Impact of Bimekizumab on MRI Inflammatory and Structural Lesions in the Sacroiliac Joints of Patients with Axial Spondyloarthritis: 52-Week Results and Post Hoc Analyses from the BE MOBILE 1 and 2 Phase 3 Studies

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Objective

To evaluate the impact of bimekizumab (BKZ) on MRI inflammatory and structural lesions in the sacroiliac joints (SIJ) of patients with axial spondyloarthritis (axSpA) to Week 52 in two phase 3 studies.

Background

- BKZ, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated consistent and sustained efficacy to Week 52 across the full disease spectrum of axSpA in the parallel phase 3 BE MOBILE 1 and BE MOBILE 2 studies.[1]
- The impact of dual inhibition of IL-17A and IL-17F on structural lesions in patients with axSpA has not yet been demonstrated.

Methods

- BE MOBILE 1 (non-radiographic [nr]-axSpA; NCT03928704) and BE MOBILE 2 (radiographic [r]-axSpA [i.e. ankylosing spondylitis[2,3]]; NCT03928743) study designs have been reported previously.[4] From Week 16, all patients received subcutaneous BKZ 160 mg every 4 weeks (Q4W) to Week 52.
- Spondyloarthritis Research Consortium of Canada sacroiliac joint (SPARCC SIJ) inflammation scores and SPARCC SIJ Structural Score (SSS; erosion, backfill, fat, ankylosis) were assessed at baseline, Week 16 and Week 52 in patients in the MRI sub-studies.
- MRIs were assessed via central reading by two independent expert readers, with an adjudicator in cases of disagreement. Inflammatory and structural lesions were assessed independently by different readers, hence the number of MRIs successfully scored could differ. All readers were blinded to timepoint and any clinical data; structural lesions were analysed post hoc.
- We report observed case data for patients across the full disease spectrum of axSpA with valid MRI assessments at all 3 timepoints.

Results

Patients

- Overall, 60% (152/254) of patients with nr-axSpA and 42% (139/332) of patients with r-axSpA were enrolled in the MRI sub-studies.
- Of these, 76% (115/152) and 78% (109/139) of patients had valid SPARCC SIJ inflammation assessments at all 3 timepoints, respectively, and 84% (128/152) and 83% (116/139) of patients had valid SPARCC SSS assessments at all 3 timepoints.

SPARCC SIJ Inflammation Scores

- Mean SPARCC SIJ inflammation scores at baseline were largely comparable between BKZ- and placebo (PBO)-randomised patients across both nr-axSpA and r-axSpA populations (**Figure 1**).
- Treatment with BKZ led to reductions from baseline in mean absolute SPARCC SIJ inflammation scores compared to PBO at Week 16; these reductions were maintained to Week 52 for continuous BKZ patients (**Figure 1**).
- Patients who switched from PBO to BKZ at Week 16 (PBO-switchers) reached similar levels of improvement at Week 52 (**Figure 1**).

SPARCC SSS

- Greater reductions from baseline in SPARCC SSS for erosions and increases from baseline in backfill and fat were observed with BKZ versus PBO at Week 16 (**Figure 2–3**), with further reductions and increases, respectively, largely observed to Week 52 in the continuous BKZ group. Similar changes were also observed in PBO-switchers from Week 16 to 52 (**Figure 2**).
- No or minimal changes in SPARCC SSS for ankylosis were observed following treatment with BKZ in patients with nr-axSpA and r-axSpA, respectively, to Week 52 (**Figure 2–3**).

Reliability

- Smallest detectable change (SDC) and intra-class correlation (ICC) reliability data for inflammation and structural lesion scores are provided in **Figure 1** and **Figure 2**.

Conclusions

At Week 16, across the full disease spectrum of axSpA, dual inhibition of IL-17A and IL-17F with bimekizumab substantially improved MRI inflammation, reduced erosions and increased backfill in the SIJ of patients versus placebo. At Week 52, both groups demonstrated significant changes in MRI inflammation, erosion, backfill and fat compared to baseline, consistent with evidence of tissue repair.

Summary

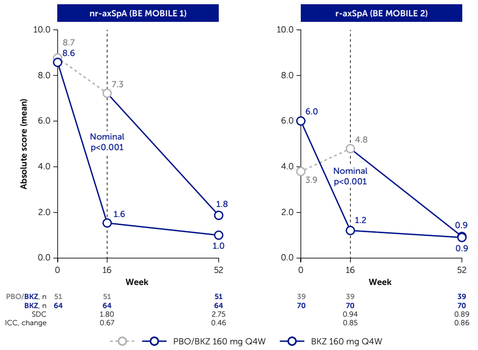
Inflammation and **structural lesions** in the sacroiliac joints are key characteristics of axial spondyloarthritis

Across the **full disease spectrum of axial spondyloarthritis,** dual inhibition of **IL-17A and IL-17F** with **bimekizumab** demonstrated:

Rapid and substantial reductions in SIJ inflammation, as measured by SPARCC SIJ score

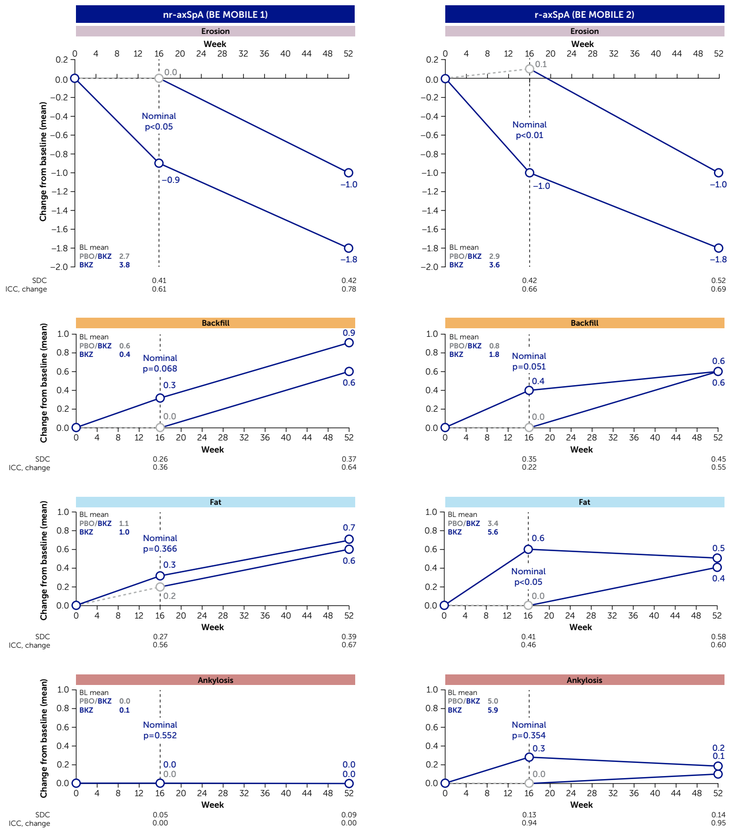
Improvements in structural lesions after 16 weeks of treatment, as measured by SPARCC SSS, potentially indicating tissue repair

Figure 1 Mean MRI SPARCC SIJ inflammation scores up to Week 52 (OC)



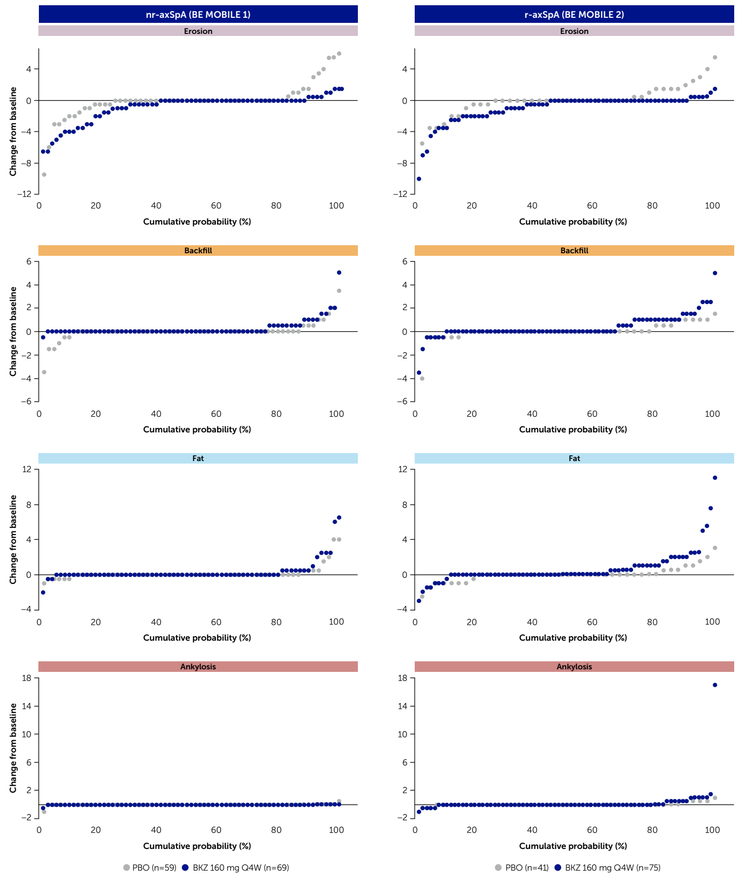
Randomised set. Includes only patients in the MRI sub-studies with valid SPARCC SIJ inflammation assessments at baseline, Week 16 and Week 52. SPARCC SIJ scores range from 0–72, with lower scores indicating less inflammation. SDC was calculated as 1.96 × standard error × √2, where standard error is the difference of the change scores between the two readers (per patient). The ICC assessed the interrater reliability using the two-way random effects mixed model for the absolute agreement between single scores from two independent readers. SDC and ICC are calculated from baseline to the week displayed (i.e. baseline to Week 16, and baseline to Week 52, for the respective timepoints shown).

Figure 2 Change from baseline in SPARCC SSS up to Week 52 (OC)



Randomised set. Includes only patients in the MRI sub-studies with valid SPARCC SSS assessments at baseline, Week 16 and Week 52. SDC was calculated as 1.96 × standard error x √2, where standard error is the difference of the change scores between the two readers (per patient). The ICC assessed the interrater reliability using the two-way random effects mixed model for the absolute agreement between single scores from two independent readers. SDC and ICC are calculated from baseline to the week displayed (i.e. baseline to Week 16, and baseline to Week 52, for the respective timepoints shown).

Figure 3 Cumulative probability plots for SPARCC SSS change from baseline at Week 16 (OC)



Randomised set. Includes only patients in the MRI sub-studies with valid SPARCC SSS assessments at baseline, Week 16 and Week 52.

axSpA: axial spondyloarthritis; **BKZ:** bimekizumab; **BL:** baseline; **ICC:** intra-class correlation; **IL:** interleukin; **MRI:** magnetic resonance imaging; **nr-axSpA:** non-radiographic axSpA; **OC:** observed case; **PBO:** placebo; **Q4W:** every 4 weeks; **r-axSpA:** radiographic axSpA; **SDC:** smallest detectable change; **SIJ:** sacroiliac joints; **SPARCC:** Spondyloarthritis Research Consortium of Canada; **SSS:** SIJ Structural Score.

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References: [1]Baraliakos X. Ann Rheum Dis 2024;83:199–213; [2]Boel A. Ann Rheum Dis 2019;78:1545–9; [3]van der Heijde D. Ann Rheum Dis 2023;82(4):515–26. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **WPM**, **SR**, **DP**, **XB**, **RGL**, **UM**, **CF**, **TV**, **CP**, **AM**, **NdP**, **MO**; Drafting of the publication, or reviewing it critically for important intellectual content: **WPM**, **SR**, **DP**, **XB**, **RGL**, **UM**, **CF**, **TV**, **CP**, **AM**, **NdP**, **MO**; Final approval of the publication: **WPM**, **SR**, **DP**, **XB**, **RGL**, **UM**, **CF**, **TV**, **CP**, **AM**, **NdP**, **MO**. **Author Disclosures: WPM:** Honoraria/consulting fees from AbbVie, BMS, Boehringer Ingelheim, Celgene, Eli Lilly, Galapagos, Janssen, Novartis, Pfizer and UCB Pharma; research grants from AbbVie, Galapagos, Pfizer and UCB Pharma; educational grants from AbbVie, Janssen, Novartis and Pfizer; Chief Medical Officer for CARE Arthritis; **SR:** Grants from AbbVie, Galapagos, MSD, Novartis, Pfizer and UCB Pharma; consulting fees from AbbVie, Eli Lilly, Galapagos, Janssen, Novartis, Pfizer, Sanofi and UCB Pharma; **DP:** Speaker for AbbVie, BMS, Eli Lilly, MSD, Novartis, Pfizer and UCB Pharma; consultant for AbbVie, Biocad, Eli Lilly, Gilead, GSK, MSD, MoonLake, Novartis, Pfizer, Samsung Bioepis and UCB Pharma; grant/research support from AbbVie, Eli Lilly, MSD, Novartis and Pfizer; **XB:** Speakers bureau from AbbVie, BMS, Chugai, Eli Lilly, Galapagos, MSD, Novartis, Pfizer and UCB Pharma; paid instructor for AbbVie, BMS, Chugai, Eli Lilly, Galapagos, MSD, Novartis, Pfizer and UCB Pharma; consultant for AbbVie, BMS, Chugai, Eli Lilly, Galapagos, Gilead, Novartis, Pfizer and UCB Pharma; grant/research support from Novartis and UCB Pharma; **RGL:** Consultant for CARE Arthritis and Image Analysis Group; **UM**, **AM**, **NdP:** Employees of UCB Pharma; **CF**, **TV:** Employees and shareholders of UCB Pharma; **CP:** Contractor for UCB Pharma and employee of Veramed; **MO:** Research grants from Abbott, Centocor and Pfizer; consulting fees from Abbott, Pfizer, Merck, Roche and UCB Pharma; speakers bureau for Abbott, BMS, Merck, Mundipharma, 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, Evelyn Turner, BSc, 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.

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