Bimekizumab Treatment Improved Key Patient-Reported Symptoms of Axial Spondyloarthritis Including Spinal Pain, Fatigue, and Morning Stiffness: 52-Week Results from Two Phase 3 Studies

Philip J. Mease,[1] Maxime Dougados,[2] Maureen Dubreuil,[3] Marina Magrey,[4] Helena Marzo-Ortega,[5] Martin Rudwaleit,[6] Christine de la Loge,[7] Carmen Fleurinck,[8] Ute Massow,[9] Vanessa Taieb,[10] Atul Deodhar[11]

0510

Objective

To report the impact of bimekizumab (BKZ) on spinal pain, stiffness, and fatigue 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, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated sustained efficacy and was well tolerated up to Week 52 in patients with non-radiographic (nr-) and radiographic (r-) axSpA (i.e., ankylosing spondylitis)[2] in the phase 3 studies BE MOBILE 1 and 2.[3]

Methods

- BE MOBILE 1 (NCT03928704) and 2 (NCT03928743) both comprised a 16-week double-blind period followed by a 36-week maintenance period (**Figure 1**).
- We report, for both studies, the mean scores to Week 52 for total and nocturnal spinal pain, and morning stiffness (mean of Bath Ankylosing Spondylitis Disease Activity Index [BASDAI] questions 5 & 6) using multiple imputation (MI); scores range from 0–10 with lower scores reflecting lower spinal pain/stiffness.
- Change from baseline (CfB) in Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue scores are also reported using MI.
- We also report the proportion of patients achieving the following using non-responder imputation (NRI):
  - Low levels of total and nocturnal pain (scores ≤2 and ≤4)
  - Meaningful improvement in fatigue (FACIT-Fatigue score CfB ≥8).

Results

- 254 patients with nr-axSpA (BKZ: 128; placebo: 126) and 332 with r-axSpA (BKZ: 221; placebo: 111) were randomized; 86.6% (220/254) and 89.8% (298/332) patients completed to Week 52, respectively.
- Across both studies, mean baseline scores for all reported outcomes indicated similarly high disease burden (**Figure 2**).

Spinal Pain and Morning Stiffness

- At Week 16, patients achieved greater improvements in mean nocturnal and total spinal pain, and morning stiffness with BKZ vs placebo (**Figure 2**).
- Mean scores improved to Week 52 with BKZ, including among patients who switched from placebo to BKZ at Week 16 (placebo/BKZ).
- Similarly, at Week 16, a higher proportion of BKZ- vs placebo-randomized patients achieved low nocturnal and total spinal scores (**Figure 3**).
- At Week 52, proportions of patients who achieved low pain levels were similar across BKZ-randomized and placebo/BKZ patients.

Fatigue

- At Week 16, BKZ-randomized patients achieved greater improvements (mean CfB [nominal p value]) in FACIT-Fatigue scores vs placebo:
  - nr-axSpA: 8.5 vs 3.9 (<0.001); least squared mean difference (LSMD): 4.2
  - r-axSpA: 8.4 vs 5.0 (0.015); LSMD: 2.2.
- Improvements at Week 52 were similar among BKZ-randomized and placebo/BKZ patients (nr-axSpA: 10.9 vs 9.2; r-axSpA: 9.9 vs 9.5).
- A higher proportion of BKZ-randomized patients also achieved a meaningful improvement in FACIT-Fatigue (CfB ≥8) compared with placebo at Week 16 (**Figure 4**); responses at Week 52 were similar across placebo/BKZ and BKZ-randomized patients.

Conclusions

Bimekizumab treatment resulted in clinically meaningful improvements in spinal pain, morning stiffness, and fatigue, which were sustained to Week 52 in patients with r- and nr-axSpA, who had a similar and high disease burden at baseline.

These findings emphasize the benefit of bimekizumab on clinical symptoms, which are important to patients and have a substantial impact on their daily lives.[3]

Summary

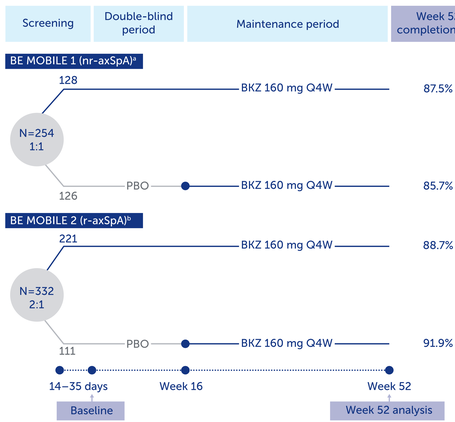
In patients across the full disease spectrum of axial spondyloarthritis, bimekizumab resulted in clinically meaningful improvements in:

Spinal pain
Total and nocturnal spinal pain

Morning stiffness
Mean of BASDAI questions 5 and 6

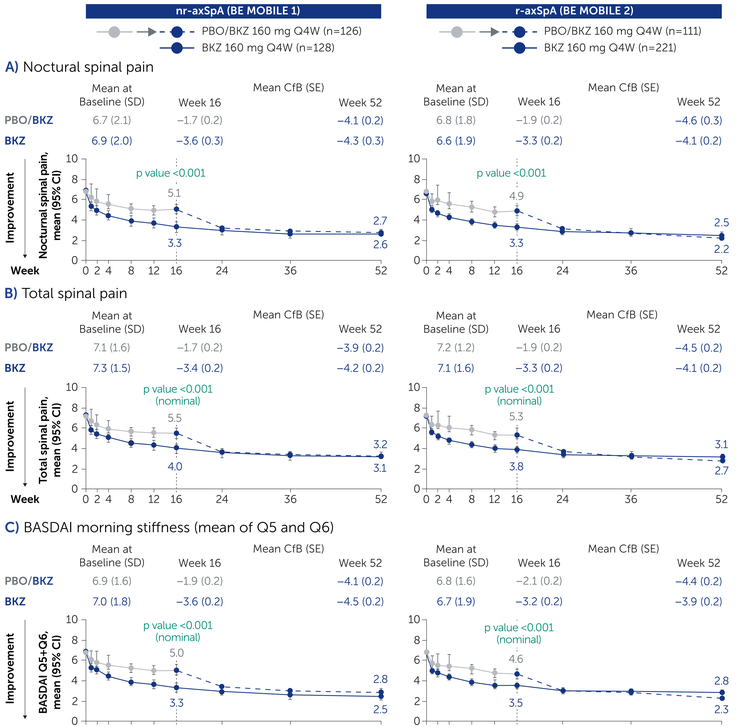
Fatigue
FACIT-Fatigue

Figure 1 BE MOBILE 1 and BE MOBILE 2 study designs



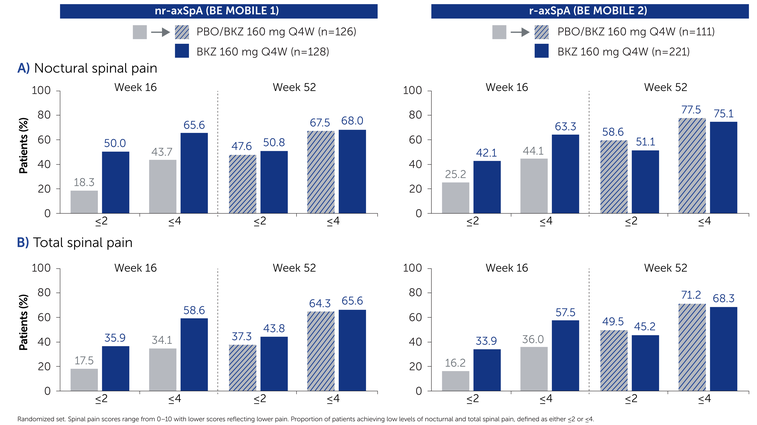
Patients were eligible to receive non-biologic rescue therapy from Week 20 at the discretion of the investigator, while continuing to receive BKZ. [a] Included patients had adult-onset nr-axSpA fulfilling ASAS classification criteria and objective signs of inflammation (active sacroiliitis on MRI and/or elevated CRP ≥6 mg/L); [b] Included patients had radiographic evidence of r-axSpA fulfilling modified New York criteria. Patients also met ASAS classification criteria.

Figure 2 Mean scores and change from baseline in nocturnal spinal pain, total spinal pain, and BASDAI morning stiffness (MI)



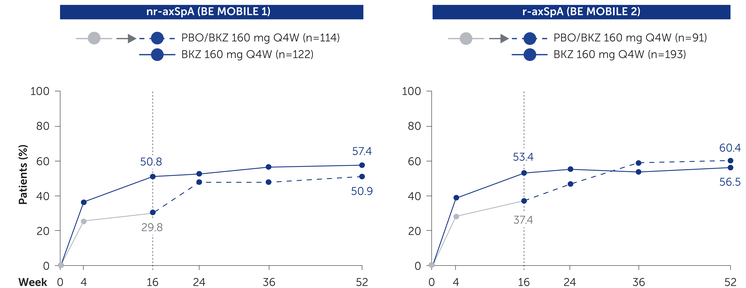
Randomized set. P values calculated at Week 16 for nocturnal spinal pain were part of a hierarchical gatekeeping strategy and used reference-based MI. P values without any multiplicity adjustment are indicated as nominal p values and should not be used as an indication of statistical significance. Error bars represent 95% CI. Spinal pain scores range from 0–10 with lower scores reflecting lower pain. BASDAI morning stiffness score assessed as mean of BASDAI questions 5 and 6; scores range from 0–10 with lower scores reflecting lower stiffness.

Figure 3 Proportion of patients achieving low levels of nocturnal spinal pain and total spinal pain (NRI)



Randomized set. Spinal pain scores range from 0–10 with lower scores reflecting lower pain. Proportion of patients achieving low levels of nocturnal and total spinal pain, defined as either ≤2 or ≤4.

Figure 4 Proportion of patients achieving a meaningful improvement (CfB ≥8) in FACIT-Fatigue score (NRI)



Randomized set, in patients with a baseline FACIT-Fatigue score of ≤44. FACIT-Fatigue score ranges from 0–52 with higher scores reflecting reduced fatigue.

ASAS: Assessment of SpondyloArthritis International Society; **axSpA:** axial spondyloarthritis; **BASDAI:** Bath Ankylosing Spondylitis Disease Activity Index; **BKZ:** bimekizumab; **CfB:** change from baseline; **CI:** confidence interval; **CRP:** C-reactive protein; **FACIT:** Functional Assessment of Chronic Illness Therapy; **IL:** interleukin; **LSMD:** least squared mean difference; **MI:** multiple imputation; **MRI:** magnetic resonance imaging; **nr-axSpA:** non-radiographic axSpA; **NRI:** non-responder imputation; **PBO:** placebo; **Q4W:** every 4 weeks; **r-axSpA:** radiographic axSpA; **SD:** standard deviation; **SE:** standard error.

Institutions: [1]Swedish Medical Center/Providence St. Joseph Health and University of Washington, Seattle, WA, USA; [2]Department of Rheumatology, Hôpital Cochin, University of Paris Cité, France; [3]Department of Rheumatology, Boston University School of Medicine, Boston, MA, USA; [4]Case Western Reserve University, University Hospitals, Cleveland, OH, USA; [5]NIHR Leeds Biomedical Research Centre, Leeds Teaching Hospitals NHS Trust and Leeds Institute of Molecular Medicine, University of Leeds, Leeds, UK; [6]University of Bielefeld, Klinikum Bielefeld, Bielefeld, Germany; [7]PCOM Analytics, Avallon, France; [8]UCB Pharma, Brussels, Belgium; [9]UCB Pharma, Monheim am Rhein, Germany; [10]UCB Pharma, Colombes, France; [11]Division of Arthritis & Rheumatic Diseases, Oregon Health & Science University, Portland, OR, USA.

References: [1]Strand V. J Clin Rheumatol 2017;23:383–91. [2]Boel A. Ann Rheum Dis 2019;78:1545–9. [3]Baraliakos X Ann Rheum Dis 2023.ard-2023-224803. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **PJM, MDo, MDu, MM, HMO, MR, CDiL, CF, UM, VT, AD**; Drafting of the publication, or reviewing it critically for important intellectual content: **PJM, MDo, MDu, MM, HMO, MR, CDiL, CF, UM, VT, AD**; Final approval of the publication: **PJM, MDo, MDu, MM, HMO, MR, CDiL, CF, UM, VT, AD**. **Author Disclosures: PJM:** Research grants from AbbVie, Amgen, BMS, Eli Lilly, Gilead, Janssen, Novartis, Pfizer, Sun Pharma, and UCB Pharma; consultancy fees from AbbVie, Acelyrin, Aclaris, Amgen, BMS, Boehringer Ingelheim, Eli Lilly, Galapagos, Gilead, GSK, Janssen, MoonLake, Novartis, Pfizer, Sun Pharma, Takeda, UCB Pharma, and Ventyx; speakers' bureau 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 from Amgen and UCB Pharma. **MM:** Consultancy fees from AbbVie, BMS, Eli Lilly, Novartis, Pfizer, and UCB Pharma; research grants from AbbVie, BMS, and UCB Pharma; speaking honoraria and/or consultancy fees from AbbVie, Biogen, Eli Lilly, Janssen, MoonLake, Novartis, Pfizer, Takeda, and UCB Pharma. **MR:** Speakers bureau from AbbVie, Boehringer Ingelheim, Chugai, Eli Lilly, Janssen, Novartis, Pfizer, and UCB Pharma; consultant of AbbVie, Eli Lilly, Novartis, and UCB Pharma. **CDiL:** Consultant to UCB Pharma. **CF, UM, VT:** Employees of UCB Pharma. **AD:** Speakers bureau for Janssen, Novartis, and Pfizer; consultant for AbbVie, BMS, Eli Lilly, Janssen, MoonLake Pharma, Novartis, Pfizer, and UCB Pharma; grant/research support from AbbVie, BMS, Celgene, Eli Lilly, MoonLake, Novartis, Pfizer, and UCB Pharma. **Acknowledgments:** 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, Isabel Raynaud, MBBS IBSc, Costello Medical, Cambridge, 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.

To receive a copy of this poster, scan the QR code or visit: UCBposters.com/ACR2023

Poster ID: 0510
Link expiration: November 29, 2023