Bimekizumab efficacy by prior biologic treatment in patients with moderate to severe hidradenitis suppurativa: 48-week pooled data from the randomized, double-blind, placebo-controlled, multicenter BE HEARD I and II phase 3 trials

Presented at Fall Clinical 2023  |  October 19–22  |  Las Vegas, NV

Synopsis
• Hidradenitis suppurativa (HS) is a chronic inflammatory skin disease that presents with painful nodules and abscesses, purulent drainage, and scarring.
• Prior biologic use may influence or predict response to subsequent biologics in inflammatory conditions of skin; but there is a lack of research investigating this influence in HS specifically.
• BKZ, a humanized IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated clinically meaningful improvements in patients with HS.
• Here, we present efficacy of BKZ by prior biologic treatment in patients with moderate to severe HS.

Objective
To investigate the impact of prior biologic use on the efficacy of BKZ in patients with moderate to severe HS.

Methods
• BE HEARD I and II were identically designed, randomized, double-blind, placebo (PBO)-controlled phase 3 studies comprising initial Weeks 0–12 and maintenance (Weeks 16–48) treatment periods (Figure 1).
• Here, we report proportions of patients achieving a 50/75/90% HS Clinical Response (HiSCR50/75/90) and Dermatology Life Quality Index Minimal Clinically Important Difference (DLQI MCID) across subgroups of prior biologic use (PBO/BKZ Q2W/Q2W and BKZ Q4W/Q4W) treated for 48 weeks in patients who received prior biologic treatment for any indication vs those who were biologic-naïve across initial randomization groups from baseline through Week 48.
• All biologic treatments received by patients were for HS; two patients initially included in the "prior biologic use" subgroup were switched to the "biologic-naïve" subgroup at Week 48, as they had not received true biologic therapy.
• Data are reported using modified mNRI (mNRI) and observed case (OC) assessments.

Results
Baseline Demographics
• Of the 1,014 patients randomized at baseline, 18.8% (n=191) of patients had previously received biologic therapy and 81.2% (n=823) were biologic-naïve.
• Sex, age, and weight were similar across patients with prior biologic use and patients who were biologic-naïve (Table 1).
• More patients with prior biologic use had Hurley Stage III compared to biologic-naïve patients (46.6% vs 37.8%, respectively; Table 1).

Response by Prior Biologic Use
• Among patients with a history of prior biologic use in the BKZ Q2W/Q4W, BKZ Q2W/Q2W, and PBO/BKZ Q4W groups, 49.2%, 48.9%, and 57.2%, respectively, achieved HiSCR50 at Week 16, respectively (Figure 2A–B).
• In biologic-naïve patients, responses with BKZ 320 mg Q2W were 56.6%, 54.4%, and 55.4%, respectively, vs PBO (54.5%) at Week 16, respectively (Figure 2B).
• At Week 48, levels of HiSCR50 response remained or increased across treatment regimens vs at Week 16 (Figure 2A–B).
• HiSCR50/75/90 responses were also observed in biologic-naïve patients (Table 2).
• High proportions of DLQI MCID responses at Week 16 were also observed in both subgroups across treatment regimens, with responses maintained to Week 48 (Figure 2C–D).

Conclusions
BKZ demonstrated consistent efficacy in the achievement and maintenance of HiSCR and DLQI MCID clinical responses to Week 48 regardless of prior biologic use in patients with moderate to severe HS.

Greater levels of HiSCR clinical responses were observed for BKZ-treated patients vs PBO-treated patients across prior biologic subgroups at Week 16.