Efficacy and safety of bimekizumab in bDMARD-naïve patients with psoriatic arthritis: 24-week results from BE OPTIMAL, a phase 3, multicentre, randomised, placebo-controlled, active reference study

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Objective
To assess the efficacy and safety of bimekizumab (BKZ) vs placebo (PBO) in biologic DMARD-naïve patients with active psoriatic arthritis (PsA) up to Week 24 in the phase 3 study BE OPTIMAL.

Introduction
BKZ is a monoclonal IgG1 antibody that selectively inhibits IL-17F.

Methods
BE OPTIMAL (NCT03859203) comprised a 16-week double-blind, PBO-controlled period, followed by a 36-week treatment-blind period.

Results
• Of 852 randomised patients, 821 (96.4%) completed Week 16 and 806 (94.6%) completed Week 24.
• Baseline characteristics were generally comparable across treatment arms (Table 1).
• At Week 16, BKZ demonstrated superiority vs PBO for the primary endpoint, ACSSO (n=260, Figure 2A).
• 47.5% patients with psoriasis affecting ≥3% body surface area at baseline achieved complete skin clearance (PASI100) at Week 16.
• Joint and skin outcomes continued to improve to Week 24 (Figure 2B).

Conclusions
In biologic DMARD-naïve patients with PsA, BKZ treatment resulted in rapid and clinically relevant improvements in efficacy outcomes vs PBO at Week 16. Responses continued to increase up to Week 24. BKZ was well tolerated and no new safety signals were observed.

References