Achievement of Low Disease Activity Over 52 Weeks in Patients with Active Axial Spondyloarthritis on Bimekizumab Treatment: Results from the Phase 3 Studies BE MOBILE 1 and BE MOBILE 2

Objective
To report achievement of low disease activity, as assessed by either ASDAS <2.1 or BASDAI <4, in patients with axial spondyloarthritis (axSpA) over 52 weeks of bimekizumab treatment.

Background
- The recommended target for axial spondyloarthritis (axSpA) is remission or low disease activity (LDA) based on American College of Rheumatology (ACR) criteria.
- The Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) remission is defined as BASDAI ≤1.3. However, even within high disease activity levels, NSAIDs may be used to variably cut-off for BASDAI that would indicate remission or LDA.
- BASDAI is a non-inflammatory biomarker that is driven entirely by patient inter/intra-class variability, and some investigators have criticized the cut-off.

Methods
- The BE MOBILE 1 study was a 32-week placebo-controlled trial in patients with nr-axSpA (n=332) and r-axSpA (n=332), including a 10-week open-label bimekizumab treatment period followed by a 22-week double-blind treatment period with bimekizumab or placebo.
- The BE MOBILE 2 study was a 32-week placebo-controlled trial in patients with nr-axSpA (n=254 and including a 10-week open-label bimekizumab treatment period followed by a 22-week double-blind treatment period with bimekizumab or placebo.

Results

Patients
- Of the 684 patients with nr-axSpA and 332 with r-axSpA randomized, most completed the 52-week study period.
- On-axis: PBO/BKZ 160 mg Q4W vs placebo; n (%): 295/332 (88.8%) vs 327/332 (98.5%).
- Off-axis: PBO/BKZ 160 mg Q4W vs placebo; n (%): 295/332 (88.8%) vs 324/332 (97.9%).

Achievement of LDA
- In patients with nr-axSpA, a greater proportion of PBO/BKZ vs placebo-treated patients achieved LDA at 52 weeks according to ASDAS <2.1, BASDAI <4, and/or non-responder imputation.
- Responses, as measured by achievement of ASDAS <2.1 and/or BASDAI <4, were sustained or improved by Week 52 with bimekizumab treatment and switched those of NRIs randomized among patients switching to BKZ from placebo at Week 16.

Comparison of ASDAS and BASDAI as Measures of LDA
- The proportion of patients achieving ASDAS <2.1 was generally higher than BASDAI <4, regardless of treatment arm (Figure 2).
- A greater proportion of patients who achieved ASDAS <2.1 also achieved BASDAI <4 than vice versa (Figure 3).

Conclusions
- Across the full disease spectrum of axSpA, dual inhibition of IF-17A and IL-22 with bimekizumab resulted in sustained achievement of LDA vs placebo to Week 16, with the proportion of patients achieving LDA increasing to Week 52.

Legend:
- ASDAS: Ankylosing Spondylitis Disease Activity Score
- BASDAI: Bath Ankylosing Spondylitis Disease Activity Index
- MI: Missing data
- MI: Non-responder imputation
- NRI: Non-response imputation

Table 1
Baseline characteristics of patients with nr-axSpA (BE MOBILE 1) and r-axSpA (BE MOBILE 2) who did or did not achieve LDA at Week 52 (NRI)

Figure 1
Study design

Figure 2
Proportion of patients achieving ASDAS <2.1, BASDAI <4, or both, over 52 weeks (NRI and MI)

Figure 3
Proportion of patients who achieved ASDAS <2.1 and/or BASDAI <4 at Week 52 (NRI)