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Bimekizumab 2-year Maintenance of Response in Moderate to Severe HS: Data from BE HEARD EXT

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Objective

To report maintenance of response to bimekizumab (BKZ) treatment through to 2 years in Year-1 responders, in patients with moderate to severe hidradenitis suppurativa (HS).

Background

- HS is a chronic inflammatory skin disease; it is important to maintain long-term clinical response to treatments.[1]
- BKZ, a humanized IgG1 monoclonal antibody which selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated clinical efficacy through 1 year in phase 3 clinical trials of patients with moderate to severe HS.[2]

Methods

- Data were pooled from the BE HEARD I&II studies and the open-label extension, BE HEARD EXT.[2,3] Week 48 BE HEARD I&II completers could enroll in BE HEARD EXT and receive open-label BKZ 320 mg every 2 weeks (Q2W) or BKZ every 4 weeks (Q4W) based on ≥90% HS Clinical Response (HiSCR90; averaged from BE HEARD I&II Weeks 36, 40, and 44) (**Figure 1**).
- Data are reported for patients randomized to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT (BKZ Total).
- Here, we report maintenance of HiSCR50/75/90 and Dermatology Life Quality Index (DLQI) minimal clinically important difference (MCID) response through 96 weeks of treatment, in BE HEARD I&II Week 48 HiSCR50/75/90 and DLQI MCID responders, respectively.
  - An MCID in DLQI was defined as an improvement of DLQI total score ≥4 from baseline. Only patients with a baseline DLQI total score of ≥4 were included.
- Data are reported using observed case (OC).

Results

- At baseline, 1,014 patients were randomized. Among 657 BE HEARD I&II Week 48 completers who entered BE HEARD EXT, 556 patients received continuous BKZ (BKZ Total).
- Among Week 48 responders in the BKZ Total group, 90.0%/86.9%/74.8% and 86.0% maintained HiSCR50/75/90 and DLQI MCID through Week 96, respectively (**Figure 2**).

Conclusion

The majority of patients who achieved HiSCR50/75/90 or DLQI MCID response after 1 year of bimekizumab treatment maintained response to 2 years.

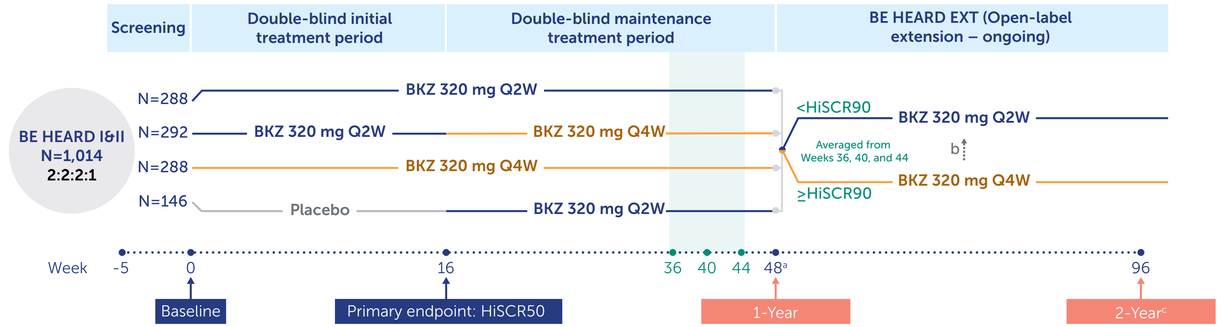
Plain Language Summary

Why was this study needed?
Previous research has shown that the drug bimekizumab works well to treat patients with hidradenitis suppurativa (HS) for 1 year. One aim of this study was to explore if bimekizumab continued to work over 2 years of treatment.

What did this study show?
The majority of patients who showed improvement in their disease with bimekizumab treatment after 1 year maintained their improvement after 2 years of bimekizumab treatment.

Why is this important?
HS can have a serious impact on patients' lives. This study showed that patients with HS who respond to bimekizumab treatment at 1 year could maintain their response over 2 years of treatment.

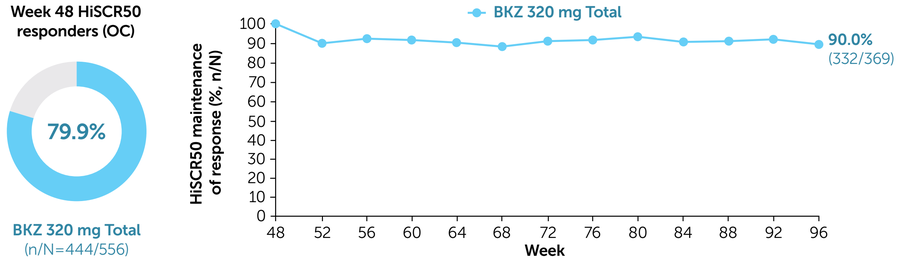
Figure 1 Study design



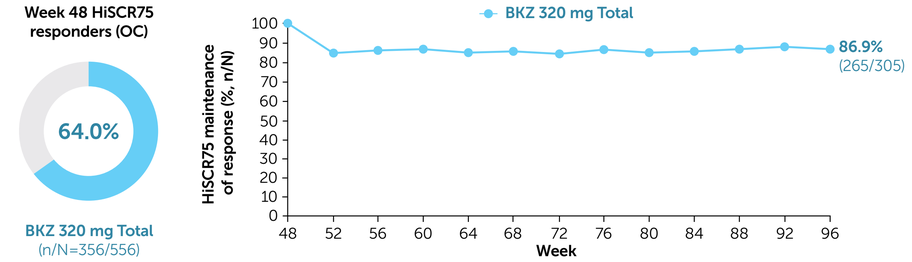
At baseline, 1,014 patients with moderate to severe HS were randomized 2:2:2:1 to BKZ 320 mg Q2W to Week 48, BKZ 320 mg Q2W to Week 16 then BKZ 320 mg Q4W to Week 48, BKZ 320 mg Q4W to Week 48, or placebo to Week 16 then BKZ 320 mg Q2W to Week 48. **[a]** Patients who completed Week 48 of BE HEARD I&II 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 2 Maintenance of response based on HiSCR and DLQI MCID (OC)

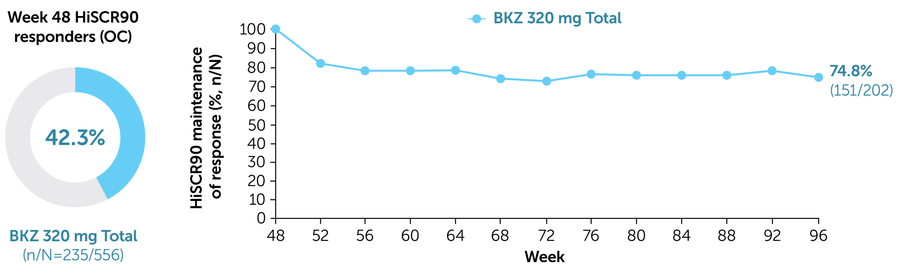
A) HiSCR50 maintenance of response



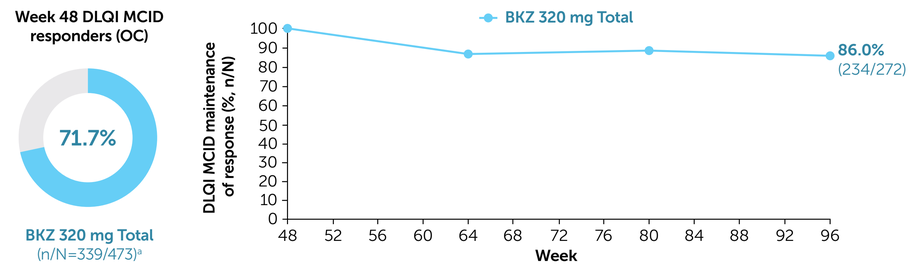
B) HiSCR75 maintenance of response



C) HiSCR90 maintenance of response



D) DLQI MCID maintenance of response



OLE set; only included patients who entered BE HEARD EXT at Week 48. BKZ Total (N=556) comprised patients randomized to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT and continued to receive BKZ. OC, n/N: denominator represents number of patients with a non-missing lesion count assessment in the given week, and percentages are calculated accordingly.
(a) Only patients with a baseline DLQI score of ≥4 are included.

Abbreviations: AN: abscess and inflammatory nodule; **BKZ:** bimekizumab; **DLQI:** Dermatology Life Quality Index; **HiSCR50/75/90:** ≥50%/75%/90% reduction from baseline in the total AN count with no increase from baseline in abscess or draining tunnel count; **HS:** hidradenitis suppurativa; **IL:** interleukin; **MCID:** minimal clinically important difference; **OC:** observed case; **OLE:** open-label extension; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks.

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References: 1. Dufour DN et al. Postgrad Med J 2014;90:216–21; 2. Kimball AB et al. Lancet. 2024;403:2504–19 (NCT04242446, NCT04242498); 3. BE HEARD EXT: www.clinicaltrials.gov/study/NCT04901195. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **MP, RC, WG, AA, GJ, EJGB, KH, RR, JL, BL, AD, JRI:** Drafting of the publication, or revising it critically for important intellectual content: **MP, RC, WG, AA, GJ, EJGB, KH, RR, JL, BL, AD, JRI**. **Author Disclosures: MLP:** Consultant and investigator for Abbvie, Eli Lilly and Company, Incyte, Janssen, MoonLake Immunotherapeutics, Novartis, Pfizer, Prometheus, Sanofi, Sonoma Biotherapeutics, and UCB; consultant for Alumis, FIDE, Trifecta Clinical, and Zura Bio; investigator for Bayer, Bristol Myers Squibb, and OASIS Pharmaceuticals; received royalties from Beth Israel Deaconess Medical Center. **RC:** Served as an advisor, consultant, speaker, and/or investigator for AbbVie, Amgen, AnaptysBio, Apogee Therapeutics, Arcutis, Argenx, ASLAN Pharmaceuticals, Beiersdorf, Boehringer Ingelheim, Bristol Myers Squibb, Cara Therapeutics, Dermavant, Eli Lilly and Company, FIDE, Formation Bio, Galderma, Genentech, GSK, Incyte, LEO Pharma, L'Oréal, Nektar Therapeutics, Novartis, Opsidio, Pfizer Inc., RAPT, Regeneron, Sanofi, Sitryx, and UCB. **WG:** Grants and research support from AbbVie, Amgen, Eli Lilly and Company, Novartis, Pfizer. Honoraria for advisory boards/invited talks/consultation: AbbVie, Actelion, Amgen, Arylide, Bausch Health, Boehringer, Celgene, Cipher, Eli Lilly and Company, Galderma, Janssen, LEO Pharma, Merck, Novartis, PeerVoice, Pfizer, Sanofi-Genzyme, Tribute, UCB, Sun Pharma, and Valeant. Clinical trials (study fees): AbbVie, Asana Biosciences, Astellas, Boerhinger Ingleheim, Celgene, Corrona/National Psoriasis Foundation, Devonian, Eli Lilly and Company, Galapagos, Galderma, Janssen, LEO Pharma, Novartis, Pfizer, Regeneron, Sun Pharma, and UCB. **AA:** On the Board of Directors for the Hidradenitis Suppurativa Foundation; served as consultant for Almirall, Boehringer Ingelheim, Incyte, InflaRx, Leo, Kymera, Sanofi, Novartis, and UCB; principal investigator for Boehringer Ingelheim and Processa. **GJ:** Honoraria from AbbVie, Boehringer Ingelheim, ChemoCentryx, Incyte, Janssen, LEO Pharma, Novartis, and UCB for participation on advisory boards; investigator for AbbVie, CSL, InflaRx, Janssen, LEO Pharma, Novartis, Regeneron, Sanofi, and UCB; speaker honoraria from AbbVie and Novartis; research grants from LEO Pharma and Novartis. **EJGB:** Received honoraria from Abbott Products Operations, bioMérieux, Brahms, GSK, InflaRx, Sobi, and XBiotech; independent educational grants from Abbott Products Operations, bioMérieux, InflaRx, Johnson & Johnson, MSD, Novartis, and Sobi; funding from the Horizon2020 Marie Sktodowska-Curie International Training Network, "the European Sepsis Academy" (granted to the National and Kapodistrian University of Athens), the Horizon 2020 European Grants ImmunoSep and RISCinCOVID (granted to the Hellenic Institute for the Study of Sepsis), and the Horizon Health grant EPIC-CROWN-2, POIN and Homi-Lung (granted to the Hellenic Institute for the Study of Sepsis). **KH:** Principal investigator for and consultancy/advisory boards from AbbVie, Boehringer Ingelheim and Novartis; speaker fees/grants from AbbVie, Boehringer Ingelheim, Eisai, Novartis, and UCB. **RR, JL, BL, AD:** Employee and shareholder of UCB. **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; his department receives income from copyright of the Dermatology Life Quality Instrument (DLQI) and related instruments. **Acknowledgments:** This study was 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, 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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