# Bimekizumab Treatment was Efficacious to 2 Years Regardless of Duration of axSpA Symptoms: Results from Two Phase 3 Studies

## Objective

To evaluate the impact of shorter vs longer duration of symptoms (DoS) on the 2-year efficacy of bimekizumab (BKZ) in the treatment of axial spondyloarthritis (axSpA).

### Background

- Recently, early axSpA has been defined for research purposes as a DoS of  $\leq 2$  years by the Assessment of SpondyloArthritis international Society (ASAS).<sup>1</sup> Evidence evaluating whether treatment in early axSpA leads to better outcomes compared with established disease is scarce.
- BKZ is a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A. • BKZ has shown efficacy to Week 52 in patients with non-radiographic (nr-) and radiographic (r-)axSpA in the phase 3 trials BE MOBILE 1 and 2.<sup>2,3</sup> Here, we report BKZ efficacy in patients with early axSpA vs

## **Methods**

- In BE MOBILE 1 (nr-axSpA; NCT03928704) and BE MOBILE 2 (r-axSpA; NCT03928743), patients were randomized to subcutaneous BKZ 160 mg every 4 weeks (Q4W) or placebo (PBO); all received BKZ in Weeks 16-52.
- At Week 52, patients could enter an ongoing open-label extension (NCT04436640) and continue BKZ treatment.
- We present a post hoc analysis of the following clinical efficacy outcomes to Week 104, in patients with DoS  $\leq 2$  or >2 years in BE MOBILE 1:
- ASAS 40% improvement (ASAS40; non-responder imputation [NRI])

established disease, across the full disease spectrum of axSpA, to 2 years.

- Axial Spondyloarthritis Disease Activity Score (ASDAS) <2.1 (multiple imputation [MI])
- Mean Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) change from baseline (CfB; MI) • We also report the above outcomes for patients with DoS  $\leq$ 5 or >5 years in BE MOBILE 1 and 2 to
- optimize subgroup sample sizes (only 17 patients had DoS  $\leq$ 2 years in BE MOBILE 2).
- In addition to the above outcomes, we report mean MRI Spondyloarthritis Research Consortium of Canada (SPARCC) sacroiliac joint (SIJ) inflammation score (observed case [OC]) for MRI sub-study patients with DoS  $\leq 5/>5$  years in BE MOBILE 1 (only 27 patients had DoS  $\leq 5$  years in the BE MOBILE 2 MRI sub-study).
- For all outcomes, continuous BKZ and PBO/BKZ switchers were pooled within each trial from Week 52.
- To compare treatment effect (BKZ vs PBO efficacy) between DoS subgroups, relative odds ratio (rOR; ASAS40, ASDAS <2.1) and relative differences (BASDAI CfB, MRI SPARCC SIJ) were calculated at Week 16, sample size permitting.

- Trials were not powered for post hoc analyses; results should be interpreted as nominal.

# Results

### **Clinical Efficacy Outcomes**

- Better outcomes were seen with BKZ vs PBO at Week 16, regardless of DoS, across all efficacy measures (Figure 1–2). Outcomes were sustained or improved in all DoS subgroups to Week 104.
- At Week 16, numerically larger proportions of BKZ-treated patients with DoS  $\leq 5/\leq 2$  years achieved ASAS40 and ASDAS <2.1 vs patients with DoS >5/>2 years.
- No statistically significant difference was detected in treatment effect with BKZ vs PBO at Week 16 between patients with DoS  $\leq$  5 vs > 5 years (BE MOBILE 1 and 2) or between patients with DoS  $\leq$  2 vs >2 years (BE MOBILE 1).
- At Week 104, numerically larger proportions of patients with DoS  $\leq 5/\leq 2$  years achieved ASAS40 and ASDAS <2.1 vs patients with DoS >5/>2 years (Figure 1-2).
- No statistically significant difference in treatment effect with BKZ vs PBO was detected at Week 16 in mean BASDAI CfB between patients with DoS  $\leq$ 5 vs >5 years, or DoS  $\leq$ 2 vs >2 years in BE MOBILE 1, but a larger improvement was found in BASDAI in patients with DoS  $\leq 5$  vs >5 years in BE MOBILE 2 (Figure 1–2).
- At Week 104, there were numerically larger reductions (i.e., improvements) from baseline in mean BASDAI for patients with DoS  $\leq 5/\leq 2$  years vs patients with DoS >5/>2 years (**Figure 1–2**).

### **MRI Inflammation**

- Baseline MRI SPARCC SIJ scores indicated more inflammation in patients with DoS  $\leq$  5 vs >5 years in BE MOBILE 1 (**Figure 3**).
- BKZ treatment led to reduction in mean MRI SPARCC SIJ scores to Week 16.
- No statistically significant difference in treatment effect was detected with BKZ vs PBO between patients with DoS  $\leq$  5 vs >5 years at Week 16 (Figure 3).
- Mean MRI SPARCC SIJ scores remained low to Week 104 and indicated resolution of inflammation, regardless of DoS.

## **Conclusions**

Overall, no statistically significant differences in the Week 16 treatment effect of bimekizumab compared to placebo were found between patients with shorter vs longer DoS. However, bimekizumab treatment demonstrated sustained efficacy through 2 years, irrespective of DoS, highlighting its therapeutic potential for both early and established axSpA.

# sympton A) MRI SPARCC SIJ

Duration of

Week PBO/BKZ DoS <5 yrs, n PBO/BKZ DoS >5 yrs, n BKZ DoS <5 yrs, n BKZ DoS >5 yrs, n 44

Randomized set. Only study participants enrolled in the MRI sub-studies are included. Beyond Week 52, all data, including n numbers, are pooled across BKZ- and PBO-randomized patients. [a] Relative differences in least-square means and 95% CIs for the comparison of BKZ vs PBO were calculated using ANCOVA, including factors for treatment, MRI/CRP classification, baseline MRI SPARCC SIJ value, DoS, and treatment  $\times$  DoS.

1 and so be a set in ternation of symptoms; IL: interleukin; MI: multiple imputation; MRI: magnetic resonance imaging; nr-axSpA: axial spondyloarthritis; BASDAI: Bath Ankylosing Spondyloarthritis; BASDAI: Bath Ankylosing; nr-axSpA: non-radiographic axSpA; NRI: non-responder set in terval; Creactive protein; Do set in terval; Creactive protein; Do set in terval; Creactive protein; Di sease Activity Score; axSpA: non-responder set in terval; Creactive protein; Do set in terval; Creactive protein; Do set in terval; Creactive protein; Do set in terval; Creactive protein; Di sease Activity Index; BKZ: binekizumab; Creactive protein; Do set in terval; Creactive protein; Di sease Activity Score; axSpA: non-responder set in terval; Creactive protein; Di sease Activity Index; BKZ: binekizumab; Creactive protein; Do set in terval; Creactive protein; Do set in terval; Creactive protein; Di sease Activity Score; axSpA: non-responder set in terval; Creactive protein; Di sease Activity Score; axSpA: non-responder set in terval; Creactive protein; Di sease Activity Score; axSpA: non-responder set in terval; Creactive protein; Di sease Activity Score; axSpA; NRI: non-responder set in terval; Creactive protein; Di sease Activity Score; axSpA; NRI: non-responder set in terval; Creactive protein; Di sease Activity Score; axSpA; NRI: non-responder set in terval; Creactive protein; Di sease Activity Score; AxSpA; NRI: non-responder set in terval; Creactive protein; Di sease Activity Score; AxSpA; NRI: non-responder set in terval; Creactive protein; Di sease Activity Score; AxSpA; NRI: non-responder set in terval; Creactive protein; Di sease Activity Score; AxSpA; NRI: non-responder set in terval; Creactive protein; Di sease Activity Score; AxSpA; NRI: non-responder set in terval; Creactive protein; Di sease Activity Score; AxSpA; NRI: non-responder set in terval; Creactive protein; Di sease Activity Score; AxSpA; NRI: non-responder set in terval; Creactive protein; Di sease Activity Score; AxSpA; NRI: non-responder set in terval; Cre imputation; OC: observed case; PBO: placebo; Q4W: every 4 weeks; r-axSpA: radiographic axSpA; RD: relative odds ratio; SIJ: sacroiliac joint; SPARCC: Spondyloarthritis Research Consortium of Canada; TNF: tumor necrosis factor; yrs: years.

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# Summary

Recently, early axSpA has been defined for research purposes as a duration of symptoms of  $\leq 2$  years.

We assessed the long-term efficacy of bimekizumab in patients with **shorter vs longer** duration of symptoms of axSpA ( $\leq 2 vs > 2$  years and  $\leq 5 vs > 5$  years) over 2 years.



### **Figure 3** MRI inflammation stratified by DoS $\leq$ 5 and >5 years in BE MOBILE 1 (OC)











Randomized set. BKZ-randomized patients received BKZ 160 mg Q4W to Week 16; all patients in their respective subgroups at baseline. Beyond Week 52, all data are pooled across BKZ- and PBO-randomized patients. [a] Odds ratios for the comparison of BKZ vs PBO were calculated using logistic regression. For patients with nr-axSpA, factors for logistic regression included treatment, MRI/CRP classification, region, DoS, and treatment × DoS. For patients with r-axSpA, factors for logistic regression included treatment, prior TNF inhibitor exposure, region, DoS, and treatment × DoS. The relative odds ratio is the odds ratio of the comparison of BKZ vs PBO with shorter vs longer DoS. This value, and its associated 95% CIs and p value, are extracted from the interaction effect of treatment and DoS from the logistic regression; [b] Relative differences in least-square means and 95% CIs for the comparison of BKZ vs PBO were calculated using ANCOVA. For patients with nr-axSpA, factors for ANCOVA included treatment, MRI/CRP classification, region, baseline BASDAI value, DoS, and treatment × DoS. For patients with r-axSpA, factors included treatment, prior TNF inhibitor exposure, region, baseline BASDAI value, DoS, and treatment × DoS. \*Larger improvements in BASDAI achieved in patients with DoS <5 vs >5 years (nominal p <0.05).

### **Figure 1** ASAS40 (NRI), ASDAS <2.1 (MI) and mean BASDAI CfB (MI) stratified by DoS <5 and >5 years in BE MOBILE 1 and 2





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ASAS40 (NRI), ASDAS <2.1 (MI) and mean BASDAI CfB Figure 2 (MI) stratified by DoS  $\leq$ 2 and >2 years in BE MOBILE 1

This value, and its associated 95% CIs and p value, are extracted from the interaction effect of treatment and DoS from the logistic regression; [b] Relative differences in least-square means and 95% CIs for the comparison of BKZ vs PBO were calculated using ANCOVA including factors for treatment, MRI/CRP classification, region, baseline BASDAI value, DoS, and treatment × DoS.

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