Bimekizumab in Patients with Active Non-Radiographic Axial Spondyloarthritis: 24-Week Efficacy & Safety from BE MOBILE 1, a Phase 3, Multicentre, Randomised, Placebo-Controlled Study

**Objective**
To assess efficacy and safety of subcutaneous bimekizumab (BKZ) in placebo (PBO) PR96 patients with active non-radiographic axial spondyloarthropathy (axSpA) up to Week 24 in 24-week phase 3 study, BE MOBILE 1.

**Methods**
- **Randomisation**: 1:1:1 randomisation to BKZ 160 mg Q4W, BKZ 160 mg Q6W or PBO for 24 weeks.
- **Eligibility**: Patients with active axSpA (BASDAI ≥4 and spinal pain ≥4) and at least one ASAS40 response at baseline. Patients were stratified by disease activity at baseline, and randomized within stratum to treatment arm.
- **Inclusion/Exclusion Criteria**: Patients with active axSpA at screening and baseline (BASDAI ≥4 and spinal pain ≥4), and at least one ASAS40 response at baseline. Patients were stratified by disease activity at baseline, and randomized within stratum to treatment arm.

**Primary Endpoint**
Change from baseline in SPARCC MRI SIJ score at Week 16 (OC). Baseline was defined as the visit before the first dose of study drug.

**Secondary Endpoints**
- ASAS40 to Week 24 (NRI)
- ASDAS-MI ASAS PRASAS20 ASAS40
- Patients (%) with MRI SIJ reduction of 30% or more at Week 16
- MRI SIJ score at Week 16
- BASDAI, mean (SD) at Week 24
- CRP, mean (SD) at Week 24
- C-reactive protein elevation ≥50% from baseline at Week 24
- Adjudicated IBD
- Adjudicated MACE
- Treatment-emergent adverse events (TEAEs; MedDRA v19.0)
- Serious adverse events
- Adverse events leading to study discontinuation
- Death

**Study Population**
- **Patients**: 394 patients (128 in each arm). Patients were stratified by disease activity at baseline, and randomized within stratum to treatment arm.
- **Randomisation**: 1:1:1 randomisation to BKZ 160 mg Q4W, BKZ 160 mg Q6W or PBO for 24 weeks.
- **Eligibility**: Patients with active axSpA at screening and baseline (BASDAI ≥4 and spinal pain ≥4), and at least one ASAS40 response at baseline. Patients were stratified by disease activity at baseline, and randomized within stratum to treatment arm.

**Study Design**
- **Randomisation**: 1:1:1 randomisation to BKZ 160 mg Q4W, BKZ 160 mg Q6W or PBO for 24 weeks.
- **Eligibility**: Patients with active axSpA at screening and baseline (BASDAI ≥4 and spinal pain ≥4), and at least one ASAS40 response at baseline. Patients were stratified by disease activity at baseline, and randomized within stratum to treatment arm.

**Results**
- **ASAS40 to Week 24 (NRI)**: 47.7% BKZ vs 21.4% PBO (p<0.001).
- **ASDAS-MI ASAS PRASAS20 ASAS40**: 71.1% BKZ vs 44.4% PBO (p<0.001).
- **Patients (%) with MRI SIJ reduction of 30% or more at Week 16**: 64.3% BKZ vs 35.4% PBO (p<0.001).
- **MRI SIJ score at Week 16**: 39.7% BKZ vs 70.2% PBO (p<0.001).

**Conclusion**
- Bimekizumab (BKZ) in placebo (PBO) PR96 patients with active axSpA resulted in rapid and clinically meaningful improvements in key signs and symptoms of disease and reduction of disease activity. Objective signs of inflammation, as measured by MRI and CRP, were markedly reduced with BKZ, and no new safety signals were observed.

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**References**