Bimekizumab safety and tolerability in patients with moderate to severe hidradenitis suppurativa: 2-year results from BE HEARD EXT

P2652

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Objective

To evaluate the safety profile of bimekizumab (BKZ) in patients with moderate to severe hidradenitis suppurativa (HS) over 2 years.

To assess whether there are changes in exposure-adjusted incidence rates (EAIRs; per 100 patient-years [PY]) of treatment-emergent adverse events (TEAEs) with each year of BKZ treatment.

Introduction

- HS is a chronic, systemic, inflammatory skin disease characterised by painful lesions.[1]
- BKZ is a humanised monoclonal IgG1 antibody which selectively inhibits interleukin (IL)-17F in addition to IL-17A.[2]

Methods

- Patients completing the 48-week BE HEARD I&II trials could enrol in the open-label extension, BE HEARD EXT, and receive open-label BKZ every 2 weeks (Q2W) or BKZ every 4 weeks (Q4W) based on Hidradenitis Suppurativa Clinical Response (HiSCR) 90 responder status using the average lesion counts from Week 36, 40 and 44 of BE HEARD I&II.[3,4]
- Pooled data are reported for patients who received ≥1 BKZ 320 mg dose across BE HEARD I&II and BE HEARD EXT (data cut-off November 2023).[3,4]
- Patients switching from placebo to BKZ at Week 16 are also included following switch to BKZ, from Week 16 onwards.
- TEAEs are reported as EAIRs (per 100 PY) over 2 years of BKZ treatment (Weeks 0–96 from start of BKZ or Weeks 16–96 for placebo to BKZ switchers).
- TEAEs are also reported separately for Year 1 (Weeks 0–48) and Year 2 (Weeks 48–96) of BKZ treatment.

Results

- Among 1,014 patients enrolled in BE HEARD I&II, 995 BKZ-treated patients, pooled across BE HEARD I&II/BE HEARD EXT, were included in this analysis (Year 1: N=995; Year 2: N=754) (**Figure 1**).
- The baseline characteristics of patients who received ≥1 doses of BKZ 320 mg are reported in **Table 1**.
- BKZ exposure is presented in **Table 2**.
- The most common TEAEs over 2 years were hidradenitis, coronavirus infection and oral candidiasis (**Table 3**).
- Overall, the EAIR of TEAEs did not increase with longer BKZ exposure over 2 years (**Figure 2**).

Conclusions

Bimekizumab was well-tolerated and demonstrated a safety profile that was consistent over 2 years in patients with moderate to severe hidradenitis suppurativa.

No new safety signals were observed for bimekizumab.

Summary

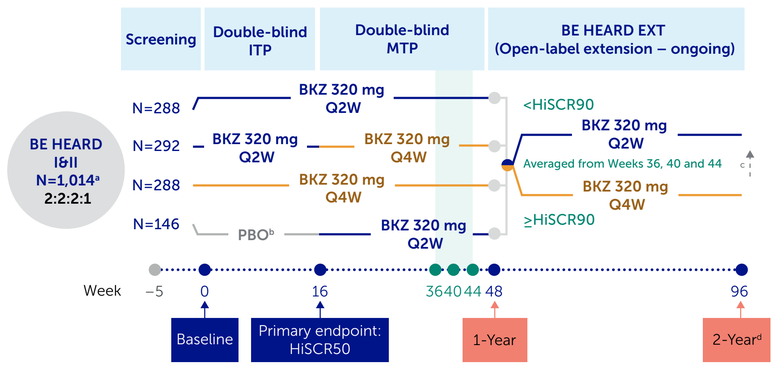
The EAIR of TEAEs in patients with moderate to severe HS did not increase with longer BKZ exposure over 2 years.

EAIR of any TEAE with each year of BKZ treatment

- **285.3**/100 PY — Year 1 (N=995)
- **266.7**/100 PY — Year 2 (N=754)
- **261.3**/100 PY — Over 2 years (N=995)

BKZ was well-tolerated over 2 years with no new safety signals observed.

Figure 1 Study design



[a] N represents the number of randomised patients; **[b]** Patients switching from placebo to BKZ at Week 16 were also included following switch to BKZ; **[c]** 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; **[d]** Cumulative 2-year data (48 weeks in BE HEARD I&II and 48 weeks in BE HEARD EXT).

Table 1 Baseline characteristics

	Patients who received ≥1 BKZ 320 mg dose[a] (N=995)
Age (years), mean (SD)	36.7 (12.2)
Sex, **female**, n (%)	564 (56.7)
Racial group, n (%)	
White, n (%)	796 (80.0)
Black, n (%)	106 (10.7)
Weight (kg), mean (SD)	97.2 (24.5)
BMI (kg/m²), mean (SD)	33.0 (8.1)
Disease duration (years), mean (SD)	8.0 (7.8)
Hurley Stage, n (%)	
II, n (%)	553 (55.6)
III, n (%)	442 (44.4)
DLQI total score, mean (SD)	11.2 (6.9)
Prior biologic use,[b] n (%)	192 (19.3)
Baseline antibiotic use, n (%)	83 (8.3)
Total AN count, mean (SD)	16.1 (16.0)
Total DT count, mean (SD)	3.6 (4.3)

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.

Table 2 BKZ exposure

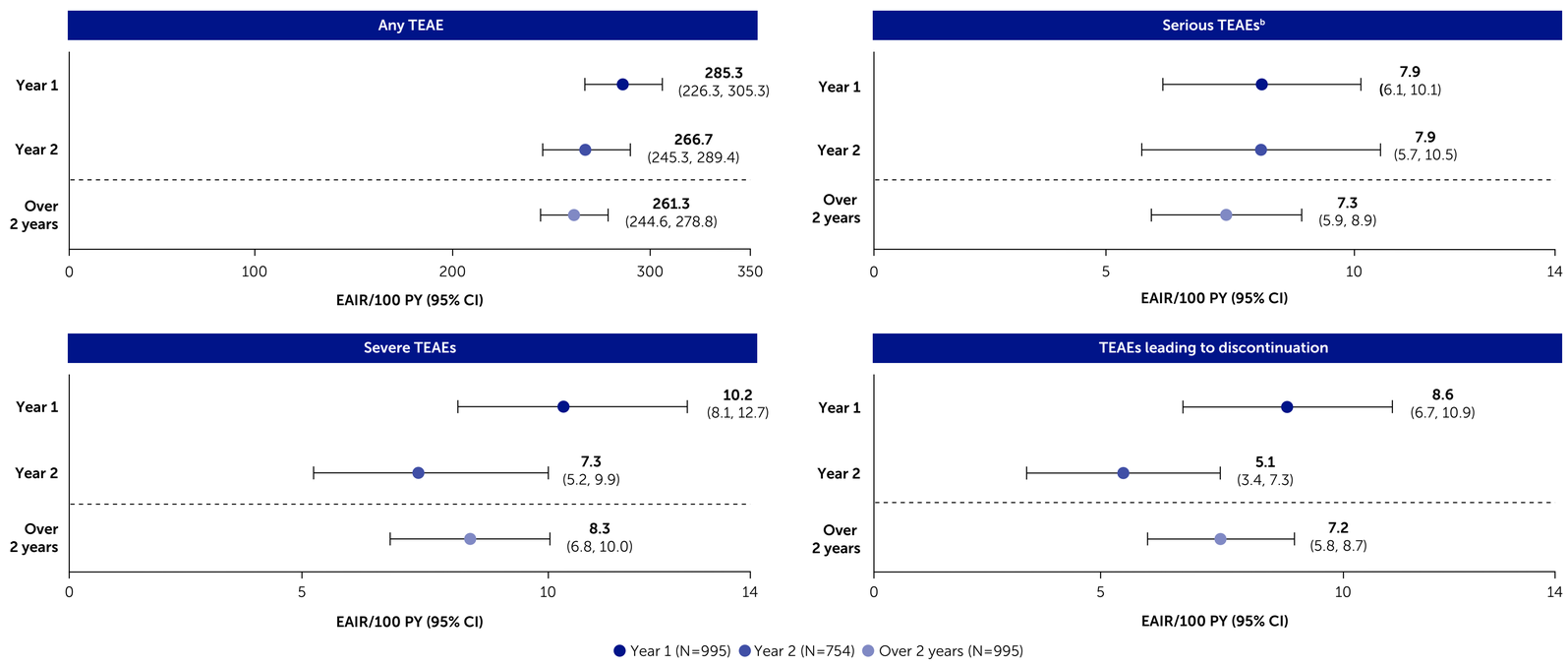
	Year 1 N=995	Year 2 N=754	Over 2 years N=995
Weeks	0–48	>48–96	0–96
Total exposure (time at risk), PY	817.7	576.6	1,394.3
Median exposure (range), days	336.0 (1–336)	336.0 (1–336)	672.0 (1–672)

Table 3 Most common TEAEs and TEAEs of interest

	Year 1 (N=995)	Year 2 (N=754)	Over 2 years (N=995)
Most common TEAEs,[a] EAIR/100 PY (95% CI)			
Hidradenitis	25.2 (21.7, 29.1)	27.1 (22.7, 32.0)	23.0 (20.4, 25.9)
Corona virus infection	14.6 (12.0, 17.5)	21.3 (17.5, 25.6)	17.3 (15.1, 19.8)
Oral candidiasis	15.4 (12.7, 18.4)	12.1 (9.4, 15.4)	12.0 (10.1, 14.0)
TEAEs of interest, EAIR/100 PY (95% CI)			
Serious infections	1.8 (1.0, 3.0)	1.7 (0.8, 3.2)	1.7 (1.1, 2.5)
Active tuberculosis	0	0	0
Fungal infections	35.3 (31.0, 40.0)	25.4 (21.3, 30.2)	27.7 (24.7, 31.0)
Candida infections	21.6 (18.4, 25.2)	17.3 (13.9, 21.2)	17.1 (14.8, 19.6)
Oral candidiasis	15.4 (12.7, 18.4)	12.1 (9.4, 15.4)	12.0 (10.1, 14.0)
Vulvovaginal candidiasis	3.6 (2.4, 5.2)	2.1 (1.1, 3.7)	2.9 (2.0, 3.9)
Neutropenia	0.1 (0.0, 0.7)	0.2 (0.0, 1.0)	0.1 (0.0, 0.5)
Definite or probable adjudicated inflammatory bowel disease	0.9 (0.3, 1.8)	0.5 (0.1, 1.5)	0.7 (0.3, 1.3)
With history of IBD[b]	0	40.6 (4.9, 146.5)	17.3 (2.1, 62.4)[c]
No history of IBD[b]	0.9 (0.3, 1.8)	0.2 (0.0, 1.0)	0.6 (0.3, 1.1)
Adjudicated major adverse cardiac event	0.4 (0.1, 1.1)	0.2 (0.0, 1.0)	0.3 (0.1, 0.7)
Adjudicated suicidal ideation and behaviour[d]	0.7 (0.3, 1.6)	0.9 (0.3, 2.0)	0.8 (0.4, 1.4)
Hepatic events	5.7 (4.1, 7.6)	6.1 (4.2, 8.5)	5.4 (4.2, 6.8)
ALT or AST elevations >3x ULN	20.4 (13.4, 29.6)	21.8 (12.7, 34.9)	10.7 (7.8, 14.4)
ALT or AST elevations >5x ULN[e]	6.3 (2.7, 12.5)	7.7 (2.8, 16.9)	3.5 (1.9, 5.9)
Serious hypersensitivity reactions[f]	0.1 (0.0, 0.7)	0	0.1 (0.0, 0.4)
Injection site reactions	8.5 (6.6, 10.8)	2.3 (1.2, 3.9)	5.9 (4.6, 7.3)
Malignancies	0.5 (0.1, 1.3)	1.0 (0.4, 2.3)	0.7 (0.3, 1.3)
Any malignancies excluding non-melanoma skin cancer	0.2 (0.0, 0.9)	1.0 (0.4, 2.3)	0.6 (0.2, 1.1)

TEAEs were coded using MedDRA v19.0. **[a]** Most common as measured over 2 years; **[b]** Number of patients with history of IBD: Year 1: n=8, Year 2: n=7, over 2 years: n=8; number of patients with no history of IBD: Year 1: n=987, Year 2: n=747, over 2 years: n=987; **[c]** Of the 8 patients with history of IBD, 2 experienced TEAEs of IBD over 2 years; **[d]** No cases of completed suicide reported; **[e]** Patients with elevations >5x ULN were a subset of patients with elevations >3x ULN; **[f]** All cases due to rash pustular; no anaphylaxis associated with BKZ reported over 2 years.

Figure 2 Incidence of TEAEs over 2 years[a]



TEAEs were coded using MedDRA v19.0 and are reported as EAIRs; error bars represent 95% CI. **[a]** The rates of some TEAEs over 2 years may be lower than the rates observed in an individual year due to the adjustment for exposure time at risk for adverse events, which for an individual patient can be up to 2 years in the over 2 years analysis and up to 1 year in the individual year analysis; **[b]** TEAEs leading to death were reported in 2 patients over 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).

ALT: alanine aminotransferase; **AN:** abscess and inflammatory nodule; **AST:** aspartate aminotransferase; **BKZ:** bimekizumab; **CI:** confidence interval; **DLQI:** Dermatology Life Quality Index; **DT:** draining tunnel; **EAIR:** exposure-adjusted incidence rate; **HiSCR90:** HS Clinical Response defined as 90% reduction from baseline in the total AN count with no increase from baseline in abscess or draining tunnel count; **HS:** hidradenitis suppurativa; **IBD:** inflammatory bowel disease; **IgG:** immunoglobulin; **IL:** interleukin; **ITP:** initial treatment period; **MTP:** maintenance treatment period; **OLE:** open-label extension; **PBO:** placebo; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks; **PY:** patient-years; **SD:** standard deviation; **TEAE:** treatment-emergent adverse event; **ULN:** upper limit of normal.

References: [1]Zouboulis CC et al. Dermatology 2015;231:184–90; [2]Adams R et al. Front Immunol 2020;11:1894; [3]Kimball AB et al. 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: **JRI**, **HBN**, **CCZ**, **GJ**, **FGB**, **TN**, **IP**, **PD**, **CC**, **KW**, **AG**; Drafting of the publication, or reviewing it critically for important intellectual content: **JRI**, **HBN**, **CCZ**, **GJ**, **FGB**, **TN**, **IP**, **PD**, **CC**, **KW**, **AG**; Final approval of the publication: **JRI**, **HBN**, **CCZ**, **GJ**, **FGB**, **TN**, **IP**, **PD**, **CC**, **KW**, **AG**. **Author Disclosures: 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, Elasmogen, Engitix, Incyte, Indero, Insmed, Kymera Therapeutics, MoonLake Immunotherapeutics, Novartis, UCB, UNION Therapeutics and Viela Bio; co copyright holder of HiSQOL©, HS Patient global assessment, and HS-IGA; his department receives income from copyright of the Dermatology Life Quality Instrument (DLQI) and related instruments. **HBN:** Grant support from AbbVie; consulting fees from 23andMe, AbbVie, Aristea Therapeutics, Boehringer Ingelheim, DAVA Oncology, Nimbus Therapeutics, Novartis, Sonoma Biotherapeutics and UCB; investigator for Pfizer; Associate Editor for JAMA Dermatology; uncompensated board member of the US Hidradenitis Suppurativa Foundation. **CCZ:** Received institution grants as a clinical and research investigator for AbbVie, 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 AccureAcne, Almirall, Biogen, Boehringer Ingelheim, Commonwealth Serum Laboratories Behring, Eli Lilly and Company, Estée Lauder, Idorsia, Incyte, L'Oréal, MSD, NAOS-BIODERMA, Novartis, Pfizer, PPM, Sanofi, ShiRhom, Takeda, UCB and ZuraBio; received lecture fees from Almirall, Amgen, Biogen, Bristol Myers Squibb, ,NAOS-BIODERMA, L'Oréal, Novartis, Pfizer and UCB; President of the EHSF e.V. and 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, chair of the ARHS Task Force group of the EADV and board member of the International Society for Behçet's Disease; Editor of the EADV News; co-copyright holder of IHS4 on behalf of the EHSF e.V. **GJ:** Honoraria from AbbVie, Boehringer Ingelheim, ChemoCentryx, Incyte, Janssen-Cilag, 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. **FGB:** Received honoraria for participation in advisory boards, in clinical trials and/or as a speaker from AbbVie, Acelyrin, Beiersdorf, Boehringer Ingelheim, Celltrion, Dr. Wolff, Incyte Corporation, Janssen Cilag, Merck, Mölnlycke, MoonLake Immunotherapeutics, Novartis, Sanofi, Sitala and UCB. **TN:** Received honoraria from AbbVie, Eli Lilly and Company, LEO Pharma, Novartis, Otsuka, Pfizer, Sanofi, Sun Pharma, Torii and UCB. **IP**, **PD**, **CC** and **KW:** Employees and shareholders of UCB. **AG:** Receives honoraria as an advisor for AbbVie, Almirall, Boehringer Ingelheim, Engitix, Immunitas Therapeutics, Incyte, Insmed, Novartis, Pfizer, Sonoma Biotherapeutics, UCB, Union Therapeutics, Zura Bio; receives research grants from AbbVie, CHORD COUSIN Collaboration (C3) and UCB. **Acknowledgements:** 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, UCB, Monheim am Rhein, Germany, for publication coordination, and Sana Yaar, PhD, Costello Medical, Manchester, UK for medical writing support and Sophie Jones, BSc, Bristol, UK for 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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