Bimekizumab effect on health-related quality of life and symptoms over 2 years: Data from BE HEARD EXT

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Objective

To report the impact of bimekizumab (BKZ) on health-related quality of life (HRQoL) and hidradenitis suppurativa (HS) symptoms in patients with moderate to severe HS through 2 years of treatment.

Introduction

- HS is a chronic, painful, inflammatory skin disease. Debilitating symptoms including skin pain, itch, odour and drainage have a substantial negative effect on patients' HRQoL.[1–3]
- BKZ, a humanised IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated clinical efficacy and improvements in patient-reported outcomes over 1 year in phase 3 clinical trials.[4,5]

Methods

- Data were pooled from the BE HEARD I&II studies and their open-label extension, BE HEARD EXT (NCT04242446, NCT04242498, NCT04901195).[5,6]
- Year 1 (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).
- Data reported for patients randomised to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT (BKZ Total group).
- HS symptoms are reported to Year 2 (Week 96):
  - **HS Symptom Questionnaire (HSSQ)** mean item scores and percentage change from baseline for skin pain, itch, smell or odour and drainage or oozing (scored 0–10 on numeric rating scales, with '0' describing no symptoms and '10' describing symptoms as bad as you can imagine; **Figure 1A**).
- HRQoL outcomes are reported to Year 2:
  - **Dermatology Life Quality Index (DLQI)** mean total score, mean absolute change from baseline and the proportions of patients reporting DLQI scores of 0/1 (no impact) and a minimal clinically important difference (MCID) (≥4-point improvement [reduction] from baseline in total score; **Figure 1B**).
  - **HS Quality of Life (HiSQOL)** response rates (total score ≤14, indicating no/mild impact) and HiSQOL total score mean change from baseline (HS-specific HRQoL; **Figure 1C**).
- Data are reported using observed case (OC).

Results

- Of 1,014 total patients in the BE HEARD I&II trials, 556 patients randomised to BKZ at baseline in BE HEARD I&II completed Year 1 and entered BE HEARD EXT.
- The complete baseline characteristics for patients participating in the BE HEARD I&II trials have been reported previously.[7]

Impact of BKZ on HS symptoms

- **HSSQ** skin pain, itch, smell or odour and drainage or oozing mean scores at baseline were 5.8, 4.9, 4.6, and 5.1, respectively, indicative of moderate to severe symptoms (**Figure 1A** and **Figure 2**).
- Mean scores decreased to 2.8, 2.9, 2.6 and 2.7 at Year 1 and to 2.2, 2.6, 2.2 and 2.2 at Year 2, indicative of milder symptom severity (**Figure 1A** and **Figure 2**).

Impact of BKZ on HRQoL

- The mean **DLQI** total score decreased from 11.0 at baseline to 5.0 at Year 1 and 4.7 at Year 2 (**Figure 1B** and **Figure 3**).
  - The proportions of patients reporting DLQI 0/1 at Year 1 and 2 were 27.4% and 33.9%, respectively (**Table 1**).
  - The proportions of patients reporting DLQI MCID was 71.7% at Years 1 and 2 (**Table 1**).
- The proportion of patients reporting no/mild impact of HS on their HRQoL (**HiSQOL** total score ≤14) at baseline was 24.1% (**Figure 1C** and **Figure 4**).
  - This increased to 72.8% at Year 1 and was maintained at Year 2 (76.8%) (**Figure 4**).
  - At Year 1, the mean change from baseline in HiSQOL total score was −13.9, which was maintained at −14.4 at Year 2 (**Table 1**).

Conclusions

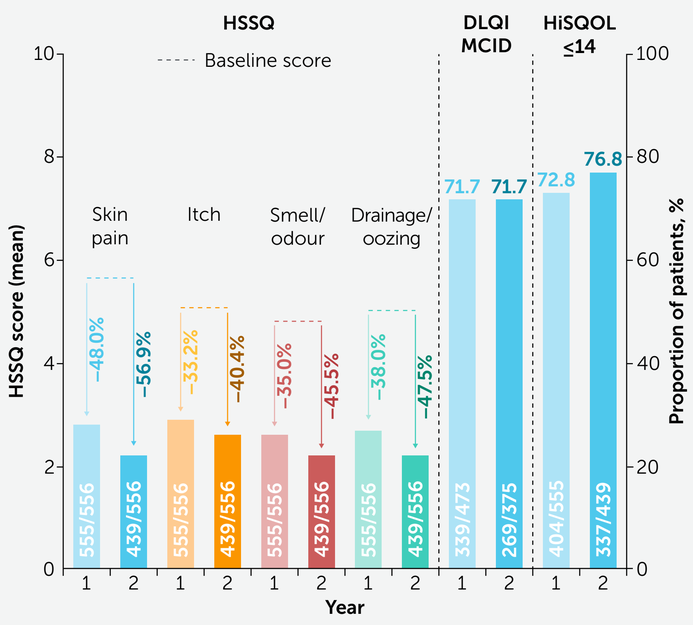
Patients treated with bimekizumab reported improvements in HS skin pain, itch, smell/odour and drainage/oozing symptoms at 1 year that were maintained to 2 years.

Patients treated with bimekizumab reported clinically meaningful improvements in HRQoL at 1 year, as assessed by both DLQI and the HS-specific HiSQOL, which were maintained to 2 years.

Summary

The impact of **BKZ** treatment on **HS symptoms and HRQoL** was assessed in patients with moderate to severe HS (BE HEARD I&II and BE HEARD EXT).

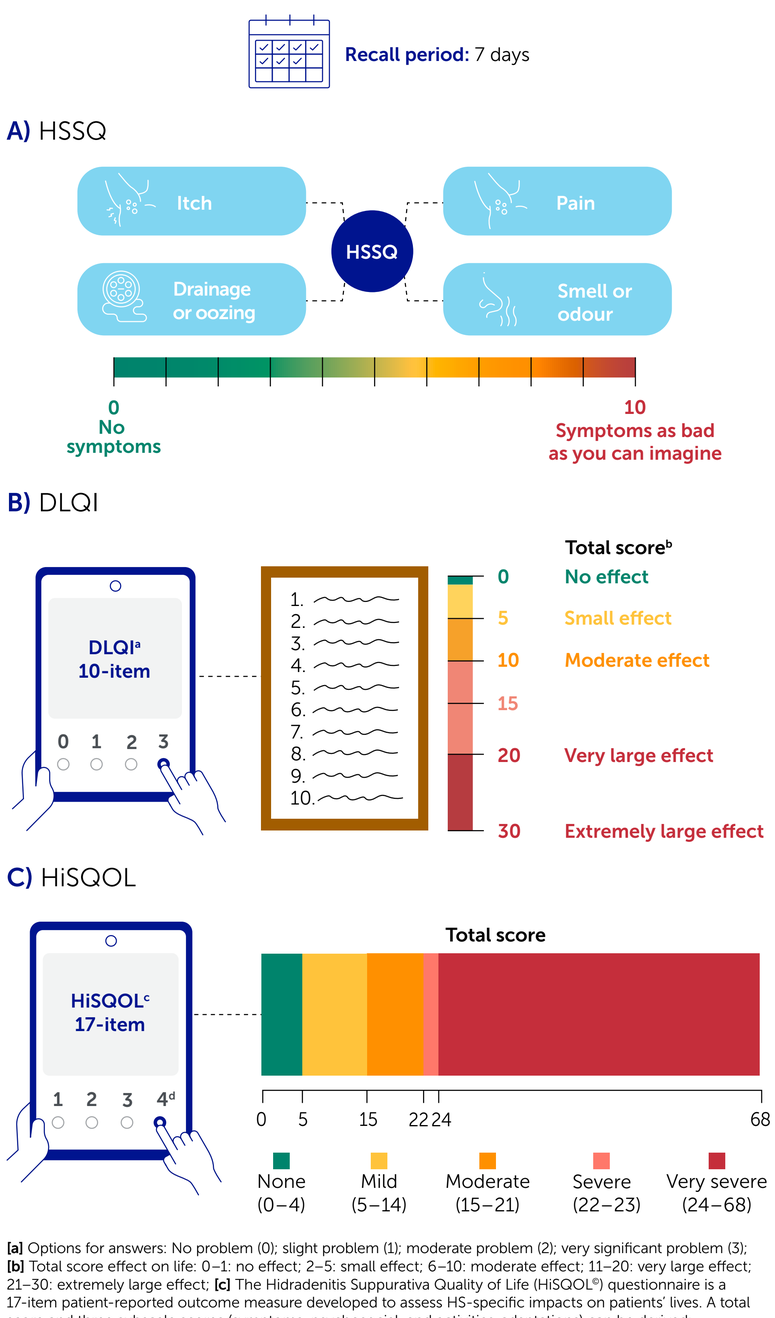
Improvements in symptoms and HRQoL at 2 years



BKZ treatment resulted in **meaningful improvements** in **symptoms** and **HRQoL** in patients with moderate to severe HS over 2 years.

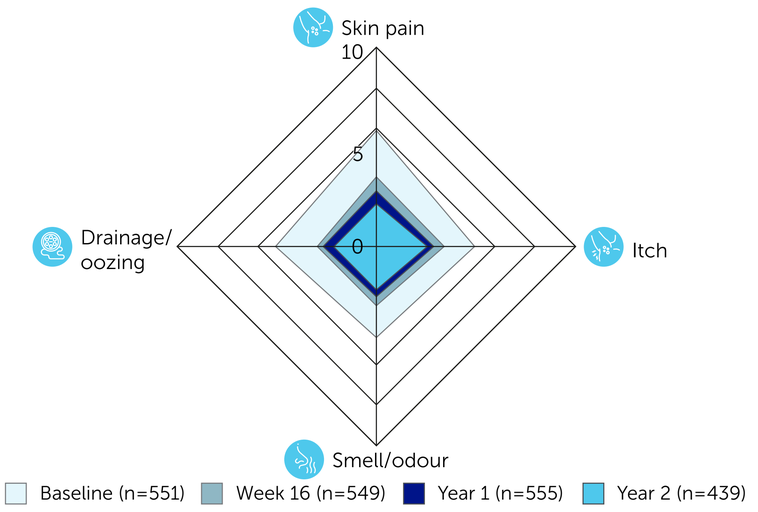
HSSQ reported as mean total item score and mean percentage change from baseline. n/N reported for mean total item score. MCID in DLQI: improvement in DLQI total score ≥4. HiSQOL total score ≤14: no/mild impact of HS on HRQoL.

Figure 1 Patient-reported outcomes



[a] Options for answers: No problem (0); slight problem (1); moderate problem (2); very significant problem (3); **[b]** Total score effect on life: 0–1: no effect; 2–5: small effect; 6–10: moderate effect; 11–20: very large effect; 21–30: extremely large effect; **[c]** The Hidradenitis Suppurativa Quality of Life (HiSQOL®) questionnaire is a 17-item patient-reported outcome measure developed to assess HS-specific impacts on patients' lives. A total score and three subscale scores (symptoms, psychosocial, and activities-adaptations) can be derived; **[d]** Additional criteria include "Not being able to do due to my HS" for questions regarding walking, exercising, sexual activity and work; "Not applicable" for questions regarding sexual activities and work.

Figure 2 HSSQ mean scores by item over 2 years



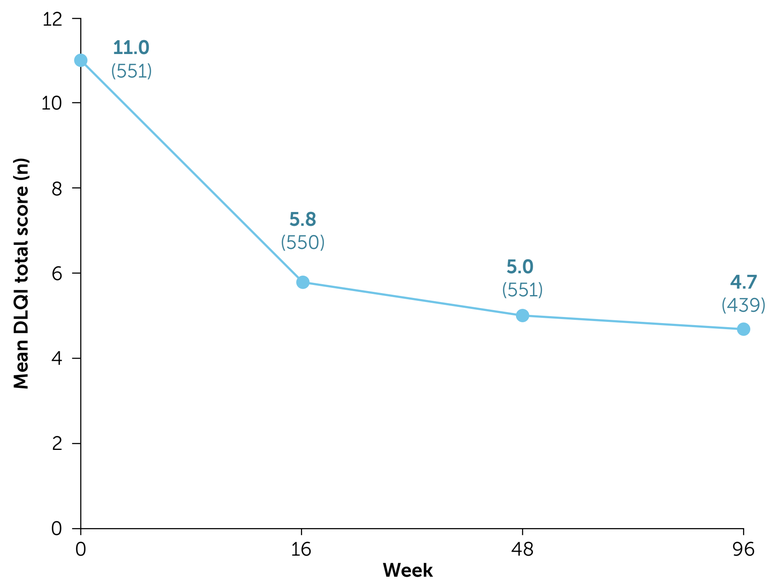
The 4 HSSQ items evaluate participants' perceptions of HS symptoms (skin pain, itch, smell or odour, drainage and oozing) over the past 7 days using an 11-point numeric rating scale with '0' indicating no symptom and '10' for symptom as bad as you can imagine. OC: n numbers represent the number of participants completing the assessment in the given week.

Table 1 DLQI and HiSQOL outcomes over 2 years

N=556	Baseline	Week 16	Year 1	Year 2
DLQI (score range: 0–30)				
DLQI 0/1, % (n/N)	4.7 (26/551)	21.3 (117/550)	27.4 (151/551)	33.9 (149/439)
DLQI 4-point MCID, % (n/N)	N/A	65.9 (311/472)	71.7 (339/473)	71.7 (269/375)
DLQI change from baseline, mean (SD) *n*	N/A	-5.2 (5.7) *546*	-6.0 (6.0) *547*	-6.0 (6.4) *436*
HiSQOL (total score range: 0–68)				
HiSQOL change from baseline, mean (SD) *n*	N/A	−12.0 (11.6) *545*	−13.9 (12.1) *551*	−14.4 (13.2) *436*

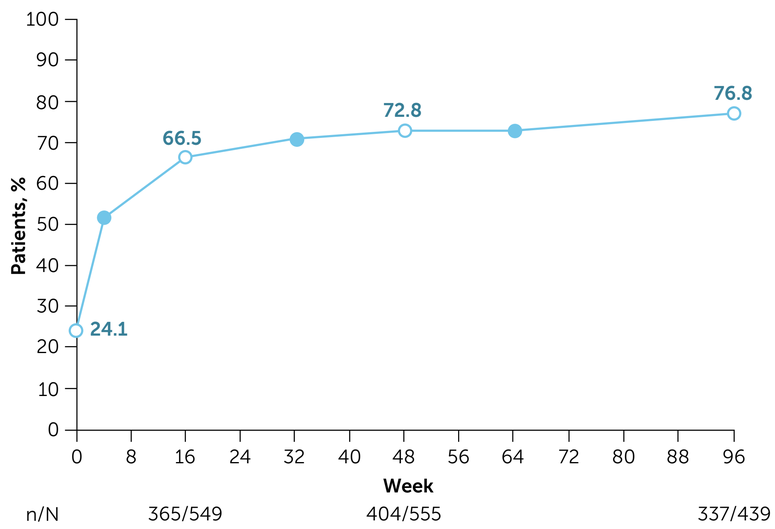
MCID in DLQI: improvement in DLQI total score ≥4. Only participants with a baseline DLQI score ≥4 were included. OC (discrete outcomes) n/N: denominator represents number of patients with non-missing data at the given week, and percentages are calculated accordingly.

Figure 3 Mean DLQI total scores over 2 years



OC, n: denominator represents number of patients with a DLQI total score assessment in the given week.

Figure 4 HiSQOL total score ≤14 over 2 years



HiSQOL total score ≤14: no/mild impact of HS on HRQoL. OC, n/N: denominator represents number of patients with a HiSQOL total score assessment in the given week, and percentages were calculated accordingly.

BKZ: bimekizumab; **DLQI:** Dermatology Life Quality Index; **HiSCR90:** Hidradenitis Suppurativa Clinical Response defined as ≥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; **MCID:** minimal clinically important difference; **N/A:** not applicable; **OC:** observed case; **IL:** interleukin; **SD:** standard deviation.

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]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]Kimball AB et al. The Lancet 2024;403:2504–19; [6]BE HEARD EXT: www.clinicaltrials.gov/study/NCT04901195; [7]Zouboulis CC et al. Presented at EADV 2024; OP7925. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **KRvS**, **ABG**, **AP**, **EV**, **JCS**, **SY**, **BL**, **JL**, **NT**, **HBN**; Drafting of the publication, or reviewing it critically for important intellectual content: **KRvS**, **ABG**, **AP**, **EV**, **JCS**, **SY**, **BL**, **JL**, **NT**, **HBN**; Final approval of the publication: **KRvS**, **ABG**, **AP**, **EV**, **JCS**, **SY**, **BL**, **JL**, **NT**, **HBN**. **Author Disclosures:** **KRvS:** Consultancy/honoraria from Boehringer Ingelheim, Novartis and UCB. **ABG:** Received research/educational grants from Bristol-Myers Squibb, Janssen, Moonlake Immunotherapeutics and UCB (all paid to Mount Sinai School of Medicine until May 1, 2025). Sub I at UTSW on studies from Bristol-Myers Squibb, Janssen and UCB. Received honoraria as an advisory board member and consultant for Bristol-Myers Squibb, Eli Lilly and Company, Janssen, Novartis, Oruka, Sanofi, SunPharma, Takeda, Teva and UCB. **AP:** Investigator, speaker and/or advisor for AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Celgene, Eli Lilly and Company, Galderma, GSK, Hexal, Janssen, LEO Pharma, MC2 Therapeutics, Medac, Merck Serono, Mitsubishi Pharma, MSD, MoonLake Immunotherapeutics, Novartis, Pfizer, Regeneron, Roche, Sandoz, Schering-Plough, Tigercat Pharma, UCB and Zuellig Pharma. **EV:** Advisory board member, consultant, grants, research support, participation in clinical trials, honorarium for speaking, participated in company sponsored speaker's bureau and/or non-financial support with the following pharmaceutical companies: AbbVie, Acelyrin, Almirall, Amgen, Biofrontera, Boehringer Ingelheim, Celgene, Eli Lilly and Company, Galderma, Gebro, Incyte, Isdin, Janssen, LEO Pharma, Merck Serono, MoonLake Immunotherapeutics, MSD, Novartis, Pfizer, Roche, Sandoz, Sanofi and UCB. **JCS:** Consultant and advisory board member of AbbVie, Almirall, Boehringer Ingelheim, Galderma, LEO Pharma, Novartis, Pierre Fabre, Sandoz, Sanofi-Genzyme and UCB; speaker for AbbVie, Almirall, Boehringer Ingelheim, Eli Lilly and Company, Janssen, LEO Pharma, Novartis, Pfizer, Pierre Fabre, Sanofi Genzyme and UCB; investigator for AbbVie, Acelyrin, Almirall Hermal, Amgen, AnaptysBio, Argenx, Aslan, Boehringer Ingelheim, Biocom, Bio Thera, Bristol-Myers Squibb, Celltrion, CuraTeQ Biologics, DICE Therapeutics, Eli Lilly and Company, Galapagos, Galderma, Helm AG, Incyte, InflaRx, Janssen, Kiniksa, Kymab Limited, LEO Pharma, MedImmune, Menlo Therapeutics, Merck, MoonLake Immunotherapeutics, Novartis, Pierre Fabre, Pfizer, Regeneron Pharmaceuticals, Takeda, Teva, Trevi Therapeutics, UCB, Uni Therapeutics and Ventyx Bioscience. **SY:** Consulting for Kaken Pharmaceutical, received travel grants or honoraria from AbbVie, Amgen, Boehringer Ingelheim, Eli Lilly and Company, Maruho, Sanofi, TAIYO Pharma and UCB; department participated in trials for AbbVie, Boehringer Ingelheim, Eli Lilly and Company, Janssen, Kaken Pharmaceutical, Kyowa Kirin Corporation, Novartis, Sanofi and UCB. **BL, JL, NT:** Employees and shareholders of UCB. **HBN:** Consulting fees from AbbVie, Medscape, Sonoma Biotherapeutics, Novartis and UCB; holds shares in Radera Inc; Editorial Board Member/Editor for JAMA Dermatology and Vice President of the US Hidradenitis Suppurativa Foundation. **Acknowledgements:** This study was funded by UCB. We thank the patients and their caregivers in addition to the investigators and their teams who contributed to this study. The authors acknowledge Susanne Wiegratz, MSc, UCB, Monheim am Rhein, Germany for publication coordination, Robert L. Rolleri for his contributions to the development of this poster, and Sarah Johnson, MSci, Costello Medical, Manchester, UK 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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