Bimekizumab impact on flare in patients with moderate to severe hidradenitis suppurativa: Pooled Week 48 results from BE HEARD I&II

John R. Ingram,[1,2] Steven Daveluy,[3] Errol Prens,[2,4] Ziad Reguiai,[2,5] Pablo Fernandez-Peñas,[6] Sayaka Yamaguchi,[7] Bartosz Lukowski,[8] Robert Rolleri,[9] Leah Davis,[9] Haley B. Naik[10]

Synopsis

- Hidradenitis suppurativa (HS) is a chronic inflammatory skin disease characterized by recurrent nodules, abscesses, and skin tunnels, with patients often experiencing worsening of symptoms, known as flares.[1,2]
- Achieving disease control is important to reduce the frequency and severity of flares.[1,2]
- Bimekizumab (BKZ) selectively inhibits interleukin (IL)-17F in addition to IL-17A and has previously demonstrated efficacy in patients with HS, in the phase 3 BE HEARD I&II trials.[3,4]

Objective

To assess the impact of BKZ on flares in patients with moderate to severe HS over 48 weeks from the phase 3 BE HEARD I&II studies.

Methods

- Pooled data from the randomized, double-blinded, placebo (PBO)-controlled, multicenter BE HEARD I&II trials included an initial (Weeks 0–16) and maintenance (Weeks 16–48) treatment period (**Figure 1**).
- The proportion of patients who experienced a flare at the given visit (single point) and the cumulative proportion (any visit up to and including the given timepoint) of patients who remained flare-free over 48 weeks are reported.
- Data are reported as observed case (OC).

Results

- Overall, 1,014 patients were randomized to BKZ Q2W/Q2W (N=288), BKZ Q2W/Q4W (N=292), BKZ Q4W/Q4W (N=288), or PBO/Q2W (N=146) in BE HEARD I&II (**Figure 1**).
- Baseline demographics and disease characteristics were comparable across treatment arms (**Table 1**).
- At every visit until and including Week 16, fewer BKZ-treated patients experienced flares than PBO-treated patients (**Figure 2**).
- After switching from PBO to BKZ at Week 16, the number of patients experiencing a flare decreased rapidly to the level observed in those continuously treated with BKZ from baseline through Week 48 (**Figure 2**).
- A substantial proportion of patients continuously treated with BKZ remained flare-free by Week 48 (**Figure 3**).
- After switching from PBO to BKZ Q2W at Week 16, the cumulative proportion of patients who remained flare-free to Week 48 was sustained (**Figure 3**).

Conclusions

Overall, patients treated with bimekizumab experienced fewer flares to Week 16 compared with patients treated with placebo. The proportion of patients who experienced flares remained low in the bimekizumab treated group to Week 48, and reduced rapidly in patients who switched from placebo to bimekizumab.

The majority of patients continuously treated with bimekizumab from baseline were flare-free at Week 16 and sustained their flare-free status to Week 48. Following switch from placebo to bimekizumab, patients experienced few new flares.

Summary

Fewer patients treated with BKZ **experienced flares** over time

Majority of patients treated with BKZ were **flare-free** at Weeks 16 and 48

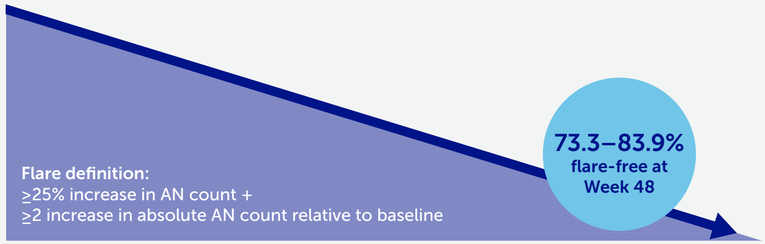


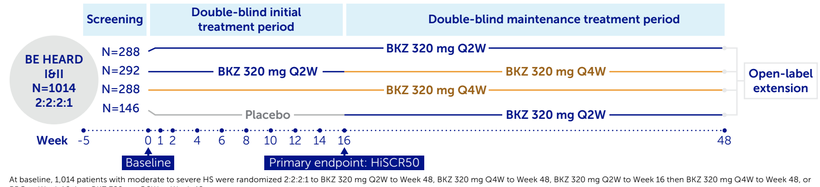
Table 1 Baseline characteristics

	BKZ 320 mg Q2W/Q2W N=288	BKZ 320 mg Q2W/Q4W N=292	BKZ 320 mg Q4W/Q4W N=288	PBO/BKZ 320 mg Q2W N=146
Age (years), mean ± SD	36.8 ± 12.4	37.0 ± 12.4	35.8 ± 11.6	37.3 ± 12.8
Sex, female, n (%)	152 (52.8)	174 (59.6)	175 (60.8)	75 (51.4)
BMI (kg/m²), mean ± SD	32.7 ± 8.6	32.7 ± 7.9	33.8 ± 7.9	33.1 ± 8.3
Duration of HS (years), mean ± SD	7.6 ± 7.4	8.3 ± 7.7	7.3 ± 7.3	9.8 ± 9.4
Baseline AN count, mean ± SD	14.7 ± 11.6	17.2 ± 16.8	17.7 ± 20.9	14.4 ± 10.0
Hurley stage, n (%)				
II	166 (57.6)	160 (54.8)	160 (55.6)	79 (54.1)
III	122 (42.4)	132 (45.2)	128 (44.4)	67 (45.9)
Baseline DT count, mean ± SD	3.8 ± 4.4	3.8 ± 4.4	3.3 ± 4.1	3.4 ± 3.8
Prior biologic use,[a] n (%)	59 (20.5)	56 (19.2)	47 (16.3)	29 (19.9)
Baseline antibiotic use, n (%)	29 (10.1)	28 (9.6)	18 (6.3)	11 (7.5)

Randomized pooled set, N=1,014. [a] Patients received prior biologic therapy for any indication.

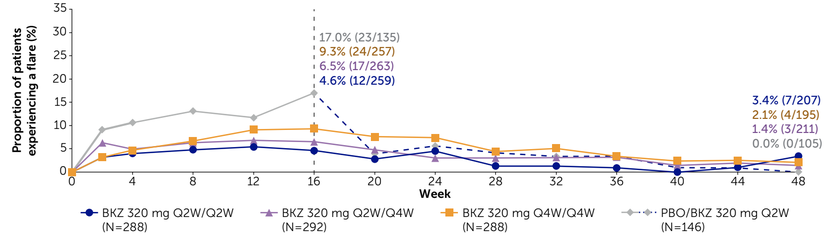
AN: abscess and inflammatory nodule; **BMI:** body mass index; **BKZ:** bimekizumab; **DT:** draining tunnels; **OC:** observed case; **PBO:** placebo; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks; **SD:** standard deviation.

Figure 1 Study design



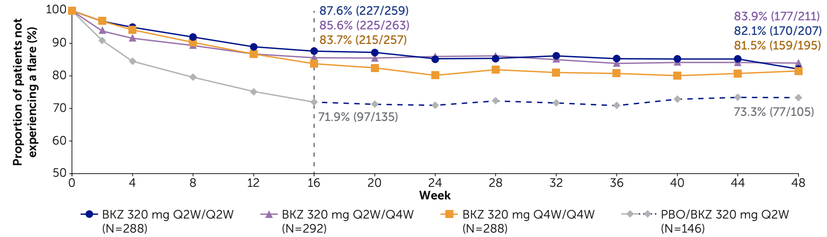
At baseline, 1,014 patients with moderate to severe HS were randomized 2:2:2:1 to BKZ 320 mg Q2W to Week 48, BKZ 320 mg Q4W to Week 48, BKZ 320 mg Q2W to Week 16 then BKZ 320 mg Q4W to Week 48, or PBO to Week 16 then BKZ 320 mg Q2W to Week 48.

Figure 2 Proportion of patients experiencing a flare at a given visit (OC)



Randomized pooled set, N=1,014. N/Nsub whereby Nsub represents the number of participants with a non-missing lesion count assessment at the given week, and percentages are calculated accordingly. Flare was defined as ≥25% increase in AN count with an absolute increase in AN count of ≥2 relative to baseline. Treatment switch after the initial treatment period for the PBO/BKZ 320 mg Q2W group started at Week 16. OC does not include patients who are missing from a given study visit (they may return after missed visits) or discontinued the study.

Figure 3 Cumulative proportion of patients remaining flare-free (OC)



Randomized pooled set, N=1,014. Proportion of patients who have not experienced a flare up to and including each visit; N/Nsub whereby Nsub represents the number of participants with a non-missing lesion count assessment at the given week, and percentages are calculated accordingly. Flare was defined as ≥25% increase in AN count with an absolute increase in AN count of ≥2 relative to baseline. Treatment switch after the initial treatment period for the PBO/BKZ 320 mg Q2W group started at Week 16. OC does not include patients who are missing from a given study visit (they may return after missed visits) or discontinued the study.

Institutions: [1]Department of Dermatology & Academic Wound Healing, Division of Infection and Immunity, Cardiff University, Cardiff, UK; [2]European Hidradenitis Suppurativa Foundation (EHSF), Dessau, Germany; [3]Department of Dermatology, Wayne State University School of Medicine, Detroit, Michigan, USA; [4]Department of Dermatology, Erasmus University Medical Center Rotterdam, Rotterdam, The Netherlands; [5]Dermatology Department, Polyclinique Courlancy-Bezannes, Reims, France; [6]Department of Dermatology, Westmead Hospital, University of Sydney, Westmead, New South Wales, Australia; [7]Department of Dermatology, University of the Ryukyus Graduate School of Medicine, Okinawa, Japan; [8]Vedim/UCB, Warsaw, Poland; [9]UCB, Morrisville, North Carolina, USA; [10]Department of Dermatology, University of California, San Francisco, California, USA.

References: [1]Masson R et al. Skin Appendage Disord 2023; epub: https://doi.org/10.1159/000536094; [2]Kirby JS et al. Br J Dermatol 2020; 182:24–28; [3]Kimball AB et al. Lancet 2024;403:2504–19 (NCT04242446, NCT04242498); [4]Adams R et al. Front Immunol 2020;11:1894. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **JRI**, **SD**, **EP**, **ZR**, **PFP**, **SY**, **BL**, **RR**, **LD**, **HBN**; drafting of the publication, or reviewing it critically for important intellectual content: **JRI**, **SD**, **EP**, **ZR**, **PFP**, **SY**, **BL**, **RR**, **LD**, **HBN**; final approval of the publication: **JRI**, **SD**, **EP**, **ZR**, **PFP**, **SY**, **BL**, **RR**, **LD**, **HBN**. **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, ChemoCentryx, Citryll, 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. **SD:** Speaker for AbbVie and UCB; consultant for AbbVie, Novartis, and UCB; research grants from AbbVie, Pfizer, and UCB. **EP:** Consultant, advisory board member, speaker for and received honoraria from Almirall, Janssen, GSK, MoonLake Immunotherapeutics, Novartis, and UCB. Department has received investigator-initiated grant support from AbbVie, Celgene, CHDR, Citryll, Janssen, Kymera, and UCB. **ZR:** Investigator, speaker and/or advisor for AbbVie, Almirall, Amgen, Avène, Bayer, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Cellitrion, CeraVe, Eli Lilly and Company, Janssen, La Roche Posay, LEO Pharma, Novartis, Pfizer, Regeneron, Sanofi, and UCB; personal fees for attending meetings or for travel from AbbVie, Almirall, Janssen, Novartis, UCB, and Sanofi. **PFP:** Served on advisory boards for AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly and Company, Janssen, L'Oreal, LEO Pharma, Merck, MSD, Novartis, Pfizer, Sanofi, and UCB; has given educational lectures for AbbVie, Amgen, Bristol Myers Squibb, Eli Lilly and Company, Galderma, Janssen, L'Oreal, LEO Pharma, Merck, MSD, Novartis, Pfizer, Sanofi, UCB, and Zuellig Pharma; has conducted clinical trials for AbbVie, Akaal Pharma, Akesobio, Amgen, Arena, AstraZeneca, Boehringer Ingelheim, Bristol Myers Squibb, CSL, Eisai, Eli Lilly and Company, Galderma, Incyte, Janssen, Jiangsu Hengrui, KoBioLabs, Kyowa Kirin, Merck, MSD, miRagen, Moderna, Nektar, Novartis, OncoSec, Pfizer, Regeneron, Sanofi, Sun Pharma, and UCB. **SY:** Consulting for Kaken Pharmaceutical, received travel grants or honoraria from AbbVie, Amgen, Boehringer Ingelheim, Eli Lilly and Company, Maruho, Sanofi, TAIYO Pharma, and UCB. Department participated in trials for AbbVie, Boehringer Ingelheim, Eli Lilly and Company, Janssen, Kaken Pharmaceutical, Kyowa Kirin, Novartis, Sanofi, and UCB. **BL**, **RR**, **LD:** Employees and shareholders of UCB. **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. **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, Marc Lynch, PhD, Costello Medical, London, United Kingdom for medical writing and editorial assistance, and the Costello Medical Creative team for graphic design assistance. All costs associated with development of this poster were funded by UCB.

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