Bimekizumab clinical efficacy responses translate into improvements in patient outcomes to Week 48 in patients with moderate to severe hidradenitis suppurativa: Results from BE HEARD I&II

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Objective

To report how achieving increasingly higher hidradenitis suppurativa (HS) Clinical Response (HiSCR) thresholds associates with improvements in health-related quality of life (HRQoL) and patient-reported skin pain with bimekizumab (BKZ) treatment.

Synopsis

- HS is a chronic skin disease whereby debilitating symptoms reduce patients' HRQoL.[1,2]
- Achievement of higher HiSCR thresholds has translated into better patient outcomes, including QoL and skin pain.[3,4]
- BKZ is a humanized Immunoglobulin (Ig)G1 monoclonal antibody that selectively inhibits interleukin (IL)-17F and IL-17A and has previously demonstrated depth and durability of response.[5,6]

Methods

- Data were pooled from the phase 3 trials BE HEARD I&II for patients with moderate to severe HS.[6] BKZ Total comprises all patients randomized to BKZ from baseline (**Figure 1**).
- BKZ-treated patients were grouped by achievement of mutually exclusive HiSCR thresholds at Weeks 16 and 48.
- Associations between HiSCR thresholds and HS QoL questionnaire (HiSQoL) response or HS symptom questionnaire (HSSQ) skin pain response were assessed at Weeks 16 and 48.
- Data are reported for patients randomized to BKZ 320 mg from baseline in BE HEARD I&II (BKZ Total).[6]
- Data are reported as observed case (OC).

Results

- Baseline characteristics for BKZ Total are reported in **Table 1**.
- Overall, 1,014 patients were randomized. For BKZ Total (N=868), 90.0% and 70.9% completed to Weeks 16 and 48, respectively.
- At Week 16, increasing HiSQoL response rates were observed with increasing HiSCR threshold achievement: HiSCR<50: 25.0%; HiSCR50–<75: 27.6%; HiSCR75–<90: 39.2%; HiSCR90–100: 57.8% (**Figure 2**).
- At Week 16, increasing HSSQ skin pain response rates were observed with increasing HiSCR thresholds: HiSCR<50: 42.5%; HiSCR50–<75: 52.9%; HiSCR75–<90: 63.9%; HiSCR90–100: 80.4% (**Figure 3**).
- At Week 48, similar trends in response rates were observed for HiSQoL (HiSCR<50: 24.7%; HiSCR50–<75: 43.9%; HiSCR75–<90: 45.3%; HiSCR90–100: 57.6%) (**Figure 2**) and HSSQ skin pain (HiSCR<50: 50.9%; HiSCR50–<75: 60.9%; HiSCR75–<90: 77.3%; HiSCR90–100: 82.7%) (**Figure 3**).

Conclusions

With bimekizumab treatment over 1 year, higher efficacy measured by HiSCR translated into greater improvements in HS-specific skin pain and health-related quality of life outcomes. Higher treatment goals should be targeted to provide better patient-reported outcomes.

Figure 1 Study design

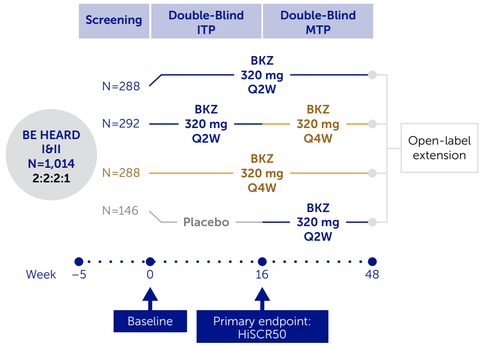
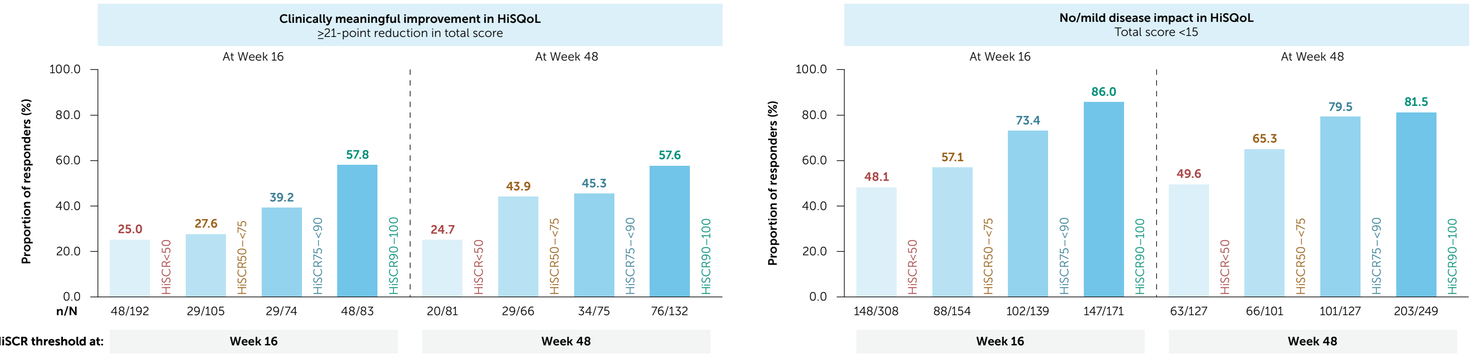


Table 1 Baseline demographics and characteristics

	BKZ 320 mg Total N=868
Age (years), mean (SD)	36.5 (12.1)
Sex, **female**, n (%)	501 (57.7)
Racial group, n (%)	
White	689 (79.4)
Black	97 (11.2)
BMI (kg/m²), mean (SD)	33.1 (8.1)
Duration of HS (years), mean (SD)	7.7 (7.4)
AN Count, mean (SD)	16.6 (16.9)
DT Count, mean (SD)	3.6 (4.3)
Hurley Stage, n (%)	
II	486 (56.0)
III	382 (44.0)
DLQI total score, mean (SD)	11.2 (6.9)
HiSQoL total score, mean (SD)	25.0 (13.3)
HSSQ skin pain score, mean (SD)	5.8 (2.4)
Prior biologic use,[a] n (%)	162 (18.7)
Baseline antibiotic use, n (%)	75 (8.6)

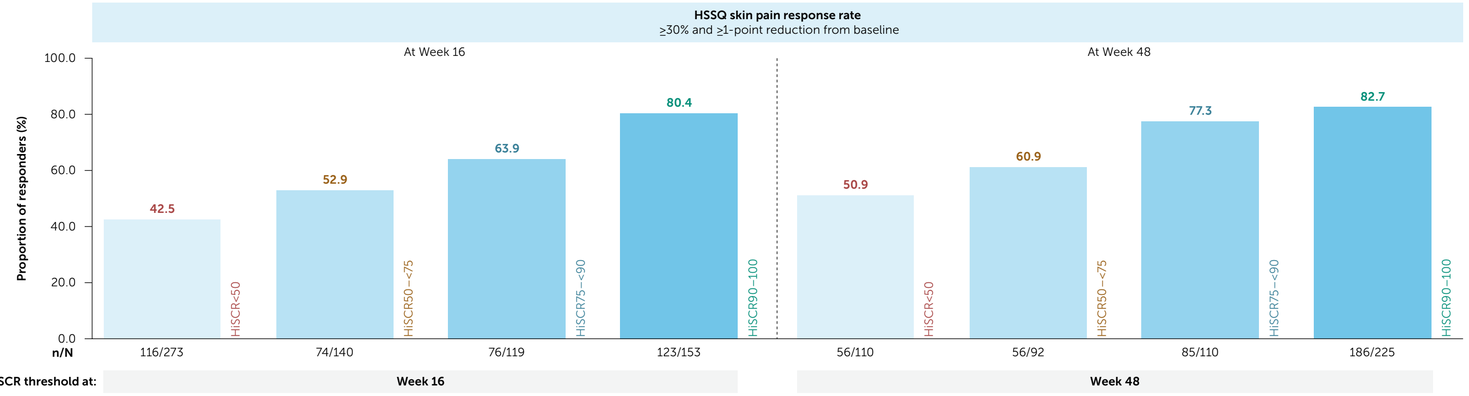
[a] Patients received prior biologic therapy for any indication.

Figure 2 HiSQoL total score responses at Week 16/48 by HiSCR threshold in BKZ total patients (OC)



Pooled data; BKZ Total (N=868) comprised patients randomized to BKZ from baseline. 90.0%/70.9% of patients completed Week 16/48. OC n/N: denominator represents number of patients with a non-missing HiSQoL assessment in the given week, and percentages are calculated accordingly.

Figure 3 HSSQ skin pain responses at Week 16/48 by HiSCR threshold in BKZ total patients (OC)



Pooled data; BKZ Total (N=868) comprised patients randomized to BKZ from baseline. 90.0%/70.9% of patients completed Week 16/48. HSSQ response for the skin pain item is defined as ≥30% reduction and ≥1-point reduction from baseline. Only study participants with a score of ≥3 at baseline are included. OC n/N: denominator represents number of patients with a non-missing HSSQ assessment in the given week, and percentages are calculated accordingly.

AN: abscess and inflammatory nodule; **BKZ:** bimekizumab; **BMI:** body mass index; **DLQI:** Dermatology Life Quality Index; **DT:** draining tunnel; **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:** Hidradenitis Suppurativa Quality of Life questionnaire; **HRQoL:** health-related quality of life; **HS:** hidradenitis suppurativa; **HSSQ:** HS symptom questionnaire; **IG:** immunoglobulin; **IL:** interleukin; **ITP:** initial treatment period; **MTP:** maintenance treatment period; **OC:** observed case; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks; **QoL:** quality of life; **SD:** standard deviation.

References: [1]Chernyshov PV et al. J Eur Acad Dermatol Venereol 2019;33:1633–43; [2]Matusiak Ł et al. Acta Derm Venereol 2018;98:191–4; [3]Gottlieb AB et al. ISPOR-US 2024: Poster 138629; [4]Horváth B et al. ISPOR-EU 2024: Poster PCR53; [5]Adams R et al. Front Immunol 2020;11:1894; [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: **ABK**, **AG**, **HLT**, **KRVS**, **EJGB**, **KH**, **BL**, **RR**, **JL**, **TV**, **LT**; Drafting of the publication, or reviewing it critically for important intellectual content: **ABK**, **AG**, **HLT**, **KRVS**, **EJGB**, **KH**, **BL**, **RR**, **JL**, **TV**, **LT**; Final approval of the publication: **ABK**, **AG**, **HLT**, **KRVS**, **EJGB**, **KH**, **BL**, **RR**, **JL**, **TV**, **LT**. **Author Disclosures: ABK:** Institution received grants from AbbVie, Admirx, AnaptysBio, Aristea, Bristol Myers Squibb, Eli Lilly and Company, Incyte, Janssen, MoonLake Immunotherapeutics, Novartis, Pfizer, Prometheus, Sonoma Biotherapeutics, and UCB; received consulting fees from AbbVie, Alumis, Avalo, Bayer, Boehringer Ingelheim, Eli Lilly and Company, Janssen, MoonLake Immunotherapeutics, Novartis, Pfizer, Priovant, Sanofi, Sonoma Biotherapeutics, Target RWE, UCB, Union Therapeutics, and Ventyx; serves on the board of directors of Almirall. **AG:** Receives honoraria as an advisor for AbbVie, Almirall, Boehringer Ingelheim, Engitix, Immunitas Therapeutics, Incyte, Insmed, Novartis, Pfizer, Sonoma Biotherapeutics, UCB, Union Therapeutics, and Zura Bio; receives research grants from AbbVie, CHORD COUSIN Collaboration (C3), and UCB. **HLT:** Consultant for Novartis and UCB. **KRVS:** Consultancy/honoraria from Boehringer Ingelheim, Novartis, and UCB. **EJGB:** Received honoraria from Abbott Products Operations, bioMérieux, Brahms, GSK, InflaRx, Sobi, and XBiotech; independent educational grants from Abbott Products Operations, bioMérieux, InflaRx, Johnson & Johnson, MSD, Novartis, and Sobi; funding from the Horizon2020 Marie Skłodowska-Curie International Training Network "the European Sepsis Academy" (granted to the National and Kapodistrian University of Athens), the Horizon 2020 European Grants ImmunoSep and RISCinCOVID (granted to the Hellenic Institute for the Study of Sepsis), and the Horizon Health grant EPIC-CROWN-2, POINT, and Homi-Lung (granted to the Hellenic Institute for the Study of Sepsis). **KH:** Principal investigator for and member of consultancy/advisory boards for AbbVie, Boehringer Ingelheim, Novartis, Sanofi, and UCB; recipient of speaker fees and/or research grants from AbbVie, Boehringer Ingelheim, Eisai, Maruho, Novartis, and UCB. **BL**, **RR**, **JL**, and **TV:** Employees and shareholders of UCB. **LT:** Co-copyright holder of HIDE® (Hidradenitis suppurativa DrainageI), HiSQOL® (Hidradenitis Suppurativa Quality of Life), and HS-IGA® (Hidradenitis Suppurativa Investigator Global Assessment); investigator for Incyte, Janssen, Novartis, and UCB; speaker fees from UCB. **Acknowledgments:** These studies were funded by UCB. We would like to thank the patients and their caregivers in addition to all the investigators and their teams who contributed to these studies. The authors acknowledge Susanne Wiegratz, UCB, Monheim am Rhein, for publication coordination, Charlotte Marris, PhD, Costello Medical, Manchester, UK for medical writing support and editorial assistance, and the Costello Medical Creative team for graphic design assistance. All costs associated with development of this presentation were funded by UCB.

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