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

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Objective

To assess the impact of bimekizumab (BKZ) on flares in patients with moderate to severe hidradenitis suppurativa (HS) over 2 years from BE HEARD EXT.

Synopsis

- HS is a chronic inflammatory skin disease characterized by recurrent nodules, abscesses, and draining tunnels, with patients often experiencing periodic worsening of symptoms, known as flares.[1,2]
- Reducing flares is important in achieving disease control and improving patient quality of life.[1]
- BKZ, a humanized monoclonal IgG1 antibody which selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated clinical efficacy through 2 years in phase 3 clinical trials of patients with moderate to severe HS.[3–5]

Methods

- Data were pooled from the BE HEARD I&II studies and BE HEARD EXT.[4,6]
- Week 48 completers could enroll in BE HEARD EXT and receive open-label BKZ 320 mg every 2 weeks (Q2W) or every 4 weeks (Q4W) based on ≥90% HS Clinical Response (HiSCR90; averaged from Weeks 36, 40, and 44 in BE HEARD I&II) (**Figure 1**).
- Data are reported for patients randomized to receive BKZ from baseline (Week 0) in BE HEARD I&II and who entered BE HEARD EXT (BKZ Total group).
- Flare at a visit was defined as ≥25% increase in abscess and inflammatory nodule (AN) count with an absolute increase in AN count of ≥2 relative to baseline.
- The proportion of patients who experienced a flare at the given visit (single point) and the cumulative proportion of patients who remained flare-free (experienced no observed flares at any visit up to and including the given timepoint) up to Weeks 16, 48, and 96 are reported.
- Flare data were not collected for the time periods between study visits. Data are reported as observed case (OC).

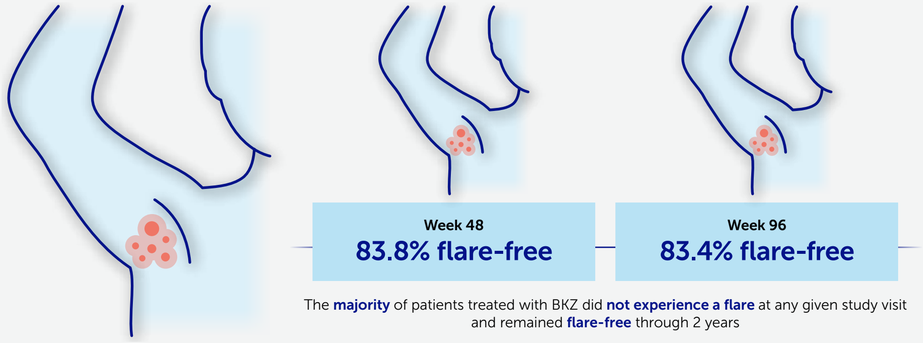
Results

- Of 1,014 total patients in the BE HEARD I&II trials, 556 patients randomized at baseline to BKZ in BE HEARD I&II completed Week 48 and entered BE HEARD EXT; 446 of these patients in BE HEARD EXT completed a lesion count assessment at Week 96.
- The majority (466/556 [83.8%]) of patients in the BKZ Total group remained flare-free up to Week 48. This was maintained through Week 96 (372/446 [83.4%]) (**Figure 2**).
- At Week 48, few (12/556 [2.2%]) patients in the BKZ Total group experienced a flare. This low rate was maintained at Week 96 (5/446 [1.1%]) (**Figure 3**).

Conclusions

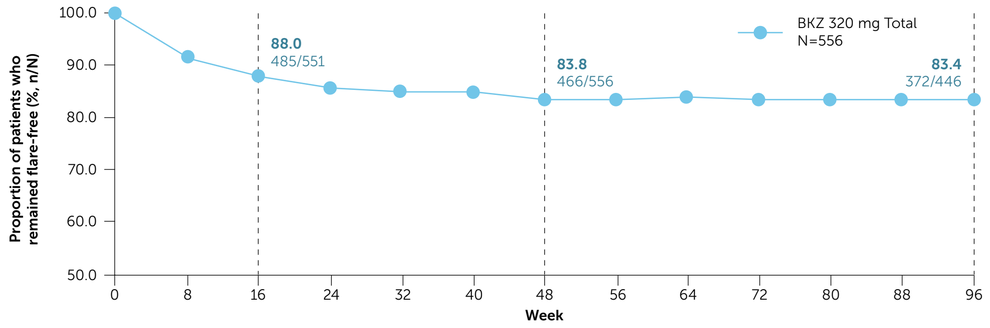
The majority of patients with moderate to severe HS treated with bimekizumab who remained in the study at Week 96 did not experience a flare at any given study visit, and remained flare-free through 2 years.

Summary



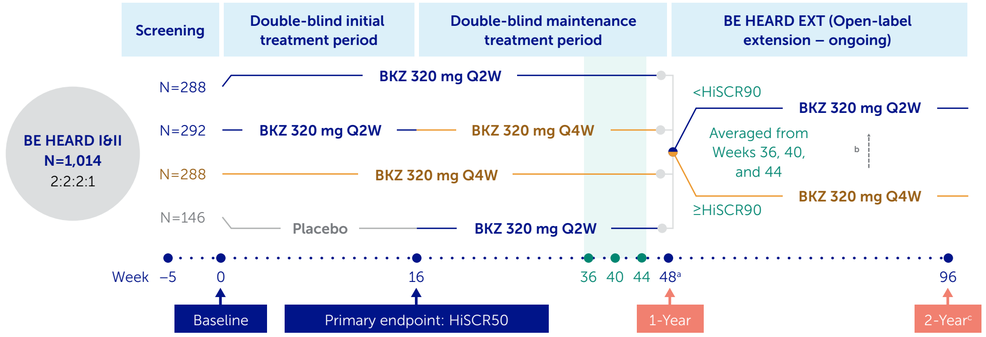
The **majority** of patients treated with BKZ did **not experience a flare** at any given study visit and remained **flare-free** through 2 years

Figure 2 Cumulative proportion of patients remaining flare-free (OC)



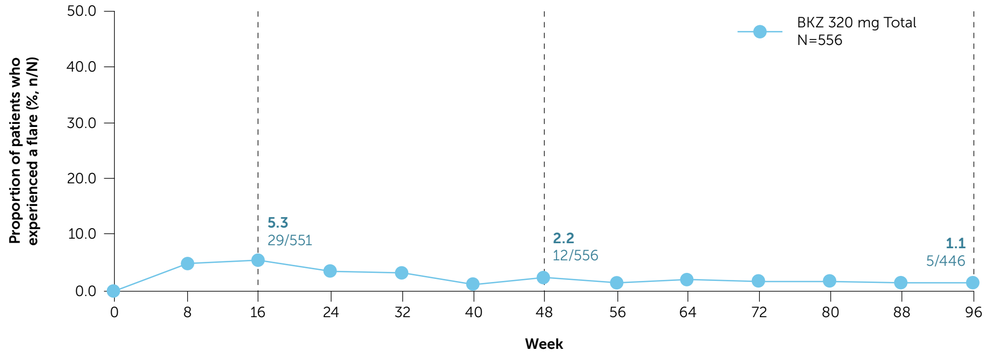
OLE set; only included patients who entered BE HEARD EXT and continued to receive BKZ. BKZ Total (N=556) was comprised of patients randomized to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT. The requirement of a visit at Week 48 to enter the OLE resulted in an increase in N number at Week 48. OC, n/N: the denominator represents the number of patients with non-missing scores at the given week, and percentages were calculated accordingly. Data were collected at additional timepoints that are not shown in this figure: at Week 2 and every 4 weeks from Week 4 through Week 96.

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 Q2W to Week 16 then BKZ 320 mg Q4W to Week 48, BKZ 320 mg Q4W to Week 48, or placebo to Week 16 then BKZ 320 mg Q2W to Week 48. **[a]** Patients who completed Week 48 of BE HEARD I&II could enroll in BE HEARD EXT and receive open-label BKZ Q2W or BKZ Q4W based on HiSCR90 responder status using the average lesion counts from Week 36, Week 40, and Week 44 of BE HEARD I&II. **[b]** 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; **[c]** Cumulative 2-year data (48 weeks in BE HEARD I&II and 48 weeks in BE HEARD EXT).

Figure 3 Proportion of patients experiencing a flare at a given visit (OC)



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AN: abscess and inflammatory nodule; **BKZ:** bimekizumab; **HiSCR50/90:** ≥50%/90% reduction of Hidradenitis Suppurativa Clinical Response criteria; **HS:** hidradenitis suppurativa; **IL:** interleukin; **OC:** observed case; **OLE:** open-label extension; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks.

References: [1]Masson R et al. Skin Appendage Disord 2024;10:224–28; [2]Kirby JS et al. Br J Dermatol 2020;182:24–28; [3]Adams R et al. Front Immunol 2020;11:1894; [4]Kimball AB et al. Lancet 2024;403:2504–2519 (NCT04242446, NCT04242498); [5]Zouboulis CC et al. Skin 2024;s473; [6]BE HEARD EXT: www.clinicaltrials.gov/study/NCT04901195. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **HBN**, **SD**, **EP**, **ZR**, **PFP**, **SY**, **BL**, **CC**, **LD**, **AM**; Drafting of the publication, or reviewing it critically for important intellectual content: **HBN**, **SD**, **EP**, **ZR**, **PFP**, **SY**, **BL**, **CC**, **LD**, **AM**; Final approval of the publication: **HBN**, **SD**, **EP**, **ZR**, **PFP**, **SY**, **BL**, **CC**, **LD**, **AM**. **Author Disclosures: HBN:** Consulting fees from AbbVie, Medscape, Sonoma Biotherapeutics, Novartis, and UCB; holds shares in Radera Inc; Editorial Board Member/Editor for JAMA Dermatology and Vice President of the US Hidradenitis Suppurativa Foundation. **SD:** Speaker for AbbVie, Novartis, and UCB; consultant for AbbVie, Novartis, and UCB; research grants from AbbVie, Incyte, Insmed, MoonLake Immunotherapeutics, Pfizer, Regeneron, Sanofi, and UCB. **EP:** Consultant, advisory board member, speaker for, and received honoraria from Almirall, GSK, Johnson & Johnson, MoonLake Immunotherapeutics, Novartis, and UCB. Department has received investigator-initiated grant support from AbbVie, Celgene, CHDR, Citryll, Johnson & Johnson, Kymera, and UCB. **ZR:** Investigator, speaker, and/or advisor for AbbVie, Almirall, Amgen, Avène, Bayer, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Celltrion, CeraVe, Eli Lilly and Company, Johnson & Johnson, La Roche-Posay, LEO Pharma, Novartis, Pfizer, Regeneron, Sanofi, and UCB; personal fees for attending meetings or for travel from AbbVie, Almirall, Amgen, Bristol Myers Squibb, Celltrion, Eli Lilly and Company, Johnson & Johnson, Novartis, Pfizer, 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 Zuellig 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, Jiangsu Hengrui, KoBioLabs, Kyowa Hakko Kirin, Merck, Merck Sharp & Dohme, miRagen, Moderna, Nektar, Novartis, OncoSec, Pfizer, Regeneron, Sanofi, Sun Pharma, and UCB. **SY:** Consultant for Kaken; 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, Johnson & Johnson, Kaken Pharmaceutical, Kyowa Kirin, Novartis, Sanofi, and UCB. **BL**, **CC**, **LD:** Employees and shareholders of UCB. **AM:** Received honoraria, travel grants, and/or acted as advisory board member for AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly and Company, Johnson & Johnson, Legit Health, LEO Pharma, L'Oréal, Novartis, Sanofi, and UCB; principal investigator in clinical trials supported by AbbVie, Bristol Myers Squibb, Eli Lilly and Company, Galderma, Johnson & Johnson, Novartis, Sanofi, and UCB. **Acknowledgments:** 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 Departments of Dermatology, Venereology, Allergology, and Immunology, Staedtisches Klinikum Dessau, Dessau, Germany, are healthcare providers of the European Reference Network for Rare and Complex Skin Diseases (ERN Skin). The authors acknowledge Susanne Wiegratz, MSc, UCB, Monheim am Rhein, Germany for publication coordination, Marc Lynch, PhD, Costello Medical, London, UK 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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