Bimekizumab Impact on Pain and Quality of Life Stratified by IHS4 Levels in Patients with Hidradenitis Suppurativa: 3-Year Results from BE HEARD EXT

Brian Kirby,[1,2] Saakshi Khattri,[3] John R. Ingram,[4] Georgios Kokolakis,[5,6] Thrasyvoulos Tzellos,[2,7,8] Ichiro Kurokawa,[9] Jérémy Lambert,[10] Sandeep Kiri,[11] Bengt Hoepken,[12] Nicola Tilt,[11] John W. Frew[13–15]

[1]St Vincent's University Hospital, Elm Park and the Charles Institute, University College Dublin, Republic of Ireland; [2]European Hidradenitis Suppurativa Foundation (EHSF), Dessau, Germany; [3]The Mount Sinai Hospital, New York, USA; [4]Division of Infection and Immunity, Cardiff University, Cardiff, UK; [5]Department of Dermatology, Venereology, and Allergology, Charité-Universitätsmedizin Berlin, corporate member of Freie Universität Berlin and Humboldt-Universität zu Berlin, Berlin, Germany; [6]Department of Dermatology, University of Crete, Greece; [7]Department of Dermatology, Nordland Hospital Trust, Bodø, Norway; [8]Department of Clinical Medicine, Faculty of Health Sciences, UiT – The Arctic University of Norway, Tromsø, Norway; [9]Department of Dermatology, Meiwa Hospital, Nishinomiya, Japan; [10]UCB, Courbevoie, France; [11]UCB, Slough, UK; [12]UCB, Monheim am Rhein, Germany; [13]Department of Dermatology, Liverpool Hospital, Sydney, New South Wales, Australia; [14]Laboratory of Translational Cutaneous Medicine, Ingham Institute for Applied Medical Research, Sydney, New South Wales, Australia; [15]School of Clinical Medicine, UNSW Medicine and Health, Sydney, New South Wales, Australia.

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Objective

To report the association between Week 48 lesion count-based IHS4 levels and improvements in patient reported outcomes in patients with moderate to severe hidradenitis suppurativa over 3 years of bimekizumab treatment.

Background

- Hidradenitis suppurativa (HS) is a chronic, progressive, inflammatory skin disease characterised by debilitating pain, lesion burden and impaired health-related quality of life (HRQoL).[1,2]
- Bimekizumab (BKZ), a humanised IgG1 monoclonal antibody, selectively inhibits interleukin (IL)-17F in addition to IL-17A, and has demonstrated efficacy in phase 3 trials.[3,4]

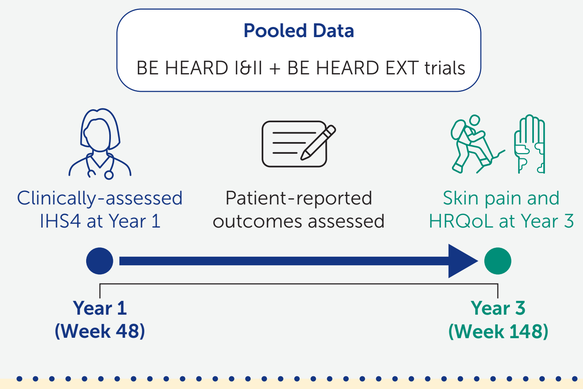
Methods

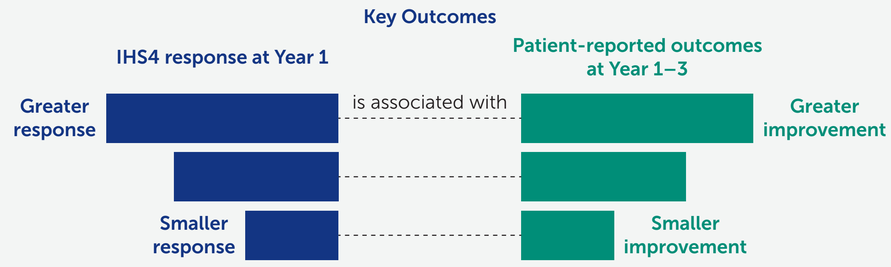
- Data were pooled from the phase 3 BE HEARD I&II trials (NCT04242446, NCT04242498) and their open-label extension, BE HEARD EXT (NCT04901195).[4,5]
  - All included patients had moderate to severe HS.
  - Data are reported for patients randomised to BKZ 320 mg from baseline in BE HEARD I&II who subsequently entered BE HEARD EXT and continued to receive BKZ.
- Patients were grouped by mutually exclusive International Hidradenitis Suppurativa Severity Score System (IHS4) response levels at Year 1 (Week 48), defined as <IHS4-55 (reduction of <55% in IHS4 score from baseline), IHS4-55–<75, IHS4-75–<90 and IHS4-90–100.
- Achievement of clinically meaningful improvements in patient reported outcomes (PROs) was assessed within each group over 3 years (148 weeks):
  - Hidradenitis Suppurativa Symptom Questionnaire (HSSQ) skin pain response: a reduction of ≥30% and ≥1-point from baseline, in patients with ≥3 pain score at baseline;
  - HS Quality of Life (HiSQOL) response: total score ≤14 (no/mild impact of HS on HRQoL) and total score ≤4 (no impact of HS on HRQoL);
  - DLQI response: DLQI 0/1 (no effect at all on a patient's life).
- Data are reported as observed case (OC).

Results

- Of the 1,014 patients in the BE HEARD I&II trials, 868 were randomised to BKZ at baseline; 556 completed Year 1 and entered BE HEARD EXT (**Figure 1**).
- At Year 1, the proportion of HSSQ skin pain responders increased with greater Year 1 IHS4 response; this pattern generally persisted through Year 3.
- Proportions of HSSQ skin pain responders according to Year 1 IHS4 response levels were overall maintained through Year 3, with numerical increases in the IHS4-55 and IHS4-55-<75 groups (**Figure 2**).
- Similar patterns were observed for the proportion of patients achieving HiSQOL ≤14 (**Figure 3a**).
- Response rate for the more stringent HiSQOL ≤4 (**Figure 3b**) and DLQI 0/1 response rates (**Figure 4**) showed a similar pattern, though there was less separation between the <IHS4-55, IHS4-55<75 and IHS-75<90 groups in the latter outcome.
  - In the <IHS4-55 group, the proportion of patients achieving a DLQI 0/1 increased from 8.1% at Year 1 to 27.7% at Year 3; corresponding proportions in the IHS4-90–100 group were 44.9% and 45.1%.

Summary & Conclusions

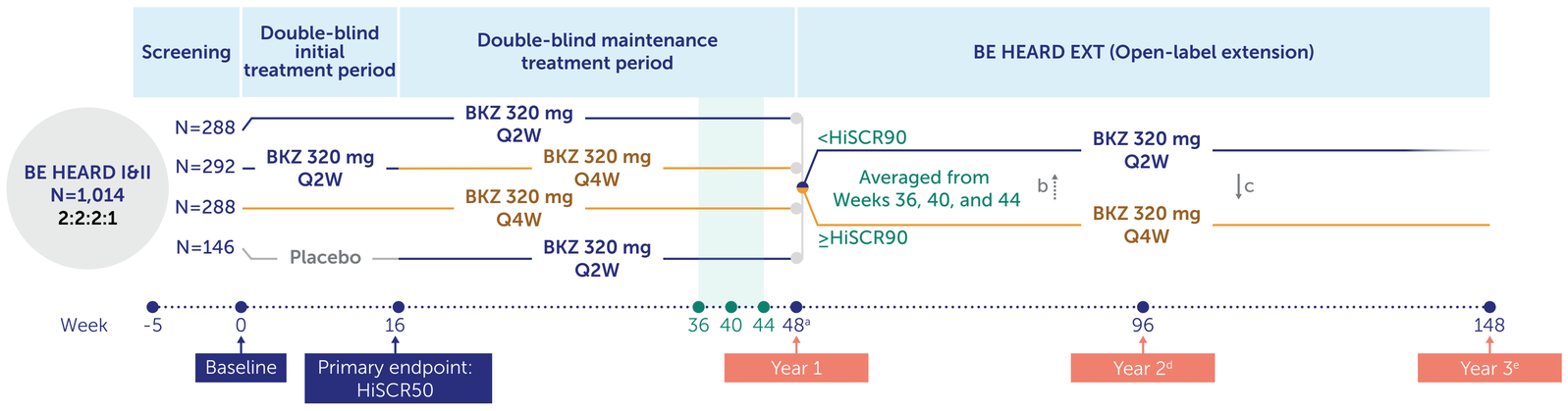




Greater reductions in lesion count at **Year 1** were associated with less skin pain and better health-related quality of life. Benefits were maintained through **Year 3**.

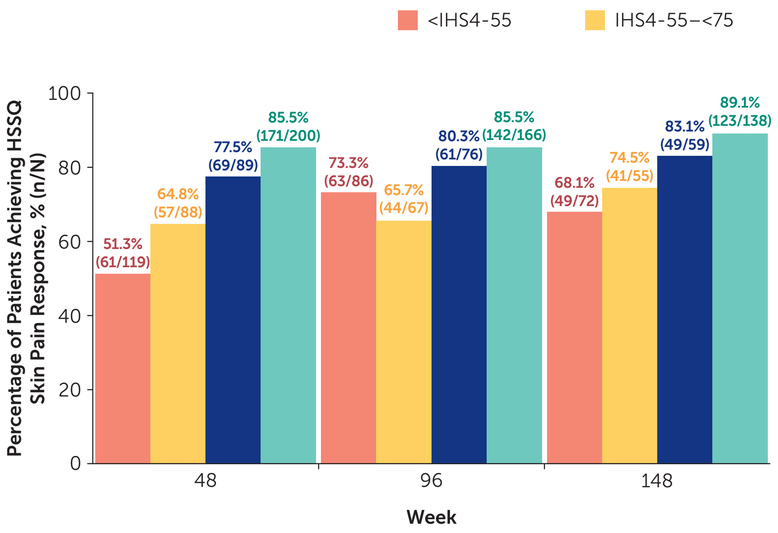
Greater Year 1 IHS4 response continued to be associated with better patient-reported skin pain and HRQoL outcomes through 3 years of bimekizumab treatment.

Figure 1 Study Design



[a] Patients who completed Week 48 of BE HEARD I&II could enrol 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] Patients receiving BKZ 320 mg Q4W in BE HEARD EXT who could not sustain an average improvement from baseline in AN count of ≥90% over any 8-week period or achieve >75% improvement from baseline in AN count at any single visit, could have their dose increased to Q2W at investigator discretion. [c] Following approval of a protocol amendment in the third year, all BE HEARD EXT patients were to receive BKZ Q4W. [d] Cumulative 2-year data (48 weeks in BE HEARD I&II and 48 weeks in BE HEARD EXT). [e] Cumulative 3-year data (48 weeks in BE HEARD I&II and 100 weeks in BE HEARD EXT).

Figure 2 HSSQ Skin Pain Response by Year 1 IHS4 Response Category



OC: N represents the number of patients with a non-missing HSSQ skin pain score at the given visit and percentages are calculated accordingly.

Figure 3 HiSQOL Impact by Year 1 IHS4 Response Category

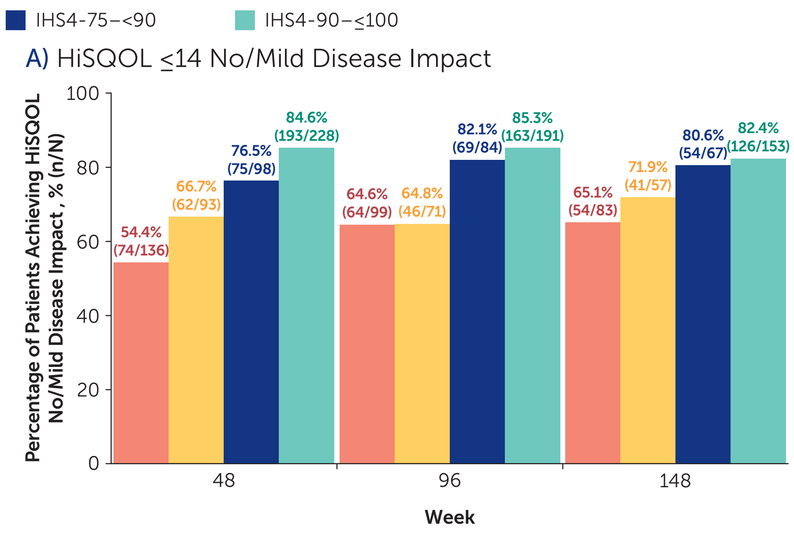
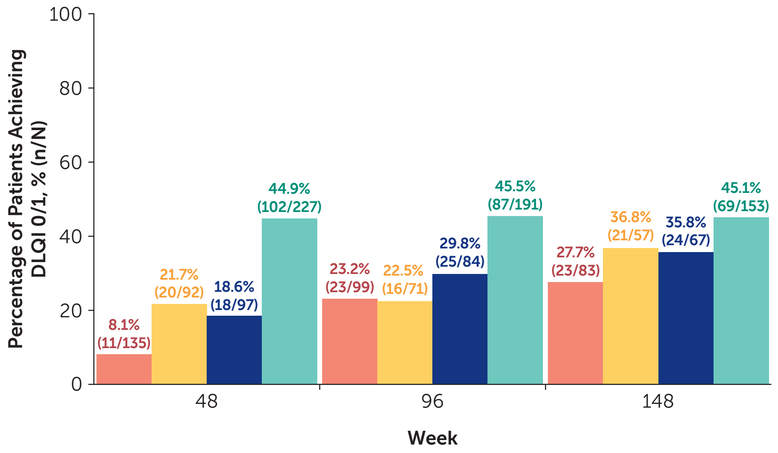
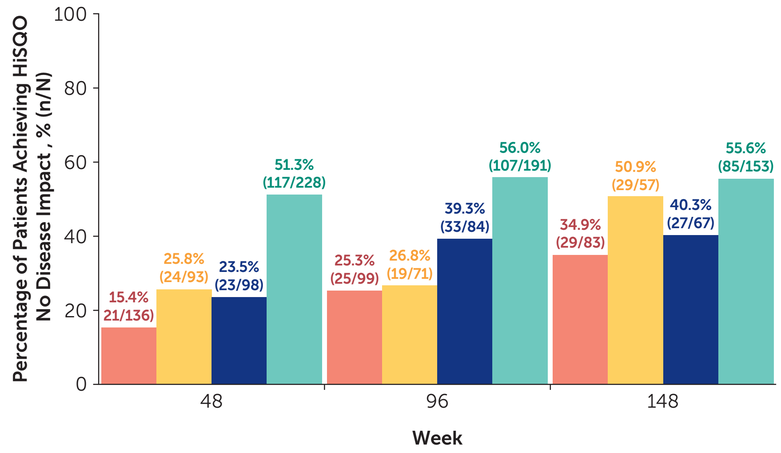


Figure 4 DLQI 0/1 by Year 1 IHS4 Response Category



OC: N represents the number of patients with a non-missing DLQI score at the given visit and percentages are calculated accordingly.



OC: N represents the number of patients with a non-missing HiSQOL score at the given visit and percentages are calculated accordingly.

Abbreviations: **AN:** abscesses and inflammatory nodules; **BKZ:** bimekizumab; **DLQI:** Dermatology Life Quality Index; **HiSCR50/90:** ≥50%/90% reduction from baseline in the total AN count with no increase from baseline in abscess or draining tunnel count; **HiSQOL:** Hidradenitis Suppurativa Quality of Life; **HRQoL:** health-related quality of life; **HS:** hidradenitis suppurativa; **HSSQ:** Hidradenitis Suppurativa Symptom Questionnaire; **IHS4:** International Hidradenitis Suppurativa Severity Score System; **IL:** interleukin; **PRO:** patient reported outcome; **OC:** observed case; **Q2W:** every two weeks; **Q4W:** every four weeks; **QoL:** quality of life.

References: [1]Kaur AP et al. Skin Health Dis 2023;3:e214; [2]Montero-Vilchez T et al. Int J Environ Res Public Health 2021;18:6709; [3]Adams R et al. Front Immunol 2020;11:1894; [4]Kimball AB et al. Lancet 2024;403:2504–19; [5]Sayed CJ et al. J Am Acad Dermatol 2026;94:867–78.

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