Bimekizumab in patients with active non-radiographic axial spondyloarthritis and active ankylosing spondylitis: 24-week efficacy and safety from the BE MOBILE phase 3 studies

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Objective
To assess the efficacy and safety of subcutaneous bimekizumab (BKZ) versus placebo in patients with active non-radiographic axial spondyloarthritis (nr-axSpA) and active ankylosing spondylitis (AS) in BE MOBILE 1 and BE MOBILE 2 studies up to Week 24 in the on-treatment, pivotal, BE MOBILE 1 and BE MOBILE 2 phase 3 studies.

Introduction
• BKZ is a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in vitro and in vivo.
• Up to Week 24, 124/244 (50.8%) patients with nr-axSpA, and 183/330 (55.5%) patients with AS (placebo: 22.5% vs BKZ: 44.8%; p<0.001) fulfilled the ASAS criteria for clinical remission.

Methods
• BE MOBILE 1 (n=1228; NCT03887040) and BE MOBILE 2 (n=1303; NCT03887041) each comprised a 16-week double-blind, placebo-controlled period followed by a 16-week maintenance period.
• Patients were ≥18 years of age with active disease at screening and baseline (BASDAI ≥4 and spinal pain ≥4), fulfilling the ASAS classification for nr-axSpA or modified New York criteria for AS.
• Primary (ASAS40) and secondary endpoints were assessed at Week 16, with efficacy including a change from baseline in BASDAI (A) and ASAS enthesitis score (B) (47.7% BKZ vs 21.4% placebo; p<0.001) and AS (44.8% BKZ vs 22.5% placebo; p<0.001) (Figure 1).

Results
 Patients
• A total of 244/254 (96.1%) patients with nr-axSpA, and 322/332 (97.0%) patients with AS (placebo: –1.5; BKZ: –6.3) and AS (placebo: 1.1; BKZ: –5.6) experienced a decrease in physical function (BASFI) and an increase in the proportion of patients with ASAS40 (124/126 vs 94/128; p<0.001) and AS (44.8% BKZ vs 22.5% placebo; p<0.001) (Figure 2).

Efficacy
• At Week 16, the primary endpoint (ASAS40) was met in patients with nr-axSpA (47.7% BKZ vs 21.4% placebo; p=0.003) (Figure 3). At Week 24, in patients with AS, the primary endpoint (ASAS40) was also met (44.8% BKZ vs 22.5% placebo; p<0.001).
• All ranked secondary endpoints met at Week 16 in both studies, including change from baseline in BASDAI (n=1228) (47.7% BKZ vs 21.4% placebo; p<0.001), and BASFI (47.7% BKZ vs 21.4% placebo; p<0.001) in patients with AS.

Safety
• BKZ was well tolerated in both studies and the safety profile was consistent with other studies.

Conclusion
Dual inhibition of IL-17A and IL-17F with BKZ in patients across the full axSpA disease spectrum (nr-axSpA and AS) resulted in consistently rapid and robust improvements in quality of life in ASAS responders, as well as objective measures of inflammation (hs-CRP and NRI) and resolution of enthesitis. These results reflect overall improvements in core symptoms, functional impact, and disease activity.

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Table 1 Baseline characteristics

Table 2 Safety overview

Table 3 Double-blind period

Figure 1 BE MOBILE 1 and BE MOBILE 2 study designs

Figure 2 ASAS40 response (Weeks 0–24)

Figure 3 Mean hs-CRP (Weeks 0–24)

Figure 4 Complete resolution of enthesitis (Weeks 0–24)

References


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