Bimekizumab impact on hidradenitis suppurativa lesions over 2 years: Data from BE HEARD EXT

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Objective

To investigate the improvement of different lesion types reported by patients with moderate to severe hidradenitis suppurativa (HS) in the BE HEARD I&II and EXT studies treated with bimekizumab (BKZ) over a period of two years.

Introduction

- HS is an inflammatory skin disease characterised by recurrent, painful and debilitating lesions which lead to potentially long-term, severe sequelae.[1,2]
- The current standard measurements of lesions used in clinical trials involve reporting the percentage of patients meeting an endpoint, which does not allow for an understanding of how specific lesion types improve for individual patients, and may not capture the large amount of within-patient variability observed.[3]
- BKZ is a humanised IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.[4]

Methods

- Data were pooled from BE HEARD I&II studies and their open-label extension, BE HEARD EXT (NCT04242446, NCT04242498, NCT04901195).[5,6] Data are reported for patients randomised to receive BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT (BKZ Total group).
- Lesion counts are reported on an individual patient-basis for draining tunnels (DT), abscesses and inflammatory nodules (IN). In addition, the overall proportion of patients who had a lesion at baseline and experienced a reduction in lesion count, or no lesions at baseline and remained lesion-free, are reported at Year 1 (Week 48) and Year 2 (Week 96).
- Cumulative 2-year data (48 weeks in BE HEARD I&II and 48 weeks in BE HEARD EXT) reported as observed case.

Results

- Of 1,014 total patients in BE HEARD I&II, 556 Year 1 completers randomised to BKZ at baseline in BE HEARD I&II entered the BE HEARD EXT. Baseline patient characteristics are shown in **Table 1**.
- The mean (median) DT, abscess and IN count in the BKZ Total group at baseline are presented in **Table 1**.
- Reductions in DT, abscess and IN count in individual patients from baseline to Years 1 and 2 were observed (**Figure 1** and **2**; animated versions of these figures available via the **QR code**).
- Clinically meaningful reductions in DT, abscess and IN count from baseline were observed at Years 1 and 2 (**Summary Figure**).

Conclusions

Over 2 years, bimekizumab treatment reduced the number of HS lesions in the majority of individuals (≥89.7%). These data show the dynamic changes in draining tunnels, abscesses and inflammatory nodules within individual patients; such data are important due to the severe long-term sequalae of these lesions.

Summary

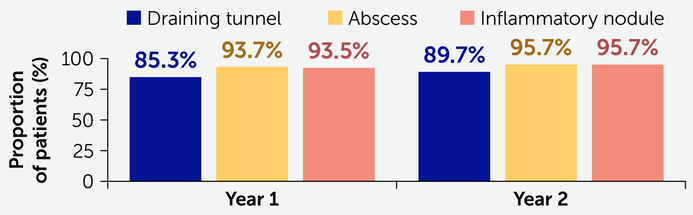
Objective

To examine the **patient-level improvement of different lesion types** reported in individual **patients with moderate to severe HS**, over **2 years of BKZ treatment**.

Results

The **majority of patients saw reductions from baseline** in draining tunnel, abscess and inflammatory nodule count at Years 1 and 2.

Proportion of patients with reductions from baseline in draining tunnel, abscess and inflammatory nodule count at Year 1 and Year 2



Conclusion

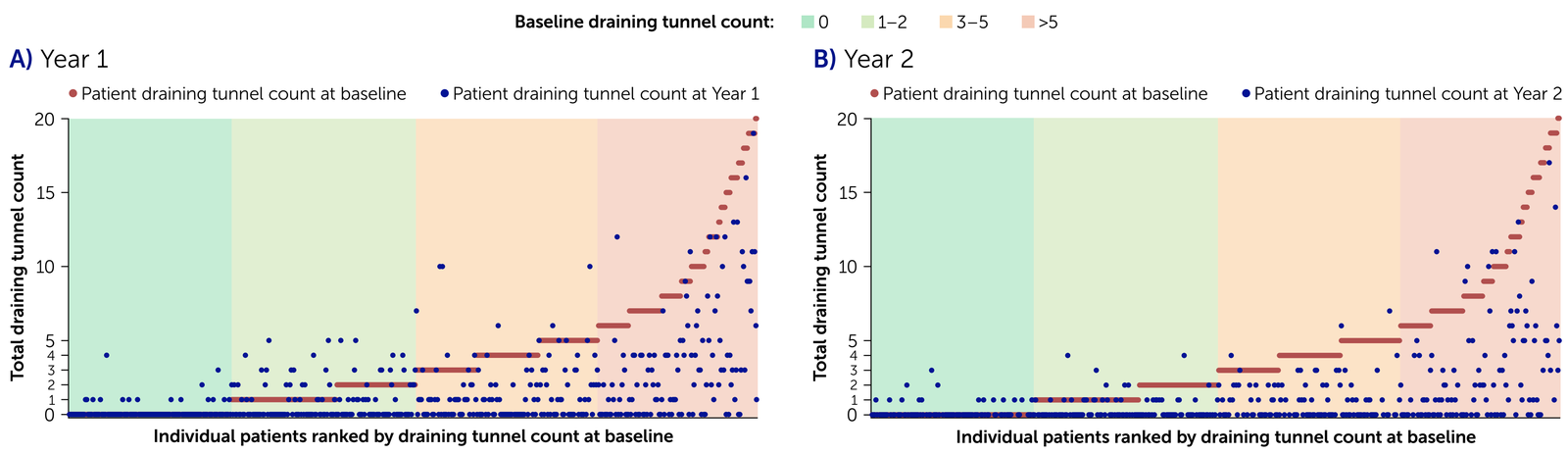
These data show that **the majority of patients saw reductions in HS lesion counts over 2 years of BKZ treatment**.

Table 1 Baseline characteristics

	BKZ 320 mg Total N=556
Age (years), mean (SD)	36.3 (12.2)
Sex, **female**, n (%)	299 (53.8)
Racial group, **white**, n (%)	448 (80.6)
Weight (kg), mean (SD)	96.2 (23.5)
Duration of HS (years), mean (SD)	7.4 (7.1)
Hurley stage, n (%)	
II	303 (54.5)
III	253 (45.5)
HiSQOL total score, mean (SD)	24.6 (12.8)
DLQI total score, mean (SD)	11.0 (6.8)
IHS4 score, mean (SD)	35.6 (31.5)
Prior biologic use, n (%)[a]	112 (20.1)
Baseline antibiotic use, n (%)	54 (9.7)
Baseline lesions, mean (median)	
Draining tunnels	3.8 (2.0)
Abscesses	3.5 (2.0)
Inflammatory nodules	13.4 (9.0)

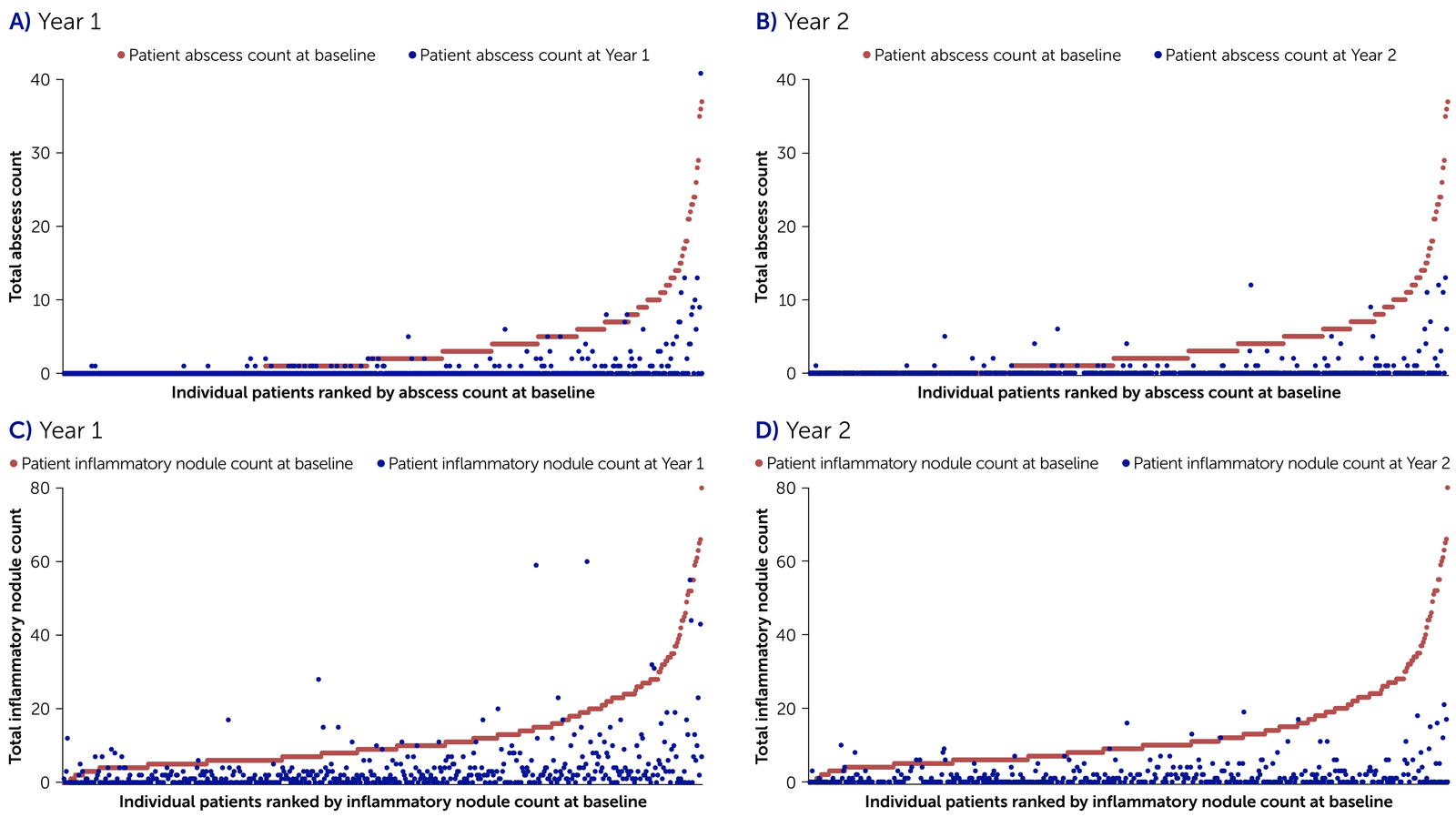
OLE set. **[a]** Patients received prior biologic therapy for any indication.

Figure 1 Individual patient data of (A) draining tunnel count at Year 1; (B) draining tunnel count at Year 2



Red dots indicate DT count for each included patient at baseline. Shaded areas indicate baseline DT count categories, as noted in the legend. **Blue** dots indicate DT count for each included patient at A) Year 1 and B) Year 2. Each patient retains their x-axis position at all timepoints, ranked by DT count at baseline. Year 1 N=556; Year 2 N=446.

Figure 2 Individual patient data of (A) abscess count at Year 1; (B) abscess count at Year 2; (C) inflammatory nodule count at Year 1; (D) inflammatory nodule count at Year 2



Red dots indicate abscess/IN count at baseline for each included patient, with shaded areas representing baseline quartiles, as noted in the legend. Patients are ranked by baseline lesion count. **Blue** dots indicate reported abscess/IN count for each included patient at A) and C) Year 1 and B) and D) Year 2. Each patient retains their x-axis position within each panel set (A and B for abscesses, C and D for INs), but not across these sets. One patient was omitted from abscess count figure panels due to their baseline count exceeding the y-axis maximum – abscess count at **baseline:** 63; **Week 48:** 42; **Week 96:** 31. Four patients omitted from the IN count figure panels due to their baseline count exceeding the y-axis maximum – IN count at **baseline:** 254, 91, 89, 87; **Week 48:** 5, 50, 24, 15; **Week 96:** 8, 5, 7, 13, respectively. Year 1 N=556; Year 2 N=446.

BKZ: bimekizumab; **DLQI:** Dermatology Life Quality Index; **DT:** draining tunnels; **HiSQOL:** Hidradenitis Suppurativa Quality of Life; **HS:** hidradenitis suppurativa; **HSSQ:** HS Symptom Questionnaire; **IHS4:** International Hidradenitis Suppurativa Severity Score System; **IL:** interleukin; **IN:** inflammatory nodules; **SD:** standard deviation.

References: [1]Margesson LJ & Danby FW. Best Pract Res Clin Obstet Gynaecol 2014;28:1013–27; [2]Zouboulis CC et al. Dermatology 2015;231:184–90; [3]Frew JW. JAAD Int 2020;1:62–72; [4]Adams R et al. Front Immunol 2020;11:1894; [5]Kimball AB et al. The Lancet 2024;403:2504–19; [6]BE HEARD EXT: www.clinicaltrials.gov/study/NCT04901195. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **AG**, **ABK**, **PG**, **VP**, **JA**, **KBG**, **NT**, **SW**, **FGB**; Drafting of the publication, or reviewing it critically for important intellectual content: **AG**, **ABK**, **PG**, **VP**, **JA**, **KBG**, **NT**, **SW**, **FGB**; Final approval of the publication: **AG**, **ABK**, **PG**, **VP**, **JA**, **KBG**, **NT**, **SW**, **FGB**. **Author Disclosures:** **AG:** Receives honoraria as an advisor for AbbVie, Almirall, Boehringer Ingelheim, Engitix, Immunitas Therapeutics, Incyte, Insmed, Novartis, Pfizer, Sonoma Biotherapeutics, UCB, Union Therapeutics and Zura Bio; receives research grants from AbbVie, CHORD COUSIN Collaboration (C3) and UCB. **ABK:** Institution 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. **PG:** Received honoraria for consulting from AbbVie, Novartis and UCB. **VP:** Consulting fees from AbbVie, Amgen, Boehringer Ingelheim, Celgene, Dermira, Eli Lilly and Company, Janssen, MedImmune, Novartis, Pfizer, Sun Pharma, UCB and Valeant. **JA:** Received honoraria for consulting and/or presentations and/or sponsoring for scientific projects and/or clinical studies from AbbVie, Incyte and UCB. **KBG:** Received consulting fees from AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Dermira, Eli Lilly and Company, Janssen, Novartis, Pfizer, Sun Pharma and UCB; research support from AbbVie, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Janssen, Novartis and UCB. **SW**, **NT:** Employees and shareholders of UCB. **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, Janssen Cilag, Johnson & Johnson, Merck, Mölnlycke, MoonLake Immunotherapeutics, Novartis, Sanofi, Sitala and UCB. **Acknowledgements:** This study was 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 acknowledge Robert Rolleri, formerly of UCB, Morrisville, North Carolina, USA for his input, George Seleiro, PhD, Costello Medical, Cambridge, 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.

Animated figures

To receive a copy of this poster and view animated patient-level lesion data, scan the QR code.

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