

Bimekizumab safety and tolerability in patients with moderate to severe hidradenitis suppurativa: 3-year results from BE HEARD EXT

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Objective

To evaluate the safety profile of bimekizumab, including selected safety topics of interest, in patients with moderate to severe hidradenitis suppurativa (HS) over 3 years.

Introduction

- HS is a chronic, progressive inflammatory disease that negatively impacts patients' quality of life.¹
- Bimekizumab, a humanised IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated efficacy and is well tolerated over 3 years in patients with HS.^{2–5}
- Given the substantial comorbidity burden associated with HS, it is important to understand the long-term safety profile of bimekizumab treatment, alongside efficacy outcomes, to inform clinical decision-making and manage risks for patients.⁶

Methods

- Data were pooled from the phase 3 BE HEARD I&II trials (NCT04242446, NCT04242498) and the open-label extension, BE HEARD EXT (NCT04901195).^{4,5}
 - Data are reported for patients with moderate to severe HS who received ≥1 bimekizumab dose over 3 years (data cut-off [DCO]: December 2024).
- Treatment-emergent adverse events (TEAEs) are reported as exposure-adjusted incidence rates (EAIRs) per 100 patient-years (PY) over 3 years for all available events whilst on bimekizumab up to the DCO (**Figure 1**).
 - EAIRs were calculated as the number of patients experiencing the event divided by the total PY at risk, providing a measure of event occurrence that accounts for patient-level differences in treatment exposure duration.
- TEAEs are also reported separately by year of bimekizumab treatment up to 3 years (Year 1: Weeks 0–48; Year 2: Weeks >48–96; Year 3: Weeks >96–144) from start of bimekizumab (baseline or Week 16 for patients initially randomised to placebo) using a programmatic cut (maximum 144 weeks; **Figure 1**).

Results

- Across BE HEARD I&II and BE HEARD EXT, 995 patients received ≥1 bimekizumab dose over 3 years and were included in this analysis (**Figure 1**).
- Over 3 years of bimekizumab exposure, totalling 2,118.6 PY, the EAIR for any TEAE was 243.3 per 100 PY (**Table 1**). The EAIRs for any TEAE did not increase over time (**Table 1** and **Figure 2A**).
 - The EAIR for serious TEAEs was 6.7 per 100 PY over 3 years; rates remained stable over time (**Table 1** and **Figure 2B**).
 - The EAIR for TEAEs leading to discontinuation was 5.3 per 100 PY over 3 years, with no increase observed over time (**Table 1** and **Figure 2C**).
- The most common TEAEs over 3 years were hidradenitis, corona virus infections and oral candidiasis, with incidence rates of 19.6, 14.1 and 9.3 per 100 PY over 3 years, respectively (**Table 1**).
 - The incidence of reported corona virus infection declined at Year 3 compared to Year 2, in line with the decline of the COVID-19 pandemic.
- The EAIR for fungal infections over 3 years was 22.4 per 100 PY; within this, the EAIR for *Candida* infections was 13.5 per 100 PY, with the most frequent types being oral candidiasis (9.3 per 100 PY) and vulvovaginal candidiasis (2.1 per 100 PY; **Table 1**).
 - Yearly fungal infection rates, including oral candidiasis, did not increase over time.
 - Over 3 years, 8 patients discontinued due to *Candida* infections.
- The EAIR for hypersensitivity reactions was 17.9 per 100 PY over 3 years, comprising mostly dermatitis and eczema (11.8 per 100 PY). Hypersensitivity reactions were reported less frequently each year (**Table 1**).
 - The majority of hypersensitivity reactions were non-serious, mild or moderate and did not lead to discontinuation.
 - Only 2/483 (0.4%) hypersensitivity reactions were serious (including 1 serious contact dermatitis reportedly due to post-surgical dressing); similarly, only 2/483 (0.4%) were severe and 5/483 (1.0%) led to discontinuation.
- EAIRs for aspartate aminotransferase (AST) or alanine aminotransferase elevations (ALT), based on laboratory evaluations with >3x and >5x the upper limit of normal (ULN), over 3 years were 2.6 and 0.9 per 100 PY, respectively and showed no increase in the by-year analysis.
- EAIRs for malignancies were low over 3 years (0.6 per 100 PY) and rates remained low each year.
- The EAIR for adjudicated suicidal ideation and behaviour (SIB) events over 3 years was 0.6 per 100 PY and rates remained stable over time (**Table 1**). There were no completed suicides over 3 years.

Conclusions

Bimekizumab was well tolerated over 3 years in patients with moderate to severe HS.

No new safety signals were observed and no increased risks were identified with longer bimekizumab exposure.

Summary

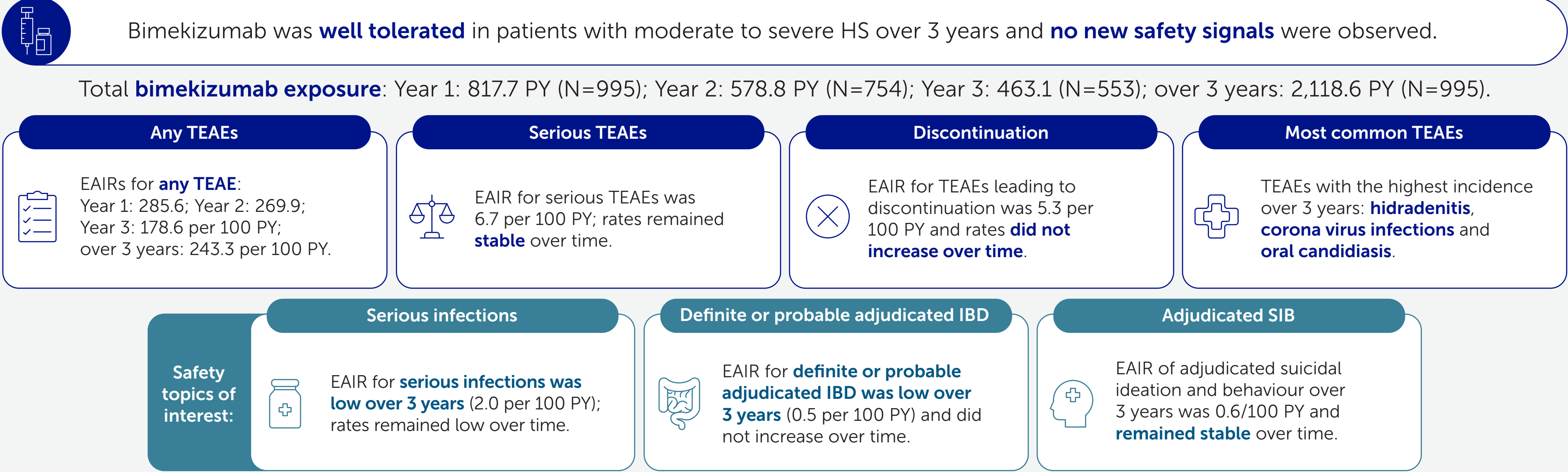


Figure 1 Study design

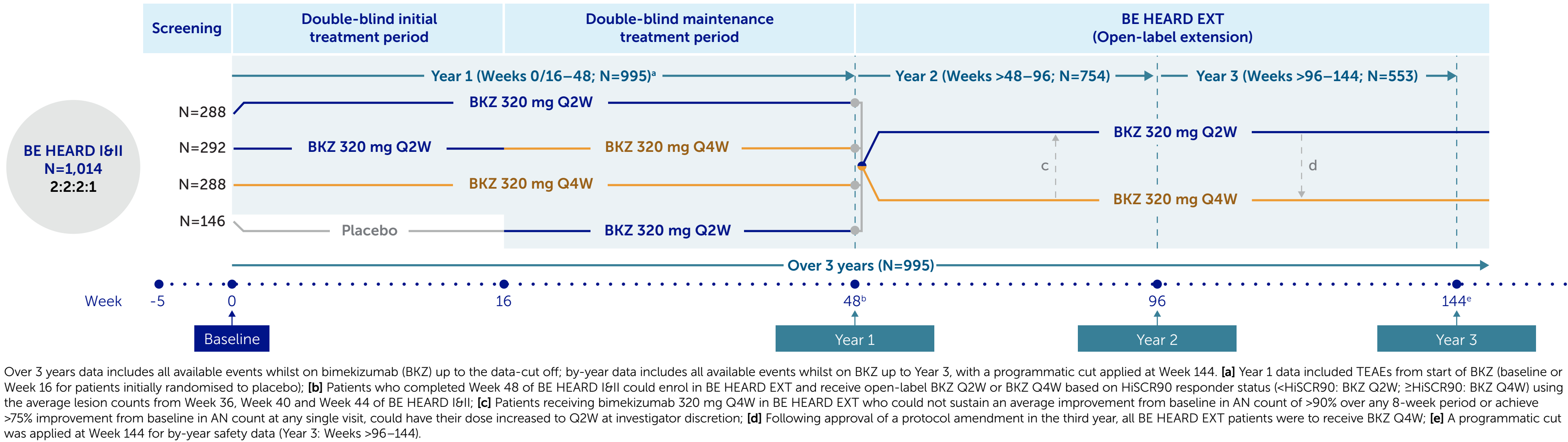
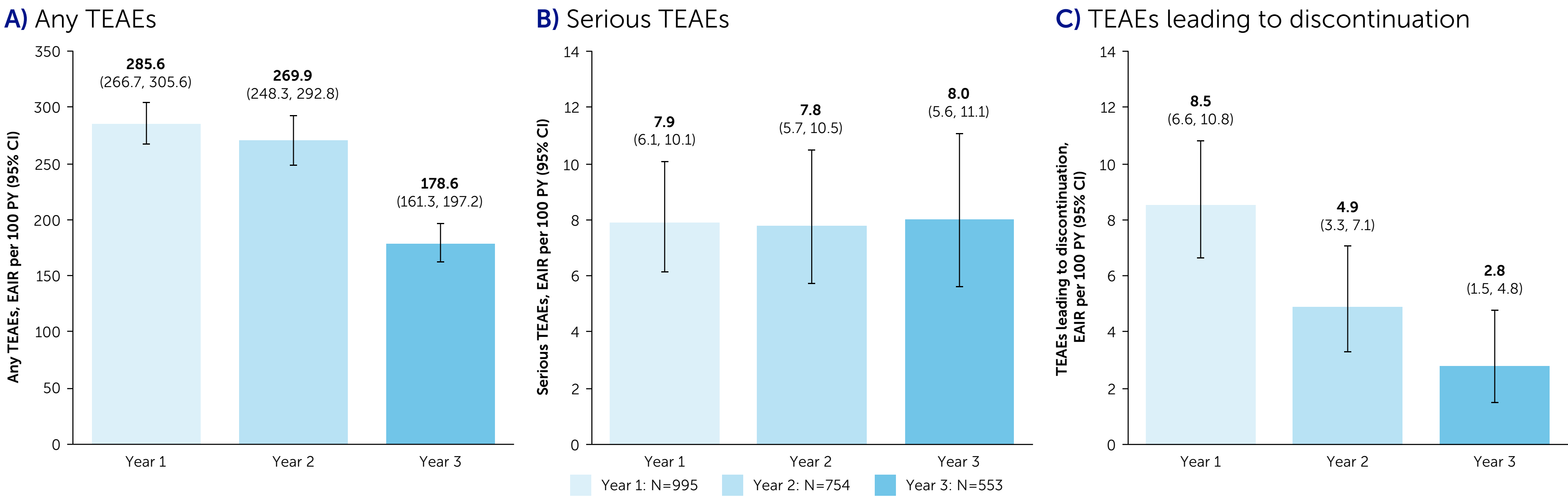


Figure 2 Incidence rates of TEAEs: any TEAEs, serious TEAEs and TEAEs leading to discontinuation over time



EAIRs per 100 PY are reported with 95% CIs for patients who received ≥1 bimekizumab dose over 3 years (BKZ Total).

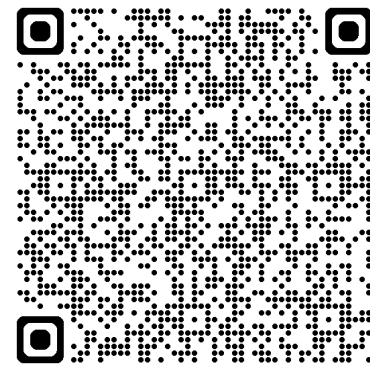
Table 1 Summary of TEAEs and TEAEs of interest over 3 years

	Year 1 Baseline–Week 48 (N=995)	Year 2 Weeks >48–96 (N=754)	Year 3 Weeks >96–144 (N=553)	Over 3 years (N=995)
Total exposure, PY	817.7	578.8	463.1	2,118.6
Summary of TEAEs, EAIR per 100 PY (95% CI)				
Any TEAE	285.6 (266.7, 305.6)	269.9 (248.3, 292.8)	178.6 (161.3, 197.2)	243.3 (227.9, 259.6)
Serious TEAEs	7.9 (6.1, 10.1)	7.8 (5.7, 10.5)	8.0 (5.6, 11.1)	6.7 (4.8, 8.6)
TEAEs leading to discontinuation	8.5 (6.6, 10.8)	4.9 (3.3, 7.1)	2.8 (1.5, 4.8)	5.3 (4.3, 6.4)
TEAEs leading to death	0.1 (0.0, 0.7)	0.3 (0.0, 1.2)	0	0.1 (0.0, 0.4)
Most common TEAEs, EAIR per 100 PY (95% CI)*				
Hidradenitis	25.2 (21.7, 29.1)	27.9 (23.4, 32.8)	18.2 (14.3, 22.7)	19.6 (17.5, 21.8)
Corona virus infections	14.6 (12.0, 17.5)	21.8 (18.0, 26.2)	7.9 (5.5, 10.9)	14.1 (12.4, 16.0)
Oral candidiasis	15.4 (12.7, 18.4)	12.1 (9.3, 15.4)	9.8 (7.1, 13.1)	9.3 (8.0, 10.8)
TEAEs of interest, EAIR per 100 PY (95% CI)				
Serious infections ^b	1.8 (1.0, 3.0)	1.7 (0.8, 3.2)	3.3 (1.8, 5.4)	2.0 (1.4, 2.7)
Fungal infections	35.3 (31.0, 40.0)	25.5 (21.4, 30.3)	21.2 (17.1, 26.1)	22.4 (20.1, 24.9)
<i>Candida</i> infections	21.6 (18.4, 25.2)	17.4 (14.1, 21.3)	12.9 (9.8, 16.8)	13.5 (11.9, 15.4)
Oral candidiasis	15.4 (12.7, 18.4)	12.1 (9.3, 15.4)	9.8 (7.1, 13.1)	9.3 (8.0, 10.8)
Vulvovaginal candidiasis	3.6 (2.4, 5.2)	2.1 (1.1, 3.7)	0.9 (0.2, 2.2)	2.1 (1.5, 2.8)
Definite or probable adjudicated IBD ^c	0.9 (0.3, 1.8)	0.5 (0.0, 1.5)	0.2 (0.0, 1.2)	0.5 (0.2, 0.9)
Adjudicated MACE	0.4 (0.1, 1.1)	0.2 (0.0, 1.0)	0.4 (0.1, 1.6)	0.3 (0.1, 0.6)
Malignancies	0.5 (0.1, 1.3)	1.0 (0.4, 2.3)	0.6 (0.1, 1.9)	0.6 (0.3, 1.1)
Excluding non-melanoma skin cancers	0.2 (0.0, 0.9)	1.0 (0.4, 2.3)	0.2 (0.0, 1.2)	0.4 (0.2, 0.8)
Adjudicated SIB ^d	0.7 (0.3, 1.6)	0.9 (0.3, 2.0)	0.4 (0.1, 1.6)	0.6 (0.3, 1.1)
Neutropenia	0.1 (0.0, 0.7)	0.3 (0.0, 1.3)	0.9 (0.2, 2.2)	0.3 (0.1, 0.6)
AST or ALT elevations				
>3x ULN	3.5 (2.3, 5.0)	3.1 (1.8, 5.0)	1.4 (0.5, 3.0)	2.6 (2.0, 3.4)
>5x ULN ^e	1.0 (0.4, 2.0)	1.1 (0.4, 2.3)	0.7 (0.1, 1.9)	0.9 (0.5, 1.4)
Hypersensitivity reactions	26.3 (22.7, 30.3)	20.0 (16.4, 24.2)	12.3 (9.2, 16.0)	17.9 (16.0, 20.1)
Dermatitis and eczema ^f	16.2 (13.4, 19.3)	15.4 (12.2, 19.0)	12.4 (10.8, 14.3)	11.8 (10.2, 13.5)
Serious hypersensitivity reactions	0.1 (0.0, 0.7)	0	0.2 (0.0, 1.2)	0.1 (0.0, 0.3)
Administration or injection site reactions	8.5 (6.6, 10.8)	2.3 (1.2, 3.9)	1.5 (0.6, 3.1)	4.2 (3.3, 5.2)

A potential limitation of this analysis is that patients who experienced fewer adverse events in the BE HEARD I&II studies may have been more likely to complete the study and enrol in BE HEARD EXT, as such long-term safety results may be influenced by survivor bias. [a] The three TEAEs over 3 years with the highest incidence are presented, per the MedDRA Preferred Terms. [b] Cellulitis was the most common serious infection reported in Year 3 (4 patients). [c] Only patients who did not have active symptomatic IBD could be enrolled; among patients with a history of IBD (n=8), 2 patients experienced flare up to 3 years; [d] No cases of completed suicide were reported; [e] Patients with elevations >3x ULN were a subset of patients with elevations >5x ULN; [f] Based on the MedDRA High Level Term 'Dermatitis and eczema'.

AE: adverse event; ALT: alanine aminotransferase; AN: abscesses and inflammatory nodules; AST: aspartate aminotransferase; BKZ: bimekizumab; CI: confidence interval; EAIR: exposure-adjusted incidence rate; HISC90/90: ≥50%/90% reduction from baseline in the total AN count with no increase from baseline in abscess or draining tunnel count; IBD: inflammatory bowel disease; MACE: major adverse cardiac event; MedDRA: Medical Dictionary for Regulatory Activities; PY: patient-years; Q2W: every two weeks; Q4W: every four weeks; SIB: suicidal ideation and behaviour; TEAE: treatment-emergent adverse event; ULN: upper limit of normal.

References: ¹Garg A et al. *Dermatol Ther* (Heidelb) 2025;15:2361–77; ²Adams R et al. *Front Immunol* 2020;11:1894; ³Kimball AB et al. *Lancet* 2024;403:2504–19; ⁴Sayed CJ et al. *J Am Acad Dermatol* 2026;94:867–78; ⁵Ingram JR et al. Presented at EADV 2025; D1T01.2E; ⁶Garg A et al. *J Am Acad Dermatol* 2022;86:1092–1101. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: AG, HBN, CCZ, GBEJ, FGB, CJS, TN, DD, CC, KW, JRI. Drafting of the publication, or reviewing it critically for important intellectual content: AG, HBN, CCZ, GBEJ, FGB, CJS, TN, DD, CC, KW, JRI. Final approval of the publication: AG, HBN, CCZ, GBEJ, FGB, CJS, TN, DD, CC, KW, JRI. **Author Disclosures:** AG: Advisor for AbbVie, Almiral, Bluefin Biomedicine, Boehringer Ingelheim, Immunitas Therapeutics, Incyte, Insmed, Navigator Medicines, Novartis, Oruka Therapeutics, Otsuka Pharmaceutical, Pfizer, Provant, Sun Pharma, Takeda, UCB, Zura Bio and receives honoraria; receives research grants from AbbVie, UCB and CHORD COUSIN Collaboration (C3); co-copyright holder of the Hidradenitis Suppurativa Investigator Global Assessment (HS-IGA[®]); Hidradenitis suppurativa Drainage (HIDE[®]) and Hidradenitis Suppurativa Quality of Life (HISQOL[®]) instruments. HBN: Consulting fees from AbbVie, Incyte, Medscape, MoonLake Immunotherapeutics, Novartis, Sonoma Biotherapeutics and UCB; speaker for AbbVie, Novartis and UCB. TN: Received honoraria from AbbVie, Eli Lilly and Company, LEO Pharma, Novartis, Otsuka, Pfizer, Sanofi, Sun Pharma, Torii and UCB. DD, CC, KW: Employees and shareholders of UCB. JRI: Received a stipend as immediate past-Chief of the British Journal of Dermatology and an authorship honorarium from UpToDate; consultant for AbbVie, Bluefin Biomedicine, Boehringer Ingelheim, Cantargia, ChemoCentrx, Cytilyl, Elasmogen, Englix, Incyte, Indero, InflRx, Insmed, Kymera Therapeutics, MoonLake Immunotherapeutics, Navigator Medicines, Novartis, Spyre Therapeutics, Sun Pharma, T-Therapeutics, UCB, UNION Therapeutics and Viela Bio; co-copyright holder of HISQOL[®], HIDE[®], HS-IGA[®], HS-LTC[®], I-GLASS[®] and Patient Global Assessment[®] instruments for HS; department receives income from copyright of the Dermatology Life Quality Index (DLQI[®]) and related instruments. **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 this study. The authors also thank Susana Lobo Berastegui, MSc, of UCB, for editorial review during poster development and publication coordination, Kate Metcalfe, BSc, Costello Medical, 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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