Bimekizumab maintenance of response over 2 years: Data from BE HEARD EXT

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Objective

To report maintenance of response from Year 1 to Year 2, in patients with moderate to severe HS, who achieved high levels of response in efficacy and health-related quality of life (HRQoL) outcomes after 1 year of bimekizumab (BKZ) treatment.

Introduction

- HS is a progressive inflammatory skin disease which imposes a substantial negative impact on patients' quality of life and a high disease burden over the long term.[1,2]
- BKZ, a humanised IgG1 monoclonal antibody which selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated efficacy in phase 3 clinical trials.[3]
- It is important to assess whether clinical response to BKZ is maintained over the long term.

Methods

- Data were pooled from the BE HEARD I&II studies and their open-label extension (OLE), BE HEARD EXT (NCT04242446, NCT04242498, NCT04901195).[3,4]
- Data reported for patients randomised to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT (OLE set; BKZ Total group).
- Maintenance of efficacy, as measured by International Hidradenitis Suppurativa Severity Score System (IHS4)-55/75/90/100, is reported from Year 1 (Week 48) to Year 2 (Week 96) in patients with a IHS4-55/75/90/100 response at Year 1.
- Maintenance of Hidradenitis Suppurativa Quality of Life (HiSQOL) response (total score ≤14: no to mild impact of HS on HRQoL; total score ≤4: no impact) is reported from Year 1 to Year 2 in patients with HiSQOL response at Year 1.[5]
- Maintenance of Dermatology Life Quality Index (DLQI) 0/1 ('no effect on patient's life') and DLQI 0–5 ('no/small effect on a patient's life'), is reported from Year 1 to Year 2 in patients with DLQI 0/1 and DLQI 0–5 at Year 1, respectively.[6]
- Data are reported using observed case (OC).

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.[3]

IHS4 outcomes

- At Year 1, 75.5% (420/556), 58.8% (327/556), 41.2% (229/556) and 25.2% (140/556) of patients achieved IHS4-55/75/90/100, respectively (**Figure 1**).
- Of patients who achieved IHS4-55 at Year 1, 90.8% maintained response at Year 2; likewise, high proportions of patients maintained IHS4-75/90 response at Year 2 (**Figure 1**).
- Among patients who achieved total resolution of inflammatory lesions at Year 1, defined by IHS4-100, 64.3% maintained response at Year 2 (**Figure 1**).

HiSQOL outcomes

- At Year 1, 72.8% of patients reported no to mild impact measured by HiSQOL (total score ≤14), 89.5% of these patients maintained HiSQOL total score response at Year 2 (**Figure 2**).
- Of patients with HiSQOL total score ≤4 at Year 1, 72.1% maintained this response at Year 2 (**Figure 2**).

DLQI outcomes

- At Year 1, 68.2% (376/551) of patients reported DLQI 0–5, of these patients 84.3% maintained DLQI 0–5 at Year 2 (**Figure 3**).
- At Year 1, 27.4% (151/551) of patients reported DLQI 0/1, of these patients 69.3% maintained DLQI 0/1 at Year 2 (**Figure 3**).

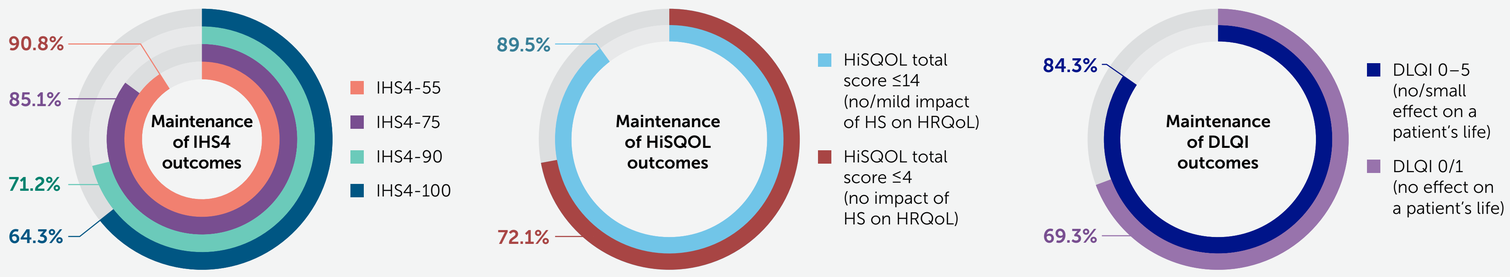
Conclusions

High proportions of patients treated with bimekizumab who achieved IHS4 outcomes at Year 1 maintained response at Year 2.

The majority of patients who achieved high efficacy and HRQoL outcomes at Year 1 maintained their response at Year 2, with bimekizumab treatment.

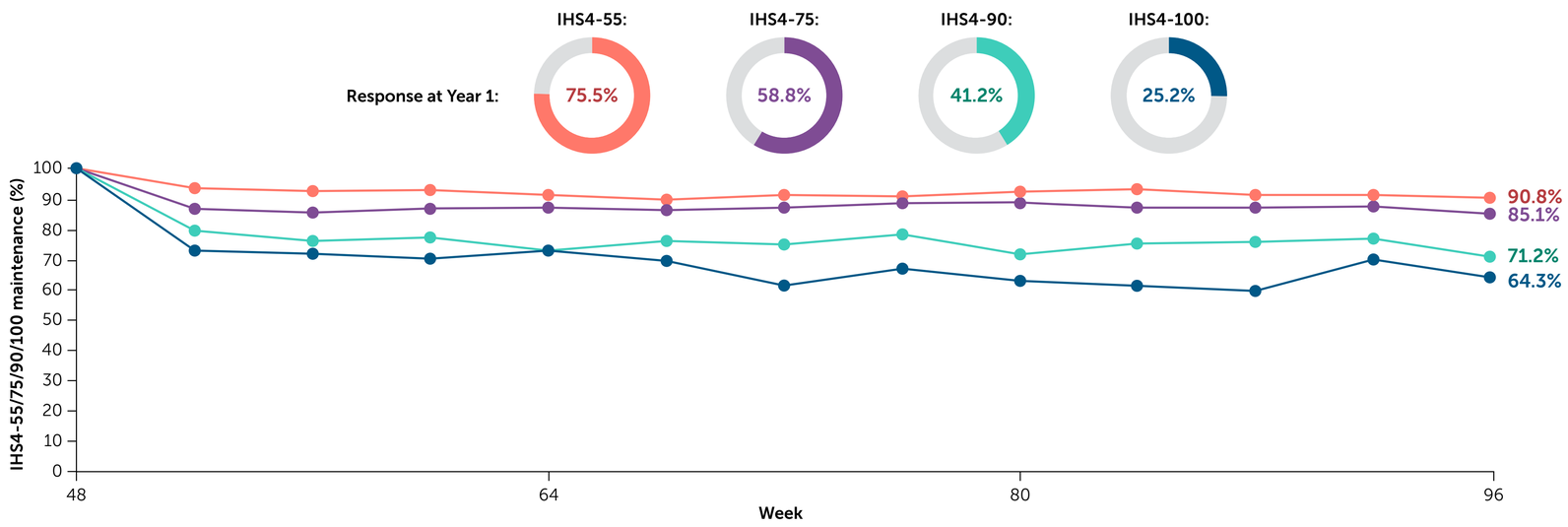
Summary

The maintenance of efficacy and HRQoL outcomes was evaluated to Year 2 in patients with high response to BKZ at Year 1.



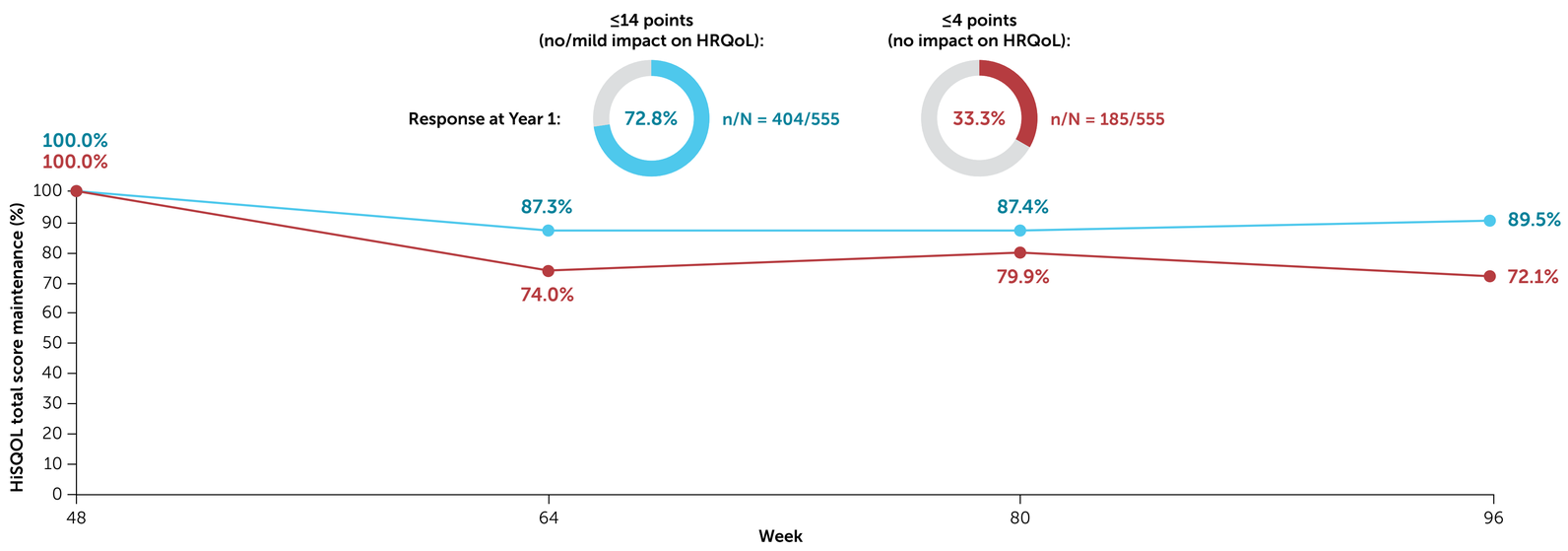
Across efficacy and HRQoL outcomes, high proportions of Year 1 responders maintained response to Year 2 of BKZ treatment, demonstrating BKZ's durability in reducing inflammation.

Figure 1 Maintenance of IHS4-55/75/90/100 response



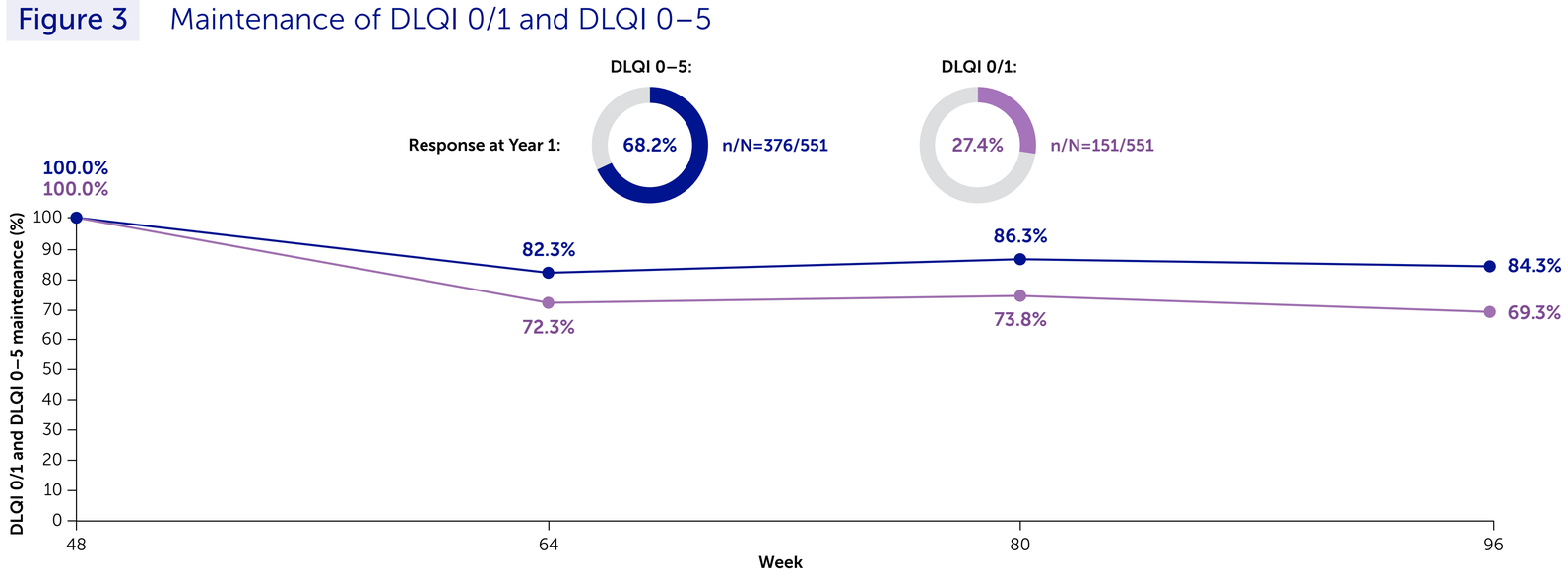
OC, n/N: denominator represents number of patients with a non-missing lesion count assessment in the given week, and percentages are calculated accordingly; changes to the denominator are due to missing visits and/or discontinuation from BE HEARD EXT. At Week 48, n/N values for IHS4-55/75/90/100 responders were as follows: IHS4-55: 420/556; IHS4-75: 327/556; IHS4-90: 229/556; IHS4-100: 140/556. At Week 96, n/N values were as follows: IHS4-55: 315/347; IHS4-75: 235/276; IHS4-90: 136/191; IHS4-100: 74/115. During the OLE period, the number of patients who discontinued from the study are as follows: IHS4-55: n=119; IHS4-75: n=87; IHS4-90: n=60; IHS4-100: 40. Data are reported for patients who achieved IHS4-55/75/90/100 at Year 1 of BE HEARD I&II.

Figure 2 Maintenance of HiSQOL total score response



OC, n/N: denominator represents number of patients with a non-missing assessment in the given week, and percentages are calculated accordingly; changes to the denominator are due to missing visits and/or discontinuation from BE HEARD EXT. At Week 96, n/N values were as follows: HiSQOL total score ≤14 points: 298/333; HiSQOL total score ≤4 points: 111/154. During the OLE period, 111 patients who achieved HiSQOL total score ≤14 at Year 1 discontinued from the study. Data are reported for patients who achieved HiSQOL total score ≤14 points and HiSQOL total score ≤4 at Year 1 of BE HEARD I&II.

Figure 3 Maintenance of DLQI 0/1 and DLQI 0–5



OC, n/N: denominator represents number of patients with a non-missing assessment in the given week, and percentages are calculated accordingly; changes to the denominator are due to missing visits and/or discontinuation from BE HEARD EXT. At Week 96, n/N values were as follows: DLQI 0–5: 258/306; DLQI 0/1: 88/127. During the OLE period, 109 patients who reported DLQI 0–5 at Year 1 and 40 patients who reported DLQI 0/1 at Year 1 discontinued from the study. Data are reported for patients who achieved DLQI 0/1 and DLQI 0–5 at Year 1 of BE HEARD I&II.

BKZ: bimekizumab; **DLQI:** Dermatology Life Quality Index; **HiSCR:** HS Clinical Response; **HiSQOL:** Hidradenitis Suppurativa Quality of Life; **HRQoL:** health-related quality of life; **IHS4:** International Hidradenitis Suppurativa Severity Score System; **IL:** interleukin; **OC:** observed case; **OLE:** open-label extension.

References: [1]Zouboulis C et al. J Eur Acad Dermatol Venereol 2015;29:619–44; [2]Schultheis M et al. Int J Dermatol. 2024;63:188–95; [3]Kimball AB et al. The Lancet. 2024;403:2504–19; [4]BE HEARD EXT: www.clinicaltrials.gov/study/NCT04901195; [5]Kirby JS et al. Br J Dermatol. 2025;193:93–104; [6]Hongbo Y et al. J Invest Dermatol 2005;125:659–64. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **JRI**, **HL**, **AK**, **APV**, **KH**, **BL**, **JL**, **TV**, **MLP**; drafting of the publication, or reviewing it critically for important intellectual content: **JRI**, **HL**, **AK**, **APV**, **KH**, **BL**, **JL**, **TV**, **MLP**; final approval of the publication: **JRI**, **HL**, **AK**, **APV**, **KH**, **BL**, **JL**, **TV**, **MLP**. **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, Cantargia, ChemoCentryx, Citryll, Elasmogen, Engitix, Incyte, Indero, Insmed, Kymera Therapeutics, MoonLake Immunotherapeutics, Novartis, UCB, UNION Therapeutics and Viela Bio; co copyright holder of HiSQOL©, HS Patient global assessment and HS-IGA; his department receives income from copyright of the Dermatology Life Quality Instrument (DLQI) and related instruments. **HL:** Consultant for Novartis and UCB. **AK:** No disclosures to declare. **APV:** Personal fees from AbbVie, Almirall, Amgen, Bristol Myers Squibb, Eli Lilly and Company, Janssen, LEO Pharma, MSD, Novartis and UCB during the conduct of the study. **KH:** Principal investigator for and member of consultancy/advisory boards for AbbVie, Boehringer Ingelheim, Novartis, Sanofi and UCB; recipient of speaker fees and/or research grants from AbbVie, Boehringer Ingelheim, Eisai, Maruho, Novartis and UCB. **BL**, **JL** and **TV:** Employees and shareholders of UCB. **MLP:** Consultant and investigator for AbbVie, Aristea Therapeutics, Avalo Therapeutics, Eli Lilly and Company, Incyte, Janssen, Merck, MoonLake Immunotherapeutics, Novartis, Pfizer, Prometheus, Sanofi, Sonoma Biotherapeutics and UCB; consultant for Alumis, FIDE, Trifecta Clinical/WCG and ZuraBio; investigator for AnaptysBio, Bayer, Bristol Myers Squibb, OASIS Pharmaceuticals and Regeneron; received royalties from Beth Israel Deaconess Medical Center; received fellowship funding to institution from AbbVie. **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 Susanne Wiegratz, MSc, UCB, Monheim am Rhein, Germany for publication coordination, Kate Metcalfe, BSc (Hons), Costello Medical, London, United Kingdom 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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