

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

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Objective

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

Introduction

- 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}
- BKZ selectively inhibits interleukin (IL)-17F in addition to IL-17A and has previously demonstrated its efficacy in patients with HS, in the phase 3 BE HEARD I&II trials.^{3,4}

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 to 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

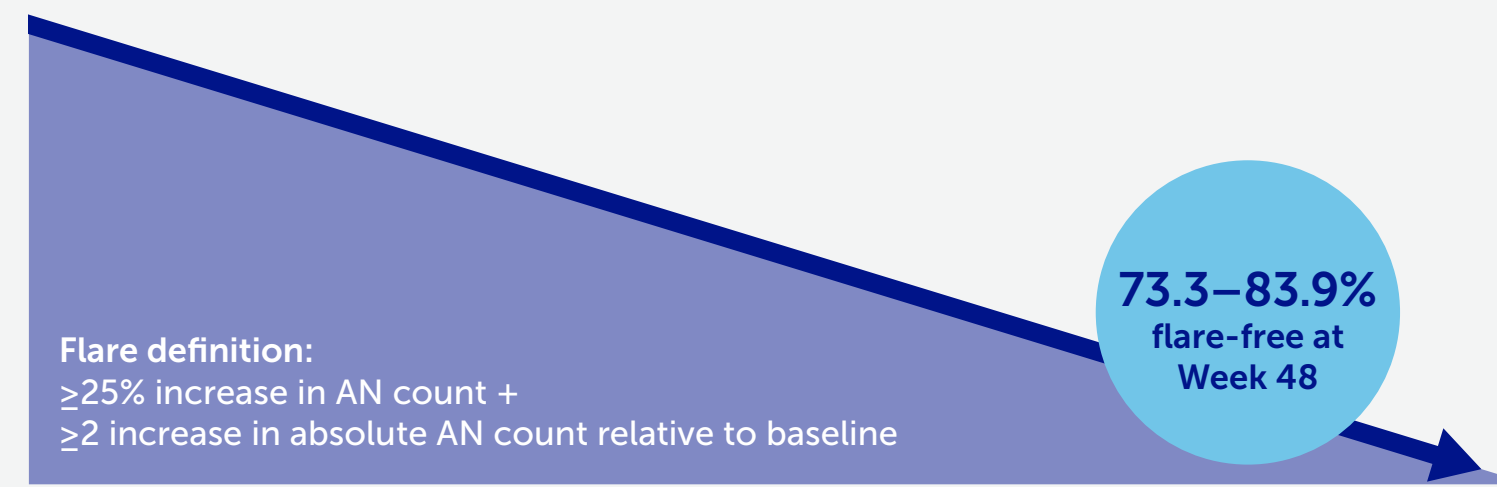


Table 1 Baseline characteristics

	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/m ²), 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; Q2/W4W: every 2/4 weeks; SD: standard deviation.

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References: ¹Masson R et al. Skin Appendage Disord 2023; epub: <https://doi.org/10.1159/000536094>; ²Kirby JS et al. Br J Dermatol 2020; 182:24–28; ³Kimball AB et al. Lancet 2024;403:2504–19 (NCT04242446, NCT04242498); ⁴Adams 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. **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 Inmed, 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, Aveva, Bayer, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Cellcrion, Ceravive, 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'Oréal, LEO Pharma, Merck, Merck Sharp & Dohme, Novartis, Pfizer, Sanofi and UCB; has given educational lectures for AbbVie, Amgen, Bristol Myers Squibb, Eli Lilly and Company, Galderma, Janssen, L'Oréal, LEO Pharma, Merck, Merck Sharp & Dohme, Novartis, Pfizer, Sanofi, UCB and Zuelliq Pharma; has conducted clinical trials for AbbVie, Akaal, Akesobio, Amgen, Arena, AstraZeneca, Boehringer Ingelheim, Bristol Myers Squibb, CSL, Eisai, Eli Lilly and Company, Galderma, Incyte, Janssen, Jianguo Hengrui, KobiLabs, Kyowa Hakkō Kirin, Merck, Merck Sharp & Dohme, 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 corporation, Novartis, Sanofi, and UCB. **BL, RR, LD:** Employees and shareholders of UCB. **HBN:** Grant support from AbbVie; consulting fees from Zsandime, AbbVie, Anistea 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 Wiegartz, 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.

Figure 1 Study design

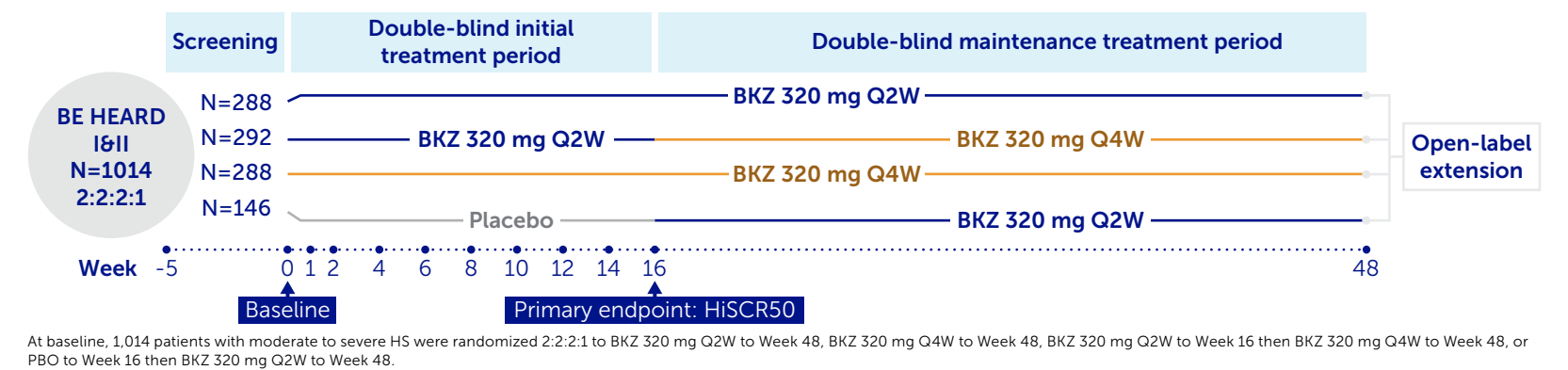


Figure 2 Proportion of patients experiencing a flare at a given visit (OC)

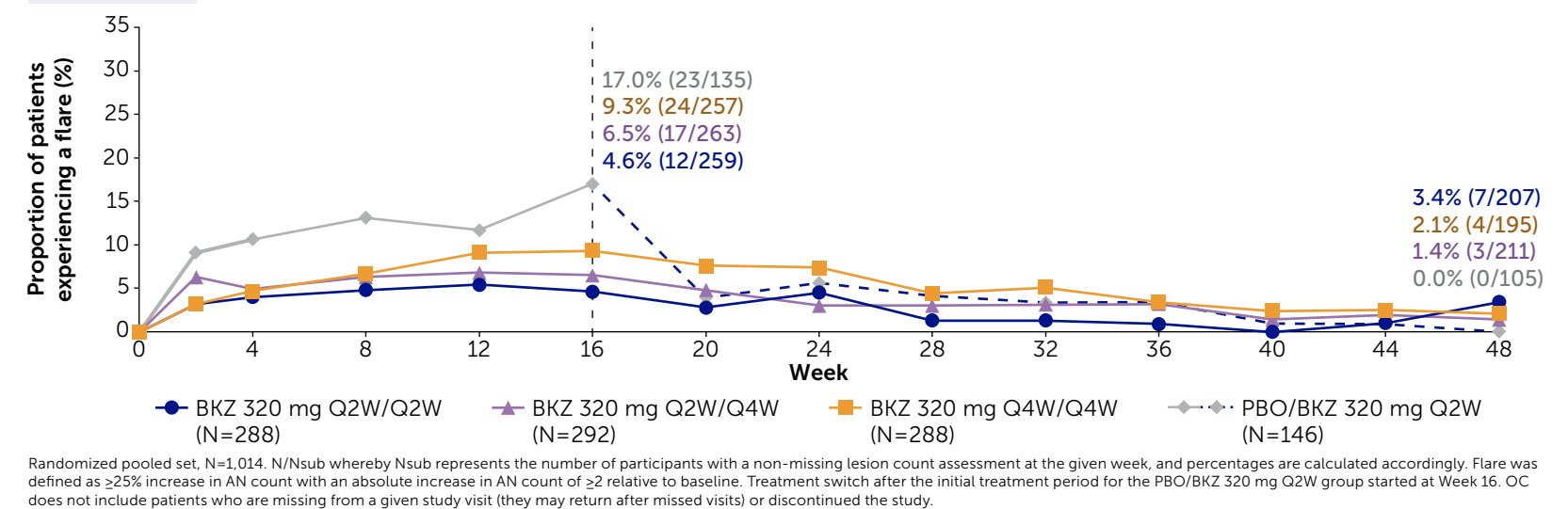
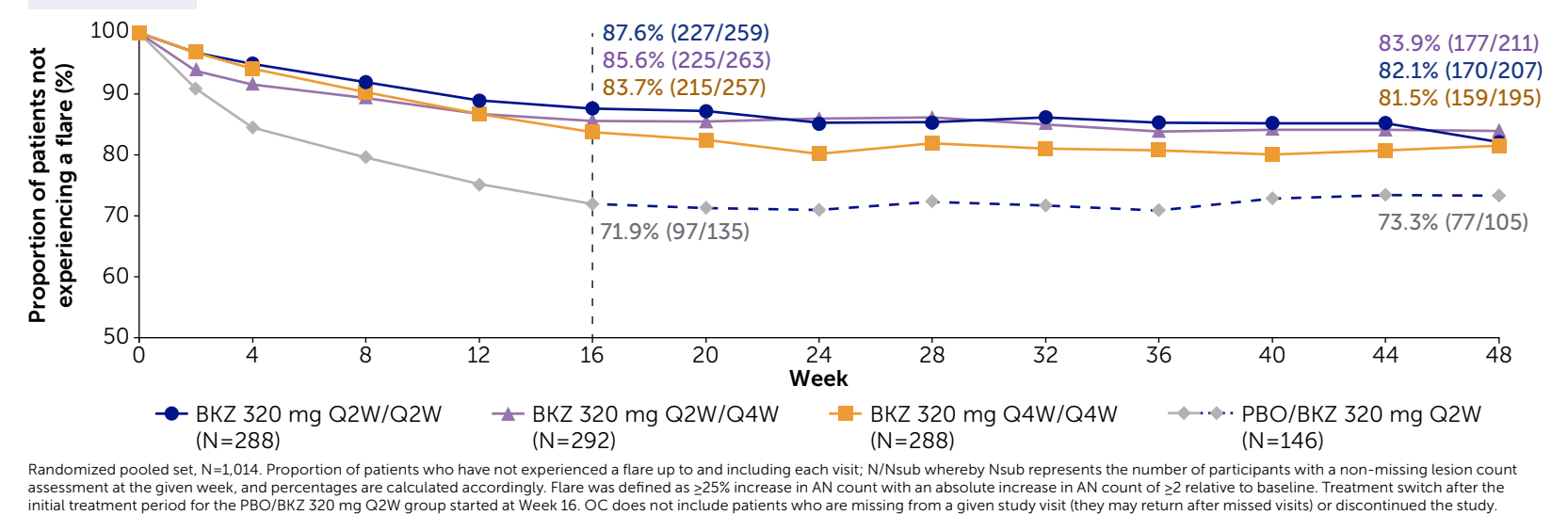


Figure 3 Cumulative proportion of patients remaining flare-free (OC)



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