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ORIGINAL RESEARCH

Bimekizumab Impact on Patient-Reported Outcomes in Patients with Moderate to Severe Hidradenitis Suppurativa: Pooled 48-Week Results from BE HEARD I&II

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ABSTRACT

***Introduction*:** Hidradenitis suppurativa (HS) symptoms (pain, itch, odour and drainage) impair quality of life (QoL). Bimekizumab, a humanised IgG1 monoclonal antibody, selectively inhibits interleukin (IL)-17A and IL-17F. The impact of bimekizumab on patient-reported outcomes (PROs) was assessed using pooled 48-week data from BE HEARD I&II (BHI&II) studies in moderate to severe HS.

***Methods*:** Patients received (initial/maintenance) bimekizumab 320 mg every 2 weeks (Q2W)/Q2W, bimekizumab Q2W/Q4W, bimekizumab Q4W/Q4W or placebo/bimekizumab Q2W. HS Symptom Daily Diary (HSSDD) and HS Symptom Questionnaire (HSSQ) captured HS-specific patient-reported symptoms; HS Quality of Life questionnaire (HiSQOL©) and Dermatology Life Quality Index (DLQI) captured health-related QoL (HRQoL). Change from baseline (CfB) and proportions of patients achieving clinically meaningful improvement thresholds or low disease impact are reported to Week 48 (observed case).

***Results*:** Of 1014 randomised patients, 868 received bimekizumab and 146 placebo. Greater numerical reductions at Week 16 were observed across HSSDD/HSSQ scores with bimekizumab

Prior Presentation: Select data, including Hidradenitis Suppurativa Symptom Questionnaire (HSSQ) item mean scores and Dermatology Life Quality Index (DLQI) domain and total scores and achievement of minimal clinically important difference, were presented at the 33rd European Academy of Dermatology and Venereology (EADV) Congress 2024, Amsterdam, the Netherlands, 25–28 September 2024. Encore presented at Fall Clinical 2024, October 24–27, Las Vegas, NV, USA.

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vs placebo. From Week 16 to 48, HSSQ scores further numerically reduced with continuous bimekizumab and substantially reduced for placebo/bimekizumab switchers. At Week 16, bimekizumab showed numerically greater improvement in HRQoL vs placebo (HiSQOL total score mean CfB: −11.7 to −10.3 vs −5.5). HiSQOL response rate (21-point total score reduction) was numerically higher by Week 4 in bimekizumab-treated patients (17.2–21.4%) vs placebo (9.2%); rates increased to Week 48 with continuous bimekizumab (42.0–47.4%) and in switchers (55.0%). Patients with very severe disease impact (HiSQOL total score ≥ 24) decreased over time with bimekizumab. At Week 16, DLQI minimal clinically important difference (4-point decrease) achievement was numerically greater with bimekizumab vs placebo (54.9–64.6% vs 49.1%). Achievement increased to Week 48 and switchers attained similar proportions (63.5–74.5% vs 76.5%). Comparable trends were observed for DLQI score of 0/1 (no HRQoL impact) achievement rates.

Conclusion: Bimekizumab demonstrated clinically meaningful improvements by Week 4 in HRQoL, which were maintained over 1 year across PROs in patients with moderate to severe HS.

Graphical Abstract available for this article.

Trial Registration: NCT04242446; NCT04242498.

PLAIN LANGUAGE SUMMARY

Hidradenitis suppurativa (HS) is a chronic skin disease that affects approximately between 4 and 10 out of every 1000 people worldwide. Patients with HS have skin lesions that cause symptoms such as pain, itch and odour. These symptoms negatively impact patients' physical and mental wellbeing, leading to a low quality of life. Additional treatment options are needed for patients with HS. Finding effective treatments is crucial to improving the lives of patients with HS. Bimekizumab is a drug approved for the treatment of HS in Europe and the USA. It works by blocking two specific proteins that are involved in causing inflammation. In this global study, we wanted to find out how patients with HS feel that bimekizumab impacts their symptoms and quality of life. Patient experience was measured using questionnaires completed by the patients themselves. The Hidradenitis Suppurativa Symptom Daily Diary (HSSDD) and Hidradenitis Suppurativa Symptom Questionnaire (HSSQ) were used to assess the impact of bimekizumab on symptoms experienced by patients with HS. The HS Quality of Life (HiSQOL©) and the Dermatology Life Quality Index (DLQI) questionnaires were used to assess the impact of bimekizumab on the quality of life of patients with HS. Bimekizumab improved the symptoms and quality of life of patients with moderate to severe HS over 1 year. This suggests that bimekizumab is an effective treatment that can reduce the serious impact HS can have on patients.

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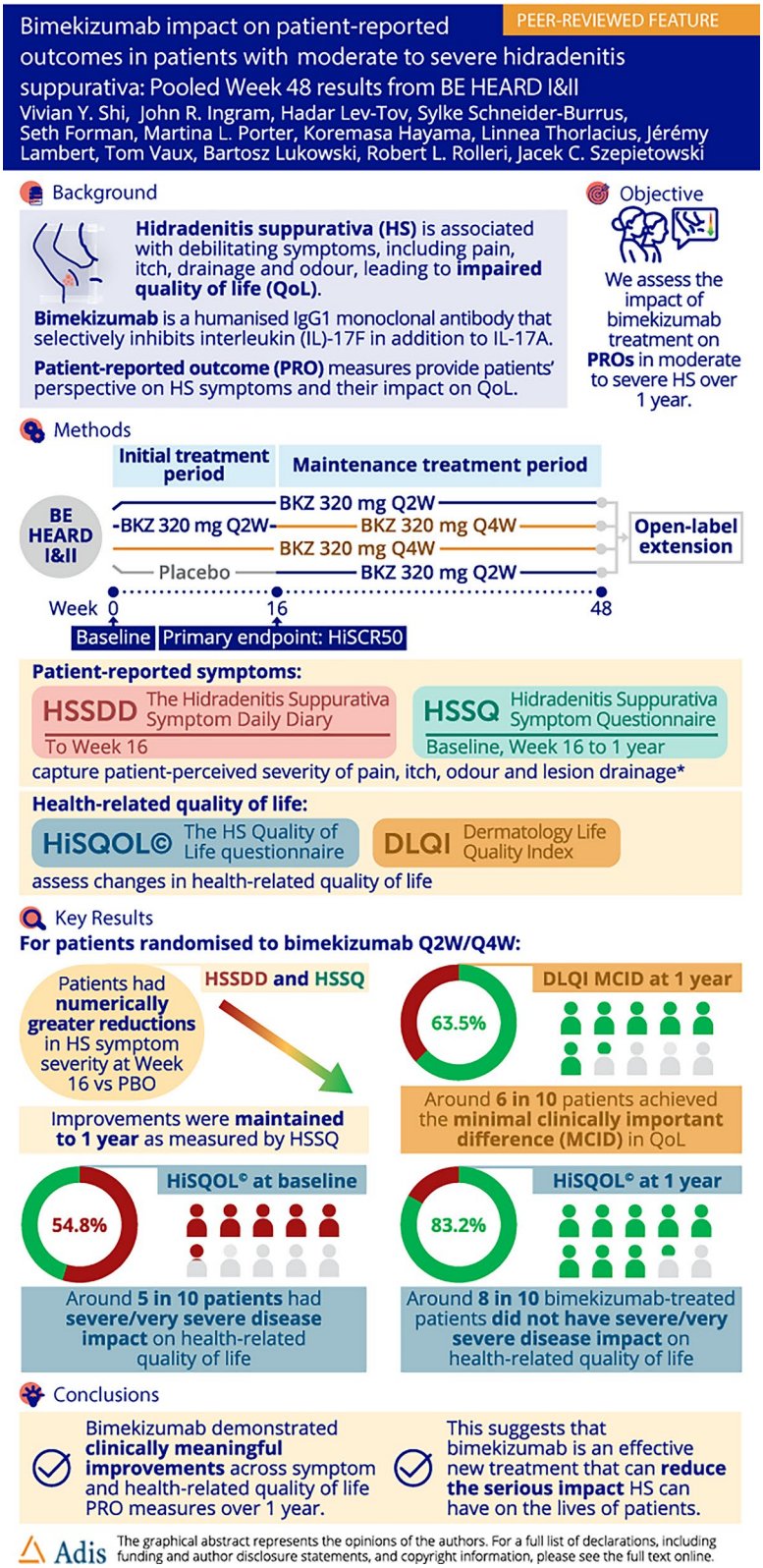
Graphical Abstract:



Keywords: BE HEARD; Bimekizumab; DLQI; Hidradenitis suppurativa; HiSQOL; HSSDD; HSSQ; IL-17 inhibitors; Inflammatory skin disease; Patient-reported outcomes

Key Summary Points

Why carry out this study?

Hidradenitis suppurativa (HS) is a chronic inflammatory skin disease associated with symptoms (such as pain, itch, odour and drainage) which can be severe and significantly affect patients' health-related quality of life (HRQoL).

This study documents the rapid and clinically meaningful improvements in HRQoL and symptoms in patients treated with bimekizumab through patient-reported outcome (PRO) measures including the Dermatology Life Quality Index (DLQI) and Hidradenitis Suppurativa Quality of Life (HiSQOL©) questionnaire, which assess HS-specific changes in HRQoL, and the HS Symptom Daily Diary (HSSDD) and HS Symptom Questionnaire (HSSQ), which capture patient-perceived severity of core HS symptoms: pain, itch, odour and drainage.

What was learned from this study?

Bimekizumab demonstrated clinically meaningful improvements by Week 4 across PROs in patients with moderate-to-severe HS, which were maintained over 1 year.

Greater numerical reductions at Week 16 were observed across HSSDD/HSSQ scores in patients receiving bimekizumab vs placebo; HSSQ scores further numerically reduced with continuous bimekizumab and substantially reduced for placebo/bimekizumab switchers from Week 16 to 48.

At Week 16, numerically greater improvements in HRQoL, as measured by HiSQOL and DLQI, were achieved with bimekizumab vs placebo; responses increased to Week 48 and patients receiving continuous bimekizumab and placebo/bimekizumab switchers achieved similar improvements.

DIGITAL FEATURES

This article is published with digital features, including a Graphical Abstract to facilitate understanding of the article. To view digital features for this article, go to https://doi.org/10.6084/m9.figshare.29225051.

INTRODUCTION

Hidradenitis suppurativa (HS) is a chronic inflammatory skin disease associated with disability and comorbidities which have a significant negative impact on patients' quality of life (QoL) [1–3]. Symptoms include, but are not limited to, pain, itch, odour and drainage from HS lesions. They create substantial burden on patients' physical health and mental and social wellbeing, with a higher risk of suicide among patients with HS [3–6].

Patient-reported outcome (PRO) measures provide the patient's perspective on HS symptoms and the impact on their life [1, 7]. Improvements in PROs have been correlated with clinical improvement, including HS Clinical Response (HiSCR) [8]. Given that disease remission can be difficult to achieve, improving PROs is critical. Accordingly, the HIdradenitis SuppuraTiva cORe outcomes set International Collaboration (HISTORIC) has established a HS-specific core outcomes set (i.e. an agreed minimum set of outcomes) that should be measured and reported in all clinical trials for HS. This core set includes the simultaneous measurement of six domains: pain, HS symptoms, physical signs, HS-specific QoL, global assessment and course of progression [9].

The BE HEARD I&II trials utilised the Dermatology Life Quality Index (DLQI) alongside HS-specific PRO measures: the Hidradenitis Suppurativa Quality of Life questionnaire (HiSQOL©) that assesses HS-specific changes in health-related quality of life (HRQoL), and the HS Symptom Daily Diary (HSSDD) and HS Symptom Questionnaire (HSSQ) to capture patient-perceived severity of core HS symptoms (pain, itch, smell or odour and drainage or oozing) [10]. HiSQOL, HSSDD and HSSQ have

demonstrated good psychometric properties; clinically meaningful within-patient improvement thresholds and severity bands have also been defined for each score within each measure [11, 12].

The interleukin (IL)-17 inflammatory pathway has been implicated in the pathology of HS, with elevated levels of IL-17A and IL-17F observed in HS tissue [13–16]. Bimekizumab is a humanised IgG1 monoclonal antibody that selectively inhibits IL-17F in addition to IL-17A, [13] and has demonstrated efficacy and safety in patients with moderate to severe HS across two phase 3 clinical trials, BE HEARD I (NCT04242446) and BE HEARD II (NCT04242498) [10].

Here, the impact of bimekizumab on PROs in patients with moderate to severe HS over 1 year is reported using pooled data from BE HEARD I&II.

METHODS

Study Design and Patients

Data were pooled from the randomised, double-blinded, placebo-controlled, multicentre phase 3 studies, BE HEARD I (NCT04242446) and BE HEARD II (NCT04242498) [10].

Moderate to severe HS was defined as ≥ 5 inflammatory lesions (abscesses and/or inflammatory nodules) affecting ≥ 2 distinct anatomic areas, one of which was Hurley stage II or III (at both screening and baseline visit). Patients had a diagnosis of HS for ≥ 6 months prior to the baseline visit based on clinical history and physical examination. Full inclusion/exclusion criteria for BE HEARD I&II have been reported previously [10].

The 48-week trials consisted of a 16-week placebo-controlled initial treatment period (Weeks 0–16) followed by a 32-week maintenance treatment period (Weeks 16–48). Patients with moderate to severe HS were randomised 2:2:2:1 at baseline (initial/maintenance) to bimekizumab 320 mg every 2 weeks (Q2W)/Q2W, bimekizumab 320 mg Q2W/every 4 weeks (Q4W), bimekizumab 320 mg Q4W/Q4W or placebo/bimekizumab 320 mg Q2W (Fig. S1) [10]. Here, data are reported for all patients randomised at baseline, with a focus on the European Medicines Agency (EMA) and US Food and Drug Administration (FDA) approved dose of bimekizumab 320 mg Q2W/Q4W [17, 18].

Data collection

Baseline demographics and disease characteristics were recorded for all included patients.

HiSQOL

The HiSQOL© assesses HS-specific changes in HRQoL, one of the six HISTORIC core outcome set domains [9]. The HiSQOL questionnaire is a 17-item, HS-specific PRO measure assessing participants' HRQoL, with a recall period of 7 days. Each item score ranges from 0 to 4 [19, 20].

Three HiSQOL subscale scores were derived from the sum of associated item scores: symptoms (four items, score range 0–16), psychosocial (five items, score range 0–20) and activities-adaptations (eight items, score range 0–32) [20]. The total score, ranging from 0 to 68, was derived by summing subscale scores. Higher scores indicate more severe impact on HRQoL. The clinically meaningful within-subject improvement upper threshold has been defined as a 21-point reduction from baseline in the HiSQOL total score. Cutoff values to define the severity of impact HS has on HRQoL for the HiSQOL total score have been defined as none (0–4), mild (5–14), moderate (15–21), severe (22–23) and very severe (≥ 24). Severity thresholds are also available for each subscale [12]. The HiSQOL questionnaire was administered electronically in local language at baseline, Weeks 4, 16, 32 and 48, or at premature end of treatment visit.

HSSDD and HSSQ

The HS Symptom Daily Diary (HSSDD) and HS Symptom Questionnaire (HSSQ) capture patient-perceived severity of core HS symptoms (pain, itch, smell or odour and drainage or oozing) [21].

HSSDD consists of five items assessing worst and average skin pain, smell or odour, itch at its

worst, and drainage or oozing from HS lesions, over the past 24 hours. Each symptom item was rated on an 11-point Numeric Rating Scale (NRS) with scores ranging from 0 ('no symptom') to 10 ('symptom as bad as you can imagine'). Each item score was derived from the weekly average of daily scores if ≥ 4 non-missing daily values were available; otherwise, the item score was reported as missing. Patients completed daily assessments electronically from screening to Week 16 [11].

HSSQ consists of four items assessing skin pain, smell or odour, itch and drainage or oozing from HS lesions, over the past 7 days. Each symptom item was rated on an 11-point NRS, where higher scores represent more severe symptoms. Using thresholds previously derived from receiver operating characteristic analysis, item severity was categorised as none, mild, moderate, severe and very severe on the subscale [11]. Assessments were completed electronically by patients at baseline, Week 16 and every other week to Week 48, or at premature end of treatment visit (symptom assessments between baseline and Week 16 were covered by the HSSDD).

DLQI

The Dermatology Life Quality Index (DLQI) consists of 10 items assessing patient perspective of how their skin disease impacts daily life. Each item was scored from 0 ('not at all' or 'not relevant') to 3 ('very much') [22]. A DLQI total score of 0 or 1 is defined as 'no impact of skin disease on a patient's life' [23]. The minimal clinically important difference (MCID) has been defined as a 4-point improvement in the DLQI total score [24]. Assessments were completed by patients every 4 weeks from baseline to Week 20 and then at Week 32, 36 and 48, or at premature end of treatment visit.

Outcomes

Outcomes reported were exploratory endpoints for BE HEARD I&II. HiSQOL total and subscale, HSSQ item and DLQI total scores to Week 48 and HSSDD item scores to Week 16 are reported. Absolute change from baseline (CfB) in HiSQOL total and subscales scores are also presented. Additionally, HiSQOL total score response rates (defined as a ≥ 21-point reduction from baseline) were calculated at Weeks 4, 16, 32 and 48 in the subgroup of patients with baseline HiSQOL total score ≥ 21. HiSQOL total and subscale scores and HSSQ item score impact/symptom severity categories (none, mild, moderate, severe and very severe) are reported at baseline and Weeks 16, 32 and 48. The proportions of patients with baseline DLQI total score of ≥ 4 achieving the 4-point MCID improvement (reduction) in DLQI are reported to Week 48, as are the proportions achieving a DLQI total score of 0 or 1 (DLQI 0/1), regardless of baseline DLQI total score.

Statistical Analysis

Error is reported using standard deviation (SD) for all outcomes. The 95% confidence intervals (CI) are used for dichotomous outcomes. All data are reported as observed case (OC), where the denominator represents number of patients with a non-missing value in the given week, and percentages are calculated accordingly. All analyses were performed using SAS© version 9.4 or later.

Ethical Approval

The study protocol, amendments and patient informed consent were reviewed by a national, regional or Independent Ethics Committee (IEC) or Institutional Review Board (IRB). This study was conducted in accordance with the current version of the applicable regulatory and International Conference on Harmonisation (ICH)–Good Clinical Practice (GCP) requirements, the ethical principles that have their origin in the principles of the Declaration of Helsinki, and the local laws of the countries involved. Ethics approval was obtained from the relevant institutional review boards at participating sites. BE HEARD I&II have previously been published and full ethical approval was acquired for both of these studies. All the results presented in this article are in aggregate

form, and no personally identifiable information was used for this study.

RESULTS

Patient Disposition and Baseline Characteristics

Baseline characteristics were recorded for the 1014 patients enrolled in BE HEARD I ($N=505$) and BE HEARD II ($N=509$), with 720 patients completing treatment to Week 48 (333 in BE HEARD I, 387 in BE HEARD II). Baseline characteristics were similar across treatment groups and were generally representative of patients with moderate to severe HS in clinical trials (Table 1) [10].

Mean (SD) baseline HiSQOL total scores were comparable across treatment groups, with scores ranging from 24.5 (13.1) to 26.4 (14.1) (Table 1). Mean HSSDD and HSSQ item scores were also comparable across treatment groups.

HiSQOL

At baseline, 98.3% (997/1014) of patients had non-missing HiSQOL scores. At Week 16, numerically greater reductions in HiSQOL total and subscale scores were observed in patients receiving bimekizumab Q2W/Q4W vs placebo (Fig. 1). Mean CfB in HiSQOL total and subscale scores (bimekizumab Q2W/Q4W vs placebo) were: total, −10.3 vs −5.5; symptoms, −2.7 vs −1.3; psychosocial, −1.9 vs −1.3; and activities-adaptations, −5.6 vs −2.9. Numerically greater reductions in HiSQOL total and subscale scores were also observed in patients randomised to BKZ Q2W/Q2W and BKZ Q4W/Q4W vs placebo. Reductions in HiSQOL total and subscale scores were further improved or maintained to Week 48 across patients randomised to bimekizumab at baseline. Following the switch from placebo to bimekizumab Q2W at Week 16, reductions were also observed, reaching similar levels to those treated continuously with bimekizumab by Week 48 (Fig. 1).

Numerically higher proportions of patients achieved a HiSQOL response by Week 4 in the bimekizumab Q2W/Q4W group (19.0%, $n=29/153$) vs the placebo group (9.2%, $n=8/87$). Response rate further increased at Week 16 and Week 48 to 29.4% ($n = 42/143$) and 47.4% ($n=54/114$), respectively. Following switch from placebo to bimekizumab Q2W at Week 16, the HiSQOL response rate increased from 12.5% ($n=10/80$) to 55.0% ($n=33/60$) at Week 48.

The proportion of patients with very severe disease impact on HRQoL (HiSQOL total score ≥ 24) notably decreased from baseline to Week 48 for patients receiving bimekizumab from baseline (Fig. 2). Following the switch at Week 16, the proportions of placebo/bimekizumab Q2W switchers reporting very severe HRQoL impact decreased by over half to Week 48. There were large increases in the proportions of patients reporting mild (5–14) or no (0–4) disease impact at Week 48 across all patients, with similar trends observed for the symptoms, psychosocial and activities-adaptations subscale scores (Fig. S2).

HSSDD

At Week 16, HSSDD completion rate was 64.6% ($n=655$). At baseline, mean HSSDD itch scores for patients receiving bimekizumab Q2W, bimekizumab Q4W and placebo were 4.5, 4.8 and 4.8, respectively. Mean HSSDD itch scores for patients receiving bimekizumab Q2W, bimekizumab Q4W and placebo decreased to 3.2, 3.5 and 3.7 at Week 16, respectively (Fig. 3). The baseline mean HSSDD smell or odour scores for patients receiving bimekizumab Q2W, bimekizumab Q4W and placebo were 4.3, 4.5 and 4.3. Numerically greater improvements in smell or odour were observed at Week 16 in bimekizumab-treated patients (2.8; Q2W and 3.4; Q4W) vs placebo (3.4). For HSSDD drainage or oozing, patients receiving bimekizumab Q2W and Q4W had baseline scores of 4.5 and 4.6, while patients in the placebo group had a score of 4.5. Patients receiving bimekizumab Q2W and Q4W saw numerically greater reductions in drainage or oozing at Week 16, with scores of 2.8 and 3.1 vs 3.6 for placebo.

Table 1 Baseline characteristics

	Bimekizumab 320 mg Q2W/Q2W *N* = 288	Bimekizumab 320 mg Q2W/Q4W *N* = 292	Bimekizumab 320 mg Q4W/Q4W *N* = 288	Placebo/bimekizumab 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)
Sex, male, *n* (%)	136 (47.2)	118 (40.4)	113 (39.2)	71 (48.6)
Racial group, white, mean (SD)	232 (80.6)	233 (79.8)	224 (77.8)	119 (81.5)
Racial group, black, mean (SD)	32 (11.1)	31 (10.6)	34 (11.8)	13 (8.9)
BMI (kg/m^2), mean (SD)	32.7 (8.6)	32.7 (7.9)	33.8 (7.9)	33.1 (8.3)
Duration of disease (years), mean (SD)	7.6 (7.4)	8.3 (7.7)	7.3 (7.3)	9.8 (9.4)
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)
Prior biologic use, *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)
DLQI total score, mean (SD)	11.2 (6.5)	10.8 (6.7)	11.7 (7.4)	12.2 (7.1)
IHS4 score, mean (SD)	33.4 (25.4)	36.0 (34.0)	35.0 (34.0)	30.6 (21.8)
HiSQOL total score, mean (SD)[a]	24.8 (12.7)	24.5 (13.1)	25.8 (13.9)	26.4 (14.1)
HSSDD item score, mean (SD)[b]				
Worst skin pain	5.5 (2.5)	5.4 (2.5)	5.6 (2.5)	5.4 (2.5)
Itch at its worst	4.6 (2.7)	4.5 (2.7)	4.8 (2.8)	4.8 (2.3)
Smell/odour	4.3 (3.1)	4.3 (3.0)	4.5 (2.9)	4.3 (2.9)
Drainage/oozing	4.6 (2.9)	4.4 (2.9)	4.6 (2.8)	4.5 (2.8)
HSSQ item score, mean (SD)[c]				
Skin pain	5.8 (2.4)	5.8 (2.3)	5.8 (2.5)	5.8 (2.5)
Itch	4.9 (2.8)	4.8 (2.8)	5.1 (2.8)	5.0 (2.6)
Smell/odour	4.6 (3.0)	4.6 (3.0)	4.7 (2.9)	4.7 (3.1)
Drainage/oozing	5.0 (2.9)	5.1 (2.8)	5.0 (2.8)	5.1 (2.9)

Randomised set

[a]98.7% (997/1010) of patients had non-missing Hidradenitis Suppurativa Quality of Life questionnaire (HiSQOL) scores at baseline

[b]HSSDD completion rate at baseline was 90.7% ($n = 934$)

[c]Hidradenitis Suppurativa Symptom Questionnaire (HSSQ) completion rate at baseline was 99.0% ($n = 1007$)

BMI body mass index, *DLQI* Dermatology Life Quality Index, *HSSQ* Hidradenitis Suppurativa Symptom Questionnaire, *IHS4* International Hidradenitis Suppurativa Severity Score System, *Q2W* every 2 weeks, *Q4W* every 4 weeks, *SD* standard deviation

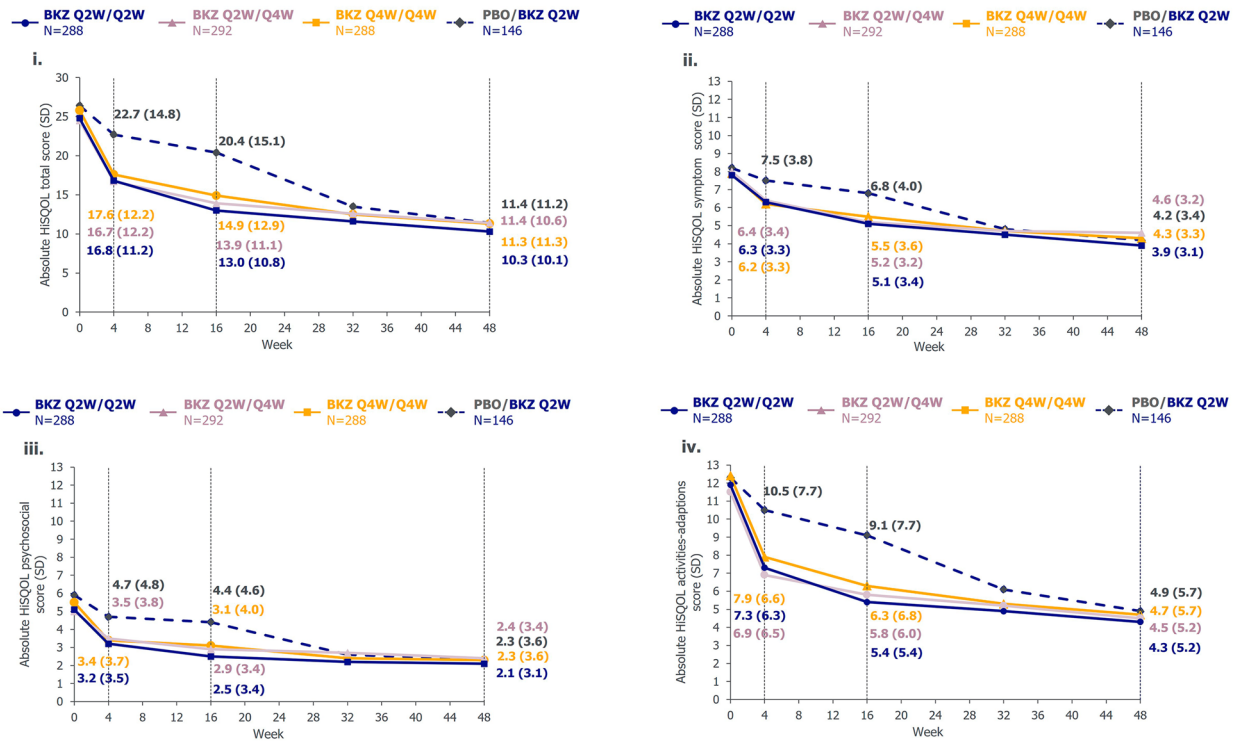


Fig. 1 Mean HiSQOL total and subscale scores over time (OC). Randomised set, $N = 1014$. **i.** HiSQOL total score (0–68); **ii.** HiSQOL symptoms score (0–16); **iii.** HiSQOL psychosocial score (0–20); **iv.** HiSQOL activities-adaptations score (0–32). Data are reported as mean (standard deviation [SD]) for total and subscale Hidradenitis Suppurativa Quality of Life (HiSQOL) scores. *BKZ* bimekizumab, *HiSQOL* Hidradenitis Suppurativa Quality of Life, *OC* observed case, *PBO* placebo, *Q2W* every 2 weeks, *Q4W* every 4 weeks, *SD* standard deviation

HSSQ

HSSQ completion rates were 89.5% ($n = 908$) and 69.6% ($n = 706$) at Weeks 16 and 48, respectively. Greater improvements (i.e. score reduction) to Week 16 were observed across HSSQ item scores in patients receiving bimekizumab Q2W/Q4W, as well as Q2W/Q2W and Q4W/Q4W, vs placebo (Fig. 4). HSSQ item scores continued to numerically improve from Week 16 to Week 48 across all treatment groups.

The proportions of patients in the bimekizumab Q2W/Q4W group with severe/very severe itch, odour and drainage decreased from baseline to Week 48, as did the placebo-randomised patients following switch to bimekizumab Q2W at Week 16 (Fig. S3). The same trend was observed in patients receiving bimekizumab Q2W/Q2W and Q4W/Q4W vs placebo.

DLQI

Mean DLQI total score decreased rapidly in patients receiving bimekizumab. Reductions were seen as early as Week 4, from 10.8 at baseline to 7.6 for bimekizumab Q2W/Q4W-treated patients, vs 12.2 to 10.1 for placebo-treated patients (mean [SD] data reported in Fig. 5i). Mean DLQI total scores decreased or were maintained to Week 48 for patients receiving bimekizumab from baseline. Following switch from placebo to bimekizumab Q2W at Week 16, mean DLQI total score decreased from 8.9 to 5.7 at Week 48, with similar scores observed across all treatment groups by Week 48 (bimekizumab Q2W/Q4W: 5.4).

Higher proportions of bimekizumab Q2W/Q4W-treated patients achieved DLQI MCID by Week 4 vs placebo; 47.9% vs 37.5%, respectively (Fig. 5ii). The same trend was seen in patients

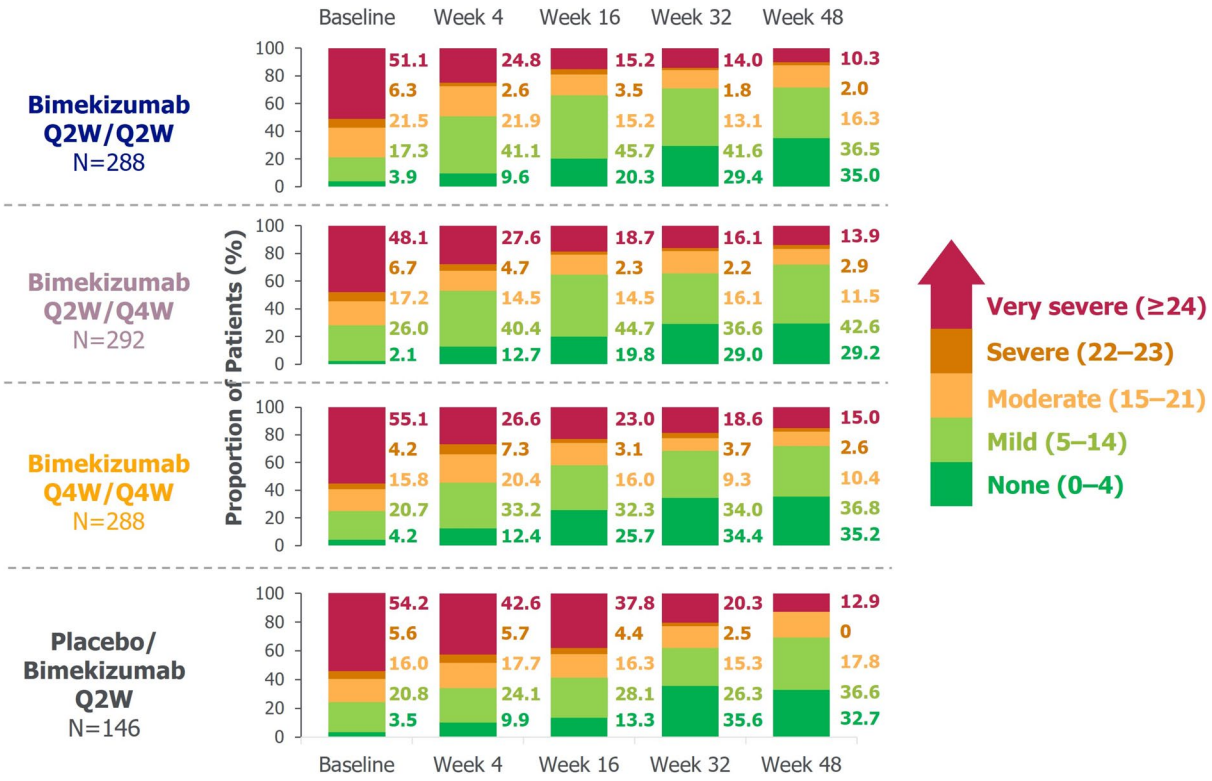


Fig. 2 Distribution of HiSQOL severity categories over time (OC). Randomised set, $N = 1014$. *HiSQOL* Hidradenitis Suppurativa Quality of Life, *OC* observed case, *Q2W* every 2 weeks, *Q4W* every 4 weeks

in the other Q2W/Q2W and Q4W/Q4W bimekizumab treatment groups. The proportions of patients achieving DLQI MCID continued to increase from Week 16 to Week 48 across all treatment groups. At Week 16, 54.9% of patients in the bimekizumab Q2W/Q4W group achieved DLQI MCID vs 49.1% in the placebo group. At Week 48, 63.5% of patients in the bimekizumab Q2W/Q4W group and 76.5% of placebo switchers achieved DLQI MCID. The same trend was seen in the other bimekizumab-treatment groups.

At Week 4, numerically higher proportions of patients treated with bimekizumab from baseline achieved a DLQI 0/1 response vs placebo (Fig. 5iii). The proportions of these patients achieving a DLQI 0/1 response increased from Week 4 to Week 16, to 17.5%, 21.4% and 18.7% for Q2W/Q4W, Q2W/Q2W and Q4W/Q4W bimekizumab groups, respectively. No increase in DLQI 0/1 score achievement was observed over the same period for patients receiving placebo (9.6%). In those receiving bimekizumab from baseline, achievement of DLQI 0/1 continued to increase to Week 48. Achievement reached comparable levels in placebo switchers at Week 48, at 24.8%.

DISCUSSION

Debilitating symptoms, including intense pain, itch, drainage and odour, have a significant impact on the wellbeing of patients with HS [25–27]. PROs are a key aspect of patient-centric HS management, providing insights into patients' perception of their condition, including symptom severity, impact on physical and social functioning and treatment experience. PRO data can be used to guide clinical decision-making and tailor treatment plans to better meet patients' individual needs, improving patient care [7]. However, to effectively assess HS

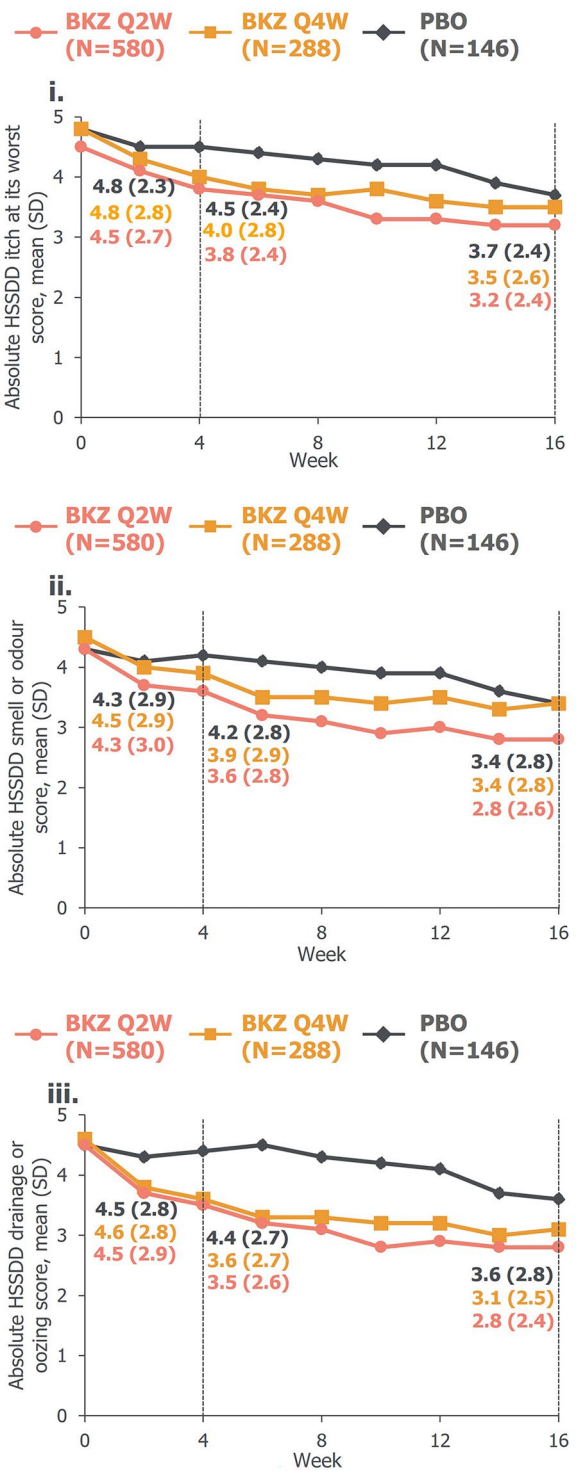


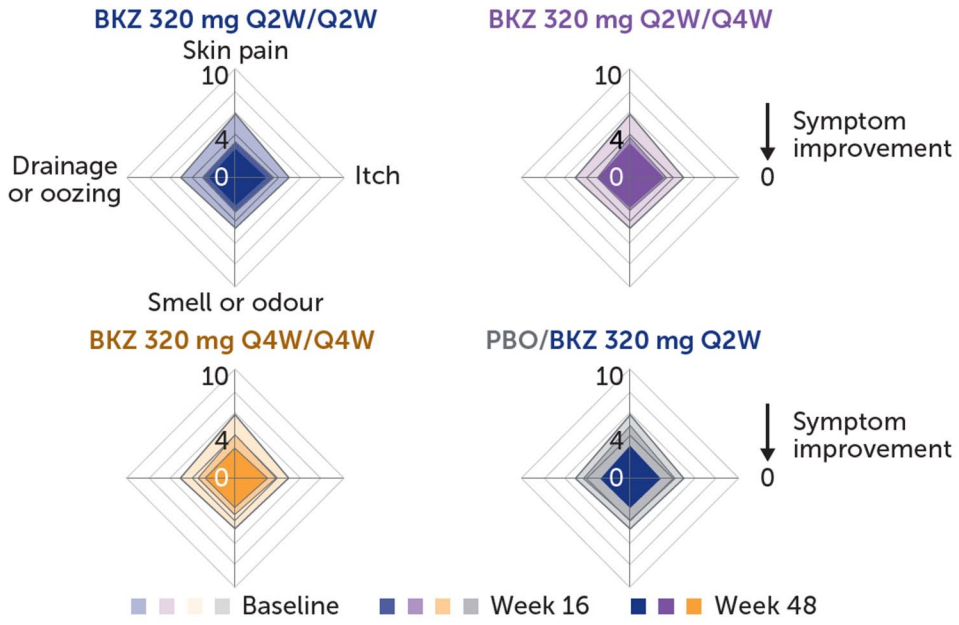
Fig. 3 Mean HSSDD subscale scores over time (OC). ▸ Pooled randomised data from the initial treatment periods of BE HEARD I&II. **i.** Hidradenitis Suppurativa Symptom Daily Diary (HSSDD) itch; **ii.** HSSDD smell or odour; **iii.** HSSDD drainage or oozing. Data are reported as mean (standard deviation [SD]) for absolute mean Hidradenitis Suppurativa Symptom Daily Diary (HSSDD) subscale scores. *BKZ* bimekizumab, *HSSDD* Hidradenitis Suppurativa Symptom Daily Diary, *OC* observed case, *PBO* placebo, *Q2W* every 2 weeks, *Q4W* every 4 weeks, *SD* standard deviation

symptoms, such endpoints must be HS-specific, fit-for-purpose and developed using established PRO guidance [28].

This analysis aimed to assess the impact of bimekizumab on PROs over 1 year of continuous treatment in the phase 3 BE HEARD I&II studies, using HiSQOL, HSSDD, HSSQ and DLQI. HS-specific, newly developed and validated PRO instruments with demonstrated good psychometric performance were used to capture both symptoms and disease impact, thus providing a holistic view of patient-perceived benefits [11, 12, 28]. The impact on patient-perceived symptoms and QoL when switching from placebo to bimekizumab was also assessed.

Bimekizumab, which selectively inhibits IL-17A and IL-17F, had a positive impact on HRQoL in patients with HS measured by both the DLQI and the HS-specific HiSQOL. Reductions in HiSQOL total and subscale scores were observed as early as Week 4 and maintained to Week 48, demonstrating a clinically meaningful impact of bimekizumab on patients' physical, social and mental wellbeing. Clinically meaningful improvements in severity categories were also observed at Week 16 and further improved through Week 48.

The positive impact of bimekizumab on core HS symptoms was assessed through Week 16 with the HSSDD, and at Week 16 through Week 48 with the HSSQ. At Week 16, bimekizumab-treated patients achieved clinically meaningful reductions from baseline in HS symptoms and symptom severity, which were maintained to Week 48. Pain is the most debilitating symptom of HS and the highest



	Bimekizumab Q2W/Q2W N=288	Bimekizumab Q2W/Q4W N=292	Bimekizumab Q4W/Q4W N=288	Placebo/bimekizumab Q2W N=146
HSSQ subscale score, mean (SD)				
Skin pain				
Baseline	5.8 (2.3)	5.8 (2.3)	5.8 (2.5)	5.8 (2.5)
Week 16	3.3 (2.5)	3.8 (2.5)	4.1 (2.6)	4.9 (2.6)
Week 48	2.7 (2.4)	3.1 (2.5)	2.8 (2.4)	2.9 (2.4)
Itch				
Baseline	4.9 (2.8)	4.8 (2.8)	5.1 (2.8)	5.0 (2.6)
Week 16	3.5 (2.7)	3.4 (2.5)	3.9 (2.9)	4.2 (2.8)
Week 48	2.8 (2.5)	3.1 (2.5)	3.0 (2.7)	2.8 (2.5)
Smell or odour				
Baseline	4.6 (3.0)	4.6 (3.0)	4.7 (2.9)	4.7 (3.1)
Week 16	3.1 (2.7)	3.1 (2.7)	3.4 (2.9)	3.9 (3.1)
Week 48	2.6 (2.6)	2.8 (2.6)	2.8 (2.7)	2.7 (2.6)
Draining or oozing				
Baseline	5.0 (2.9)	5.1 (2.8)	5.0 (2.8)	5.1 (2.9)
Week 16	3.1 (2.6)	3.1 (2.5)	3.4 (2.7)	4.3 (2.9)
Week 48	2.5 (2.6)	2.9 (2.4)	2.8 (2.5)	2.6 (2.5)

Fig. 4 Mean absolute HSSQ subscale scores over time (OC). Randomised set, $N = 1014$. Data are reported as mean (standard deviation [SD]) Hidradenitis Suppurativa Symptom Questionnaire (HSSQ) item scores. *BKZ* bimekizumab, *HSSQ* Hidradenitis Suppurativa Symptom Questionnaire, *OC* observed case, *PBO* placebo, *Q2W* every 2 weeks, *Q4W* every 4 weeks, *SD* standard deviation

ranked domain in the HISTORIC core outcome set [9]. An analysis describing the impact of bimekizumab on pain demonstrated that bimekizumab reduced pain across PRO measures and

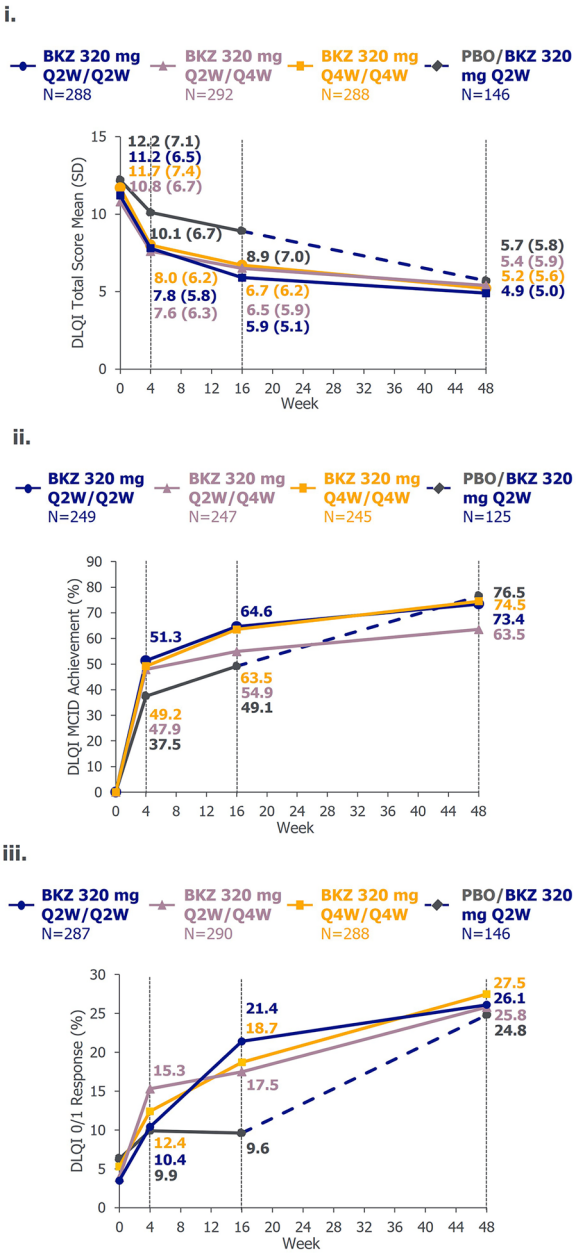


Fig. 5 DLQI total score, DLQI MCID (≥ 4-point reduction from baseline) and DLQI 0/1 response to Week 48 (OC). Randomised set. **i.** Dermatology Life Quality Index (DLQI) total score; **ii.** DLQI Minimal clinically important difference (MCID), defined as the improvement (decrease) of DLQI total score from baseline of ≥ 4; only participants with a baseline DLQI score of ≥ 4 are included; **iii.** DLQI 0/1 response, defined as achievement of DLQI total score of 0 or 1 (indicating no impact of skin disease on a patient's life). *BKZ* bimekizumab, *DLQI* Dermatology Life Quality Index, *MCID* minimal clinically important difference, *OC* observed case, *Q2W* every 2 weeks, *Q4W* every 4 weeks, *SD* standard deviation

pain response definitions [29]. Management of itch is an important treatment objective, since it is another burdensome symptom of HS with a strong correlation to QoL [3]. Monoclonal antibodies which inhibit the IL-17A receptor have previously been shown to improve itch in patients with HS [30, 31]. Odour can also significantly affect a patient's QoL, causing embarrassment and contributing to low self-esteem [3, 32]. In the current study, bimekizumab-treated patients showed notable reductions in HSSQ/HSSDD itch and smell or odour scores over 1 year. The positive impact of bimekizumab on core HS symptoms was further demonstrated by the consistent improvement in HiSQOL total and subscale scores over time. The difference in magnitude of changes observed at Week 16 between the HSSQ and HSSDD could be explained by the difference in recall period, and for itch specifically, by the concept captured (itch at its worst for HSSDD and itch for HSSQ).

Currently, there is a paucity of published data on the role of IL-17 inhibition in reducing itch and odour in HS, although the mechanism behind itch resolution in psoriasis has been previously reported [33]. The BE HEARD I&II trials are the first to investigate the impact of bimekizumab using HS-specific symptom measures, marking a step towards understanding the connection between IL-17 inhibition and itch and odour improvement in HS.

Bimekizumab-treated patients demonstrated improvements to Week 16 across all PRO measures utilised. Improvements were maintained or improved through Week 48, showing a sustained positive impact on HRQoL with bimekizumab in patients with moderate to severe HS. Week 16 placebo/bimekizumab Q2W switchers experienced rapid improvements in symptoms, achieving levels comparable to patients receiving bimekizumab from baseline by Week 48. Anti-inflammatory treatment, such as bimekizumab, does not target scarring and discolouration, which may have an impact on patients' QoL.

The BE HEARD I&II population includes a substantial representative sample of patients with moderate to severe HS. HS-specific HiSQOL,

HSSDD and HSSQ were utilised in addition to the non-HS-specific DLQI; they are psychometrically-validated instruments developed in accordance with FDA PRO guidance [28, 34, 35]. BE HEARD is the first phase 3 programme to use the HS-specific HiSQOL instrument to capture HRQoL. This work demonstrated consistent improvements in HS symptoms and HRQoL across multiple instruments and outcomes. In BE HEARD I&II, the kinetics for clinical outcomes and PROs were similar, suggesting no time lag between lesion reduction and patient-perceived reduction in symptom severity and improved HRQoL [10]. Future analyses should explore the association between improvements in PROs and achievement of stringent clinical criteria.

The HRQoL data presented here were collected from controlled clinical trials. Additionally, as HSSQ and HSSDD are relatively new tools, scope remains for future observational studies in routine practice to provide insight into patients' real-world experience with bimekizumab. The timings of HSSQ assessments (baseline, Week 16, then alternate weeks to Week 48) may mean that some subtleties were not captured in the first 16 weeks, although symptoms were recorded daily with the HSSDD.

CONCLUSIONS

Bimekizumab demonstrated clinically meaningful improvements as early as Week 4 across multiple PRO measures in patients with moderate to severe HS, which were maintained over 1 year.

Bimekizumab, a humanised IgG1 monoclonal antibody which inhibits IL-17F in addition to IL-17A, is an effective new treatment that may manage the impact of HS in patients with moderate to severe HS and improve HS symptoms and HRQoL.

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Data Availability. Underlying data from this manuscript may be requested by qualified researchers 6 months after product approval in the US and/or Europe, or global development is discontinued, and 18 months after trial completion. Investigators may request access to anonymised individual patient-level data and redacted trial documents which may include: analysis–ready datasets, study protocol, annotated case report form, statistical analysis plan, dataset specifications and clinical study report. Prior to use of the data, proposals need to be approved by an independent review panel at www.Vivli.org and a signed data sharing agreement will need to be executed. All documents are available in English only, for a pre-specified time, typically 12 months, on a password protected portal.

Declarations

Conflict of Interest. Vivian Y. Shi: On the board of directors for the Hidradenitis Suppurativa Foundation (HSF), advisor for the National Eczema Association, shareholder of Learn Health and has served as an advisory board member, investigator, speaker, and/or received research funding from AbbVie, Altus Lab/cQuell, Alumis, Aristea Therapeutics, Boehringer Ingelheim, Burt's Bees, Dermira, Eli Lilly and Company, Galderma, Genentech, GpSkin, Incyte, Kiniksa, LEO Pharma, Menlo Therapeutics, MYOR, Novartis, Pfizer, Polyfins Technology, Regeneron, Sanofi Genzyme, Skin Actives Scientific, Sun Pharma, Target-PharmaSolutions and UCB. John R. Ingram: Received a stipend as immediate past-Editor-in-Chief of the *British Journal of Dermatology* and an authorship honorarium from UpToDate. Consultant for AbbVie, Boehringer Ingelheim, Cantargia, ChemoCentryx, Citryll, Engitix, Incyte, Insmed, Kymera Therapeutics, MoonLake Immunotherapeutics, Novartis, UCB, UNION Therapeutics and Viela Bio. Co-copyright holder of HiSQOL, Investigator Global Assessment and Patient Global Assessment instruments for HS and department receives income from copyright of the Dermatology Life Quality Index (DLQI) and related instruments. Affiliated with the European Hidradenitis Suppurativa Foundation (EHSF) e.V., Dessau, Germany. Hadar Lev-Tov: Consultant for Novartis and UCB. Sylke Schneider-Burrus: Received honoraria for participation in advisory boards, in clinical trials, and/or as speaker from AbbVie, Biogen, Boehringer Ingelheim, Hexal, MoonLake Immunotherapeutics, Novartis, Sanofi and UCB. Seth Forman: Investigator/consultant and/or advisor to AbbVie, Aclaris, Almirall, Arcutis, ASLAN Pharmaceuticals, BioHaven, Boehringer Ingelheim, Bristol Myers Squibb, Cali, Concert, Eli Lilly and Company, Evelo, Horizon Therapeutics, Incyte, Janssen, Merck, Pfizer, UCB and Vertex. Martina L. Porter: Consultant and investigator for AbbVie, Avalo Therapeutics, Aristea, Eli Lilly and Company, Incyte, Janssen, MoonLake Immunotherapeutics, Novartis, Pfizer, Prometheus, Sanofi, Sonoma Biotherapeutics and UCB; consultant for Alumis, FIDE, Trifecta Clinical/WCG and ZuraBio; investigator for Anaptys Bio, Bayer, Bristol Myers Squibb, OASIS Pharmaceuticals and Regeneron; received royalties from Beth Israel Deaconess Medical Center. Koremasa Hayama: Principal investigator for and consultancy/advisory boards from AbbVie, Boehringer Ingelheim and Novartis; speaker fees/grants from AbbVie, Boehringer Ingelheim, Eisai, Novartis and UCB. Linnea Thorlacius: Co-copyright holder of HIDE© (HIdradenitis suppurativa DrainagE), HiSQOL© (Hidradenitis Suppurativa Quality of Life) and HS-IGA© (Hidradenitis Suppurativa Investigator Global Assessment). Investigator for Incyte, Janssen, Novartis and UCB. Speaker fees from UCB. Jérémy Lambert, Tom Vaux, Bartosz Lukowski, Robert L. Rolleri: Employees and shareholders of UCB. Jacek C. Szepietowski: Consultant and advisory board member of AbbVie, LEO Pharma, Novartis, Pierre Fabre, Sanofi-Genzyme, UCB, Sandoz, Almirall, Boehringer Ingelheim and Galderma; speaker for AbbVie, Almirall, Boehringer Ingelheim, Janssen, Eli Lilly and Company, LEO Pharma, Novartis, Pfizer, Pierre Fabre, Sanofi Genzyme

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Ethical Approval. The study protocol, amendments and patient informed consent were reviewed by a national, regional or Independent Ethics Committee (IEC) or Institutional Review Board (IRB). This study was conducted in accordance with the current version of the applicable regulatory and International Conference on Harmonisation (ICH)–Good Clinical Practice (GCP) requirements, the ethical principles that have their origin in the principles of the Declaration of Helsinki, and the local laws of the countries involved. Ethics approval was obtained from the relevant institutional review boards at participating sites. BE HEARD I&II have previously been published and full ethical approval was acquired for both of these studies. All the results presented in this article are in aggregate form, and no personally identifiable information was used for this study.

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