Bimekizumab Maintains Improvements in Efficacy Endpoints and has a Consistent Safety Profile Through 52 Weeks in Patients with Non-Radiographic Axial Spondyloarthritis and Ankylosing Spondylitis: Results from Two Parallel Phase 3 Studies

Presented at ACR Convergence 2022 | Philadelphia, Pennsylvania, USA | November 10–14

Objective

To report efficacy and safety of bimekizumab (BKZ) in patients with active non-radiographic axial spondyloarthritis (nr-axSpA) and ankylosing spondylitis (AS) up to Week 52 in the pivotal phase 3 studies, BE MOBILE 1 and 2, respectively.

Background

• BKZ, a fully human, bi-specific monoclonal antibody that selectively inhibits interleukin-17 (IL-17) in addition to IL-17A, was enrolled as a primary and ranked secondary endpoint in both studies. The results of these end points are only reported in the phase 3 BE MOBILE 1 and 2 studies, respectively.

Methods

• BE MOBILE 1 (NCT03398787; nr-axSpA) and BE MOBILE 2 (NCT03928743; AS) were conducted in parallel, each enrolled 24-week double-blind periods (BKZ-controlled period followed by a 36-week maintenance period Figure 1).

• Primary and secondary efficacy endpoints were assessed at Week 52 and are presented in this analysis through Week 52 (Figure 2).

• Treatment-emergent adverse events (TEAEs) following first BKZ exposure are reported at the Week 52 data cut (safety set).

Results

Patients

• 2004/2046 (BE MOBILE 1/2) randomized patients with nr-axSpA and (296/330) (BE MOBILE 2) with AS completed Week 52.

• Baseline characteristics were reflective of patient population with moderate-to-severe nr-axSpA and AS (Table 1).

Efficacy

• In both studies, in BKZ-randomized patients, the primary and ranked secondary endpoints were assessed. The current analysis includes patients who switched from PBO to BKZ at Weeks 16 or 28 (BE MOBILE 1), efficacy at Week 52 was assumed to be 100% for BKZ-randomized patients.

• ASAS40 responses in BKZ-randomized patients increased from Week 16 to Week 52 (Figure 2).

• ASAS40 responses at Week 52 were consistent across both TNF-α naïve and TNF-α-inadequate responder populations (Table 2).

• At Week 52, ASAS40 in both studies was achieved by >50% of BKZ-randomized patients with nr-axSpA and AS, respectively.

• The Week 52 reductions from baseline in objective signs of inflammation (ASDAS-CRP) and improvements in Function (BASMI) and Quality of Life (ASQoL) continued through 52 weeks.

• Complete resolution of enthesitis (Maastricht Ankylosing Spondylitis Enthesitis Score [MASES] ≤0) in patients with baseline MASES ≥2 at 52 weeks was achieved by 54.3% and 50.8% of BKZ vs 44.6% and 46.3% of PBO/BKZ at Week 24.

• The most frequent TEAEs were nasopharyngitis, upper respiratory tract infection, and oral candidiasis.

Safety

• At the Week 52 data cut, 75.3% (BE MOBILE 1) and 75.5% (BE MOBILE 2) of patients with nr-axSpA and AS continued the study due to Adjudicated IBD, respectively.

• The most frequent TEAEs were nasopharyngitis, upper respiratory tract infection, and oral candidiasis.

• Two COVID-19 infections were reported (nr-axSpA: 3, AS: 3), none of which resulted in hospitalization. In the analysis of TEAEs following first BKZ exposure, these events were not reported. Incidence of influenza-related disease and events were low (Table 5).

Conclusions

Across the full axSpA disease spectrum, dual inhibition of IL-17A in addition to IL-17F with bimekizumab is associated with consistent suppression of inflammation and improvements in function and quality of life. In Week 52, new safety signals were observed, consistent with the safety profile established in prior studies.

L14

Xenofon Baraliakos,1 Atul Deodhar,2 Désirée van der Heijde,3 Marina Magery,4 Walter P. Hakimowycz,4 Tetsuya Tozima5 Hui Xu,5 Marga Cortijsen,6 Ute Massow7 Carmen Fleurinc8 Alicia M. Ellis,9 Tom Vaxa,9 Julie Shepherd-Smith,9 Alexander Marten,9 Lianne S. Gensler9

1Department of Medicine, Rheumatology, University Hospital Kiel, Kiel, Germany; 2Division of Rheumatology, Immunology and Allergy, University of California San Francisco, San Francisco, CA, USA; 3Department of Rheumatology, Leiden University Medical Center, Leiden, The Netherlands; 4Division of Rheumatology, University of Alberta, Edmonton, AB, Canada; 5Department of Rheumatology, Rheumatoid Arthritis Research, Chugai Pharmaceutical Co., Ltd., Tokyo, Japan; 6Department of Rheumatology, Canada, Amsterdam, The Netherlands; 7Department of Rheumatology, Rheumatoid Arthritis Research, Chugai Pharmaceutical Co., Ltd., Tokyo, Japan; 8Department of Rheumatology, Gilead Sciences, Inc., Foster City, CA, USA; 9Division of Rheumatology, Immunology and Allergy, University of California San Francisco, San Francisco, CA, USA