Bimekizumab cumulative clinical benefit in patients with moderate to severe hidradenitis suppurativa through 1 year of the BE HEARD I&II phase 3 trials

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Synopsis

- Hidradenitis suppurativa (HS) is a chronic, inflammatory skin disease which has a significant impact on health-related quality of life (HRQoL).[1]
- Bimekizumab (BKZ) is a humanized IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.[2]
- Evaluating the cumulative benefit of treatment over time using area under the curve (AUC) analyses captures the speed, level and durability of patients' responses and provides a more holistic assessment of patient's disease compared with assessment at specific timepoints only.[3]

Objective

To report the cumulative benefit of BKZ treatment on HS clinical response (HiSCR) through 16 and 48 weeks using AUC analyses.

Methods

- Pooled data from the randomized, double-blind, placebo (PBO)-controlled, multicenter BE HEARD I&II trials included an initial (Week 0–16) and maintenance (Week 16–48) treatment period (**Figure 1**).[4]
- Cumulative clinical benefit was estimated as the total AUC through Week 48 for patients achieving HiSCR50/75/90 (≥50/75/90% reduction in the total abscess and inflammatory nodule count from baseline with no increase from baseline in abscess or draining tunnel count).
- The estimated number of days for which patients achieved each response was calculated as the proportion of the total possible AUC for each outcome multiplied by the total number of days in the time period (Weeks 0–16: 112 days; Weeks 16–48: 224 days; Weeks 0–48: 336 days).
- Data are reported as observed case (OC).

Results

- Overall, 868 patients were randomized to receive BKZ (BKZ Q2W/Q2W: N=288, BKZ Q2W/Q4W: N=292, and BKZ Q4W/Q4W: N=288) and 146 patients were randomized to receive PBO/BKZ Q2W. Patients randomized to BKZ from baseline were included in the BKZ Total group.
- Through 16 weeks, the total number of days patients achieved HiSCR50/75/90 was approximately twice as high in the BKZ groups vs PBO (**Figure 2**).
- Clinically meaningful cumulative benefits in HiSCR50/75/90 were observed across the BKZ from baseline treatment arms through Week 48. Benefit was also demonstrated from Weeks 16–48 for Week 16 PBO to BKZ switchers (**Figure 2**).

Conclusions

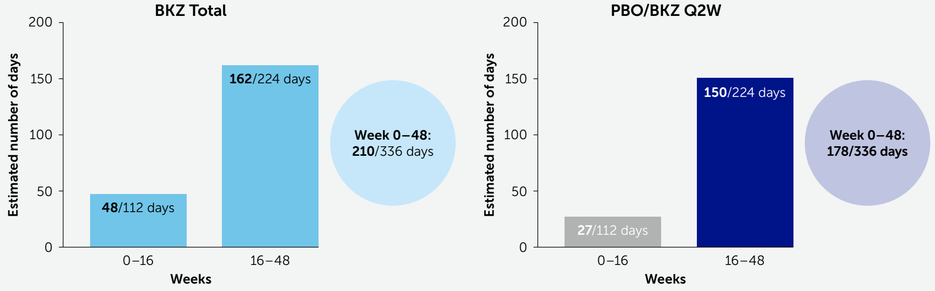
Higher levels of cumulative clinical benefit were observed for patients who received bimekizumab through Week 16 compared with those who received placebo. Benefit increased substantially from Week 16 through Week 48 for both patients receiving bimekizumab from baseline and Week 16 placebo to bimekizumab switchers.

However, the total number of days of clinical outcome achievement remained higher in those on bimekizumab from baseline vs placebo to bimekizumab switchers.

While HS is characterized by significant fluctuations in course, these results demonstrate the rapid, high-level, and durable responses that can be obtained with bimekizumab.

Summary

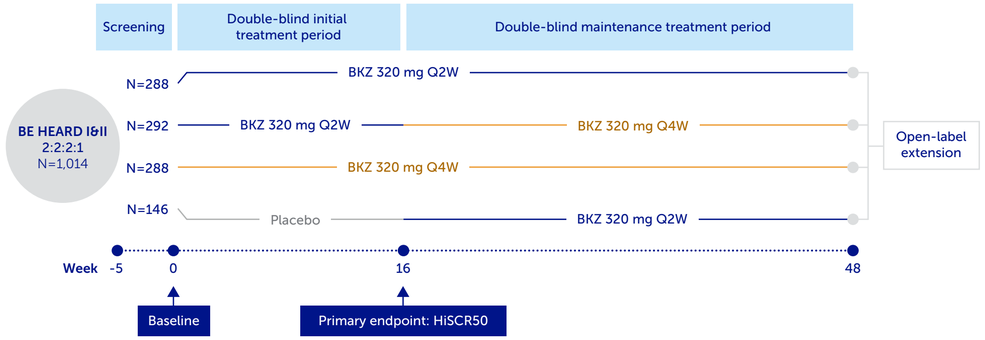
Estimated number of days for which patients achieved HiSCR50 from Weeks 0–48 (OC)



The **cumulative clinical benefit of BKZ through 48 weeks** was evident for both **patients receiving BKZ from baseline** and **PBO to BKZ switchers**.

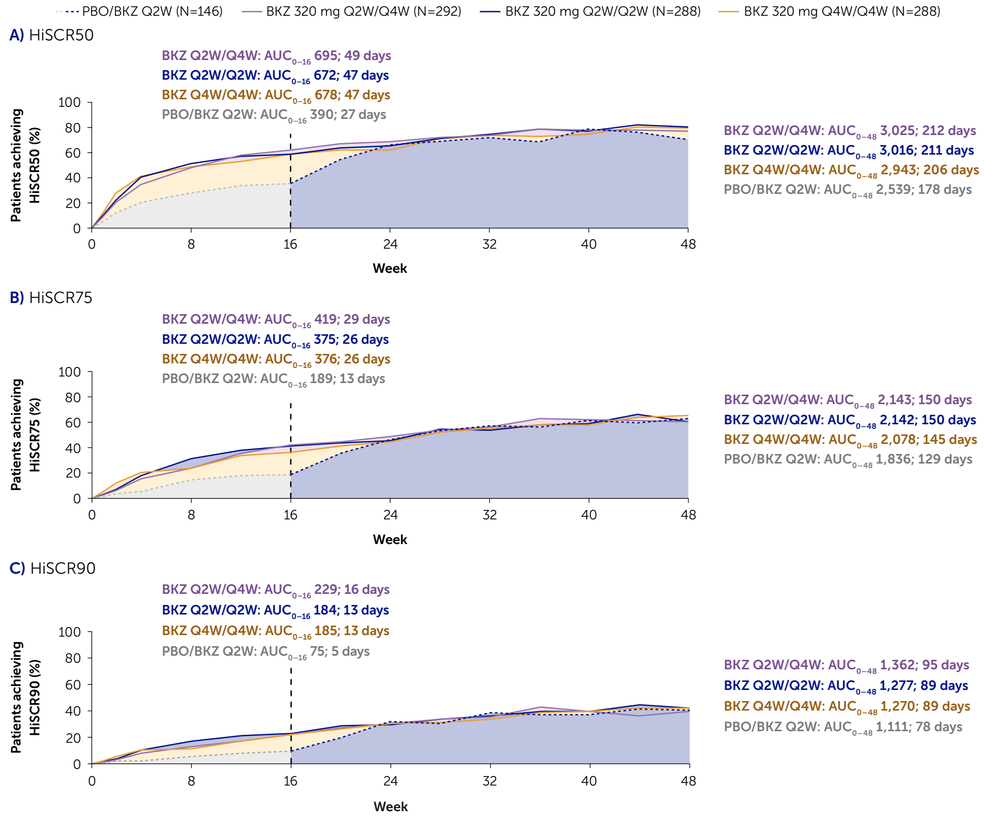
The **total number of days of clinical outcome achievement** remained **higher in those on BKZ from baseline** vs PBO to BKZ switchers, highlighting the **importance of early treatment**.

Figure 1 BE HEARD I&II study design



At baseline, 1,014 adult patients were randomized 2:2:2:1 (initial [Weeks 0–16]/maintenance [Weeks 16–48]) to receive BKZ 320 mg every 2 weeks (Q2W)/Q2W, BKZ Q2W/every 4 weeks (Q4W), BKZ Q4W/Q4W or PBO/BKZ Q2W.

Figure 2 Total AUC and cumulative benefit through 16 weeks and 48 weeks for clinical outcomes (OC)



Data are presented as the total AUC and estimated mean number of days that patients achieved HiSCR50/75/90 through the stated intervals (0–16, 0–48). HiSCR50/75/90 was achieved at a given visit if there was a ≥50/75/90% reduction in the total abscess and inflammatory nodule count from baseline with no increase from baseline in abscess or draining tunnel count. N represents number of patients with a non-missing lesion count assessment in the given week, and percentages are calculated accordingly.

AUC: area under the curve; **BKZ:** bimekizumab; **HRQoL:** health-related quality of life; **HS:** hidradenitis suppurativa; **HiSCR:** HS Clinical Response; **HiSCR50/75/90:** ≥50/75/90% reduction in the total abscess and inflammatory nodule count with no increase from baseline in abscess or draining tunnel count; **OC:** observed case; **PBO:** placebo; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks.

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