, OC)



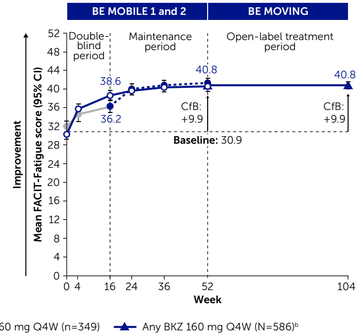
Pooled randomised set (N=586). Baseline scores are from Week 0 of feeder study. Morning stiffness assessed as the mean of BASDAI Q5 and Q6 scores (total score range: 0–10). Improvement indicated by reduced scores. Study participants with missing data at the given timepoint which are preceded by an intercurrent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

Figure 3 Mean score and change from baseline in fatigue, as measured by FACIT-Fatigue and BASDAI Q1, to Week 104, and FACIT-Fatigue responders

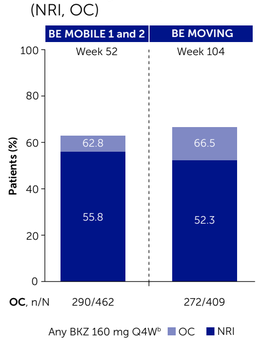
A) BASDAI Q1 (MI)



B) FACIT-Fatigue (MI)



C) FACIT-Fatigue responders[a] (NRI, OC)



Pooled randomised set (N=586). Baseline scores are from Week 0 of feeder study. Improvement indicated by reduced scores for BASDAI Q1 (total score range: 0–10) and increased scores for FACIT-Fatigue (total score range: 0–52). Study participants with missing data at the given timepoint which are preceded by an intercurrent event are imputed using MI. [a] ≥8-point increase from baseline in patients with FACIT-Fatigue score ≥44 at baseline (N=520); [b] Includes patients originally randomised to placebo in BE MOBILE 1 or 2.

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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References: [1]Strand V. J Clin Rheumatol 2017;23:383–91; [2]Baraliakos X. Ann Rheum Dis 2023; 83(2):199–213. [3]Baraliakos X. EULAR 2024 [Poster POS0806]; [4]Mease PJ. ACR 2023 [Poster 0510]. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **HMO**, **PJM**, **MDo**, **MDu**, **MM**, **MR**, **M-ADA**, **CdIL**, **CF**, **VT**, **UM**, **AD**; Drafting of the publication, or reviewing it critically for important intellectual content: **HMO**, **PJM**, **MDo**, **MDu**, **MM**, **MR**, **M-ADA**, **CdIL**, **CF**, **VT**, **UM**, **AD**; Final approval of the publication: **HMO**, **PJM**, **MDo**, **MDu**, **MM**, **MR**, **M-ADA**, **CdIL**, **CF**, **VT**, **UM**, **AD**. **Author Disclosures: HMO:** Research grants from Janssen, Novartis, Pfizer, and UCB Pharma; Consultant of Eli Lilly, Janssen, MoonLake, Novartis, Pfizer and UCB Pharma; Speakers' bureau from AbbVie, Biogen, Eli Lilly, Janssen, Novartis, Pfizer, Takeda, and UCB Pharma; **PJM:** Research grants from AbbVie, Acelyrin, Amgen, Bristol Myers Squibb, Eli Lilly, Janssen, Novartis, Pfizer, and UCB Pharma; Consulting fees from AbbVie, Acelyrin, Aclaris, Alumis, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly, Imagene, Janssen, MoonLake, Novartis, Pfizer, Takeda, UCB Pharma, and Ventyx; Speakers' bureau fees from AbbVie, Amgen, Eli Lilly, Janssen, Novartis, Pfizer, and UCB Pharma; **MDo:** Consultancy/speaker fees/research grants from AbbVie, Eli Lilly, Merck, Novartis, Pfizer, and UCB Pharma; **MDu:** Educational grant from Pfizer paid to institution; Consulting fees (e.g. advisory boards) from Amgen and UCB Pharma; **MM:** Consultancy fees from AbbVie, Bristol Myers Squibb, Eli Lilly, Novartis, Pfizer, and UCB Pharma; Research grants from AbbVie, Bristol Myers Squibb, and UCB Pharma; **MR:** Speakers' bureau from AbbVie, Boehringer Ingelheim, Chugai, Eli Lilly, Janssen, Novartis, Pfizer, and UCB Pharma; Consultant for AbbVie, Eli Lilly, Novartis, and UCB Pharma; **M-ADA:** Speaking honoraria and/or consultancy fees from Amgen, AbbVie, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly, Galapagos, Janssen, Novartis, Pfizer, and UCB Pharma; **CdIL:** Consultant for UCB Pharma; **CF, VT:** Employees and shareholders of UCB Pharma; **UM:** Employee of UCB Pharma; **AD:** Speaker for Eli Lilly, Janssen, Novartis, Pfizer, and UCB Pharma; Consultant for AbbVie, Bristol Myers Squibb, Eli Lilly, Janssen, MoonLake, Novartis, Pfizer, and UCB Pharma; Grant/research support from Bristol Myers Squibb, Celgene, Eli Lilly, Janssen, MoonLake Pharma, Novartis, Pfizer, and UCB Pharma. **Acknowledgements:** We would like to thank the patients and their caregivers in addition to all the investigators and their teams who contributed to these studies. The authors acknowledge Celia Menckeberg, PhD, UCB Pharma, for publication coordination, Sneha Krishnamurthy, MSc, Costello Medical, London, UK for medical writing and editorial assistance, and the Costello Medical Creative team for design support. These studies were funded by UCB Pharma. All costs associated with development of this presentation were funded by UCB Pharma.

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