Bimekizumab Improves HRQoL in Patients with Moderate to Severe HS: 3-Year BE HEARD EXT HiSQOL Data

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Objective

To report health-related quality of life (HRQoL) outcomes, measured by the Hidradenitis Suppurativa (HS) Quality of Life (HiSQOL) score, in patients with moderate to severe HS treated with bimekizumab over 3 years.

Background

- HS is a chronic, progressive skin disease that negatively impacts HRQoL.[1,2]
- Timely diagnosis and treatment are critical to avoid irreversible disease progression and improve HRQoL.[1,2]
- Bimekizumab, a humanized IgG1 monoclonal antibody, selectively inhibits interleukin (IL)-17A and IL-17F and is approved for the treatment of moderate to severe HS.[3–5]

Methods

- Data were pooled from the phase 3 BE HEARD I&II (NCT04242446, NCT04242498) trials and their open-label extension, BE HEARD EXT (NCT04901195), for patients with moderate to severe HS.[6,7]
- Data are reported for patients randomized to bimekizumab 320 mg at baseline in BE HEARD I&II who enrolled in BE HEARD EXT and continued to receive bimekizumab (Bimekizumab Total).
- The proportions of patients in each of the severity categories of HRQoL impact are reported at baseline, Year 1 (Week 48), Year 2 (Week 96), and Year 3 (Week 148) for HiSQOL total score and the HiSQOL symptoms, psychosocial, and activities-adaptations subscales.
  - Severity categories (none/mild/moderate/severe/very severe) are defined in **Figure 1**, in accordance with previously published severity thresholds.[8]
- Data are reported as observed case (OC).

Results

- Of 868 patients randomized to bimekizumab in BE HEARD I&II, 556 patients entered BE HEARD EXT.
- Baseline demographics and disease characteristics of patients are reported in **Table 1**. At baseline, mean HiSQOL total score was 24.6.

HiSQOL total score

- At baseline (N=551), over half of patients (57.5%) reported a severe or very severe impact of HS on HRQoL, as measured by the HiSQOL total score (**Figure 2**).
- By Year 1 (N=555), the proportion of patients with severe or very severe impact (14.6%) substantially decreased and the majority of patients reported no or mild impact (72.8%).
- Further numerical improvements were observed at Year 3 (N=360), with 76.4% of patients reporting no or mild impact of HS on HRQoL.
- Notably, the proportion of patients with no impact of HS on HRQoL increased from 2.9% at baseline to 33.3% at Year 1 and 47.2% at Year 3.

HiSQOL symptom subscale

- At baseline, 63.0% of patients reported a severe or very severe impact of HS symptoms on HRQoL (**Figure 3**).
- By Year 1, less than one quarter of patients reported severe or very severe impact (23.2%) and the majority of patients reported no or mild impact (62.5%); 31.7% of patients reported no impact.
- Improvements continued to Year 3, with 46.1% of patients reporting no impact of HS symptoms on HRQoL.

HiSQOL psychosocial subscale

- At baseline, 64.6% of patients reported a severe or very severe psychosocial impact of HS on HRQoL (**Figure 4**).
- By Year 1, the proportion of patients reporting a severe or very severe impact reduced to 31.4%; the majority of patients reported no or mild impact (61.4%), with 48.6% reporting no psychosocial impact.
- Further increases in the proportions of patients reporting no impact were observed by Year 3 (56.1%).

HiSQOL activities-adaptations subscale

- At baseline, 64.6% of patients reported a severe or very severe impact in the HiSQOL activities-adaptations subscale (**Figure 5**).
- By Year 1, fewer than one fifth of patients (19.5%) reported a severe or very severe impact, while 64.5% of patients reported no or mild impact, including 40.9% who reported no impact.
- Further improvements were observed to Year 3, with half of patients reporting no impact (50.0%).

Conclusions

Bimekizumab demonstrated HRQoL improvements over 3 years in patients with moderate to severe HS, as measured by HiSQOL total score and subscale severity categories.

Over three quarters of patients reported no or mild impact of HS on HRQoL at Year 3 of bimekizumab treatment using the HiSQOL questionnaire, demonstrating a substantial improvement from approximately one quarter at baseline.

Patients reported notable and consistent HRQoL improvements in the symptoms, psychosocial, and activities-adaptations HiSQOL subscales over 3 years, highlighting the broad benefits of bimekizumab across different aspects of patients' lives.

Plain Language Summary

Why was this study needed?

- Hidradenitis suppurativa (HS) is a long-term skin disease that has a large, negative impact on patients' health, wellbeing, and their ability to do usual activities.
- It is important that patients receive early treatment for the symptoms of HS to reduce the impact of the condition on their lives.

What did this study show?

- Bimekizumab is a medicine used to treat HS.
- The negative impact of HS on patients' lives was much lower after 3 years of bimekizumab treatment compared with the start of treatment.

Why is this important?

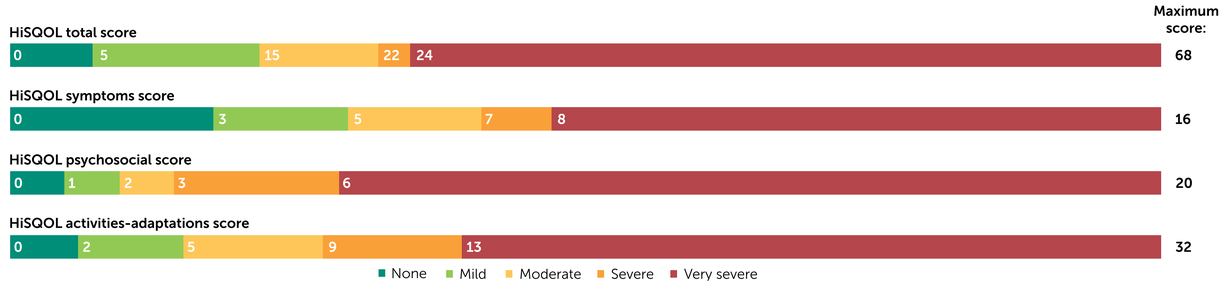
- HS causes pain and discomfort that affects patients' everyday lives and overall wellbeing.
- Bimekizumab can reduce the impact of HS and help patients achieve a better quality of life.

Table 1 Baseline demographics and disease characteristics

	BKZ Total patients N=556
Age, years, mean (SD)	36.3 (12.2)
Sex, female, n (%)	299 (53.8)
Racial group,[a] n (%)	
White	448 (80.6)
Black or African American	55 (9.9)
Asian	29 (5.2)
Other	20 (3.6)
BMI, kg/m², mean (SD)	32.5 (7.8)
Duration of HS, years, mean (SD)	7.4 (7.1)
AN count, mean (SD)	16.9 (18.5)
DT count, mean (SD)	3.8 (4.3)
Hurley stage,[b] n (%)	
II	303 (54.5)
III	253 (45.5)
Prior biologic use,[c] n (%)	112 (20.1)
Baseline antibiotic use, n (%)	54 (9.7)
HiSQOL scores, mean (SD)	
Total score	24.6 (12.8)
Symptom subscale score	7.9 (3.3)
Psychosocial subscale score	5.0 (4.3)
Activities-adaptations subscale score	11.7 (6.9)

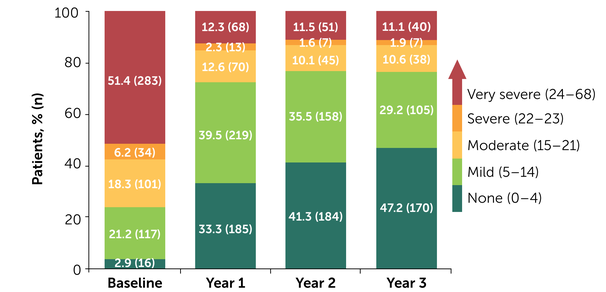
OLE set; only included patients who entered BE HEARD EXT at Week 48. Data are reported for patients randomized to bimekizumab (BKZ) from baseline in BE HEARD I&II who entered BE HEARD EXT and continued to receive BKZ (BKZ Total; N=556). **[a]** 4 (0.7%) patients had missing data; **[b]** Hurley stage for each patient refers to the worst overall Hurley stage of the Hurley stages recorded across all anatomical regions; **[c]** Patients received prior biologic therapy for any indication.

Figure 1 Severity thresholds for HiSQOL total and subscale scores



Bars are not to scale. Numbers within the coloured bars indicate the lower score for each severity threshold. The HiSQOL questionnaire is a 17-item patient-reported outcome measure developed to assess HS-specific impacts on patients' lives.

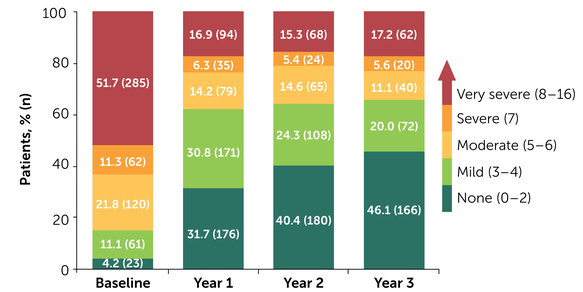
Figure 2 HiSQOL total score severity categories



Mean HiSQOL total score:	Baseline N=551	Year 1 N=555	Year 2 N=445	Year 3 N=360
	24.6	10.7	9.7	9.2

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

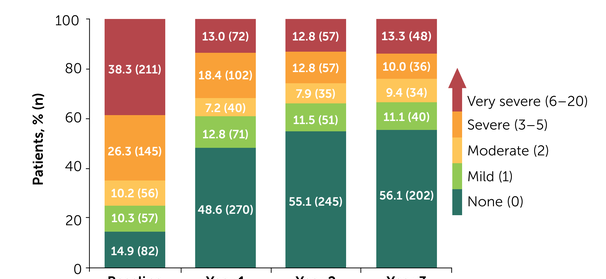
Figure 3 HiSQOL symptom subscale severity categories



Mean HiSQOL symptom subscale score:	Baseline N=551	Year 1 N=555	Year 2 N=445	Year 3 N=360
	7.9	4.2	3.9	3.7

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

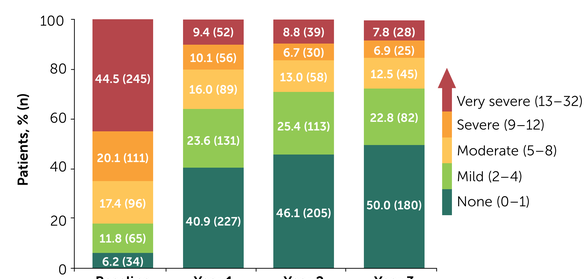
Figure 4 HiSQOL psychosocial subscale severity categories



Mean HiSQOL psychosocial subscale score:	Baseline N=551	Year 1 N=555	Year 2 N=445	Year 3 N=360
	5.0	2.2	1.9	1.9

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

Figure 5 HiSQOL activities-adaptations subscale severity categories



Mean HiSQOL activities-adaptations subscale score:	Baseline N=551	Year 1 N=555	Year 2 N=445	Year 3 N=360
	11.7	4.3	3.9	3.6

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

Abbreviations: AN: abscess and inflammatory nodule; **BKZ:** bimekizumab; **BMI:** body mass index; **DT:** draining tunnel; **HiSQOL:** Hidradenitis Suppurativa Quality of Life; **HRQoL:** health-related quality of life; **HS:** hidradenitis suppurativa; **IL:** interleukin; **OC:** observed case; **OLE:** open-label extension; **SD:** standard deviation.

References: [1]Bechara FG et al. Dermatol Ther (Heidelb) 2025;5:2317–33; [2]Margesson LJ & Danby FW Best Pract Res Clin Obstet Gynaecol 2014;28:1013–27; [3]Adams R et al. Front Immunol 2020;11:1894; [4]BIMZELX® (bimekizumab) Summary of Product Characteristics. April 2024; https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf; [5]BIMZELX® (bimekizumab) Prescribing Information. November 2024: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761151s010lbl.pdf; [6]Kimball AB et al. Lancet 2024;403:2504–19; [7]Sayed CJ et al. J Am Acad Dermatol 2026;94:867–78; [8]Kirby JS et al. Br J Dermatol 2025;193:93–104.

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