Bimekizumab 2-year impact on HSSQ skin pain in moderate to severe HS: data from BE HEARD EXT

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Objective

To report impact on pain outcomes with bimekizumab (BKZ) treatment in patients with hidradenitis suppurativa (HS) through 2 years of the pooled phase 3 BE HEARD I&II trials and their open-label extension, BE HEARD EXT.

Introduction

- Pain is experienced by most patients with HS and is considered one of the most debilitating symptoms of HS impacting quality of life.[1] Pain may be driven by aberrant interleukin (IL)-17 signalling.[2]
- BKZ is a humanised IgG1 monoclonal antibody that selectively inhibits IL-17F in addition to IL-17A.[3]

Methods

- The phase 3 BE HEARD I&II (NCT04242446, NCT04242498) and BE HEARD EXT (NCT04901195) study designs are shown in **Figure 1**.[4,5] We report skin pain outcomes, using the HS Symptom Questionnaire (HSSQ) individual skin pain item, to Week 96:
  - Skin pain response, defined as a 30% reduction and ≥1-point reduction in participants with a baseline score of ≥3
  - Absolute and percentage change from baseline (CfB) in skin pain score
  - Distribution of skin pain severity categories.
- Data are reported for all patients randomised to BKZ 320 mg in BE HEARD I&II who enrolled in BE HEARD EXT (BKZ Total).
- Data are reported using observed case (OC).

Results

- High levels of HSSQ skin pain response achieved at 1 year were maintained through 2 years (**Figure 2**).
- Clinically meaningful reductions from baseline in HSSQ skin pain score observed over 1 year were maintained to 2 years (**Figure 3**).
- Over 2 years, an increasing proportion of patients had no or mild skin pain (**Figure 4**).

Conclusions

Clinically meaningful improvements in skin pain observed over 1 year were maintained over 2 years of bimekizumab treatment across assessed HSSQ skin pain outcomes.

An increasing proportion of patients reported no or mild skin pain over 2 years of treatment with bimekizumab.

Plain language summary

Why was this study needed?
Hidradenitis suppurativa (HS) is a chronic skin condition which causes pain that impacts patients' quality of life. Studies have shown that the drug bimekizumab can help reduce this pain in patients with HS.

What did this study show?
Skin pain was reduced in patients treated with bimekizumab. These improvements lasted throughout two years of treatment.

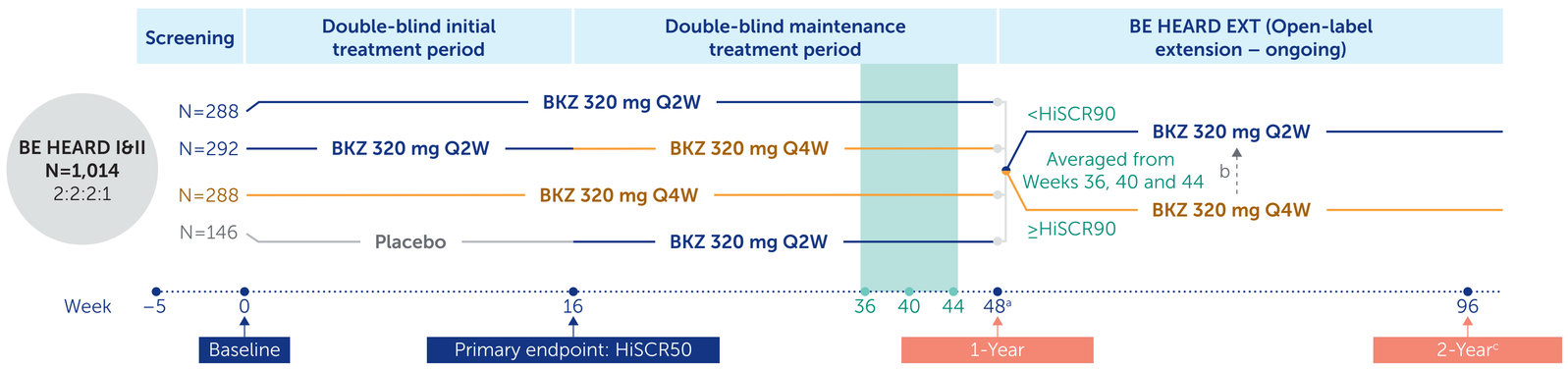
Why is this important?
Pain greatly impacts the daily life of patients with HS. Bimekizumab reduces HS skin pain and may have an important, positive impact on patients' lives.

Table 1 Baseline characteristics

	BKZ 320 mg Total[a] N=556
Age (years), mean (SD)	36.3 (12.2)
Sex, female, n (%)	299 (53.8)
Racial group, n (%)	
White	448 (80.6)
Black or African American	55 (9.9)
BMI (kg/m²), mean (SD)	32.5 (7.8)
Duration of disease (years), mean (SD)	7.4 (7.1)
AN count, mean (SD)	16.9 (18.5)
DT count, mean (SD)	3.8 (4.3)
Hurley stage, n (%)	
II	303 (54.5)
III	253 (45.5)
HSSQ skin pain score, mean (SD)	5.8 (2.4)
DLQI total score, mean (SD)	11.0 (6.8)
Prior biologic use,[b] n (%)	112 (20.1)
Baseline antibiotic use, n (%)	54 (9.7)

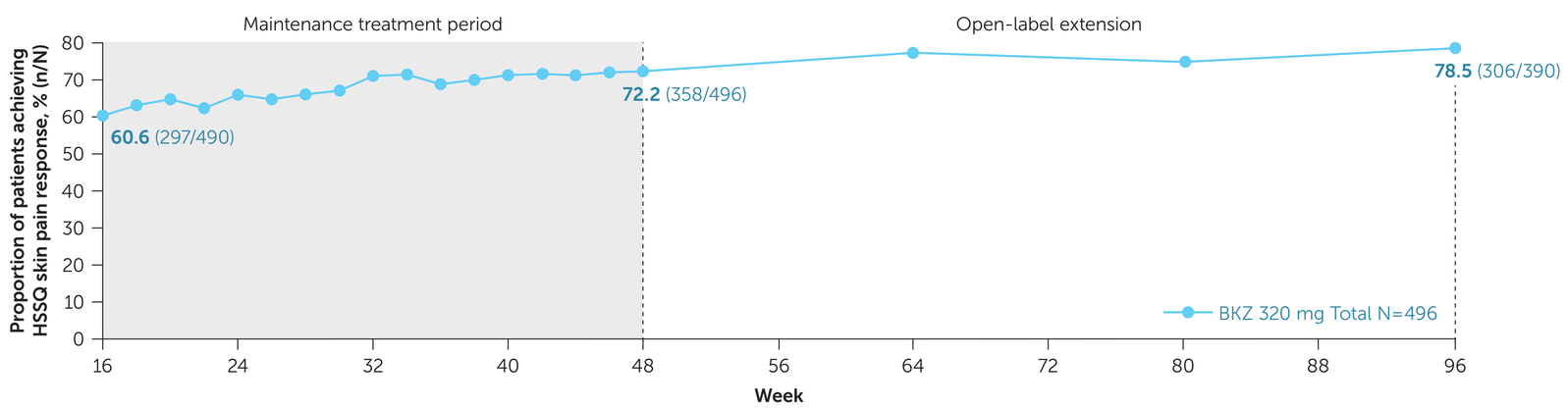
OLE set: N=657; only patients who entered BE HEARD EXT at Week 48 were included. **[a]** BKZ Total comprised patients randomised to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT; **[b]** Patients received prior biologic therapy for any indication.

Figure 1 Study design



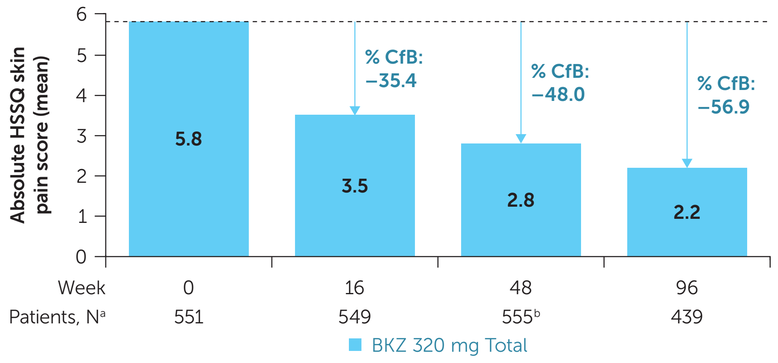
Among 657 BE HEARD I&II completers who entered BE HEARD EXT, 556 patients received BKZ from baseline. **[a]** Patients who completed Week 48 of BE HEARD I&II could enrol in BE HEARD EXT and receive open-label BKZ Q2W or BKZ Q4W based on HiSCR90 responder status using the average lesion counts from Week 36, Week 40 and Week 44 of BE HEARD I&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).

Figure 2 HSSQ skin pain response from Weeks 16–96 (OC)



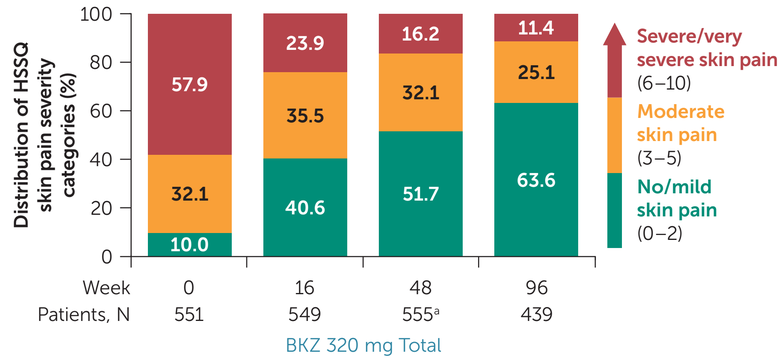
OLE set; only included patients who entered BE HEARD EXT at Week 48. BKZ Total (n=556) comprised patients randomised to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT and continued to receive BKZ. Data for patients in BKZ Total who had a score of ≥3 at baseline are presented. HSSQ data collected at baseline, then every 2 weeks from Week 16 to Week 48, then every 16 weeks to Week 96. OC, n/N: N represents the number of participants with non-missing data at the given week and percentages are calculated accordingly.

Figure 3 Mean score and percentage change from baseline in HSSQ skin pain scores from Weeks 0–96 (OC)



OLE set; only included patients who entered BE HEARD EXT at Week 48. BKZ 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 data collected at baseline, then every 2 weeks from Week 16 to Week 48, then every 16 weeks to Week 96. **[a]** N numbers are reported for mean absolute HSSQ skin pain score. Percentage CfB in HSSQ skin pain scores, N: Week 16: 537, Week 48: 543, Week 96: 430; **[b]** The requirement of a visit at Week 48 to enter the OLE resulted in an increase in N number at Week 48.

Figure 4 Distribution of HSSQ skin pain severity categories from Weeks 0–96 (OC)



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AN: abscess and inflammatory nodule; **BKZ:** bimekizumab; **BMI:** body mass index; **CfB:** change from baseline; **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; **HS:** hidradenitis suppurativa; **HSSQ:** HS Symptom Questionnaire; **Ig:** immunoglobulin; **IL:** interleukin; **OC:** observed case; **OLE:** open-label extension; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks; **RA:** receptor A; **RC:** receptor C; **SD:** standard deviation.

References: [1]Garg A et al. J Am Acad Dermatol 2020;82;366–76; [2]Jiang X et al. Front Immunol 2022;13:999407; [3]Adams R et al. Front Immunol 2020;11:1894; [4]Kimball AB et al. Lancet 2024;403:2504–19; [5]BE HEARD EXT: https://clinicaltrials.gov/study/NCT04901195.

Author Contributions: Substantial contributions to study conception/design or acquisition/analysis/interpretation of data: **LAVO**, **VYS**, **HL-T**, **EP**, **JRI**, **JWF**, **HF**, **RR**, **JL**, **CC**, **LD**, **JS**; Drafting of the publication or revising it critically for important intellectual content: **LAVO**, **VYS**, **HL-T**, **EP**, **JRI**, **JWF**, **HF**, **RR**, **JL**, **CC**, **LD**, **JS**; Final approval of the publication: **LAVO**, **VYS**, **HL-T**, **EP**, **JRI**, **JWF**, **HF**, **RR**, **JL**, **CC**, **LD**, **JS**, **GK**. **Author Disclosures: LAVO:** On the board of directors for the Hidradenitis Suppurativa Foundation (HSF); consultant and/or advisory board member for ChemoCentryx, Novartis and UCB; received grant funding from Pfizer. **VYS:** On the board of directors for the 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. **HL-T:** Consultant for Novartis. **EP:** Consultant, advisory board member, speaker for and received honoraria from Almirall, GSK, Janssen, MoonLake Immunotherapeutics, Novartis and UCB; department received investigator-initiated grant support from AbbVie, Celgene, CHDR, Citryll, Janssen, Kymera and UCB. **JRI:** Received a stipend as immediate past-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, Novartis, UCB, UNION Therapeutics and Viela Bio; co-copyright holder of HiSQOL© and Investigator Global Assessment and Patient Global Assessment instruments for HS; department receives income from copyright of the Dermatology Life Quality Instrument (DLQI) and related instruments. **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, Pfizer and UCB; received research support from Ortho Dermatologics and Sun Pharma. **HF:** Received honoraria or fees for serving on advisory boards, as a speaker and as a consultant, as well as grants as an investigator from AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Daiichi Sankyo, Eisai, Eli Lilly and Company, Janssen, Japan Blood Products Organization, JMEC, Kaken Pharmaceutical, Kyowa Kirin, LEO Pharma, Maruho, Mitsubishi Tanabe, Nihon Pharmaceutical, Novartis, Otsuka Pharmaceutical, Sanofi, Sato Pharmaceutical, Sun Pharma, Taiho Pharmaceutical, Torii Pharmaceutical, UCB and Ushio. **RR**, **JL**, **CC**, **LD:** Employees and shareholders of UCB. **JCS:** Consultant and advisory board member of AbbVie, Almirall, Boehringer Ingelheim, Galderma, LEO Pharma, Novartis, Pierre Fabre, Sandoz, Sanofi and UCB; speaker for AbbVie, Almirall, Boehringer Ingelheim, Eli Lilly and Company, Janssen, LEO Pharma, Novartis, Pierre Fabre, Pfizer, Sanofi and UCB; investigator for AbbVie, Acelyrin, Almirall Hermal, Amgen, AnaptysBio, Argenx, ASLAN Therapeutics, Boehringer Ingelheim, Biocom, Bio Thera, Bristol Myers Squibb, Celltrion, CuraTeQ Biologics, DICE Therapeutics, Eli Lilly and Company, Helm AG, Galapagos, Galderma, Janssen, Incyte, InflaRx, 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. **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. **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, UK, for medical writing and Sophie Jones, BSc, Costello Medical, Bristol, UK, for editorial assistance and the Costello Medical Creative Team for graphic design support. All costs associated with development of this poster were funded by UCB.

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