Sustained Improvements with Bimekizumab in Pain, Morning Stiffness, Fatigue, Physical Function and Health-Related Quality of Life in Patients with Axial Spondyloarthritis: 3-Year Results from Two Phase 3 Studies

POS0921

Victoria Navarro-Compán,[1] Uta Kiltz,[2,3] Philip J. Mease,[4] Maureen Dubreuil,[5] Karl Gaffney,[6] Atul Deodhar,[7] Christine de la Loge,[8] Diana Voiniciuc,[9] Jason Coarse,[10] Helena Marzo-Ortega[11]

[1]La Paz University Hospital, IdiPaz, Department of Rheumatology, Madrid, Spain; [2]Ruhr-University Bochum, Bochum, Germany; [3]Rheumazentrum Ruhrgebiet, Herne, Germany; [4]Providence-Swedish Medical Center and University of Washington, Department of Rheumatology, Seattle, Washington, USA; [5]Boston University School of Medicine, Department of Rheumatology, Boston, Massachusetts, USA; [6]Norfolk and Norwich University Hospital NHS Trust, Department of Rheumatology, Norfolk, UK; [7]Oregon Health & Science University, Division of Arthritis and Rheumatic Diseases, Portland, Oregon, USA; [8]UCB, Brussels, Belgium; [9]UCB, Slough, UK; [10]UCB, Morrisville, North Carolina, USA; [11]NIHR Leeds Biomedical Research Centre, Leeds Teaching Hospitals NHS Trust and Leeds Institute of Rheumatic and Musculoskeletal Medicine, University of Leeds, Leeds, UK

Objective

To evaluate the impact of bimekizumab (BKZ) on spinal pain, morning stiffness, fatigue, physical function and health-related quality of life (HRQoL) in patients across the full disease spectrum of axial spondyloarthritis (axSpA) up to 3 years.

Introduction

- Spinal pain, morning stiffness and fatigue are key contributors to the axSpA disease burden, impacting daily physical function and overall HRQoL.
- BKZ is a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.
- BKZ has shown sustained improvements in spinal pain, morning stiffness, fatigue, physical function and overall HRQoL to Week 104 in patients with axSpA in the phase 3 studies BE MOBILE 1 and 2, and their combined open-label extension (OLE).[1,2] Here, we show patient-reported data to 3 years.

Methods

- BE MOBILE 1 (non-radiographic [nr]-axSpA; NCT03928704) and BE MOBILE 2 (radiographic [r-]axSpA; NCT03928743) each comprised a 16-week, double-blind, placebo-controlled period and a 36-week maintenance period.
- All patients received subcutaneous BKZ 160 mg every 4 weeks (Q4W) from Week 16; at Week 52, eligible patients could enter the combined OLE (BE MOVING; NCT04436640).
- Reported data are pooled to Week 164 across patients with nr-axSpA and r-axSpA from BE MOBILE 1 and 2 and the combined OLE.
  - Mean change from baseline scores are presented for total and nocturnal spinal pain, morning stiffness (mean of Bath Ankylosing Spondylitis Disease Activity Index [BASDAI] Q5 and 6), fatigue (BASDAI Q1 and FACIT-Fatigue), physical function (Bath Ankylosing Spondylitis Functional Index [BASFI]) and health-related quality of life (HRQoL; 36-Item Short Form Survey Physical Component Summary [SF-36 PCS] and Ankylosing Spondylitis Quality of Life [ASQoL]) using multiple imputation (MI).
  - Proportions of patients achieving thresholds for total and nocturnal spinal pain, morning stiffness or BASFI (score <2 or <4). FACIT-Fatigue (≥8-point improvement) or ASQoL (≥4-point improvement) are presented using modified non-responder imputation (mNRI) and observed case (OC).

Results

Patients

- Of 586 randomised patients across BE MOBILE 1 and 2 (nr-axSpA: 254; r-axSpA: 332), 494 (84.3%) patients entered the OLE and 425/494 (86.0%) patients completed to Week 164.
- Baseline characteristics were comparable between patients in BE MOBILE 1 and 2.[1]

Spinal pain and morning stiffness

- Improvements observed from baseline to Week 52 in total and nocturnal spinal pain and morning stiffness were sustained through Week 164 (**Figure 1**).
- At Week 164, over 30% of patients achieved scores <2 and over 55% achieved <4 in total spinal pain, nocturnal spinal pain and morning stiffness (**Figure 2**).

Fatigue

- Fatigue improvements from baseline (BASDAI Q1 and FACIT-Fatigue) were also sustained from Week 52 to Week 164 (**Figure 3A–B**).
- Approximately 55% of patients achieved a meaningful improvement in FACIT-Fatigue at Week 164 (**Figure 3C**).

Physical function and HRQoL

- Improvements from baseline to Week 52 in measures of physical function (BASFI) and HRQoL (SF-36 PCS and ASQoL) were sustained to Week 164 (**Figure 4**).
- At Week 164, over 30% of patients achieved BASFI score <2 and over 60% achieved <4, while over 65% achieved clinically meaningful ASQoL improvement (**Figure 5**).
- Patients did not show notable impairment of SF-36 MCS score at baseline (mean score: 51.4),[4] which was maintained to Week 164 (CfB: +1.7).

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

Conclusions

Patients across the full disease spectrum of axSpA showed consistently sustained improvements in spinal pain, morning stiffness, fatigue, physical function and HRQoL after 3 years of bimekizumab treatment.

These findings emphasise the long-term value of bimekizumab treatment in addressing symptoms which are central to the patient experience and profoundly affect patients' daily lives.

Summary

In patients across the full disease spectrum of axSpA, bimekizumab resulted in sustained improvements over three years in spinal pain, morning stiffness, fatigue, physical function and HRQoL.

Around half of patients (mNRI) achieved thresholds at Week 164 for:

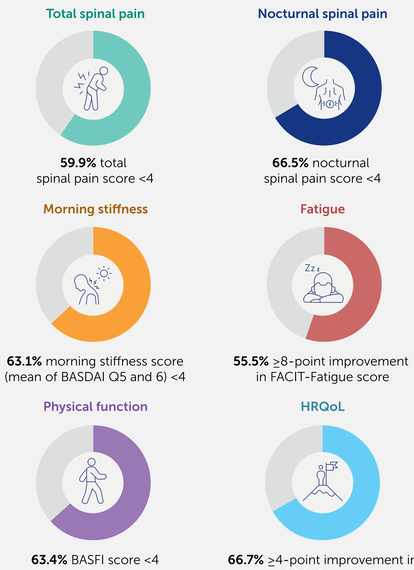
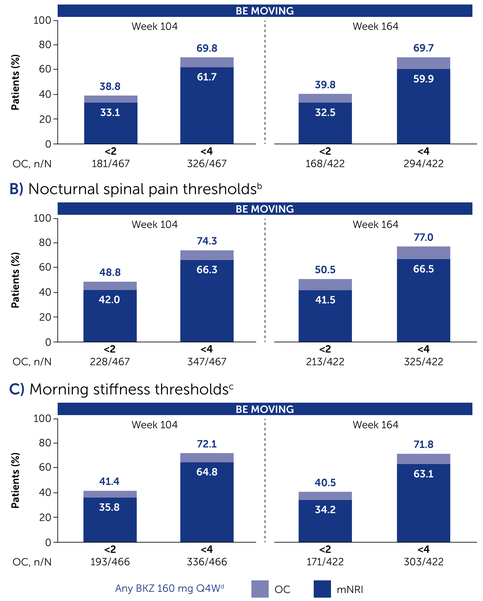
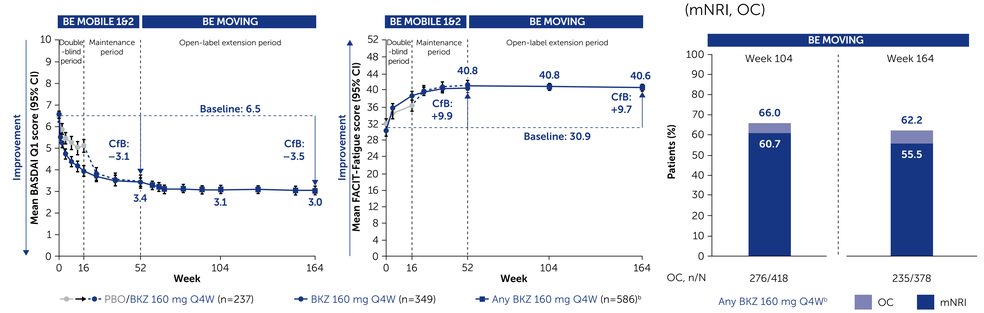


Figure 2 Spinal pain and morning stiffness scores <2 or <4 at Week 104 and 164 (mNRI, OC)



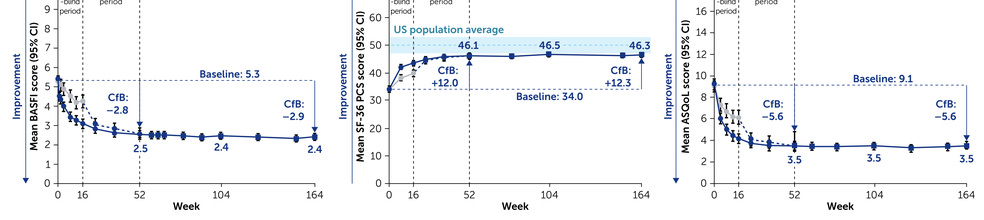
Pooled randomised set (N=586). Morning stiffness was assessed as the mean of BASDAI Q5 and Q6. mNRI considered all visits following discontinuation due to adverse events or lack of efficacy as non-response; all other missing data were imputed with MI and the response derived from the imputed values. **[a]** At baseline, 580 and 558 patients had a total spinal pain score of >2 and >4, respectively; **[b]** At baseline, 567 and 511 patients had a nocturnal spinal pain score of >2 and >4, respectively; **[c]** At baseline, 583 and 545 patients had a morning stiffness score of >2 and >4, respectively; **[d]** Includes patients originally randomised to placebo in BE MOBILE 1 or 2.

Figure 3 Fatigue to Week 164, and FACIT-Fatigue score ≥8-point improvement at Week 104 and 164



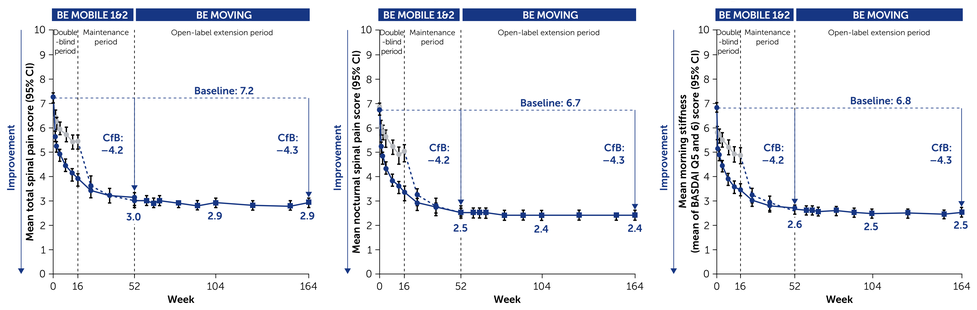
Pooled randomised set (N=586). Error bars represent 95% CI scores. Baseline scores are from Week 0 of BE MOBILE 1 or 2. From Week 16, all patients received BKZ 160 mg Q4W. Improvement is indicated by reduced scores for BASDAI Q1 (total score range: 0–10) and increased scores for FACIT-Fatigue (total score range: 0–52). mNRI considered all visits following discontinuation due to adverse events or lack of efficacy as non-response; all other missing data were imputed with MI and the response derived from the imputed values. **[a]** In patients with FACIT-Fatigue score ≤44 at baseline (N=520);[3] **[b]** Includes patients originally randomised to placebo in BE MOBILE 1 or 2.

Figure 4 BASFI, SF-36 PCS and ASQoL to Week 164 (MI)



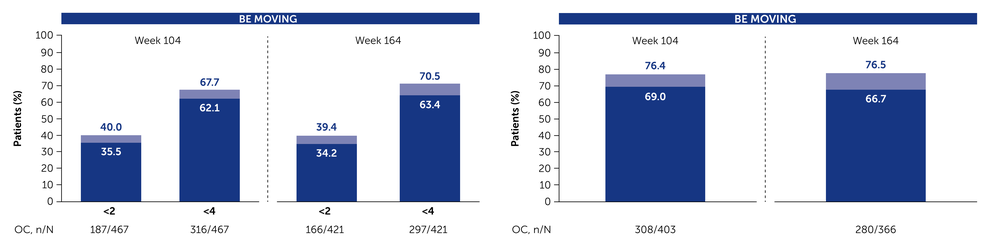
Pooled randomised set (N=586). Error bars represent 95% CI scores. Baseline scores are from Week 0 of BE MOBILE 1 or 2. From Week 16, all patients received BKZ 160 mg Q4W. Possible BASFI scores range from 0–10 and possible ASQoL and SF-36 PCS scores range from 0–18. Improvement indicated by reduced scores for BASFI and ASQoL and increased scores for SF-36 PCS. For SF-36 PCS, group-level mean scores between 47 and 53 (blue shaded area) can be considered within the 'average' or 'normal' range for the US general population.[4] **[a]** Includes patients originally randomised to placebo in BE MOBILE 1 or 2.

Figure 1 Spinal pain and morning stiffness to Week 164 (MI)



Pooled randomised set (N=586). Error bars represent 95% CI scores. Baseline scores are from Week 0 of BE MOBILE 1 or 2. From Week 16, all patients received BKZ 160 mg Q4W. Morning stiffness was assessed as the mean of BASDAI Q5 and Q6. Total score range for spinal pain and morning stiffness: 0–10. **[a]** Includes patients originally randomised to placebo in BE MOBILE 1 or 2.

Figure 5 BASFI score <2 or <4 and ASQoL score ≥4-point improvement at Week 104 and 164 (mNRI, OC)



Pooled randomised set (N=586). mNRI considered all visits following discontinuation due to adverse events or lack of efficacy as non-response; all other missing data were imputed with MI and the response derived from the imputed values. **[a]** At baseline, 527 and 435 patients had a BASFI score of >2 and >4, respectively; **[b]** ≥4-point decrease from baseline in patients with ASQoL score ≥4 at baseline (N=504); **[c]** Includes patients originally randomised to placebo in BE MOBILE 1 or 2.

ASQoL: Ankylosing Spondylitis Quality of Life; **axSpA:** axial spondyloarthritis; **BASDAI:** Bath Ankylosing Spondylitis Disease Activity Index; **BASFI:** Bath Ankylosing Spondylitis Functional Index; **BKZ:** bimekizumab; **CfB:** change from baseline; **CI:** confidence interval; **FACIT:** Functional Assessment of Chronic Illness Therapy; **HRQoL:** health-related quality of life; **MI:** multiple imputation; **mNRI:** modified non-responder imputation; **nr-axSpA:** non-radiographic axSpA; **NRI:** non-responder imputation; **OC:** observed case; **OLE:** open-label extension; **PBO:** placebo; **Q4W:** every 4 weeks; **r-axSpA:** radiographic axial spondyloarthritis; **SF-36 MCS:** 36-Item Short Form Survey Mental Component Summary; **SF-36 PCS:** 36-Item Short Form Survey Physical Component Summary; **US:** United States.

References: [1]Marzo-Ortega H. Arthritis Rheumatol 2024;76:0592. [2]Navarro-Compán V. Arthritis Rheumatol 2024;76:1480. [3]Celia D. J Patient Rep Outcomes 2024;8:92. [4]Maruish ME. User's manual for the SF-36v2 Health Survey (3rd ed.). Lincoln, RI: QualityMetric Inc. 2011. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **VNC**, **UK**, **PJM**, **MD**, **KG**, **AD**, **CdlL**, **DV**, **JC**, **HMO;** Drafting of the publication, or reviewing it critically for important intellectual content: **VNC**, **UK**, **PJM**, **MD**, **KG**, **AD**, **CdlL**, **DV**, **JC**, **HMO;** Final approval of the publication: **VNC**, **UK**, **PJM**, **MD**, **KG**, **AD**, **CdlL**, **DV**, **JC**, **HMO**. **Author Disclosures: VNC:** Speakers bureau for AbbVie, Eli Lilly, Fresenius Kabi, Janssen, MSD, Novartis, Pfizer and UCB; consultant for AbbVie, Alfasigma, Eli Lilly, Galapagos, Moonlake, MSD, Novartis, Pfizer and UCB; grant/research support from AbbVie and Novartis. **UK:** Grant and research support and consultancy fees from AbbVie, Amgen, Biocad, Biogen, BMS, Chugai, Eli Lilly, Fresenius, Gilead, Grunenthal, GSK, Hexal, Janssen, MSD, Novartis, onNowissen.de, Pfizer, Roche, UCB and Viatris. **PJM:** Research grants from AbbVie, Acelyrin, Amgen, BMS, Eli Lilly, Johnson & Johnson Innovative Medicine, Novartis, Pfizer, Sana and UCB; consulting fees from AbbVie, Acelyrin, Amgen, BMS, Century, Cullinan, Eli Lilly, Immagene, Johnson & Johnson Innovative Medicine, MoonLake, Novartis, Pfizer, Spyre, Takeda and UCB; speakers bureau fees from AbbVie, Amgen, Eli Lilly, Johnson & Johnson Innovative Medicine, Novartis, Pfizer and UCB. **MD:** Educational grant from Pfizer paid to institution; consulting fees (e.g. advisory boards) from Amgen and UCB; funding from Rheumatology Research Foundation, Boston University School of Medicine, Department of Medicine and Boston Medical Center. **KG:** Speakers bureau for AbbVie, Eli Lilly, Novartis and UCB; consultant of AbbVie, Eli Lilly, Novartis and UCB; grant/research support from AbbVie, Gilead, Eli Lilly, Novartis and UCB. **AD:** Speaker for Eli Lilly, J&J, Novartis, Pfizer and UCB; consultant for BMS, Eli Lilly, J&J, MoonLake, Novartis, Pfizer and UCB; grant/research support from BMS, Eli Lilly, J&J, Novartis, Pfizer and UCB. **CdlL:** Consultant for UCB. **DV:** Former contractor for UCB and employee of Veramed. **JC:** Employee and shareholder of UCB. **HMO:** Speaking honoraria and/or consultancy fees from AbbVie, Amgen, Biogen, Eli Lilly, Janssen, MoonLake, Novartis, Pfizer, Takeda and UCB; research grants from Janssen, Novartis, Pfizer and UCB. **Acknowledgements:** We would like to thank the patients and their caregivers in addition to all the investigators and their teams who contributed to this study. The authors acknowledge Celia Menckeberg, PhD, UCB, Breda, The Netherlands for publication coordination, Syaujina Fakhira, MSc, Costello Medical, Cambridge, UK, for medical writing and editorial assistance, and the Costello Medical Creative team for design support. Funded by UCB. All costs associated with development of this presentation were funded by UCB.

To receive a copy of this poster, scan the QR code.
Link expiration:
12 September 2025