Bimekizumab Maintained Stringent Clinical Responses Through Week 52 in Patients with Axial Spondyloarthritis: Results from the Phase 3 Studies BE MOBILE 1 and BE MOBILE 2

Objective

To report the maintenance of stringent clinical responses through one year of treatment with bimekizumab (BKZ) in patients with non-radiographic axial spondyloarthritis (nr-axSpA) and radiographic axial spondyloarthritis (r-axSpA; i.e., ankylosing spondylitis)¹ in two phase 3 studies.

Background

- Axial spondyloarthritis (axSpA) is a chronic rheumatic disease which requires optimal management and disease control.
- Long-term maintenance of response is an internationally recommended treatment target.²
- BKZ is a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A. BKZ has demonstrated consistent and sustained clinical efficacy to Week 52 in patients across the full disease spectrum of axSpA in the phase 3 studies BE MOBILE 1 and $2.^3$

Methods

- In BE MOBILE 1 (NCT03928704; nr-axSpA) and BE MOBILE 2 (NCT03928743; r-axSpA), patients were randomized to receive subcutaneous BKZ 160 mg every 4 weeks (Q4W) or placebo to Week 16. From Weeks 16–52, all patients received BKZ 160 mg Q4W.^{4,5}
- Maintenance of Assessment of SpondyloArthritis international Society 40% (ASAS40) response, ASAS partial remission (PR) response, and Ankylosing Spondylitis Disease Activity Score (ASDAS) <2.1 (low disease activity [LDA]) or <1.3 (inactive disease [ID]) to Week 52 were assessed among BKZ-randomized patients who responded/achieved those levels at Week 16.
- Non-responder imputation (NRI) and multiple imputation (MI) were used for missing ASAS and ASDAS data, respectively. Observed case (OC) data are also reported. Week 16 and 52 responder rates for all BKZ-randomized patients are included for context (NRI or MI).
- The number of treatment-emergent adverse events (TEAEs) to Week 52 are reported for patients who received ≥ 1 dose of BKZ, including patients who switched from placebo to BKZ at Week 16.

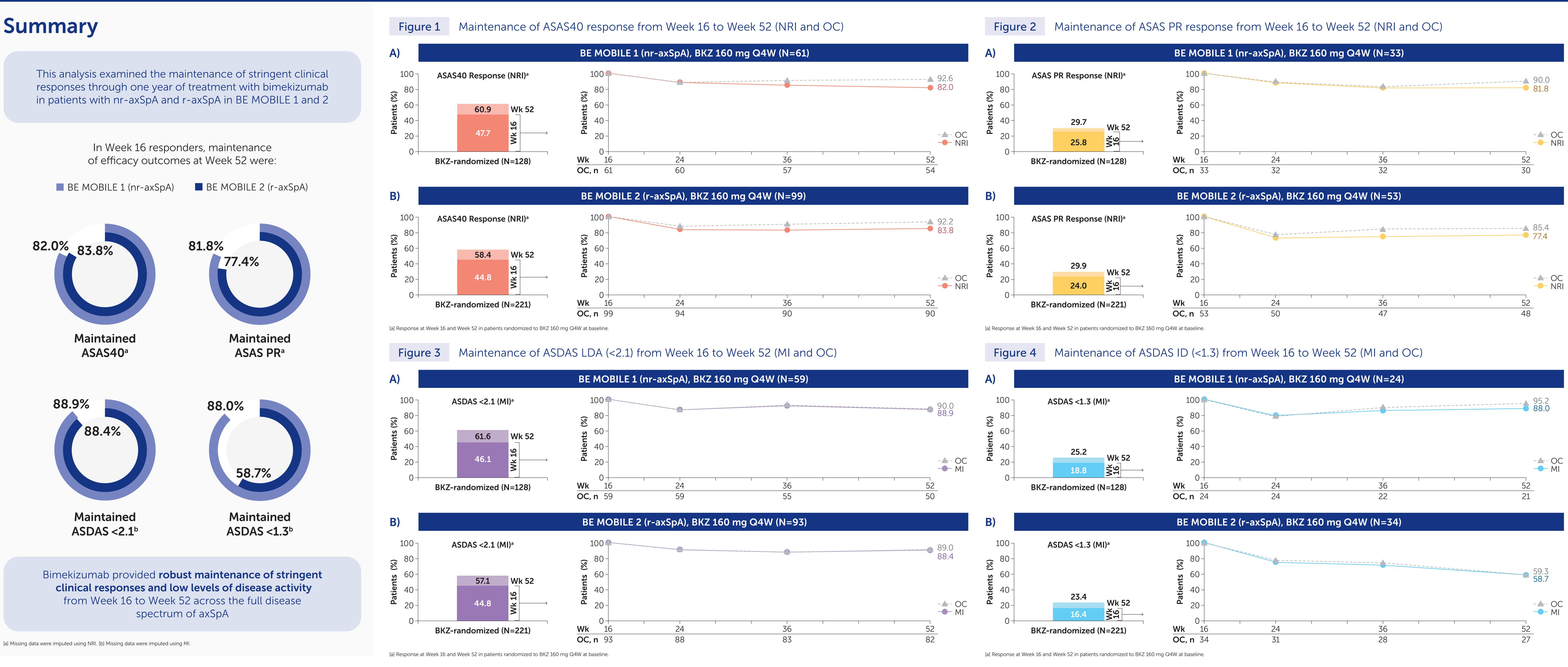
Results

- A total of 128 and 221 patients were randomized to BKZ 160 mg Q4W in BE MOBILE 1 and 2, respectively, with 112 (87.5%) and 196 (88.7%) patients completing the studies to Week 52.
- Of BKZ-randomized patients in BE MOBILE 1 and 2 that achieved ASAS40 at Week 16, 82.0% and 83.8% maintained this response at Week 52 (NRI, Figure 1). Similarly, of patients that achieved ASAS PR at Week 16, the majority maintained this response at Week 52 (Figure 2).
- Of patients that achieved ASDAS LDA at Week 16, 88.9% and 88.4% maintained this response at Week 52 (MI, Figure 3). Among Week 16 ASDAS ID responders, this was maintained by 88.0% and 58.7% at Week 52 (MI, Figure 4).
- To Week 52 of BE MOBILE 1 and 2, 183/244 (75.0%) and 249/330 (75.5%) patients reported \geq 1 TEAE whilst receiving BKZ, respectively; 9 (3.7%) and 20 (6.1%) reported serious TEAEs.

Conclusions

Bimekizumab provided robust maintenance of stringent clinical responses and low levels of disease activity from Week 16 to Week 52 across the full disease spectrum of axSpA. This is consistent with previously reported observations of bimekizumab treatment over three years in patients with r-axSpA in the phase 2b study BE AGILE and its open-label extension.⁶





ment of Rheumatology, Leiden University Medical Center, Leiden, the Netherlands; ³Rheumazentrum Ruhrgebiet Herne, Ruhr-University Bochum, Bochum, Germany; ⁴Division of Rheumatology, Inflammation and Harvard Medical School, Boston, MA, USA; ⁵UCB Pharma, Brussels, Belgium; ⁶UCB Pharma, Brussels, Belgium; ⁶UCB Pharma, Colombes, Pharma, Colombes, Belgium; ⁶UCB Pharma, Brussels, Belgium; ⁶UCB Pharma, Brussels, Belgium; ⁶UCB Pharma, Colombes, Belgium; ⁶UCB Pharma, Brussels, Belgium; ⁶UCB Pharma, Brussels, Belgium; ⁶UCB Pharma, Colombes, Belgium; ⁶UCB Pharma, Brussels, Belgium; ⁶UCB Pharma, B Ei Lilly, Bayer, BMS, Calapagos, MSD, Novartis, Pfizer, and UCB Pharma; consultancy fees from AbbVie, BMS, Chugai, Eli Lilly, Galapagos, MSD, Novartis, Pfizer, and UCB Pharma; consultancy fees from AbbVie, BMS, Chugai, Eli Lilly, Galapagos, MSD, Novartis, Pfizer, and UCB Pharma; consultancy fees from AbbVie, BMS, Chugai, Eli Lilly, Galapagos, MSD, Novartis, Pfizer, and UCB Pharma; consultancy fees from AbbVie, BMS, Chugai, Eli Lilly, Galapagos, MSD, Novartis, Pfizer, and UCB Pharma; consultancy fees from AbbVie, BMS, Chugai, Eli Lilly, Galapagos, MSD, Novartis, Pfizer, and UCB Pharma; consultancy fees from AbbVie, BMS, Chugai, Eli Lilly, Galapagos, MSD, Novartis, Pfizer, and UCB Pharma; consultancy fees from AbbVie, BMS, Chugai, Eli Lilly, Galapagos, MSD, Novartis, Pfizer, and UCB Pharma; consultancy fees from AbbVie, BMS, Chugai, Eli Lilly, Galapagos, MSD, Novartis, Pfizer, and UCB Pharma; consultancy fees from AbbVie, BMS, Chugai, Eli Lilly, Galapagos, MSD, Novartis, Pfizer, and UCB Pharma; consultancy fees from AbbVie, BMS, Chugai, Eli Lilly, Galapagos, MSD, Novartis, Pfizer, and UCB Pharma; consultancy fees from AbbVie, BMS, Chugai, Eli Lilly, Galapagos, MSD, Novartis, Pfizer, and UCB Pharma; consultancy fees from AbbVie, BMS, Chugai, Eli Lilly, Galapagos, MSD, Novartis, Pfizer, and UCB Pharma; consultancy fees from AbbVie, BMS, Chugai, Eli Lilly, Galapagos, MSD, Novartis, Pfizer, and UCB Pharma; consultancy fees from AbbVie, BMS, Chugai, Eli Lilly, Galapagos, MSD, Novartis, Pfizer, and UCB Pharma; consultancy fees from AbbVie, BMS, Chugai, Eli Lilly, Galapagos, MSD, Novartis, Pfizer, and UCB Pharma; consultancy fees from AbbVie, BMS, Chugai, Eli Lilly, Galapagos, MSD, Novartis, Pfizer, and UCB Pharma; consultancy fees from AbbVie, BMS, Chugai, Eli Lilly, Galapagos, MSD, Novartis, Pfizer, and UCB Pharma; consultancy fees from AbbVie, BMS, Chugai, Eli Lilly, Galapagos, MSD, Novartis, Pfizer, and UCB Pharma; consultancy fees from AbbVie, BMS, Chugai, Eli Lilly, Galapagos, MSD, Novartis, Pfizer, and UCB Pharm **Novartis**, Pfizer, and UCB Pharma: **VT, CF, CC:** Employee and shareholder of UCB Pharma: **VT, CF, CC:** Employee and shareholder of UCB Pharma: **VT, CF, CC:** Employee and shareholder of UCB Pharma: **VT, CF, CC:** Employee and shareholder of UCB Pharma: **VT, CF, CC:** Employee and shareholder of UCB Pharma: **VT, CF, CC:** Employee and shareholder of UCB Pharma: **VT, CF, CC:** Employee and shareholder of UCB Pharma: **VT, CF, CC:** Employee and shareholder of UCB Pharma: **VNC:** Speakers bureau for AbbVie, Eli Lilly, Fresenius Kabi, Janssen, MSD, Novartis, Pfizer, and UCB Pharma: **VT, CF, CC:** Employees of UCB Pharma: **VT, CF, CC:** Employee and shareholder of UCB Pharma: **VNC:** Speakers bureau for AbbVie, Eli Lilly, Fresenius Kabi, Janssen, MSD, Novartis, Pfizer, and UCB Pharma: **VT, CF, CC:** Employee and shareholder of UCB Pharma: **VT, CF, CC:** Employe the exterior and their caregivers in addition to all the investigators 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 to all the investigators and the costello Medical Creative team for design support. These studies were funded by UCB Pharma, for publication to all the investigators 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 to all the investigators and the costello Medical Creative team for design support. These studies were funded by UCB Pharma, for publication were funded by UCB Pharma, for publication coordination, Patrick Cox, BSc, Costello Medical Weiter and the costello Medical Creative team for design support. These studies were funded by UCB Pharma, for betwee team for design support. These studies are transformad to the costello Medical Weiter and the costello Weiter and the costello

NRI: non-responder imputation; **ASAS PR:** Assessment of Spondyloarthritis; **BKZ:** bimekizumab; **ID:** inactive disease; **IL:** interleukin; **LDA:** low disease; **ASAS PR:** Assessment of Spondyloarthritis; **BKZ:** bimekizumab; **ID:** inactive disease; **PR:** partial remission; **ASAS PR:** Assessment of Spondyloarthritis; **BKZ:** bimekizumab; **ID:** inactive disease; **IL:** interleukin; **LDA:** low disease activity; **AI:** multiple imputation; **OC:** observed case; **PR:** partial remission; **ASAS PR:** Assessment of Spondyloarthritis; **BKZ:** bimekizumab; **ID:** inactive disease; **IL:** interleukin; **LDA:** low disease activity; **AII:** multiple imputation; **OC:** observed case; **PR:** partial remission; **ASAS PR:** Assessment of Spondyloarthritis; **BKZ:** bimekizumab; **ID:** inactive disease; **IL:** interleukin; **LDA:** low disease; **PR:** partial remission; **ASAS PR:** Assessment of Spondyloarthritis; **BKZ:** bimekizumab; **ID:** inactive disease; **IL:** interleukin; **LDA:** low disease; **IL:** interleukin; **LDA:** low disease; **ASAS PR:** Assessment of Spondyloarthritis; **BKZ:** bimekizumab; **ID:** inactive disease; **IL:** interleukin; **LDA:** low disease; **IL:** interleukin; **LDA:** low disease; **IC:** assessment of Spondyloarthritis; **BKZ:** bimekizumab; **ID:** assessment of Spondyloarthritis; **BKZ:** assessment of Spondyloarthritis; **BKZ:** bimekizumab; **ID:** assessment of Spondyloarthritis; **BKZ:** assessment of Spondyloart

Fabian Proft,¹ Désirée van der Heijde,² Xenofon Baraliakos,³ Joerg Ermann,⁴ Carmen Fleurinck,⁵ Ute Massow,⁶ Natasha de Peyrecave,⁵ Vanessa Taieb,⁷ Astrid van Tubergen,⁸ Victoria Navarro-Compán⁹

Presented by: Cori Cooper¹⁰