# Bimekizumab Impact on Core Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) Domains for Patients with Psoriatic Arthritis: 52-Week Results from Four Phase 3 Studies

### Objective

To report bimekizumab (BKZ) efficacy across the core Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) domains to Week 52 from two phase 3 trials in psoriatic arthritis (PsA), with axial domain outcomes from two phase 3 trials in axial spondyloarthritis (axSpA).

### Background

- The GRAPPA domain-based treatment recommendations for PsA focus on:<sup>1</sup>
- Six key domains: peripheral arthritis, axial disease, enthesitis, dactylitis, skin psoriasis, and nail psoriasis
- **PsA-related conditions**: uveitis and inflammatory bowel disease (IBD).
- BKZ, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated superior clinical efficacy versus placebo (PBO) to Week 16 in phase 3 clinical trials of patients with PsA.<sup>2,3</sup>
- In patients with psoriasis, superior skin domain efficacy has been demonstrated versus secukinumab (IL-17A inhibitor), ustekinumab (IL-12/23 inhibitor), and adalimumab (TNF inhibitor [TNFi]).4-6

### Methods

- Patients were randomized to receive subcutaneous BKZ 160 mg or PBO every 4 weeks (Q4W) in BE OPTIMAL (NCT03895203; biologic disease-modifying antirheumatic drug [bDMARD] naïve patients with PsA), BE COMPLETE (NCT03896581; patients with PsA who had a prior inadequate response or intolerance to TNFis [TNFi-IR]), BE MOBILE 1 (NCT03928704; non-radiographic axSpA) and BE MOBILE 2 (NCT03928743; radiographic axSpA, i.e. ankylosing spondylitis). BE OPTIMAL included a reference arm (adalimumab 40 mg Q2W) to Week 52; data not shown.<sup>2,3,7</sup>
- From Week 16, all PBO-randomized patients received BKZ 160 mg Q4W to Week 52 (PBO/BKZ). BE COMPLETE Week 16 and BE OPTIMAL Week 52 completers could enter BE VITAL (NCT04009499; open-label extension).
- For BE MOBILE 1 and 2, only outcomes related to axial disease are reported here.
- Outcomes are reported by GRAPPA domain. Missing data were imputed using non-responder imputation (NRI) for binary outcomes and multiple imputation (MI) for continuous outcomes, or reported using observed case (OC).

### Results

- Week 52 completion was high (BE OPTIMAL: 770/852 [90.4%], BE COMPLETE: 347/400 [86.8%], BE MOBILE 1: 220/254 [86.6%], BE MOBILE 2: 298/332 [89.8%]). Baseline demographics and disease characteristics have been previously reported.<sup>2,3,</sup>
- Across all GRAPPA domains, improvements from Week 16 were sustained to Week 52 in BKZ-treated patients across all studies. Individual domain responses were generally consistent between bDMARD-naïve and TNFi-IR patients.
- Pooled results from **BE MOBILE 1 and 2** demonstrated BKZ efficacy in patients with axSpA and were suggestive of efficacy for axial disease in PsA.<sup>1</sup>
- Responses were generally consistent between BKZ and PBO/BKZ patients at Week 52. To Week 52, there were no instances of uveitis (BE OPTIMAL; BE COMPLETE). Four (0.5%) patients in BE OPTIMAL had probable or definite adjudicated IBD; no patients had adjudicated IBD in BE COMPLETE.

## Conclusions

Treatment with bimekizumab resulted in robust and sustained improvements across GRAPPA domains with low rates of IBD and no uveitis to Week 52 for both bDMARD-naive and TNFi-IR patients with PsA; results from patients with axSpA support efficacy in the axial domain.









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### PBO/BKZ 160 mg Q4W --- → --- ■ Ø BKZ 160 mg Q4W --- ■





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