Sustained Improvements with Bimekizumab in Spinal Mobility, Physical Function and Health-Related Quality of Life in Patients with Axial Spondyloarthritis: 2-Year Results from Two Phase 3 Studies

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Objective

To assess the impact of bimekizumab (BKZ) on spinal mobility, physical function, and health-related quality of life (HRQoL) over 2 years in patients across the full disease spectrum of axial spondyloarthritis (axSpA).

Background

- Patients with axSpA experience severely impaired physical function and HRQoL.[1]
- BKZ is a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.
- In the phase 3 BE MOBILE 1 and 2 studies, BKZ demonstrated sustained improvements in physical function and HRQoL to Week 52 in patients with active axSpA, with similar improvements in patients with non-radiographic (nr-) and radiographic axSpA (r-axSpA; i.e., ankylosing spondylitis [AS]).[2]

Methods

- BE MOBILE 1 (NCT03928704) and 2 (NCT03928743) both comprised a 16-week double-blind period followed by a 36-week maintenance period.[3]
  - At Week 52, all patients who completed either study without meeting any withdrawal criteria were eligible to be enrolled into BE MOVING (NCT04436640), an ongoing open-label extension study.
- We report scores for Bath AS Metrology Index (BASMI), Bath AS Functional Index (BASFI), Short Form-36 (SF-36) Physical Component Summary (PCS), individual SF-36 domains, and AS Quality of Life (ASQoL) to Week 104 (Week 52 of BE MOVING), using multiple imputation (MI).
- We also report the proportion of patients achieving a BASFI score ≤2 and clinically meaningful ASQoL improvement (reduction of ≥4 points in patients with a score ≥4 at baseline) to Week 104, using non-responder imputation (NRI) and observed case (OC).
- Data are pooled for all randomized patients with nr-axSpA and r-axSpA in BE MOBILE 1 and 2.

Results

Patients

- Of 586 originally randomized patients with axSpA (nr-axSpA: 254; r-axSpA: 332), 494 patients (nr-axSpA: 208; r-axSpA: 286) entered BE MOVING at Week 52. A total of 456 patients (nr-axSpA: 189; r-axSpA: 267) completed to Week 104.
- As previously reported, at baseline in BE MOBILE 1 and 2, BASMI, BASFI, SF-36 PCS, and ASQoL scores were similar across placebo- and BKZ-randomized patients (**Figure 1**).[3]

Spinal Mobility and Physical Function

- Previously reported improvements from baseline at Week 52 with BKZ were sustained to Week 104 in BASMI and BASFI (**Figure 1**).[3]
- At Week 104, 42.8% of patients achieved a BASFI score of ≤2 (NRI; **Figure 2**).

Health-Related Quality of Life

- Improvements from baseline to Week 52 in SF-36 PCS and ASQoL were also sustained to Week 104 (**Figure 1**).
  - After 2 years of BKZ treatment, the mean SF-36 PCS score approached the lower bound of the US general population norm (**Figure 1**).[4]
  - Improvements across all individual SF-36 domains were observed from baseline to Week 104 (**Figure 3**).
- At Week 104, 59.7% of patients achieved clinically meaningful ASQoL improvement (NRI; **Figure 2**).

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

Conclusions

Bimekizumab treatment resulted in sustained improvements in spinal mobility, physical function, and health-related quality of life over 2 years in patients across the full disease spectrum of axSpA.

Summary

After 2 years of treatment with bimekizumab, patients across the full disease spectrum of axSpA demonstrated sustained improvements in:

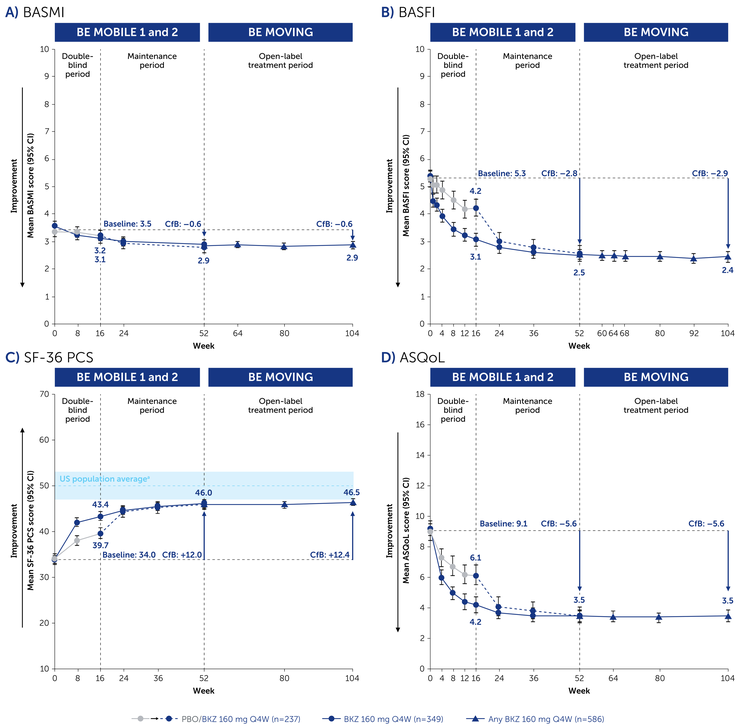
Spinal mobility
−0.6 mean improvement from baseline in BASMI (MI)

Physical function
43% achieved BASFI ≤2 (NRI)

Health-related quality of life
60% achieved a ≥4-point improvement in ASQoL (NRI)

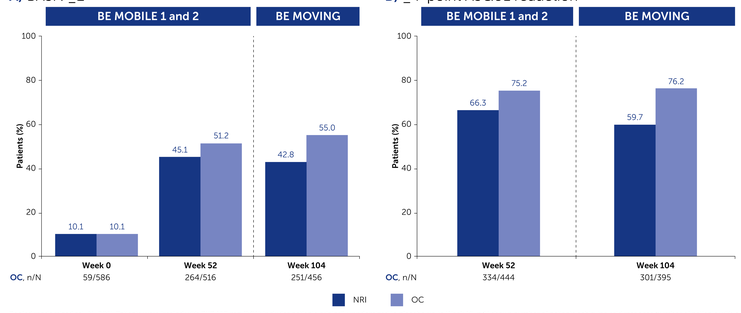
Improvements in SF-36 PCS and all individual SF-36 domains were also observed from baseline to Week 104

Figure 1 Mean BASMI, BASFI, SF-36 PCS and ASQoL improvement from baseline to Week 104 (MI)



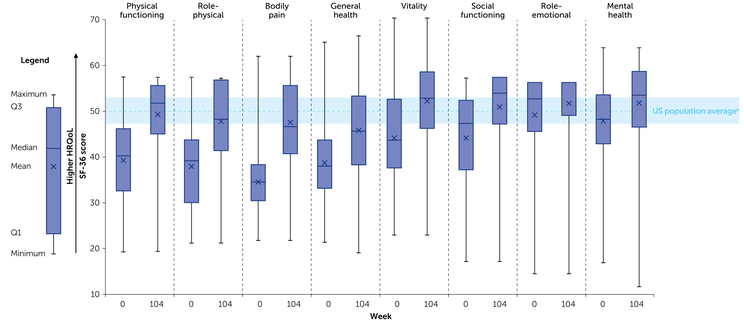
Pooled randomized set. Baseline scores are from Week 0 of feeder study. Error bars represent 95% CI. BASMI and BASFI scores range from 0–10; mean (SD) SF-36 PCS score in US general population is 50 (10); ASQoL scores range from 0–18. **[a]** For SF-36 PCS, group-level mean scores between 47 and 53 (blue shaded area) can be considered within the 'average' or 'normal' range for the US general population.[4]

Figure 2 Proportion of patients achieving BASFI score ≤2 or a ≥4-point reduction in ASQoL from baseline at Week 52 and Week 104 (NRI, OC)



Pooled randomized set (N=586). Patients were treated with BKZ 160 mg Q4W; includes patients originally randomized to placebo up to Week 16. n/N shows number of patients achieving said response/number of patients with a measurement at this time point. Possible BASFI scores range from 0–10 and possible ASQoL scores range from 0–18; a decrease in BASFI and ASQoL indicates improvement. **[a]** Among patients with ASQoL score ≥4 at baseline (N=504).

Figure 3 SF-36 individual domain scores at baseline and Week 104 (absolute values; MI)



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AS: ankylosing spondylitis; **ASQoL:** Ankylosing Spondylitis Quality of Life; **axSpA:** axial spondyloarthritis; **BASFI:** Bath Ankylosing Spondylitis Functional Index; **BASMI:** Bath Ankylosing Spondylitis Metrology Index; **BKZ:** bimekizumab; **CfB:** change from baseline; **CI:** confidence interval; **HRQoL:** health-related quality of life; **IL:** interleukin; **MI:** multiple imputation; **nr-axSpA:** non-radiographic axSpA; **NRI:** non-responder imputation; **OC:** observed case; **PBO:** placebo; **PCS:** Physical Component Summary; **Q:** quartile; **Q4W:** every 4 weeks; **r-axSpA:** radiographic axSpA; **SD:** standard deviation; **SF-36:** Short Form-36; **US:** United States.

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References: [1]Strand V. J Clin Rheumatol 2017;23:385–91; [2]Dubreuil M. RMD Open 2024;10:e004202; [3]Baraliakos X. Ann Rheum Dis 2024;83:199–213; [4]Maruish ME. User's manual for the SF-36v2 Health Survey (3rd ed.). **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **VNC**, **MD**, **KG**, **JK**, **CdlL**, **CF**, **UM**, **VT**, **TV**, **AD**; Drafting of the publication, or reviewing it critically for important intellectual content: **VNC**, **MD**, **KG**, **JK**, **CdlL**, **CF**, **UM**, **VT**, **TV**, **AD**; Final approval of the publication: **VNC**, **MD**, **KG**, **JK**, **CdlL**, **CF**, **UM**, **VT**, **TV**, **AD**. **Author Disclosures: VNC:** Speakers bureau for AbbVie, Eli Lilly, Fresenius Kabi, Janssen, MSD, Novartis, Pfizer, and UCB; consultant for AbbVie, Eli Lilly, Galapagos, MoonLake, MSD, Novartis, Pfizer, and UCB; grant/research support from AbbVie and Novartis. **MD:** Educational grant from Pfizer paid to institution; consulting fees (e.g., advisory boards) from Amgen and UCB. **KG:** Speakers bureau for AbbVie, Eli Lilly, Novartis, and UCB; consultant for AbbVie, Eli Lilly, Novartis, and UCB; grant/research support from AbbVie, Eli Lilly, Gilead, Novartis, and UCB. **JK:** Research Support (paid to UMass Chan Medical School) from Aker BioMarine AS, Biogen, Galapagos NV, and SetPoint Medical; consultant for AbbVie Inc., Alvotech Swiss AG, Amgen Inc., Boehringer Ingelheim GmBH, BMS, Fresenius Kabi, Novartis Pharmaceuticals Corp., Organon LLC, Pfizer, Samsung Bioepis, Sandoz Inc., Scipher Medicine (relationship has ended), Tejin Pharma Ltd., UCB, Viatris Inc., and Yuhan Corp.; Independent Data Monitoring Committee member for Immagene LLC (relationship has ended) and Kolon TissueGene Inc.; from Wolters Kluwer NV (for UpToDate). **CdlL:** Consultant for UCB. **UM:** Employee of UCB. **VT, TV:** Employees and shareholders of UCB. **AD:** Speaker for Eli Lilly, Janssen, Novartis, Pfizer, and UCB; consultant for BMS, Eli Lilly, Janssen, MoonLake, Novartis, Pfizer, and UCB; grant/research support from Bristol Myers Squibb, Celgene, Eli Lilly, Novartis, Pfizer, and UCB. **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, Breda, The Netherlands for publication coordination, Chloe Foulds, MBiol, Costello Medical, Manchester, UK for medical writing and editorial assistance, and the Costello Medical Creative team for graphic design assistance. These studies were funded by UCB. All costs associated with development of this presentation were funded by UCB.

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