Bimekizumab impact on pain and quality of life stratified by IHS4 levels in patients with hidradenitis suppurativa: 2-year results from BE HEARD EXT

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Objective

To report the associations between Week 16 achievement of International Hidradenitis Suppurativa (HS) Severity Score System (IHS4) levels, and improvements in skin pain and health-related quality of life (HRQoL), over 2 years.

Introduction

- The majority of patients with HS experience disease-associated pain, a highly burdensome symptom that negatively impacts patients' HRQoL.1
- Lesion-based disease severity is assessed by the IHS4, HS skin pain is measured using the HS symptom questionnaire (HSSQ) and HRQoL is evaluated by the HS Quality of Life questionnaire (HiSQOL).
- Bimekizumab (BKZ) is a humanised IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, both of which are abundant in HS lesional skin.^{2,3}

Methods

- Data were pooled from the phase 3 BE HEARD I&II studies (NCT04242446, NCT04242498) and the open-label BE HEARD EXT (NCT04901195).4,5
- Week 48 BE HEARD I&II completers could enrol in BE HEARD EXT and receive open-label 320 mg BKZ every 2 weeks or every 4 weeks based on ≥90% HS Clinical Response (HiSCR90) averaged from Weeks 36, 40 and 44 (**Figure 1**).
- Data are reported for patients randomised to BKZ at baseline in BE HEARD I&II, who enrolled in BE HEARD EXT (BKZ Total).
- Associations between mutually exclusive Week 16 IHS4 response levels (<IHS4-55 [percentage change from baseline in IHS4 score of <55%], IHS4-55-<IHS4-75, IHS4-75-<IHS4-90 and IHS4-90-IHS4-100) and achievement of clinically meaningful improvements in HSSQ skin pain response (≥30% and ≥1-point reduction from baseline) are reported at Weeks 16, 48 and 96.
- Associations between Week 16 IHS4 response levels and achievement of HiSQOL total response (total score >21-point reduction from baseline) and HiSQOL low/no disease impact response (HiSQOL total score ≤14) are also reported at Weeks 16, 48 and 96.
- Data are reported as observed case (OC)

Results

- At baseline, 1,014 patients were randomised. Among the 657 BE HEARD I&II Week 48 completers who entered BE HEARD EXT, 556 patients received continuous BKZ from baseline (Table).
- At Week 16, the proportions of patients achieving HSSQ skin pain response increased with increasing Week 16 IHS4 response levels (Figure 2).
- Proportions of HSSQ skin pain responders according to Week 16 IHS4 response levels were maintained or increased at Weeks 48 and 96 (Figure 2).
- Similarly, at Week 16, the proportions of patients achieving HiSQOL total response (Figure 3A) and low/no disease impact response (Figure 3B) increased with increasing Week 16 IHS4 levels. Proportions of HiSQOL total and low/no impact responders according to Week 16 IHS4 response levels were maintained or increased at Weeks 48 and 96.

Conclusions

Higher IHS4 response levels at Week 16 with bimekizumab treatment generally translated into greater improvements in skin pain and HRQoL. This trend was maintained to 2 years.

This analysis demonstrates the importance to HS patients for treatments that provide the highest possible level of response to clinical outcomes.

Summary Patients with HS who achieved more stringent IHS4 response levels at Week 16 with bimekizumab treatment, reported greater improvements in skin pain and health-related quality of life to Week 96. Week 16 **Increasing IHS4 response levels** HSSQ skin pain response 62.2% 68.5% 80.6% 46.0% **Increasing IHS4 response levels** HiSQOL total response

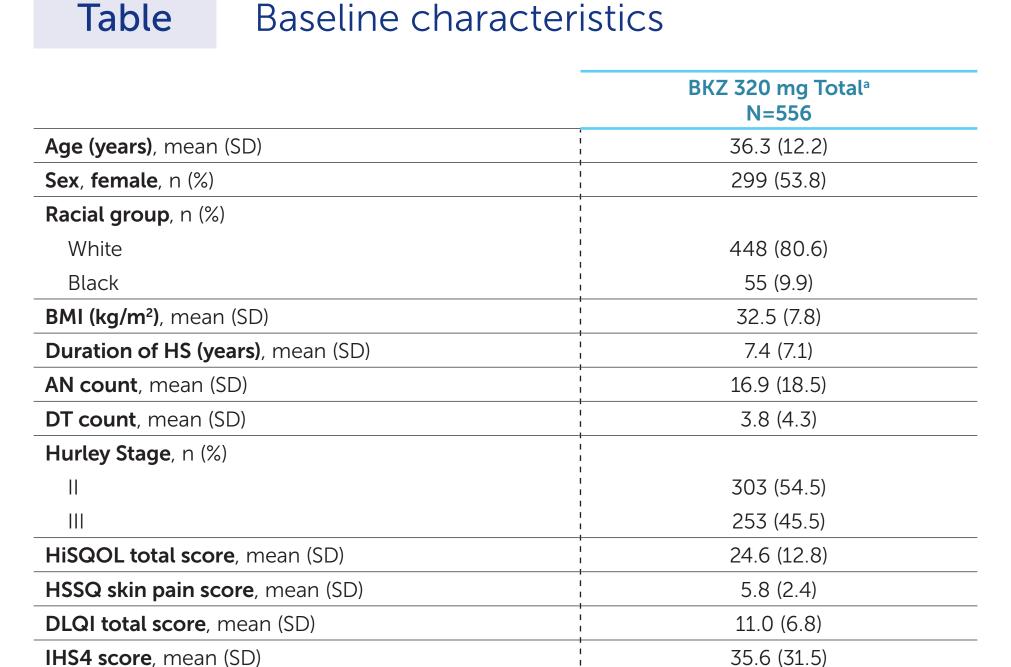
38.7%

49.3%

■ IHS4-55-<IHS4-75

■ IHS4-90-IHS4-100

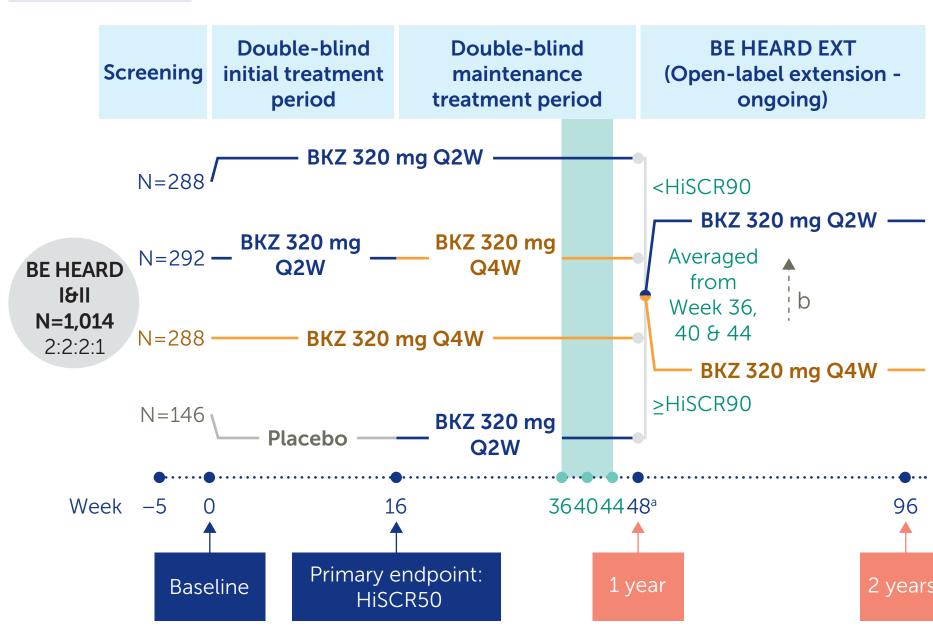
54.2%



OLE set; only included patients who entered BE HEARD EXT at Week 48. [a] Data are reported for patients randomised to BKZ from baseline who entered BE HEARD EXT and continued to receive BKZ; [b] Patients received prior biologic therapy for any indication.

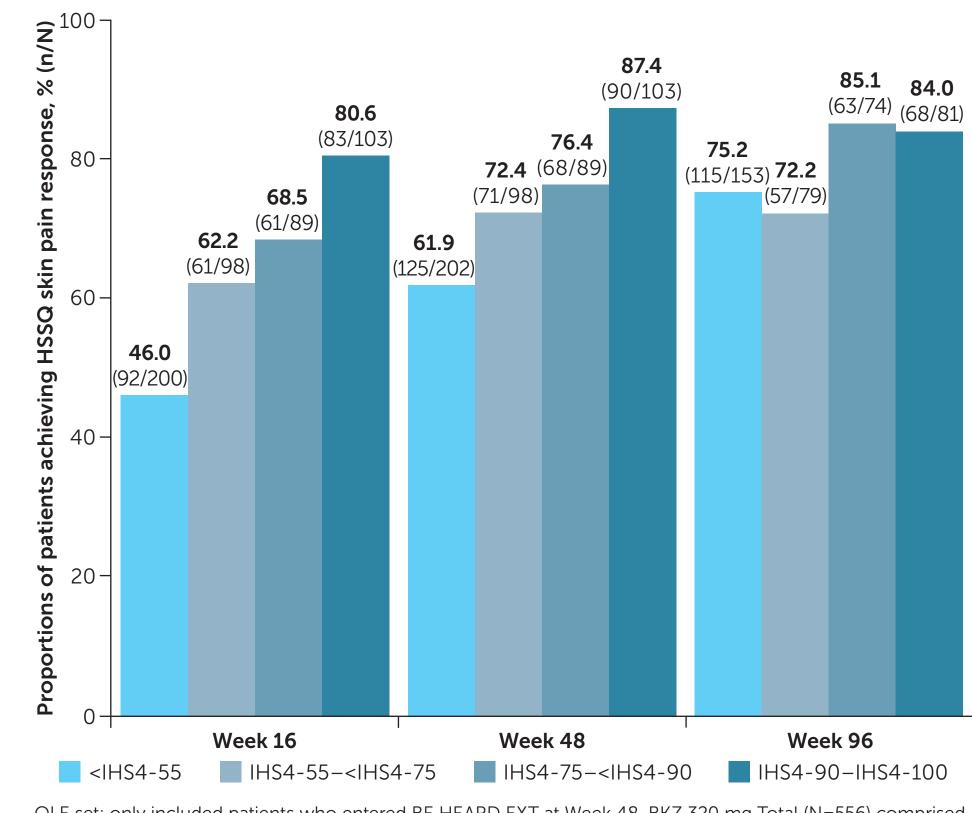
<IHS4-55

Study design



[a] Patients who completed Week 48 of BE HEARD I&II could enrol in BE HEARD EXT and receive open-label BKZ every 2 weeks (Q2W) or BKZ every 4 weeks (Q4W) based on HiSCR90 responder status using the average lesion counts from Week 36, Week 40 and Week 44 of BE HEARD Iⅈ [b] In the first 48 weeks of the ongoing BE HEARD EXT, dose adjustment from BKZ Q4W to BKZ Q2W was permitted based on prespecified criteria for reduction in improvement from baseline in AN count; [c] Cumulative 2-year data (48 weeks in BE HEARD I&II and 48 weeks in BE HEARD EXT).

HSSQ skin pain response at Weeks Figure 2 16, 48 and 96 by Week 16 IHS4 response level (OC)



OLE set; only included patients who entered BE HEARD EXT at Week 48. BKZ 320 mg Total (N=556) comprised patients randomised to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT and continued to receive BKZ. HSSQ response for skin pain score is defined as >30% and >1-point reduction from baseline in HSSQ. Only patients with a score of >3 at baseline are included. OC, n/N: N represents the number of patients with non-missing data at the given week, and percentages are calculated accordingly.

HiSQOL response at Weeks 16, 48 and 96 by Week 16 IHS4 response level (OC) Figure 3

112 (20.1)

54 (9.7)

A) HiSQOL total response^a

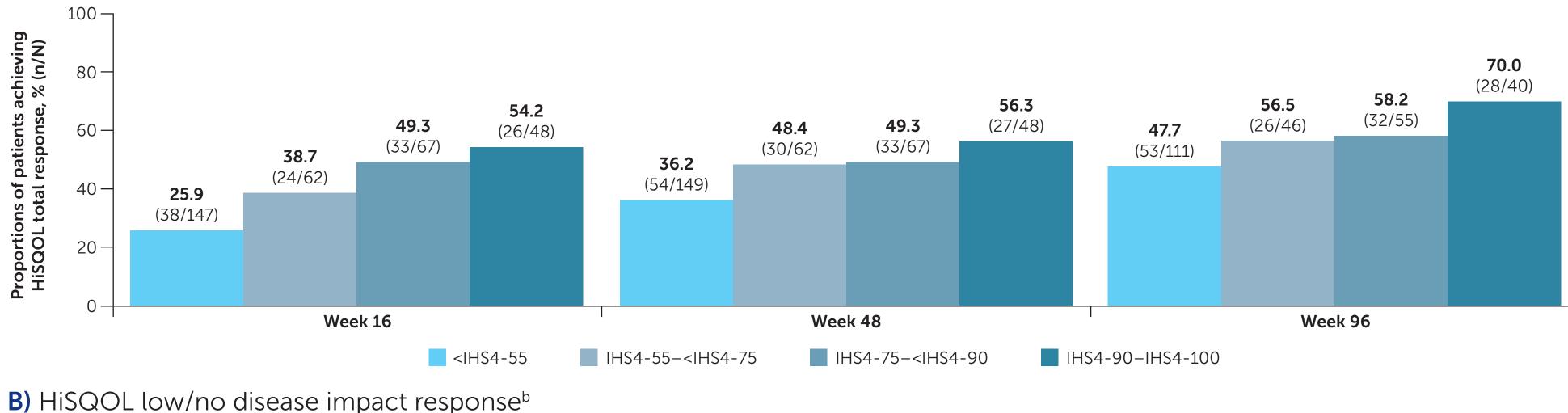
Prior biologic use,^b n (%)

Baseline antibiotic use, n (%)

25.9%

<IHS4-55

■ IHS4-75-<IHS4-90



87.7 87.7 87.6 (100/114)(100/114)(78/89)78.3 77.4 76.0 73.0 ach (n/N) (65/83)71.4 (72/93)(76/100) 69.4 67.0 (73/100) (80/112)(118/170)(75/112)(147/224)(113/222)Week 16 Week 48 Week 96

OLE set; only included patients who entered BE HEARD EXT at Week 48. BKZ 320 mg Total (N=556) comprised patients randomised to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT and continued to receive BKZ. [a] HiSQOL total response is defined >21-point reduction from baseline in HiSQOL total score; only patients with a score of >21 at baseline are included; [b] HiSQOL low/no disease impact response is defined as a HiSQOL total score of ≤ 14 . OC, n/N: N represents the number of patients with non-missing data at the given week, and percentages are calculated accordingly.

IHS4-75-<IHS4-90

IHS4-90-IHS4-100

IHS4-55-<IHS4-75

AN: abscess and inflammatory nodule; BKZ: bimekizumab; BMI: body mass index; DLQI: Dermatology Life Quality Index; DT: draining tunnel; HiSCR50/90: >50%/90% reduction from baseline in the total AN count with no increase from baseline in abscess or draining tunnel count; HiSQOL: Hidradenitis Suppurativa Quality of Life; HS: hidradenitis suppurativa; HSSQ: HS symptom questionnaire; HS4: International Hidradenitis Suppurativa Severity Score System; OC: observed case; OLE: open-label extension; Q2W: every 2 weeks; Q4W: every 4 weeks; SD: standard deviation.

References: ¹Garg A et al. J Am Acad Dermatol 2020;82:366–76; ²Adams R et al. Front Immunol 2020;11:1894; ³Krueger JG et al. Br J Dermatol 2024;190:149–62; ⁴Kimball AB et al. Lancet 2024;403:2504–19; ⁵BE HEARD EXT: www.clinicaltrials.gov/study/NCT04901195. RR, NT, JWF; Final approval of the publication: BK, SK, JRI, GK, TT, IK, JL, SW, RR, NT, JWF. Author Disclosures: BK: Received research support from or has been a principal investigator (clinical trials) for AbbVie, Almirall, Janssen, Merck, MoonLake Immunotherapeutics, Novartis, Pfizer, and UCB; has been a consultant for AbbVie, Almirall, Celgene, Janssen, MC2 Therapeutics, MoonLake Immunotherapeutics, MoonLake Immun Immunotherapeutics, Novartis, Pfizer, UCB and Union; and has been on scientific advisory boards for AbbVie, Almirall, Celgene, Eli Lilly and Company, Janssen, MoonLake Immunotherapeutics, Novartis, Pfizer and UCB. SK: Received research grants from AbbVie, Acelyrin, Bristol Myers Squibb and Incyte; consulting/advisory boards and speakers bureau for AbbVie, Eli Lilly and Company, Janssen, LEO Pharma, Regeneron and UCB. **JRI:** Received a stipend as recent Editor-in-Chief of the British Journal of Dermatology and an authorship honorarium from UpToDate; consultant for AbbVie, Boehringer Ingelheim, Cantargia, ChemoCentryx, Citryll, Engitix, Incyte, Insmed, Kymera Therapeutics, MoonLake Immunotherapeutics and Viela Bio; co-copyright holder of HiSQOL®, and HS Patient global assessment, and HS-IGA; his department receives income from copyright of the Dermatology Life Quality Instrument (DLQI) and related instruments. **GK:** Received travel grants or honoraria, has been a consultant member of advisory boards and speaker bureaus or has served as an investigator for AbbVie, Actelion, Almirall, Amgen, Basilea, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Hexal-Sandoz, Janssen, LEO Pharma, MSD, Novartis, Pfizer, Sanofi, Takeda and UCB. TT: Consultancy/advisory boards/speaker fees from AbbVie, Boehringer Ingelheim, Novartis and UCB; treasurer of the European Hidradenitis Suppurativa Foundation e.V. IK: None to declare. JL, SW, RR, NT: Employees and shareholders of UCB. JWF: Conducted advisory work for AbbVie, Boehringer Ingelheim, ChemoCentryx, Janssen, Kyowa Kirin, LEO Pharma, Pfizer, Regeneron and UCB; participated in trials for Boehringer Ingelheim, CSL, Eli Lilly and Company, Pfizer and UCB; received research support from Ortho Dermatologics and Sun Pharma. 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, Isabel Merrien, PgDip, Costello Medical, London, England for medical writing and editorial assistance and the Costello Medical Creative Team for design support. All costs associated with development of this poster were funded by UCB.



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