3000252

Bimekizumab 2-year Efficacy by Prior Biologic Use in Moderate to Severe HS: Data from BE HEARD EXT

Vivian Y. Shi,[1] Jennifer Hsiao,[2] Christopher J. Sayed,[3,4] Georgios Kokolakis,[5] Linnea Thorlacius,[6,7] Antonio Martorell-Calatayud,[8] Vincent Piguet,[9] Pablo Fernandez-Peñas,[10] Shinichi Imafuku,[11] Robert Rolleri,[12] Christina Crater,[12] Varisha Khalid,[13] Nicola Tilt,[14] Brian Kirby[4,15]

Objective

To report bimekizumab (BKZ) efficacy outcomes using pooled data from BE HEARD I&II (BHI&II) and their open-label extension (OLE) BE HEARD EXT (BHEXT) by prior biologic use to Week 96.

Background

- Prior biologic use may identify patients with inflammatory skin conditions as more difficult to treat with subsequent biologics.[1] However, additional research (sub-group analyses), including for hidradenitis suppurativa (HS), is needed.[1]
- BKZ is a humanized IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.[2]

Methods

- BHI&II were two identically designed, randomized, double-blinded, placebo (PBO)-controlled, multicenter trials that included an initial (Weeks 0–16) and maintenance (Weeks 16–48) treatment period (**Figure 1**).[3]
- BHI&II Week 48 completers could enroll in the OLE BHEXT and receive open-label BKZ 320 mg Q4W (achievement of ≥90% HS Clinical Response [≥HiSCR90]) or BKZ Q2W (achievement of <HiSCR90).[4]
- Data were pooled from the BHI&II studies and BHEXT. Here, we report HiSCR50/75/90/100 achievement and abscess and inflammatory nodule (AN) count of 0/1/2 achievement at Week 48/96 for all patients randomized to BKZ in BHI&II who enrolled in BHEXT (BKZ Total).
- Data reported as observed case (OC).

Results

- At baseline, 1,014 patients were randomized. Among 657 BHI&II Week 48 completers who entered the BHEXT, 556 patients received continuous BKZ (biologic-experienced: 112 [20.1%]; biologic-naïve: 444 [79.9%]). Of these, 79.5% (biologic-experienced; n=89) and 80.4% (biologic-naïve; n=357) remained in the study at Week 96.
- Baseline demographics were comparable across biologic-experienced and biologic-naïve patients, although higher proportions of Hurley Stage III disease were seen in biologic-experienced patients vs biologic-naïve patients (64.3% vs 40.8%; **Table 1**).
- Clinically meaningful HiSCR50/75/90/100 response rates observed at Week 48 were maintained or increased to Week 96 among both biologic-experienced and biologic-naïve patients (**Figure 2**).
- Clinically meaningful proportions of biologic-experienced and biologic-naïve patients achieved an AN count of 0/1/2 at Week 48, with further increases to Week 96 (**Figure 3**).

Conclusions

Over 2 years, BKZ demonstrated high response rates for HiSCR50/75/90/100 and AN count of 0/1/2 in biologic-naïve and biologic-experienced patients, with biologic-naïve patients demonstrating numerically higher response rates throughout.

Given the smaller sample size for biologic-experienced patients and the use of OC data, results should be interpreted with caution.

Plain Language Summary

Why was this study needed?
Hidradenitis suppurativa (HS) is a painful, long-term skin condition. Researchers are looking for new ways to better treat HS. Biologics are used to treat HS, and bimekizumab is a new biologic in development for the treatment of HS. There is limited research on whether patients' previous use of biologics may impact their response to bimekizumab treatment.

What did this study show?
The results of the study showed that bimekizumab worked for patients whether or not they had taken biologics previously.

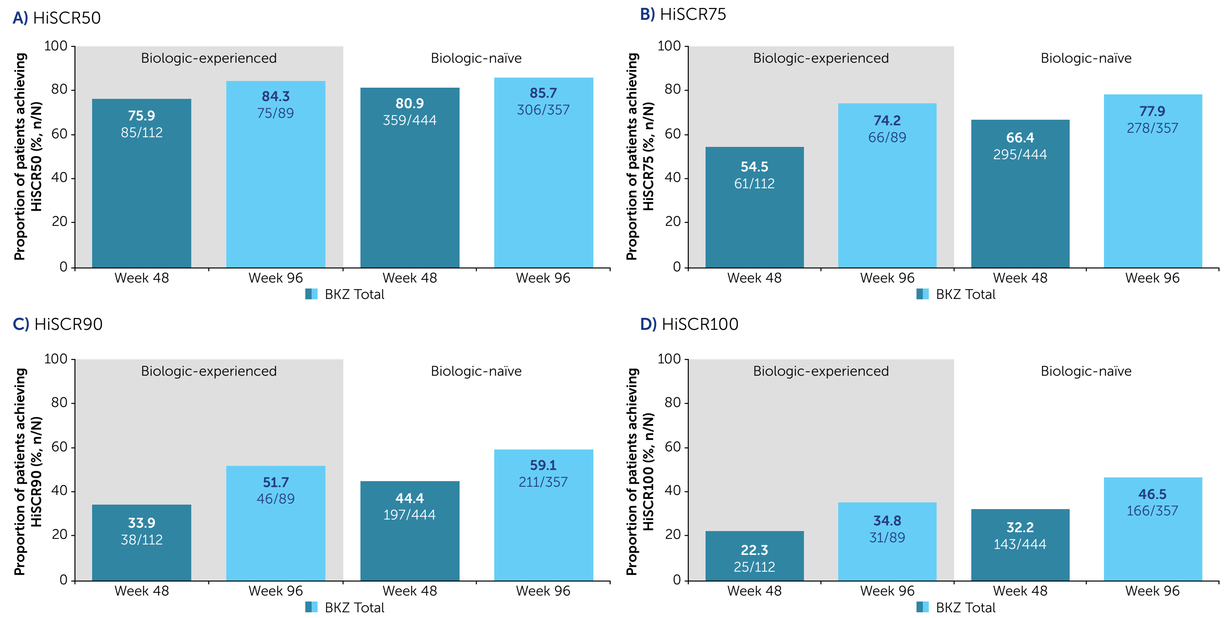
Why is this important?
Bimekizumab may help to reduce the impact of the disease in patients with HS. This includes both patients who have previously taken biologics, and those who have not.

Table 1 Baseline characteristics

	Biologic-experienced[a] n=112	Biologic-naïve n=444
Age (years), mean ± SD	37.5 ± 12.6	36.0 ± 12.0
Sex, female, n (%)	55 (49.1)	244 (55.0)
Racial group, white, n (%)	97 (86.6)	351 (79.1)
Weight (kg), mean ± SD	97.1 ± 24.3	96.0 ± 23.3
BMI (kg/m²), mean ± SD	32.4 ± 7.6	32.5 ± 7.9
Duration of HS (years), mean ± SD	8.3 ± 6.9	7.2 ± 7.2
Hurley Stage, n (%)		
II	40 (35.7)	263 (59.2)
III	72 (64.3)	181 (40.8)
Total AN count, mean ± SD	17.6 ± 27.3	16.7 ± 15.6
Total DT count, mean ± SD	5.6 ± 5.7	3.3 ± 3.7
Baseline antibiotic use, n (%)	7 (6.3)	47 (10.6)

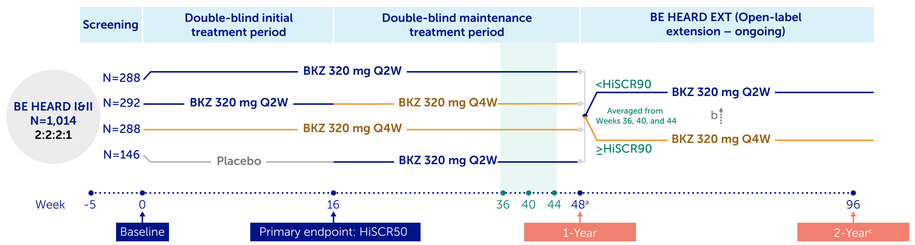
OLE set; only included patients who entered BE HEARD EXT at Week 48. BKZ Total (n=556) comprised patients randomized to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT and continued to receive BKZ. **[a]** Patients received prior biologic therapy for any indication.

Figure 2 HiSCR50/75/90/100 achievement by prior biologic use subgroup at Week 48 and 96 (OC)



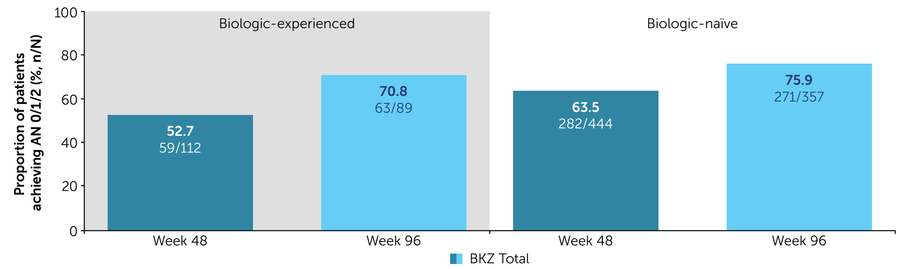
OLE set; only included patients who entered BE HEARD EXT at Week 48. BKZ Total (n=556) comprised patients randomized to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT and continued to receive BKZ. HiSCR50/75/90/100: ≥50%/75%/90%/100% reduction from baseline in the total AN count with no increase from baseline in abscess or draining tunnel count. OC, n/N: denominator represents number of patients with a non-missing lesion count assessment in the given week, and percentages are calculated accordingly.

Figure 1 Study design



At baseline, 1,014 patients with moderate to severe HS were randomized 2:2:2:1 to BKZ 320 mg Q2W to Week 48, BKZ 320 mg Q4W to Week 48, BKZ 320 mg Q2W to Week 16 then BKZ 320 mg Q4W to Week 48, or placebo to Week 16 then BKZ 320 mg Q2W to Week 48. **[a]** Patients who completed Week 48 of BHI&II could enroll in BHEXT 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 BHI&II; **[b]** In the first 48 weeks of the ongoing BHEXT, 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 BHI&II and 48 weeks in BHEXT).

Figure 3 AN count of 0/1/2 achievement by prior biologic use subgroup at Week 48 and 96 (OC)



OLE set; only included patients who entered BE HEARD EXT at Week 48. BKZ Total (n=556) comprised patients randomized to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT and continued to receive BKZ. OC, n/N: denominator represents number of patients with a non-missing lesion count assessment in the given week, and percentages are calculated accordingly.

Abbreviations: AN: abscess and inflammatory nodule; **BHI&II:** BE HEARD I&II; **BHEXT:** BE HEARD EXT; **BKZ:** bimekizumab; **DT:** draining tunnel; **HiSCR:** HS Clinical Response; **HiSCR50/75/90/100:** ≥50%/75%/90%/100% reduction in the total abscess and inflammatory nodule count from baseline with no increase from baseline in abscess or draining tunnel count; **HS:** hidradenitis suppurativa; **IL:** interleukin; **OC:** observed case; **OLE:** open-label extension; **PBO:** placebo; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks; **SD:** standard deviation.

Institutions: [1]Department of Dermatology, University of Washington, Seattle, WA, USA; [2]Department of Dermatology, University of Southern California, Los Angeles, CA, USA; [3]Department of Dermatology, University of North Carolina School of Medicine, Chapel Hill, NC, USA; [4]European Hidradenitis Suppurativa Foundation (EHSF), Dessau, Germany; [5]Psoriasis Research and Treatment Center, Clinic of Dermatology, Venereology, and Allergology, Charité-Universitätsmedizin, Berlin, Germany; corporate member of Freie Universität Berlin and Humboldt-Universität zu Berlin, Berlin, Germany; [6]Department of Dermatology, Zealand University Hospital, Roskilde, Denmark; [7]Health Sciences Faculty, University of Copenhagen, Copenhagen, Denmark; [8]Department of Dermatology, Hospital de Manises, Valencia, Spain; [9]Division of Dermatology, Department of Medicine, Women's College Hospital, University of Toronto, Toronto, Ontario, Canada; [10]Department of Dermatology, Westmead Hospital, University of Sydney, Westmead, New South Wales, Australia; [11]Department of Dermatology, Faculty of Medicine, Fukuoka University, Fukuoka, Japan; [12]UCB, Morrisville, NC, USA; [13]UCB, Brussels, Belgium; [14]UCB, Slough, UK; [15]St Vincent's University Hospital, Elm Park and the Charles Institute, University College Dublin, Republic of Ireland.

References: 1. Wade R et al. Syst Rev 2020;9:132; 2. Glatt S et al. JAMA Dermatol 2021;157:e212905; 3. Kimball AB Lancet 2024;403:2504–19 (NCT04242446, NCT04242498); 4. BE HEARD EXT: www.clinicaltrials.gov/study/NCT04901195. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **VYS**, **JH**, **CJS**, **GK**, **LT**, **AMC**, **VP**, **PFP**, **SI**, **RR**, **CC**, **VK**, **NT**, **BK**. Drafting of the publication, or revising it critically for important intellectual content: **VYS**, **JH**, **CJS**, **GK**, **LT**, **AMC**, **VP**, **PFP**, **SI**, **RR**, **CC**, **VK**, **NT**, **BK**. Final approval of the publication: **VYS**, **JH**, **CJS**, **GK**, **LT**, **AMC**, **VP**, **PFP**, **SI**, **RR**, **CC**, **VK**, **NT**, **BK**. **Author Disclosures: VS:** On the board of directors for the Hidradenitis Suppurativa Foundation (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, 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. **JH:** On the board of directors for the Hidradenitis Suppurativa Foundation; served as a speaker for AbbVie; advisor for AbbVie, Boehringer Ingelheim, Novartis, and UCB. **CJS:** Investigator for AbbVie, ChemoCentryx, Incyte, InflaRx, Novartis, and UCB; consultancy fees from AbbVie, Alumis, AstraZeneca, InflaRx, Incyte, Logical Images, Sonoma Biotherapeutics, and UCB; speaker for AbbVie and Novartis. **GK:** Received travel grants or honoraria, or has been a consultant member of advisory boards and speaker bureaus or has served as investigator for AbbVie, Actelion, Almirall, Amgen, Basilea, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Hexal-Sandoz, Janssen, LEO Pharma, Eli Lilly, MSD, Novartis, Pfizer, Sanofi, Takeda, and UCB. **LT:** Received speaker honoraria from UCB and is co copyright holder of HiSQOL® and HS-IGA. **AMC:** Received honoraria and/or travel grants and/or acted as an advisory board member for AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly, Janssen, LEO Pharma, L'Oreal, Novartis, Sanofi, and UCB. Worked as a principal investigator in clinical trials supported by AbbVie, Bristol Myers Squibb, Galderma, Janssen, Eli Lilly, Novartis, Sanofi, and UCB. **VP:** Consulting fees from AbbVie, Amgen, Boehringer Ingelheim, Celgene, Dermira, Janssen, Eli Lilly, Medimmune, Novartis, Pfizer, Sun Pharma, UCB, and Valeant. **PFP:** Served on advisory boards for: AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly, Janssen, L'Oreal, LEO Pharma, Merck, Merck Sharp & Dohme, Novartis, Pfizer, Sanofi, and UCB; has given educational lectures for AbbVie, Amgen, Bristol Myers Squibb, Eli Lilly, Galderma, Janssen, L'Oreal, LEO Pharma, Merck, Merck Sharp & Dohme, Novartis, Pfizer, Sanofi, UCB, and Zuellig Pharma; has conducted clinical trials for AbbVie, Akaal, Akesobio, Amgen, Arena, AstraZeneca, Boehringer Ingelheim, Bristol Myers Squibb, CSL, Eisai, Eli Lilly, Galderma, Incyte, Janssen, Jiangsu Hengrui, KoBioLabs, Kyowa Hakko Kirin, Merck, Merck Sharp & Dohme, miRagen, Moderna, Nektar, Novartis, OncoSec, Pfizer, Regeneron, Sanofi, Sun Pharma, and UCB. **SI:** Received grants from: AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Kyowa Kirin, LEO Pharma, Pfizer, and UCB; speaker fees from AbbVie, Daiichi Sankyo, Eisai, Eli Lilly, GSK, Janssen, Kyowa Kirin, LEO Pharma, Maruho, Mitsubishi-Tanabe, Novartis, Sun Pharma, and Taiho Pharma. **RR**, **CC**, **VK**, **NT**: Employees and shareholders of UCB. **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, Merck, MoonLake Immunotherapeutics, Novartis, Pfizer, and UCB; has received honoraria from AbbVie, Almirall, Celgene, Eli Lilly, Janssen, MoonLake Immunotherapeutics, Novartis, Pfizer, and UCB; and has been on scientific advisory boards for AbbVie, Almirall, Celgene, Eli Lilly, Janssen, MoonLake Immunotherapeutics, Novartis, Pfizer, and UCB. **Acknowledgments:** 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, Kate Metcalfe, BSc, Costello Medical, London, 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.

To receive a copy of this poster, scan the QR code or visit:
UCBposters.com/SHSA2024
Poster ID: 3000252
Link expiration: 01 February 2025