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 in patients with non-radiographic axial spondyloarthritis and radiographic axial spondyloarthritis (i.e., ankylosing spondylitis) 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.
- Bimekizumab (BKZ) is a monoclonal IgG1 antibody that selectively inhibits interleukin-17 (IL-17) and has demonstrated efficacy 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.

**Methods**
- In BE MOBILE 1 (NCT03192784), non-radiographic axSpA (nr-axSpA) and BE MOBILE 2 (NCT03383074), radiographic axSpA (r-axSpA) patients were randomised to receive subcutaneous BKZ 160 mg every 4 weeks (Q4W) from Week 16 to Week 52, in addition to l Bra, BKZ was demonstrated to provide maintenance of ASDAS LDA 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.
- Maintenance of Assessment of SpondyloArthritis international Society 40% or 44% response (ASAS40 or ASAS40a) was the primary endpoint of the phase 3 studies. A non-inferiority margin of 10% was pre-specified.
- Week 16 and 52 responder rates for all BKZ-randomised patients completing the studies to Week 52 were randomised 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.
- Of BKZ-randomised patients in BE MOBILE 1 and 2 that achieved ASAS40 or ASAS40a at Week 16, 82.0% and 88.4% maintained this response at Week 52 (NRI), respectively, with 12.1% and 7.5% lost to follow-up. Among Week 16 responders, maintenance of ASAS40 response was 88.0% (NRI) and 81.8% (MI) at Week 52 (Figure 1).
- Similarly, of patients that achieved ASAS PR at Week 16, 84.2% and 77.4% maintained this response at Week 52 (NRI), respectively, with 0% and 1.0% lost to follow-up. Among Week 16 responders, maintenance of ASAS PR response was 77.4% (NRI) and 70.7% (MI) at Week 52 (Figure 2).
- Bimekizumab maintained 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 on three pairs in patients with r-axSpA in the phase 2 study BE AGILE and its open-label extension (Figure 3).

**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. It is consistent with previously reported observations of bimekizumab treatment on three pairs in patients with r-axSpA in the phase 2 study BE AGILE and its open-label extension.

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References:

**Figure 1** Maintenance of ASAS40 response from Week 16 to Week 52 (NRI and OC).

**Figure 2** Maintenance of ASAS PR response from Week 16 to Week 52 (NRI and OC).

**Figure 3** Maintenance of ASDAS LDA (<2.1) from Week 16 to Week 52 (MI and OC).

**Figure 4** Maintenance of ASDAS ID (>-1.3) from Week 16 to Week 52 (MI and OC).

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