Bimekizumab efficacy and safety through 2 years in patients with hidradenitis suppurativa: Results from the phase 3 BE HEARD I&II trials and open-label extension BE HEARD EXT

Christos C. Zouboulis,[1,2] Amit Garg,[3] Christopher J. Sayed,[1,4] Gregor Jemec,[1,5,6] Georgios Kokolakis,[1,7] John R. Ingram,[1,8] Akimichi Morita,[9] Pratiksha Dokhe,[10] Ingrid Pansar,[11] Robert Rolleri,[12] Christina Crater,[12] Asim Datye,[13] Alexa B. Kimball[14]

Synopsis

- Hidradenitis suppurativa (HS) is a chronic and debilitating inflammatory skin disease.[1]
- Interleukin (IL)-17F and IL-17A are highly expressed in HS lesional skin and play a role in disease immunopathogenesis.[2–4]
- Bimekizumab (BKZ), a humanized IgG1 monoclonal antibody that selectively inhibits IL-17F in addition to IL-17A, has previously demonstrated clinically meaningful improvements in patients with moderate to severe HS.[5,6]

Objective

To report efficacy and safety data of BKZ in patients with HS over 2 years from the pooled phase 3 BE HEARD I&II (BHI&II) trials and their open-label extension (OLE), BE HEARD EXT (BHEXT).

Methods

- In BHI&II, patients with moderate to severe HS were randomized 2:2:2:1 (initial 16-week [wk]/maintenance 32-wk) to BKZ 320 mg every 2 wks (Q2W)/Q2W, Q2W/Q4W, Q4W/Q4W, or placebo/BKZQ2W. Wk48 completers could enroll in BHEXT and receive open-label BKZQ2W or Q4W based on ≥90% HS Clinical Response (HiSCR90; averaged from Wk36/40/44).[6,7]
- We reported HiSCR50/75/90/100 rates, percentage change from baseline (%CfB, mean±SD) in International HS Severity Score System (IHS4), draining tunnel (DT) count, and Dermatology Life Quality Index (DLQI) 0/1 achievement over 2 years.
- Safety outcomes were reported for patients who received ≥1 BKZ dose across BHI&II/BHEXT.
- Data were reported for patients randomized to BKZ in BHI&II and entered BHEXT (BKZ Total).
- Data were reported as observed case (OC).

Results

- Of 1,014 total patients initially enrolled in BHI&II, 556 patients randomized at baseline to BKZ completed Wk48 and entered BHEXT, 446 patients completed Wk96 (**Figure 1**).
- The population was consistent with moderate to severe HS patient populations seen in clinical trials (**Table 1**).[8–10]
- At Wk48, HiSCR50/75/90/100 was achieved by 79.9/64.0/42.3/30.2% of patients; responses were maintained to Wk96: 85.4/77.1/57.6/44.2% (**Figure 2**).
- Substantial reductions in IHS4 score at Wk48 (−70.3 ± 39.6 %CfB) were maintained to Wk96 with a −79.8 ± 28.1 %CfB (**Figure 3A**).
- Clinically meaningful reductions in total DT count at Wk48 (−57.5 ± 72.9%CfB) were further reduced to Wk96 with a −73.7 ± 45.7%CfB (**Figure 3B**).
- DLQI total score 0/1 response rates at Wk48 (27.4%) were maintained to Wk96 at 33.9% (**Figure 3C**).
- Safety data were consistent with 1 year data from BHI&II (**Table 2**).[6]

Conclusions

Efficacy and health-related quality of life outcomes were maintained through 2 years of treatment.

No new safety signals were observed, and the safety profile over 2 years was consistent with findings from BHI&II and studies of bimekizumab in other indications.[11–13]

These data highlight the durability and consistency of bimekizumab treatment in patients with moderate to severe HS.

Summary

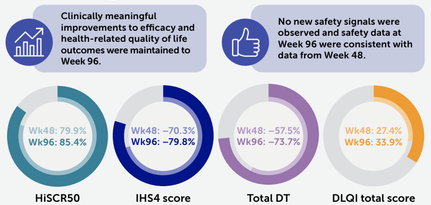
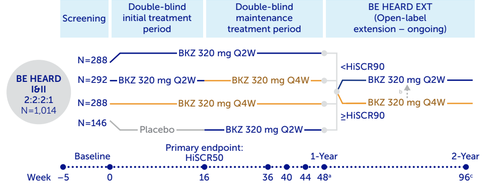


Figure 1 Study design



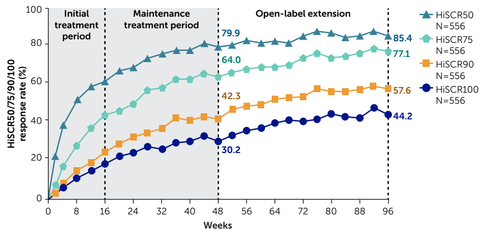
[a] Patients who completed Wk48 of BHI&II could enroll in BHEXT and receive open-label BKZ Q2W or BKZ Q4W based on HiSCR90 responder status using the average lesion counts from Wk36, Wk40, and Wk44 of BHI&II; [b] In the first 48Wks of the ongoing BHEXT, dose adjustment from BKZ Q4W to BKZ Q2W was permitted based on prespecified criteria for reduction in improvement from baseline in AN count; [c] Cumulative 2-year data (48Wks in BHI&II and 48Wks in BHEXT).

Table 1 Baseline characteristics

	BKZ Total[a] N=556
Age, years, mean ± SD	36.3 ± 12.2
Sex, female, n (%)	299 (53.8)
Racial group, white, n (%)	448 (80.6)
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)
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; included only patients who entered BHEXT at Wk48. [a] BKZ Total comprised of patients randomized to BKZ from baseline in BHI&II who entered BHEXT; [b] Patients received prior biologic therapy for any indication.

Figure 2 HiSCR rates over time in BKZ Total group (OC)



OLE set: N=657; included only patients who entered BHEXT at Wk48. Data for patients in BKZ Total are presented. BKZ Total comprised of patients randomized to BKZ from baseline in BHI&II who entered BHEXT (N=556). Wk48 n/N: HiSCR50, 444/556; HiSCR75, 356/556; HiSCR90, 235/556; HiSCR100, 168/556. Wk96 n/N: HiSCR50, 381/446; HiSCR75, 344/446; HiSCR90, 257/446; HiSCR100, 197/446. OC, n/N: denominator represents number of patients with a non-missing lesion count assessment in the given week, and percentages are calculated accordingly (i.e. where data recorded after an intercurrent event are included as recorded).

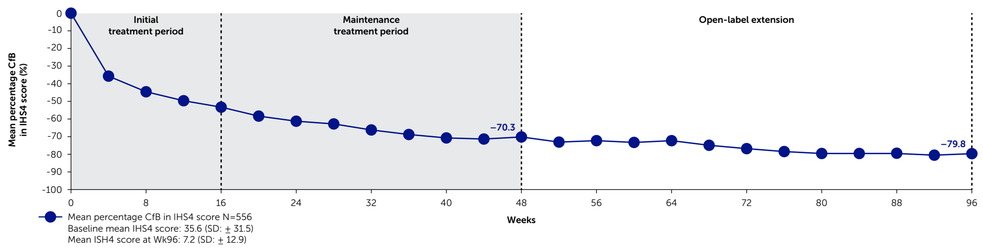
Table 2 Overview of safety outcomes over 2 years[a]

	Patients with ≥1 dose BKZ N=995	
EAIR/100 PY (95% CI)	**Over 1 year (Weeks 0–48)[b] Total exposure: 8.1 per 100 PY**	**Over 2 years (Weeks 0–96) Total exposure: 17.7 per 100 PY**
Any TEAE	287.0 (267.9, 307.1)	248.9 (233.0, 265.5)
Serious TEAEs	8.1 (6.3, 10.4)	7.2 (6.0, 8.6)
Severe TEAEs	10.4 (8.2, 12.9)	7.7 (6.4, 9.2)
TEAEs leading to discontinuation	8.5 (6.6, 10.8)	6.3 (5.1, 7.6)
All deaths[c]	0.1 (0.0, 0.7)	0.1 (0.0, 0.4)
Most common TEAEs		
Hidradenitis	25.7 (22.1, 29.6)	20.5 (18.2, 23.0)
Coronavirus infection	14.0 (11.4, 16.9)	15.3 (13.4, 17.4)
Oral candidiasis[d]	14.7 (12.1, 17.7)	10.5 (8.9, 12.2)
Serious infections	2.0 (1.1, 3.2)	1.9 (1.3, 2.6)
Fungal infections	34.2 (30.0, 38.9)	24.4 (21.8, 27.2)
Any malignancies	0.5 (0.1, 1.3)	0.7 (0.4, 1.3)
Any hepatic events	5.6 (4.1, 7.5)	4.7 (3.7, 5.8)
Adjudicated suicidal ideation and behavior[e]	0.6 (0.2, 1.4)	0.7 (0.4, 1.3)
Definite or probable adjudicated IBD		
With history of IBD (n=8)	0.0 (N/A)	14.2 (1.7, 51.2)
No history of IBD (n=987)	0.9 (0.4, 1.8)	0.5 (0.2, 0.9)

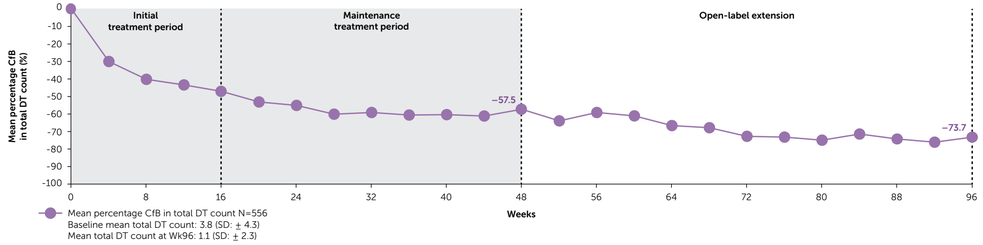
TEAEs were coded using MedDRA v19.0 and reported using EAIRs per 100 PY. [a] TEAEs for all patients who received ≥1 BKZ dose over 1 (Weeks 0–48) and 2 years (Weeks 0–96), including patients who switched at Week 16 from placebo to BKZ 320 mg Q2W (n=134; for these patients, events are reported after the switch to BKZ and for 80 weeks of BKZ treatment); [b] Data originally presented at EADV 2023: Bechara FG et al. P0087; [c] Across 2 years, one patient with significant cardiovascular history died due to congestive heart failure. One patient died due to possible central nervous system infection in the context of deteriorating HS; [d] The majority of oral candidiasis cases were mild to moderate and were resolved/recovering with standard anti-fungal therapy; [e] There were no events of completed suicide.

Figure 3 Percentage change from baseline in key efficacy outcomes

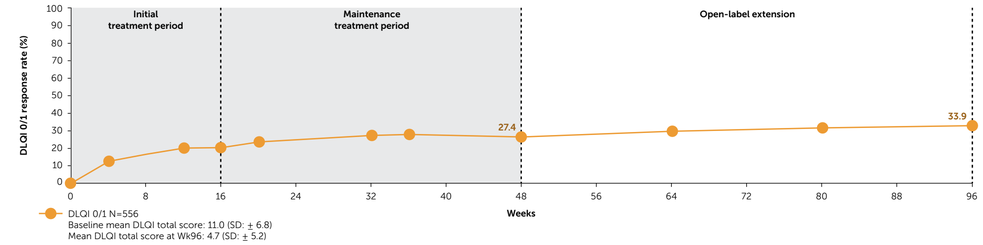
A) IHS4 score over time[a]



B) Total DT count over time[b]



C) DLQI total score 0/1 response rates over time[c]



OLE set: N=657; included only patients who entered BHEXT at Wk48. Data for patients in BKZ Total are presented. BKZ Total comprised patients randomized to BKZ from baseline in BHI&II who entered BHEXT. OC, n/Nsub: Nsub represents the number of participants with non-missing data at the given week, and percentages are calculated accordingly (i.e. where data recorded after an intercurrent event are included as recorded). [a] Wk48 n/N: 556/556, Wk96 n/N: 446/556; [b] Wk48 n/N: 425/556, Wk96 n/N: 350/556; [c] Wk48 n/N: 151/551, Wk96 n/N: 149/439.

AN: abscess and inflammatory nodule; **BHI&II:** BE HEARD I&II; **BHEXT:** BE HEARD EXT; **BKZ:** bimekizumab; **BMI:** body mass index; **CfB:** change from baseline; **CI:** confidence interval; **DLQI:** Dermatology Life Quality Index; **DT:** draining tunnel; **EAIR:** exposure-adjusted incidence rate; **HiSCR:** Hidradenitis Suppurativa Clinical Response; **HiSCR50/75/90/100:** ≥50/75/90/100% reduction from baseline in the total abscess and inflammatory nodule count with no increase from baseline in abscess or draining tunnel count; **HS:** hidradenitis suppurativa; **IBD:** inflammatory bowel disease; **Ig:** immunoglobulin; **IHS4:** International HS Severity Score System; **IL:** interleukin; **N/A:** not applicable; **OC:** observed case; **OLE:** open-label extension; **PY:** patient-years; **QXW:** every X weeks; **SD:** standard deviation; **TEAE:** treatment-emergent adverse event; **Wk:** Week.

Institutions: [1]European Hidradenitis Suppurativa Foundation e.V (EHSF), Dessau, Germany; [2]Departments of Dermatology, Venereology, Allergology and Immunology, Staedtisches Klinikum Dessau, Brandenburg Medical School Theodor Fontane and Faculty of Health Sciences Brandenburg, Dessau, Germany; [3]Northwell, New Hyde Park, NY, USA; [4]Department of Dermatology, University of North Carolina School of Medicine, Chapel Hill, NC, USA; [5]Department of Dermatology, Zealand University Hospital, Roskilde, Denmark; [6]Department of Clinical Medicine, Faculty of Health and Medical Science, University of Copenhagen, Copenhagen, Denmark; [7]Psoriasis Research and Treatment Center, Clinic of Dermatology, Venereology, and Allergology, Charité–Universitätsmedizin Berlin, corporate member of Freie Universität Berlin and Humboldt–Universität zu Berlin, Berlin, Germany; [8]Department of Dermatology & Academic Wound Healing, Division of Infection and Immunity, Cardiff University, Cardiff, UK; [9]Department of Geriatric and Environmental Dermatology, Nagoya City University Graduate School of Medical Sciences, Nagoya, Japan; [10]UCB, Slough, UK; [11]UCB, Brussels, Belgium; [12]UCB, Morrisville, NC, USA; [13]UCB, Oakville, Ontario, Canada; [14]Beth Israel Deaconess Medical Center and Harvard Medical School, Boston, MA, USA.

References: [1]Zouboulis CC et al. Exp Dermatol 2020;29:1154–70; [2]Skelton A et al. J Invest Dermatol 2023;143:S87; [3]Kimball AB et al. Exp Dermatol 2022;31:1522–32; [4]Zouboulis VA et al. Pharmaceutics 2021;14(1):44; [5]Adams R et al. Front Immunol 2020;11:1894; [6]Kimball AB et al. Lancet 2024;403:2504–19 (NCT04242446, NCT04242498); [7]BE HEARD EXT: https://clinicaltrials.gov/study/NCT04901195; [8]Glatt S et al. JAMA Dermatol 2021;157:1279–88; [9]Kimball AB et al. N Engl J Med 2016;375:422–34; [10]Kimball AB et al. Lancet 2023;401:747–61; [11]Reich K et al. N Engl J Med 2021;385:142–52; [12]Merola JF et al. Lancet 2023;401:38–48; [13]van der Heijde D et al. Ann Rheum Dis 2023;82:515–26. **Author Disclosures: CCZ:** Received institution grants as a clinical and research investigator for AstraZeneca, Boehringer Ingelheim, Bristol Myers Squibb, Brandenburg Medical School Theodor Fontane, EADV, European Union, German Federal Ministry of Education and Research, GSK, Incyte, InflaRx, MSD, Novartis, Relaxera, Sanofi, and UCB; received honoraria as a consultant for Almirall, Biogen, Boehringer Ingelheim, CSL Behring, Eli Lilly and Company, Estée Lauder, Idorsia, Incyte, LEO Pharma, L'Oréal, MSD, NAOS-BIODERMA, Novartis, PPM, Sanofi, SciRhom, Takeda, UCB, and ZuraBio; received lecture fees from Almirall, Amgen, NAOS-BIODERMA, Biogen, Bristol Myers Squibb, L'Oréal, Novartis, Pfizer, and UCB; president of the EHSF e.V., president of the Deutsches Register Morbus Adamantiades-Behçet e.V., board member of the International Society for Behçet's Disease, coordinator of the ALLOCATE Skin group of the ERN Skin and chair of the ARHS Task Force group of the EADV, editor of the EADV News; co-copyright holder of IHS4 on behalf of the EHSF e.V. **AG:** Receives honoraria as an advisor for AbbVie, Boehringer Ingelheim, Incyte, Insmed, Novartis, Pfizer, Sonoma Biotherapeutics, UCB, and Union Therapeutics; receives research grants from AbbVie, CHORD COUSIN Collaboration (C3), and UCB. **CJS:** Investigator for AbbVie, AstraZeneca, ChemoCentryx, Incyte, InflaRx, Novartis, and UCB; consultancy fees from AbbVie, Alumis, AstraZeneca, InflaRx, Incyte, Logical Images, Moonlight Immunotherapeutics, Sandoz, Sanofi, Sonoma Biotherapeutics, and UCB; speaker for AbbVie and Novartis. **GJ:** Honoraria from AbbVie, Boehringer Ingelheim, ChemoCentryx, Incyte, Janssen, LEO Pharma, Novartis, and UCB for participation on advisory boards; investigator for AbbVie, CSL, InflaRx, Janssen, LEO Pharma, Novartis, Regeneron, Sanofi, and UCB; speaker honoraria from AbbVie and Novartis; research grants from LEO Pharma and Novartis. **GK:** Received travel grants or honoraria, 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, Eli Lilly and Company, Hexal-Sandoz, Janssen, LEO Pharma, MSD, Novartis, Pfizer, Sanofi, Takeda, and UCB. **JRI:** Received a stipend as Editor-in-Chief of the British Journal of Dermatology and an authorship honorarium from UpToDate; consultant for AbbVie, Boehringer Ingelheim, ChemoCentryx, Citryll, Incyte, MoonLake Immunotherapeutics, Novartis, UCB, and Union Therapeutics; served on advisory boards for Insmed, Kymera Therapeutics, and Viela Bio; co-copyright holder of HiSQOL and HS-IGA; department receives income from copyright of the Dermatology Life Quality Instrument (DLQI) and related instruments. **AM:** Research grants, consulting fees, and/or speaker's fees from AbbVie, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eisai, Eli Lilly and Company, Janssen, Kyowa Hakko Kirin, LEO Pharma, Maruho, Mitsubishi Tanabe Pharma, Nichi-Iko, Nippon Kayaku, Novartis, Pfizer, Sun Pharma, Taiho Pharmaceutical, Torii Pharmaceutical, UCB, and Ushio. **PD**, **IP**, **RR**, **CC**, **AD:** Employees and shareholders of UCB. **ABK:** 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. **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, MSc, UCB, Monheim am Rhein, Germany for publication coordination, and May-Li MacKinnon, PhD, Costello Medical, Manchester for medical writing and editorial assistance. All costs associated with the development of this presentation were funded by UCB.

To receive a copy of this poster, scan the QR code or visit: UCBposters.com/WCM2025

Poster ID: 063618
Link expiration: February 3, 2025