Association Between Increasingly Stringent Clinical Responses and Improvements in Pain, HRQoL, and Work Productivity in Patients with Hidradenitis Suppurativa: 1-Year Phase 3 Results from BE HEARD I&II

Barbara Horváth,[1] Michael F. Mørup,[2] Leah Davis,[3] Bartosz Lukowski,[4] Jérémy Lambert,[5] Alice B. Gottlieb[6]

Objective

To explore the association between achievement of increasingly stringent, or higher, clinical responses and improvements in patient-reported outcomes for pain, health-related quality of life (HRQoL) and work productivity to 1 year in patients with moderate to severe hidradenitis suppurativa (HS).

Background

- HS is a chronic inflammatory skin disease characterised by painful and recurrent skin lesions.[1]
- Patients with HS experience debilitating symptoms including severe pain, drainage, odour and fatigue, that significantly reduce a patient's quality of life (QoL) and work productivity.[1–3]
- Bimekizumab (BKZ) is a humanised IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A and has demonstrated clinical efficacy in patients with moderate to severe HS.[4]
- The importance of new HS treatments that help patients reach higher thresholds of clinical response has been demonstrated in a previous analysis, in which achievement of higher clinical response after 16 weeks translated into improved patient outcomes.[5]

Methods

- In the BE HEARD I&II phase 3 trials, patients with moderate to severe HS were randomised 2:2:2:1 to BKZ 320 mg every 2 weeks (Q2W), BKZ every 4 weeks (Q4W), BKZ Q2W/Q4W, or placebo/BKZ Q2W (**Figure 1**).[6]
- In this analysis, patients were pooled regardless of treatment. Patients were then grouped by achievement of mutually exclusive clinical response levels or disease severity at Week 48:
  - HS Clinical Response (HiSCR) levels: <50% improvement from baseline (<HiSCR50); 50–<75% improvement (HiSCR50–<75); 75–<90% improvement (HiSCR75–<90); 90–100% improvement (HiSCR90–100);
  - International Hidradenitis Suppurativa Severity Score System (IHS4) categories: ≥11 points (severe HS); 4–10 points (moderate HS); ≤3 points (mild HS).
- Associations between achievement of higher thresholds of clinical response (HiSCR) or disease severity (IHS4) and improvements in the following patient-reported outcomes at Week 48 were assessed:
  - HS Symptom Questionnaire (HSSQ) skin pain change from baseline (CfB) score (11-point numeric rating scale ranging from 0: 'no skin pain' to 10: 'skin pain as bad as you can imagine');
  - HSSQ skin pain response (30% reduction and ≥1-point reduction from baseline in patients with a score of ≥3 at baseline);
  - HS QoL (HiSQOL) total score change from baseline (score range 0–68, higher score indicates lower HRQoL);
  - Change from baseline in Work Productivity and Activity Impairment (WPAI) percent overall work impairment (assesses employment status, work absenteeism, work impairment while working, overall work and daily activity impairment attributable to HS).
- Observed case (OC) data are reported.

Results

- Of the 1,014 patients randomised in BE HEARD I&II, 720 (71.0%) completed Week 48. Baseline characteristics for all randomised patients are presented in **Table 1**.
- At Week 48, as patients achieved higher HiSCR levels or lower disease severity as measured by IHS4, a greater proportion of patients achieved HSSQ skin pain response (**Figure 2**).
- At Week 48, mean improvements (reductions) from baseline in HSSQ skin pain score (95% confidence intervals [CI]) increased with achievement of more stringent response thresholds: <HiSCR50: –1.5 (–1.9, –1.1); HiSCR50–<75: –2.3 (–2.9, –1.7); HiSCR75–<90: –3.0 (–3.4, –2.6) and HiSCR90–100: –3.8 (–4.1, –3.5).
- Similarly, numerically greater mean improvements (reductions) were seen at Week 48 in the HiSQOL total score in patients achieving more stringent HiSCR thresholds and in patients with lower disease severity, per IHS4 (**Figure 3**).
- At Week 48, numerically greater improvements were observed for WPAI percent overall work impairment in patients with lower disease severity, per IHS4 (**Figure 4**). No linear improvements were observed in WPAI with increasing HiSCR thresholds.

Conclusions

Achievement of increasingly stringent, or higher, clinical responses and lower disease severity was associated with greater improvements in skin pain and HRQoL at 1 year in patients with HS, with some improvements also seen in work productivity with decreasing disease severity.

These analyses demonstrate that achieving higher efficacy thresholds results in less pain, better QoL and improvements in work productivity, which are important treatment goals.

Summary

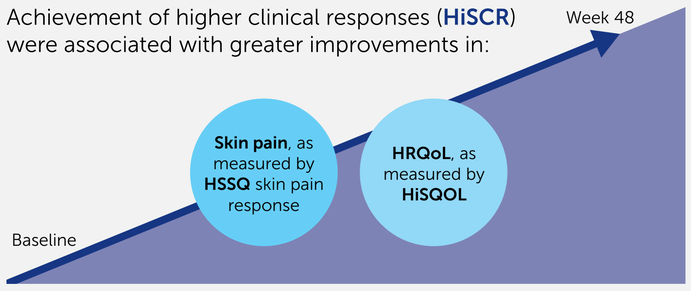


Table 1 Baseline Characteristics

	All patients N=1,014
Age (years), mean (SD)	36.6 (12.2)
Sex, **Female**, n (%)	576 (56.8)
Racial group, White, n (%)	808 (79.7)
BMI (kg/m²), mean (SD)	33.1 (8.1)
Duration of disease (years), mean (SD)	8.0 (7.8)
AN count, mean (SD)	16.3 (16.1)
DT count, mean (SD)	3.6 (4.3)
Hurley Stage, n (%)	
II	565 (55.7)
III	449 (44.3)
IHS4 score, mean (SD)	34.2 (30.2)
IHS4 category, n (%)	
Severe	869 (85.7)
Moderate	144 (14.2)
Mild	1 (0.1)
HSSQ skin pain score, mean (SD)	5.8 (2.4)
HiSQOL total score, mean (SD)	25.2 (13.4)
Prior biologic use,[a] n (%)	191 (18.8)
Baseline antibiotic use, n (%)	86 (8.5)

Pooled randomised set. **[a]** Patients received prior biologic therapy for any indication.

Figure 1 BE HEARD I&II Study Design

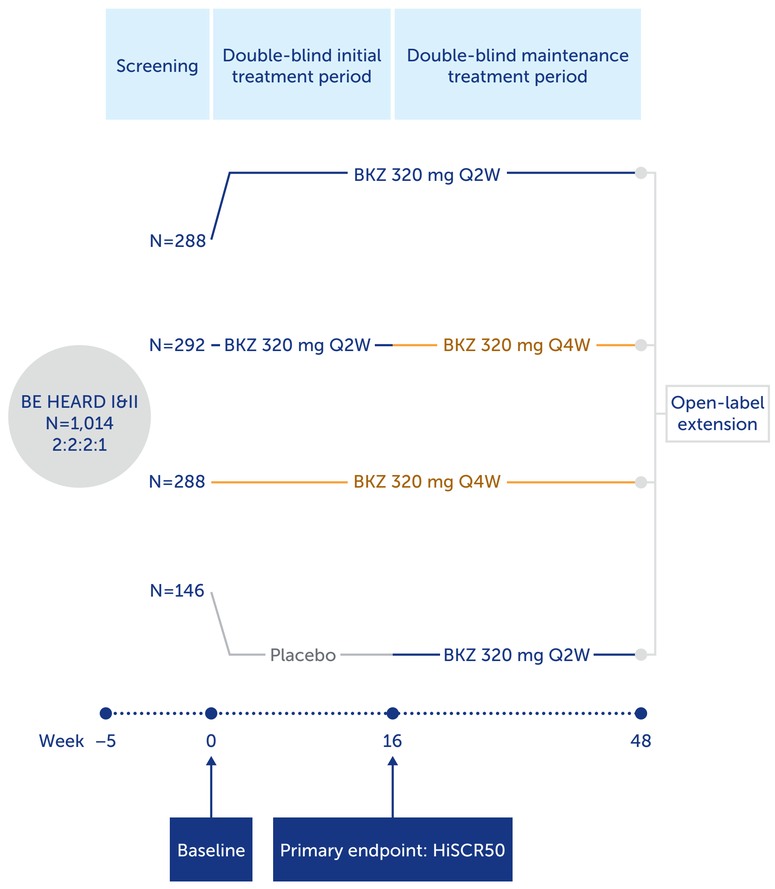
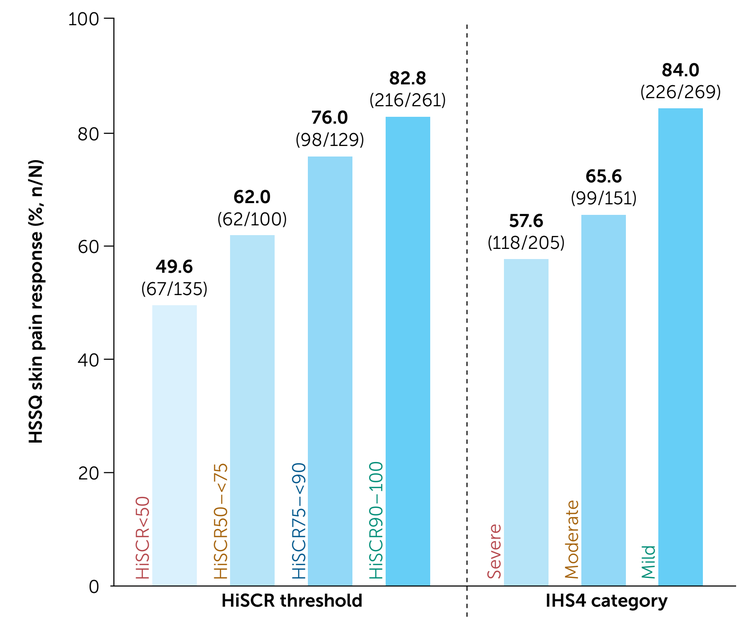


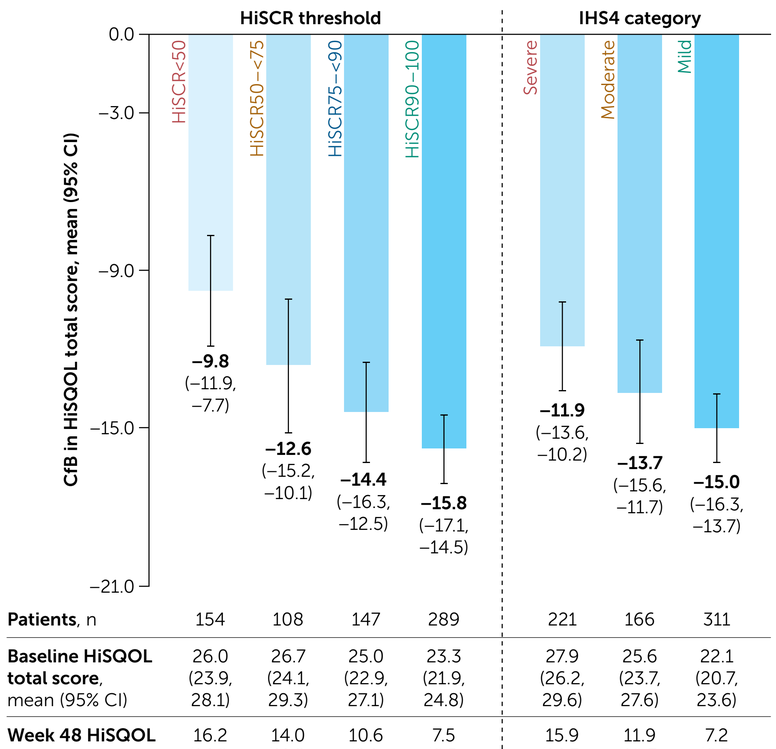
Figure 2 HSSQ Skin Pain Response at Week 48 (by HiSCR Threshold and IHS4 Severity Categories at Week 48 [OC])



	HiSCR<50	HiSCR50–<75	HiSCR75–<90	HiSCR90–100	Severe	Moderate	Mild
Baseline HSSQ skin pain score, mean (95% CI)	5.8 (5.4, 6.2)	6.2 (5.8, 6.6)	5.7 (5.4, 6.1)	5.7 (5.4, 5.9)	6.4 (6.1, 6.7)	5.8 (5.5, 6.1)	5.4 (5.1, 5.7)
Week 48 HSSQ skin pain score, mean (95% CI)	4.3 (3.9, 4.6)	3.9 (3.4, 4.4)	2.8 (2.4, 3.1)	1.9 (1.6, 2.1)	4.1 (3.8, 4.4)	3.4 (3.0, 3.7)	1.8 (1.6, 2.1)

Categories are mutually exclusive; IHS4 categories: ≥11 points (severe HS); 4–10 points (moderate HS); ≤3 points (mild HS). HSSQ skin pain response defined as a 30% reduction and ≥1-point reduction from baseline in HSSQ skin pain score; reported in patients with a HSSQ skin pain score of ≥3 at baseline.

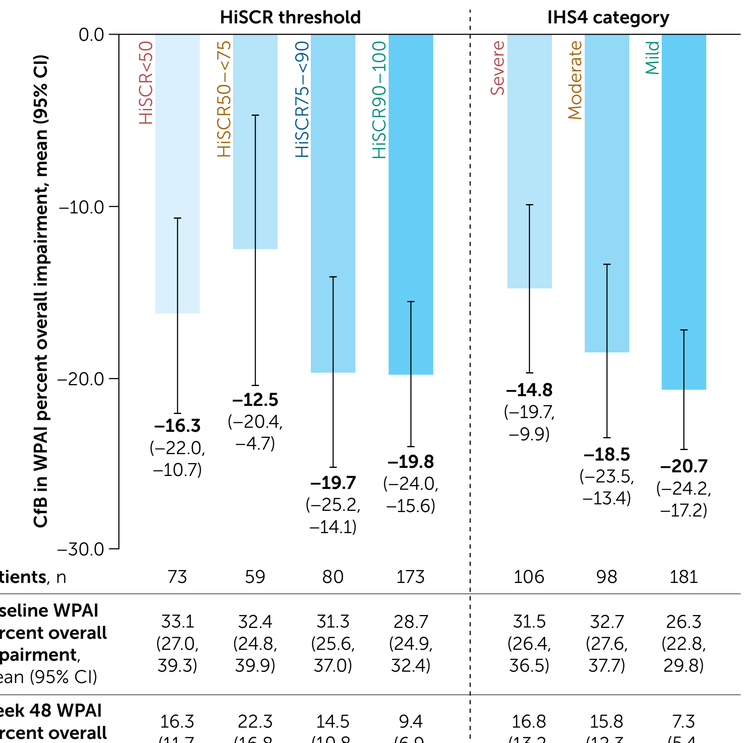
Figure 3 HiSQOL Improvement from Baseline at Week 48 (by HiSCR Threshold and IHS4 Severity Categories at Week 48 [OC])



	HiSCR<50	HiSCR50–<75	HiSCR75–<90	HiSCR90–100	Severe	Moderate	Mild
Patients, n	154	108	147	289	221	166	311
Baseline HiSQOL total score, mean (95% CI)	26.0 (23.9, 28.1)	26.7 (24.1, 29.3)	25.0 (22.9, 27.1)	23.3 (21.9, 24.8)	27.9 (26.2, 29.6)	25.6 (23.7, 27.6)	22.1 (20.7, 23.6)
Week 48 HiSQOL total score, mean (95% CI)	16.2 (14.2, 18.1)	14.0 (11.8, 16.2)	10.6 (9.1, 12.1)	7.5 (6.5, 8.5)	15.9 (14.3, 17.5)	11.9 (10.3, 13.5)	7.2 (6.3, 8.2)

Categories are mutually exclusive; IHS4 categories: ≥11 points (severe HS); 4–10 points (moderate HS); ≤3 points (mild HS).

Figure 4 WPAI Percent Overall Impairment Improvement from Baseline at Week 48 (by HiSCR Threshold and IHS4 Severity Categories at Week 48 [OC])



	HiSCR<50	HiSCR50–<75	HiSCR75–<90	HiSCR90–100	Severe	Moderate	Mild
Patients, n	73	59	80	173	106	98	181
Baseline WPAI percent overall impairment, mean (95% CI)	33.1 (27.0, 39.3)	32.4 (24.8, 39.9)	31.3 (25.6, 37.0)	28.7 (24.9, 32.4)	31.5 (26.4, 36.5)	32.7 (27.6, 37.7)	26.3 (22.8, 29.8)
Week 48 WPAI percent overall impairment, mean (95% CI)	16.3 (11.7, 20.9)	22.3 (16.8, 27.7)	14.5 (10.8, 18.1)	9.4 (6.9, 11.8)	16.8 (13.2, 20.3)	15.8 (12.3, 19.4)	7.3 (5.4, 9.1)

Categories are mutually exclusive; IHS4 categories: ≥11 points (severe HS); 4–10 points (moderate HS); ≤3 points (mild HS).

AN: abscess and inflammatory nodule; **BKZ:** bimekizumab; **BMI:** body mass index; **CfB:** change from baseline; **CI:** confidence intervals; **DT:** draining tunnel; **HS:** hidradenitis suppurativa; **HiSCR:** HS Clinical Response; **HiSCR50/75/90/100:** 50%/75%/90%/100% reduction in total abscess and inflammatory nodule count from baseline with no increase from baseline in abscess or draining tunnel count; **HiSQOL:** HS Quality of Life; **HRQoL :** health-related quality of life; **HSSQ:** HS Symptom Questionnaire; **IHS4:** International Hidradenitis Suppurativa Severity Score System; **IL:** interleukin; **OC:** observed case; **QoL:** quality of life; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks; **SD:** standard deviation; **WPAI:** Work Productivity and Activity Impairment.

Institutions: [1]Faculty of Medical Sciences, University Medical Center Groningen, Groningen, The Netherlands; [2]UCB, Copenhagen, Denmark; [3]UCB, Morrisville, North Carolina, USA; [4]Vedim/UCB, Warsaw, Poland; [5]UCB, Colombes, France; [6]Department of Dermatology, The Icahn School of Medicine at Mount Sinai, New York, New York, USA.

References: [1]Zouboulis CC et al. Dermatology 2015;231:184–90; [2]Chernyshov PV et al. J Eur Acad Dermatol Venereol 2019;33:1633–43; [3]Montero-Vilchez T et al. Int J Environ Res Public Health. 2021;18:6709; [4]Adams R et al. Front Immunol 2020;11:1894; [5]Gottlieb AB et al. ISPOR-US 2024:138629; [6]Kimball AB et al. Lancet 2024;403:2504–19 (NCT04242446, NCT04242498). **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **BH**, **MFM**, **LD**, **BL**, **JL**, **ABG**; Drafting of the publication, or reviewing it critically for important intellectual content: **BH**, **MFM**, **LD**, **BL**, **JL**, **ABG**; Final approval of the publication: **BH**, **MFM**, **LD**, **BL**, **JL**, **ABG**. **Author Disclosures: BH:** Received research/educational grants from AbbVie, Janssen-Cilag, Solenne B.V. and Novartis; received consulting fees from AbbVie, Akari Therapeutics, Celgene, Janssen-Cilag, LEO Pharma, Novartis, Philips, Regeneron, Roche, Sanofi and UCB; participated in advisory boards for AbbVie, Janssen-Cilag, Novartis and UCB. **MFM**, **LD**, **BL**, **JL:** Employees and shareholders of UCB. **ABG:** received research/educational grants from Highlight 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, DE Therapeutics, Eli Lilly and Company, Highlight 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, Sana Yaar, PhD, Costello Medical, Manchester, UK for medical writing and editorial assistance and the Creative team at Costello Medical for graphic design assistance. All costs associated with development of this poster were funded by UCB.

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