Bimekizumab impact on patient-reported outcomes in patients with moderate to severe hidradenitis suppurativa: Pooled Week 48 results from BE HEARD I&II

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Synopsis

- Hidradenitis suppurativa (HS) is a chronic, painful inflammatory skin disease which has a substantial negative effect on patients' quality of life.[1,2]
- Bimekizumab (BKZ), a humanized IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated clinical efficacy in phase 3 clinical trials.[3,4]
- Here, we report the impact of BKZ on patient-reported outcomes (PROs) in patients with moderate to severe HS through Week 48.

Objective

To report the impact of BKZ on PROs in patients with moderate to severe HS from the phase 3 BE HEARD I&II studies.

Methods

- Pooled data from two identically designed, randomized, double-blinded, placebo (PBO)-controlled, multicenter trials (BE HEARD I&II) included an initial (Weeks 0–16) and maintenance (Weeks 16–48) treatment period (**Figure 1**).[3]
- **HS Symptom Questionnaire (HSSQ) symptom item** mean scores (range: 0 ['no symptom'] to 10 ['symptom as bad as you can imagine'], on a numeric rating scale) are reported to Week 48 for all items: skin pain, itch, smell or odor, and drainage or oozing.
- Proportions of patients achieving minimal clinically important difference (MCID) for **Dermatology Life Quality Index** (**DLQI**; scored 0–30; improvement from baseline score ≥4) are reported at Week 16 and Week 48.
- DLQI domain scores are reported at baseline, Week 16 and Week 48 across six subdomains: symptoms and feelings, daily activities, leisure, personal relationships (scored: 0–6), work and school, and treatment (scored: 0–3).
- Data are reported as observed case (OC).

Results

Baseline demographics

- Overall, 1,014 patients were randomized to BKZ or PBO (**Figure 1**).
- Across treatment arms, baseline demographics and baseline scores within each of the HSSQ items and DLQI domains were comparable (**Table 1**, **Figure 2**, **Figure 3**).

Impact of BKZ on PROs

- At Week 16, greater improvements (i.e. score reductions) from baseline over time were observed in each HSSQ symptom item in patients treated with BKZ vs PBO (**Figure 2**).
  - From Weeks 16–48, HSSQ item scores were substantially reduced in PBO switchers, with further slight numerical decreases observed in those treated with BKZ from baseline (**Figure 2**).
- At Week 16, greater improvements (i.e. score reductions) from baseline across DLQI domains were seen in patients treated with BKZ vs PBO (**Figure 3**).
  - DLQI domain scores were markedly reduced from Weeks 16–48 in Week 16 PBO switchers, with further numerical improvements observed in those treated with BKZ from baseline (**Figure 3**).
- At Week 16, MCID in DLQI was achieved in a greater proportion of patients treated with BKZ vs PBO (**Figure 4**).
  - At Week 48, the proportion of patients treated with BKZ from baseline achieving MCID in DLQI increase further numerically, with Week 16 PBO switchers attaining similar proportions (**Figure 4**).

Conclusions

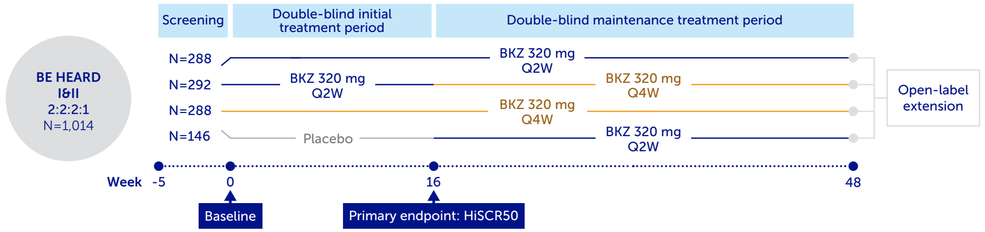
Patients treated with bimekizumab demonstrated clinically meaningful improvements in HRQoL and HS symptoms from baseline to Week 16, with improvements maintained or further improved to Week 48.

Patients who switched from placebo to bimekizumab at Week 16 achieved similar improvements to Week 48 as those who received bimekizumab from baseline.

Summary

Over 48 weeks, patients treated with BKZ showed **clinically meaningful improvements** in **patient-reported outcomes:**

Figure 1 Study design



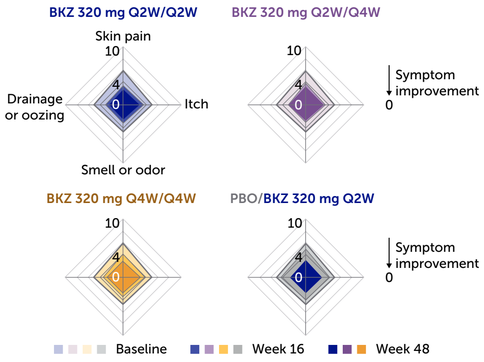
At baseline, 1,014 patients with moderate to severe HS were randomized 2:2:2:1 to BKZ 320 mg Q2W to Week 48, BKZ 320 mg Q4W to Week 48, BKZ 320 mg Q2W to Week 16 then BKZ 320 mg Q4W to Week 48, or PBO to Week 16 then BKZ 320 mg Q2W to Week 48.

Table 1 Baseline characteristics

	BKZ 320 mg Q2W/Q2W N=288	BKZ 320 mg Q2W/Q4W N=292	BKZ 320 mg Q4W/Q4W N=288	PBO/BKZ 320 mg N=146
Age (years), mean ± SD	36.8 ± 12.4	37.0 ± 12.4	35.8 ± 11.6	37.3 ± 12.8
Sex, **female**, n (%)	152 (52.8)	174 (59.6)	175 (60.8)	75 (51.4)
BMI (kg/m²), mean ± SD	32.7 ± 8.6	32.7 ± 7.9	33.8 ± 7.9	33.1 ± 8.3
Racial group, **white**, n (%)	232 (80.6)	233 (79.8)	224 (77.8)	119 (81.5)
Weight (kg), mean ± SD	96.7 ± 25.6	95.9 ± 24.0	99.0 ± 23.6	97.5 ± 24.3
Duration of HS (years), mean ± SD	7.6 ± 7.4	8.3 ± 7.7	7.3 ± 7.3	9.8 ± 9.4
AN count, mean ± SD	14.7 ± 11.6	17.2 ± 16.8	17.7 ± 20.9	14.4 ± 10.0
DT count, mean ± SD	3.8 ± 4.4	3.8 ± 4.4	3.3 ± 4.1	3.4 ± 3.8
Hurley Stage, n (%)				
II	166 (57.6)	160 (54.8)	160 (55.6)	79 (54.1)
III	122 (42.4)	132 (45.2)	128 (44.4)	67 (45.9)
DLQI Total score, mean ± SD	11.2 ± 6.5	10.8 ± 6.7	11.7 ± 7.4	12.2 ± 7.1
HSSQ symptom item scores, mean ± SE				
Skin pain	5.8 ± 0.1	5.8 ± 0.1	5.8 ± 0.1	5.8 ± 0.2
Itch	4.9 ± 0.2	4.8 ± 0.2	5.1 ± 0.2	5.0 ± 0.2
Smell or odor	4.6 ± 0.2	4.6 ± 0.2	4.7 ± 0.2	4.7 ± 0.3
Drainage or oozing	5.0 ± 0.2	5.1 ± 0.2	5.0 ± 0.2	5.1 ± 0.2
Baseline antibiotic use, n (%)	29 (10.1)	28 (9.6)	18 (6.3)	11 (7.5)

Randomized pooled set; baseline characteristics evaluated at Week 0.

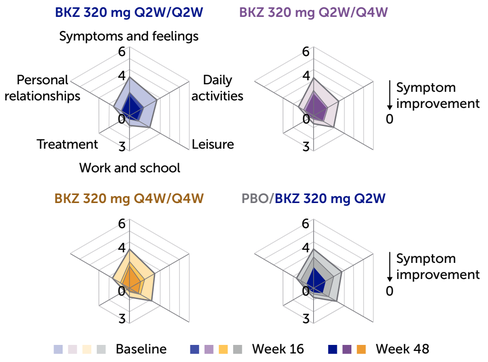
Figure 2 HSSQ mean scores by item at baseline, Week 16 and Week 48 (OC)



n-values for HSSQ assessment:	BKZ Q2W/Q2W	BKZ Q2W/Q4W	BKZ Q4W/Q4W	PBO/BKZ Q2W
Baseline	285	284	285	144
Week 16	256	262	257	135
Week 48	203	209	193	101

The total number of patients initially randomized to each treatment group were as follows: BKZ Q2W/Q2W: 288; BKZ Q2W/Q4W: 292; BKZ Q4W/Q4W: 288; PBO/BKZ Q2W: 146. The variable 'n' represents the number of patients undertaking HSSQ assessment at each timepoint across treatment arms.

Figure 3 DLQI domain scores at baseline, Week 16 and Week 48 (OC)



n-values for HSSQ assessment:	BKZ Q2W/Q2W	BKZ Q2W/Q4W	BKZ Q4W/Q4W	PBO/BKZ Q2W
Baseline	285	284	285	144
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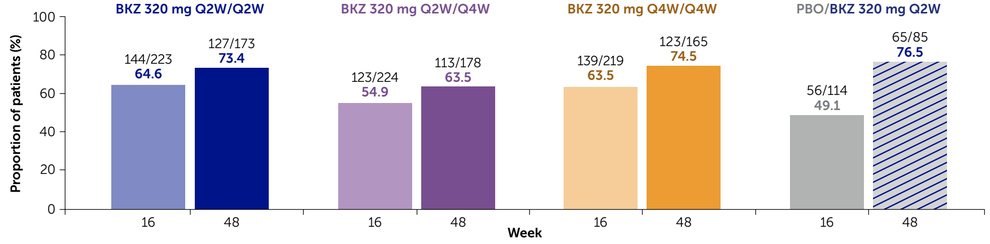
Figure 4 Proportion of patients achieving MCID for DLQI at Week 16 and Week 48 (OC)



MCID in DLQI is defined as a ≥4-point improvement (reduction) from baseline in DLQI Total score, in patients with a baseline score of ≥4. Across treatment groups, the total number of patients with a baseline total score in DLQI of ≥4 was as follows: BKZ Q2W/Q2W: 249; BKZ Q2W/Q4W: 247; BKZ Q4W/Q4W: 245; PBO/BKZ Q2W: 125. OC n/Nsub denominator represents number of patients with a DLQI Total score assessment in the given week, and percentages were calculated accordingly.

AN: abscess and inflammatory nodule; **BKZ:** bimekizumab; **DLQI:** Dermatology Life Quality Index; **DT:** draining tunnel; **HS:** hidradenitis suppurativa; **HSSQ:** HS Symptom Questionnaire; **IL:** interleukin; **MCID:** minimal clinically important difference; **OC:** observed case; **PBO:** placebo; **PRO:** patient-reported outcome; **SD:** standard deviation; **SE:** standard error; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks.

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References: [1]Garg A et al. J Am Acad Dermatol 2020;82:366–76; [2]Kaur AP et al. Skin Health Dis 2023;3:e214; [3]Kimball AB et al. Lancet 2024;403(10443):2504–19 (NCT04242496, NCT04242498); [4]Adams R et al. Front Immunol 2020;11:1894. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **JCS**, **HL**, **VYS**, **SSB**, **AC**, **KH**, **JL**, **TV**, **BL**, **RR**, **ABG**; Drafting of the publication, or reviewing it critically for important intellectual content: **JCS**, **HL**, **VYS**, **SSB**, **AC**, **KH**, **JL**, **TV**, **BL**, **RR**, **ABG**; Final approval of the publication: **JCS**, **HL**, **VYS**, **SSB**, **AC**, **KH**, **JL**, **TV**, **BL**, **RR**, **ABG**. **Disclosures: JCS:** Consultant and advisory board member of AbbVie, LEO Pharma, Novartis, Pierre Fabre, Sanofi Genzyme, Trevi Therapeutics; speaker for AbbVie, Almirall, Eli Lilly and Company, LEO Pharma, Novartis, Pfizer, Pierre Fabre, Sanofi-Genzyme, and UCB; investigator for AbbVie, Amgen, Bristol Myers Squibb, Galapagos, Galderma, Incyte, InflaRX, Janssen, Kiniksa, Kymab Limited, Menlo Therapeutics, Merck, Novartis, Pfizer, Regeneron Pharmaceuticals, Trevi Therapeutics, and UCB. **HL:** Consultant for Novartis. **VYS:** On the board of directors for the Hidradenitis Suppurativa Foundation (HSF), advisor for the National Eczema Association, shareholder of Learn Health and has served as an advisory board member, investigator, speaker, and/or received research funding from AbbVie, Altus Lab/cQuell, Alumis, Aristea Therapeutics, Boehringer Ingelheim, Burt's Bees, Dermira, Eli Lilly and Company, Galderma, Genentech, GpSkin, Incyte, Kiniksa, LEO Pharma, Menlo Therapeutics, MYOR, Novartis, Pfizer, Polyfins Technology, Regeneron, Sanofi Genzyme, Skin Actives Scientific, Sun Pharma, Target-PharmaSolutions, and UCB. **SSB:** Received honoraria for participation in advisory boards, in clinical trials, and/or as speaker from AbbVie, Biogen, Boehringer Ingelheim, Hexal, MoonLake, Novartis, Sanofi, and UCB. **AC:** Investigator and/or speaker and/or advisor for AbbVie, Almirall, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly and Company, Galderma, Janssen, LEO Pharma, Novartis, Pfizer, Regeneron, Sandoz, Sanofi, and UCB. **KH:** Principal investigator for and consultancy/advisory boards from AbbVie, Boehringer Ingelheim, and Novartis; speaker fees/grants from AbbVie, Boehringer Ingelheim, Eisai, Novartis, and UCB. **JL**, **TV**, **BL** and **RR:** Employees and shareholders of UCB. **ABG:** Receives research/educational grants from Highlights Therapeutics, Bristol-Myers Squibb, Janssen, and UCB (all paid to Mount Sinai School of Medicine); received honoraria as an advisory board member and consultant for Amgen, AnaptysBio, Avotres Therapeutics, Boehringer Ingelheim, Bristol-Myers Squibb, Dice Therapeutics, Eli Lilly and Company, Highlights Therapeutics, Janssen, Novartis, Sanofi, Teva, UCB, and Xbiotech (stock options for RA). **Acknowledgements:** These studies were funded by UCB. We thank the patients and their caregivers in addition to the investigators and their teams who contributed to these studies. The authors acknowledge Susanne Wiegratz, MSc, UCB, Monheim am Rhein, Germany for publication coordination, May-Li MacKinnon, PhD, Costello Medical, Manchester, UK for medical writing and editorial assistance and the Costello Medical Creative team for graphic design assistance. All costs associated with development of this poster were funded by UCB.

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