Bimekizumab impact on pain in moderate to severe hidradenitis suppurativa: Week 16 results from BE HEARD I & II

Lauren A.V. Orenstein,[1] Vivian Shi,[2] Hadar Lev-Tov,[3] Errol Prens,[4,5] Maurizio Podda,[4,6] Hideki Fujita,[7] Jérémy Lambert,[8] Robert Rolleri,[9] Edward Muller,[10] Jacek C. Szepietowski[4,11]

Synopsis

- Pain is the most commonly reported symptom by patients with hidradenitis suppurativa (HS), increasing in intensity with disease severity and substantially impacting quality of life.[1] Chronic pain can be caused by interleukin (IL)-17-mediated inflammation.[2]
- Bimekizumab (BKZ) is a monoclonal immunoglobulin G1 antibody which selectively inhibits IL-17F in addition to IL-17A.[3]

Objective

To report the impact of BKZ on skin pain assessed with the HS Symptom Daily Diary (HSSDD) for 16 weeks in the BE HEARD I & II phase 3 trials.

Methods

- BE HEARD I & II were randomized, double-blinded, placebo (PBO)-controlled phase 3 studies (**Figure 1**).[4,5]
- Pain was measured for 16 weeks using the HSSDD Average Skin Pain item and Worst Skin Pain item (scored daily and averaged weekly). Patients were asked to rank their skin pain on a scale that ranged from 0 (no skin pain) to 10 (skin pain as bad as you can imagine), in response to the following prompts:
  - For Average Skin Pain: "Please rate your skin pain from your HS lesions on an average in the past 24 hours".
  - For Worst Skin Pain: "Please rate your skin pain from your HS lesions at its worst in the past 24 hours".
- HSSDD Average Skin Pain responder rates: proportion of patients who achieved a clinically meaningful change, defined as ≥30% improvement and ≥1 point reduction from a baseline score of ≥3, in the HSSDD Average Skin Pain score.
- HSSDD Worst Skin Pain responder rates: proportion of patients who achieved a clinically meaningful change from baseline in the HSSDD Worst Skin Pain score, defined by three distinct thresholds:
  - A ≥30% improvement and ≥1-point reduction for patients with a baseline score of ≥3; or
  - A ≥3-point reduction for patients with a baseline score of ≥3;[6] or
  - A ≥4-point reduction for patients with a baseline score of ≥4.[6]
- HSSDD Average and Worst Skin Pain change from baseline data are reported using multiple imputation (MI). HSSDD Average and Worst Skin Pain responder rates are reported using observed case (OC) and modified non-responder imputation (mNRI).
  - For mNRI, patients who discontinued due to lack of efficacy/adverse events, or received systemic antibiotics identified as rescue medication for HS by the principal investigator, were considered non-responders; MI was used for all other missing data.

Results

- At baseline, 1,014 patients were randomized to BKZ Q2W (n=580), BKZ Q4W (n=288), or PBO (n=146) for 16 weeks (**Figure 1**).
- At Week 16, BKZ-treated patients had greater reductions in the HSSDD Average and Worst Skin Pain item scores compared to those receiving PBO (**Table 1**).
- For the Average Skin Pain item, numerically greater responder rates were seen in the BKZ Q2W and the BKZ Q4W groups, compared with PBO, up to Week 16 (**Figure 2**).
- Similarly, for the Worst Skin Pain item, numerically higher responder rates were seen to Week 16 in the BKZ Q2W and the BKZ Q4W groups, compared with PBO, across all reported response thresholds (**Figure 3**).
- Improvements in Average and Worst Skin Pain were rapid for BKZ-treated patients and maintained across 16 weeks, for all reported response thresholds (**Figures 2** and **3**).

Conclusions

Patients with moderate to severe HS, treated with BKZ for 16 weeks, experienced rapid clinically meaningful reductions in skin pain compared to PBO-treated patients.

Summary

Why was this study needed?
Hidradenitis suppurativa (HS) is a painful, long-term skin condition with limited treatment options available for patients.

What did this study show?
A new drug in development for HS, called bimekizumab, showed rapid reductions in skin pain.

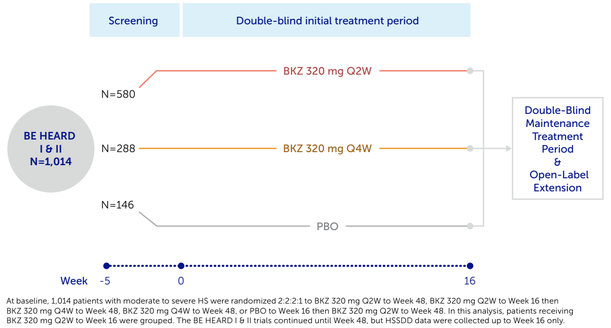
Why is this important?
Pain is the most common symptom experienced by patients with HS. New drugs, such as bimekizumab, may help decrease pain for patients living with HS.

Table 1 HSSDD average and worst skin pain item baseline scores and change from baseline to Week 16 scores (MI)

	BKZ 320 mg Q2W (n=580)	BKZ 320 mg Q4W (n=288)	PBO (n=146)
Baseline (mean ± SD)			
n	482	250	116
Average Skin Pain	4.66 ± 2.51	4.91 ± 2.57	4.75 ± 2.38
Worst Skin Pain	5.41 ± 2.48	5.61 ± 2.54	5.43 ± 2.50
Week 16 change from baseline (mean ± SE)			
Average Skin Pain	−1.75 ± 0.11	−1.41 ± 0.16	−0.79 ± 0.19
Worst Skin Pain	−1.89 ± 0.12	−1.47 ± 0.17	−0.69 ± 0.21

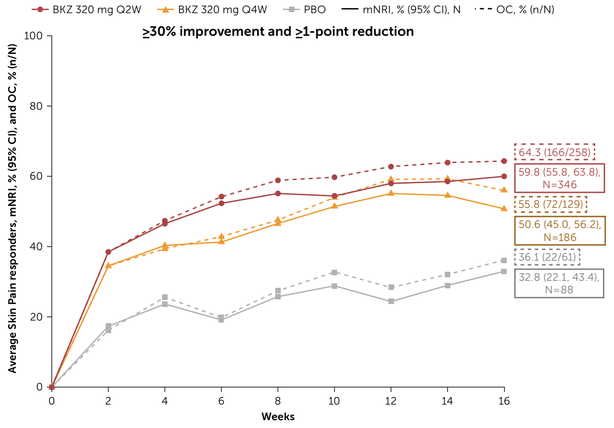
Randomized set. Baseline HSSDD scores are computed as the average of the closest consecutive 7 days to the baseline visit with at least 4 non-missing daily scores in the 2 weeks prior to the baseline visit, not including the baseline visit itself. MI: patients who discontinued study treatment due to lack of efficacy/adverse events, or who received systemic antibiotics identified as rescue medication for HS by the principal investigator, were set to missing and subsequently imputed using MI. All other missing data were also imputed using MI.

Figure 1 Study design



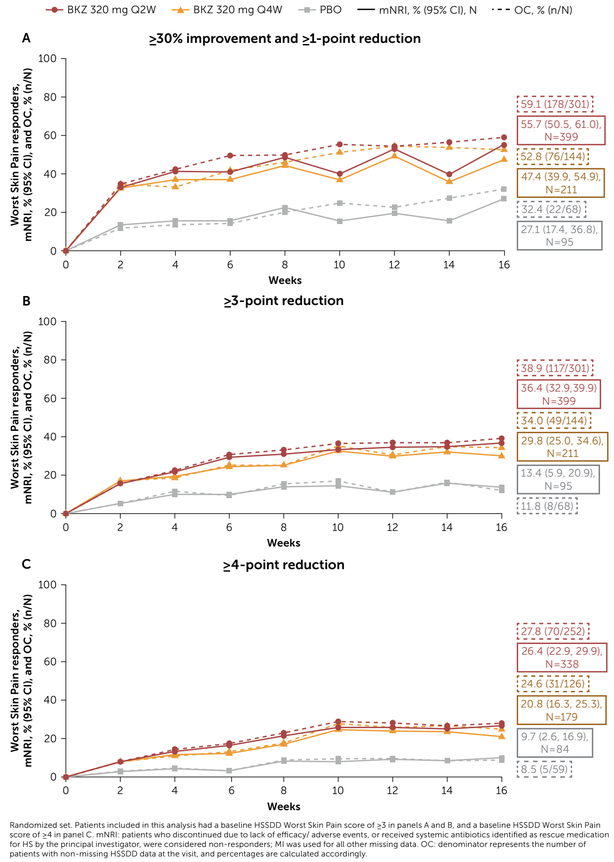
At baseline, 1,014 patients with moderate to severe HS were randomized 2:2:2:1 to BKZ 320 mg Q2W to Week 48, BKZ 320 mg Q2W to Week 16 then BKZ 320 mg Q4W to Week 48, BKZ 320 mg Q4W to Week 48, or PBO to Week 16 then BKZ 320 mg Q2W to Week 48. In this analysis, patients receiving BKZ 320 mg Q2W to Week 16 were grouped. The BE HEARD I & II trials continued until Week 48, but HSSDD data were collected up to Week 16 only.

Figure 2 HSSDD average skin pain responder rates (mNRI, OC)



Randomized set. Patients included in this analysis had a baseline HSSDD Average Skin Pain score of ≥3. mNRI: patients who discontinued due to lack of efficacy/adverse events, or received systemic antibiotics identified as rescue medication for HS by the principal investigator, were considered non-responders; MI was used for all other missing data. OC: denominator represents the number of patients with non-missing HSSDD data at the visit, and percentages are calculated accordingly.

Figure 3 HSSDD worst skin pain responder rates (mNRI, OC)



Randomized set. Patients included in this analysis had a baseline HSSDD Worst Skin Pain score of ≥3 in panels A and B, and a baseline HSSDD Worst Skin Pain score of ≥4 in panel C. mNRI: patients who discontinued due to lack of efficacy/ adverse events, or received systemic antibiotics identified as rescue medication for HS by the principal investigator, were considered non-responders; MI was used for all other missing data. OC: denominator represents the number of patients with non-missing HSSDD data at the visit, and percentages are calculated accordingly.

BKZ: bimekizumab; **HS:** hidradenitis suppurativa; **HSSDD:** Hidradenitis Suppurativa Symptom Daily Diary; **IL:** interleukin; **MI:** multiple imputation; **mNRI:** modified non-responder imputation; **OC:** observed case; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks; **SD:** standard deviation; **SE:** standard error.

Institutions: [1]Department of Dermatology, Emory University School of Medicine, Atlanta, GA, USA; [2]Department of Dermatology, University of Arkansas for Medical Sciences, Little Rock, AR, USA; [3]Dr. Phillip Frost Department of Dermatology and Cutaneous Surgery, University of Miami Miller School of Medicine, Miami, FL, USA; [4]European Hidradenitis Suppurativa Foundation (EHSF), Dessau, Germany; [5]Department of Dermatology, Erasmus University Medical Center Rotterdam, Rotterdam, The Netherlands; [6]Department of Dermatology, Darmstadt Hospital, Darmstadt, Germany; [7]Division of Cutaneous Science, Department of Dermatology, Nihon University School of Medicine, Tokyo, Japan; [8]UCB Pharma, Colombes, France; [9]UCB Pharma, Morrisville, NC, USA; [10]UCB Pharma, Slough, UK; [11]Department of Dermatology, Venereology and Allergology, Wroclaw Medical University, Wroclaw, Poland.

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