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

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. Chronic pain can be caused by interleukin (IL)-17-mediated inflammation.
- Bimekizumab (BKZ) is a monoclonal immunoglobulin G1 antibody which selectively inhibits IL-17A and IL-17F in addition to IL-17F.

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-blind, parallel (PBO)-controlled phase 3 studies (Figures 1).1,2
- 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 rate their skin pain on an analog scale from 0 (no pain) to 10 (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 from baseline 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 ≥3-point reduction for patients with a baseline score of ≥5
  - A ≥30% improvement and ≥2-point reduction for patients with a baseline score of ≥4.5
  - A ≥30% improvement and ≥1-point reduction for patients with a baseline score of ≥4
- HSSDD Average and Worst Skin Pain change from baseline data are reported using multiple imputation (MI).
- MI: patients who discontinued due to lack of efficacy, adverse events, or received systemic antibiotics identified as rescue medication were considered non-responders. MI was used for all other missing data.

Results
- In baseline, 1,504 patients were randomized to BKZ Q2W (n=506), BKZ Q4W (n=508), or PBO (n=490) 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 the 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.

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

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.

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

What is the impact of this study?
It provides evidence that bimekizumab may be an effective treatment option for patients with HS, potentially improving their quality of life.

Why is this important?
Understanding the impact of bimekizumab on skin pain can help guide treatment decisions and improve patient care.

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

<table>
<thead>
<tr>
<th>Item</th>
<th>Baseline</th>
<th>Week 16</th>
<th>Percentage Change</th>
</tr>
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<tbody>
<tr>
<td>Average Skin Pain</td>
<td>4.61 ± 2.11</td>
<td>1.16 ± 1.33</td>
<td>-74.8%</td>
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<tr>
<td>Worst Skin Pain</td>
<td>5.41 ± 2.40</td>
<td>2.80 ± 2.53</td>
<td>-36.8%</td>
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</tbody>
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Figure 1: Study design

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

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

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