Bimekizumab Improves Skin Pain Over 3 Years in Hidradenitis Suppurativa: Data from BE HEARD EXT

Hadar Lev-Tov,[1] Lauren A.V. Orenstein,[2] Vivian Y. Shi,[3] John R. Ingram,[4,5] Hessel H. van der Zee,[5,6] John W. Frew,[7–9] Hideki Fujita,[10] Christina Crater,[11] Jérémy Lambert,[12] Tae Oh,[13] Nicola Tilt,[14] Jacek C. Szepietowski[5,15,16]

[1]Dr. Phillip Frost Department of Dermatology and Cutaneous Surgery, University of Miami Miller School of Medicine, Miami, FL, USA; [2]Department of Dermatology, Emory University School of Medicine, Atlanta, GA, USA; [3]Department of Dermatology, University of Washington, Seattle, WA, USA; [4]Department of Dermatology & Academic Wound Healing, Division of Infection and Immunity, Cardiff University, Cardiff, UK; [5]European Hidradenitis Suppurativa Foundation (EHSF) e.V., Dessau, Germany; [6]Erasmus Medical Center, Rotterdam, The Netherlands; [7]Department of Dermatology, Liverpool Hospital, Sydney, New South Wales, Australia; [8]Laboratory of Translational Cutaneous Medicine, Ingham Institute for Applied Medical Research, Sydney, New South Wales, Australia; [9]School of Clinical Medicine, UNSW Medicine and Health, Sydney, New South Wales, Australia; [10]Division of Cutaneous Science, Department of Dermatology, Nihon University School of Medicine, Tokyo, Japan; [11]UCB, Morrisville, NC, USA; [12]UCB, Courbevoie, France; [13]UCB, Smyrna, GA, USA; [14]UCB, Slough, UK; [15]Division of Dermatology, Venereology and Clinical Immunology, Faculty of Medicine, Wroclaw University of Science and Technology, Wroclaw, Poland; [16]Cityclinic, Medical and Psychological Center, Wroclaw, Poland.

Presenter: Kelly Hughes

Objective

To evaluate the effect of bimekizumab (BKZ) treatment over 3 years on self-reported pain in patients with moderate to severe hidradenitis suppurativa (HS) from the BE HEARD I&II and BE HEARD EXT trials.

Background

- Pain is experienced by most patients with HS and is considered one of the most debilitating symptoms of the disease, substantially impacting patients' quality of life.[1]
- BKZ is a humanized IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.[2]
- Treatment with BKZ has previously demonstrated clinically meaningful improvements in skin pain over 1 year (48 weeks), which was maintained over 2 years (96 weeks).[3]

Methods

- Data were pooled from the phase 3 BE HEARD I&II trials (NCT04242446/NCT04242498) and the open-label extension, BE HEARD EXT (NCT04901195), for patients with moderate to severe HS.[4,5]
- Data are reported for patients who were randomized to BKZ 320 mg from baseline in BE HEARD I&II and entered BE HEARD EXT (BKZ Total).
- The HS Symptom Questionnaire (HSSQ) skin pain item evaluates patients' perceptions of HS skin pain over the past 7 days using an 11-point numeric rating scale with '0' indicating "no pain" and '10' indicating pain "as bad as you can imagine". The following outcomes were reported to Year 3 (Week 148):
  - Absolute and percentage change from baseline (CfB) in skin pain score;
  - Skin pain response, defined as a 30% reduction and ≥1-point reduction in HSSQ skin pain score in patients with a baseline score of ≥3;
  - Distribution of skin pain severity categories (no pain: 0; mild: 1–2; moderate: 3–5; severe/very severe: 6–10).[6]
- Data are reported using observed case (OC) and modified non-responder imputation (mNRI) for binary outcomes, and multiple imputation (MI) for continuous outcomes.
  - mNRI: patients with HS who discontinued treatment due to lack of efficacy or treatment-related adverse events were considered non-responders; MI was used for other missing data.
  - MI: patients with HS who discontinued treatment due to lack of efficacy or treatment-related adverse events were considered missing; MI was used for all missing data.

Results

- Of the 1,014 patients in BE HEARD I&II, 556 randomized to BKZ at baseline completed Year 1 and entered BE HEARD EXT (BKZ Total).
- Baseline demographics and clinical characteristics of patients are presented in **Table**.
- Clinically meaningful reductions from baseline in HSSQ skin pain score observed at Year 1 were maintained to Year 3 (**Figure 1**).
  - Mean (standard deviation [SD]) absolute CfB in HSSQ skin pain score was −3.0 (2.8) at Year 1 and −3.9 (2.9) at Year 3.
- Among patients with baseline pain score ≥3 (N=496), high proportions of patients achieved HSSQ skin pain response at Year 1 (72.2%), which was maintained to Year 3 (80.9%; **Figure 2**).
- The proportion of patients reporting no or mild skin pain increased from 10% at baseline to over 65% at Year 3 (**Figure 3**).
- Similar trends were observed across imputation methods (**Figures 1–3**).

Conclusion

Clinically meaningful improvements in skin pain observed over 1 year of bimekizumab treatment were maintained over 3 years across assessed HSSQ skin pain outcomes.

Summary

Why was this study needed?

Hidradenitis suppurativa (HS) is a chronic skin condition that causes pain and negatively impacts patients' quality of life. Studies have shown that this pain can be reduced in patients treated with bimekizumab.

What did this study show?

Patients treated with bimekizumab reported improvements in skin pain, which were maintained over three years of treatment.

Why is this study important?

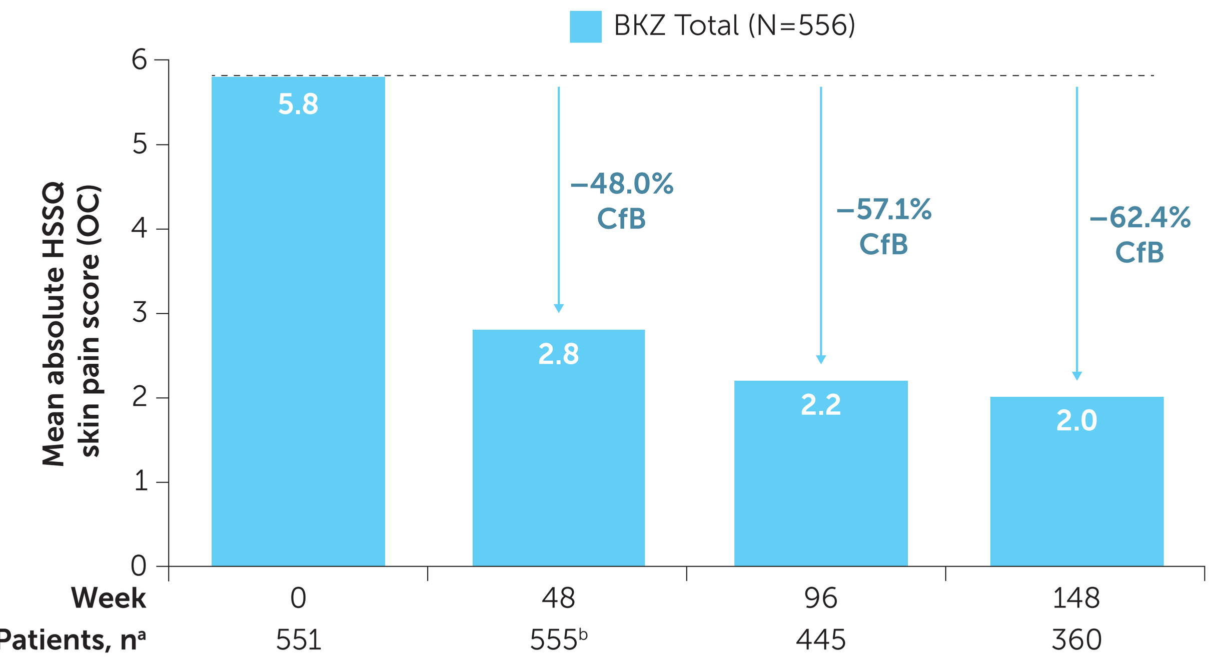
HS causes significant pain that affects patients' daily activities and overall well-being. Bimekizumab reduces this pain, which can help patients achieve a better quality of life.

Table Baseline characteristics

	BKZ Total N=556
Age, years, mean (SD)	36.3 (12.2)
Sex, female, n (%)	299 (53.8)
Racial group, n (%)	
White	448 (80.6)
Black or African American	55 (9.9)
BMI, kg/m², mean (SD)	32.5 (7.8)
Duration of disease, 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[a], n (%)	
II	303 (54.5)
III	253 (45.5)
Prior biologic use[b], n (%)	113 (20.3)
Baseline antibiotic use, n (%)	54 (9.7)
HSSQ skin pain score, mean (SD)	5.8 (2.4)
DLQI total score, mean (SD)	11.0 (6.8)
HiSQOL total score, mean (SD)	24.6 (12.8)

[a] Hurley stage for each patient refers to the worst overall Hurley Stage of the Hurley Stages recorded across all anatomical regions; [b] Patients received prior biologic therapy for any indication.

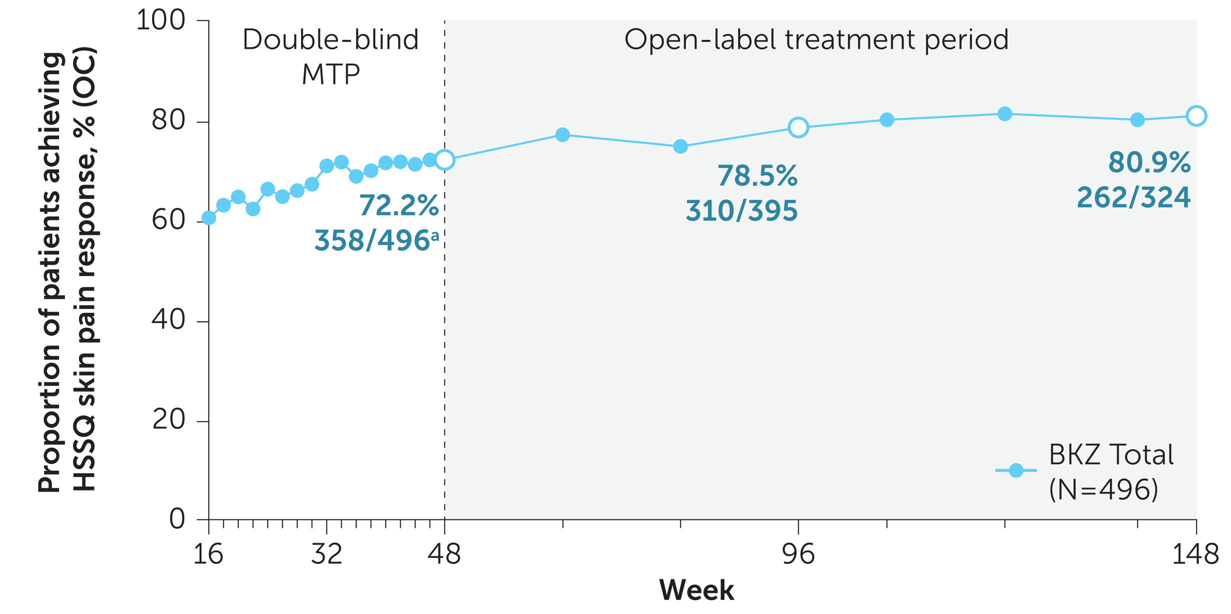
Figure 1 Mean absolute and percentage change from baseline in HSSQ skin pain scores over 3 years



Week	0	48	96	148
Mean absolute HSSQ skin pain score (**MI**)[c]	5.8	2.8	2.4	2.2
Mean percentage CfB in HSSQ skin pain score, % (**MI**)[d]	N/A	−48.1%	−55.1%	−57.5%

[a] For OC, n numbers are reported for mean absolute HSSQ skin pain score in the given week. Mean percentage CfB in HSSQ skin pain scores, n: Week 48, 543; Week 96, 436; Week 148, 354; [b] The requirement of a visit at Week 48 to enter the OLE resulted in an increase in n number at Week 48; [c] For MI, N=555 for mean absolute HSSQ skin pain score; [d] For MI, N=547 for percentage CfB in HSSQ skin pain score.

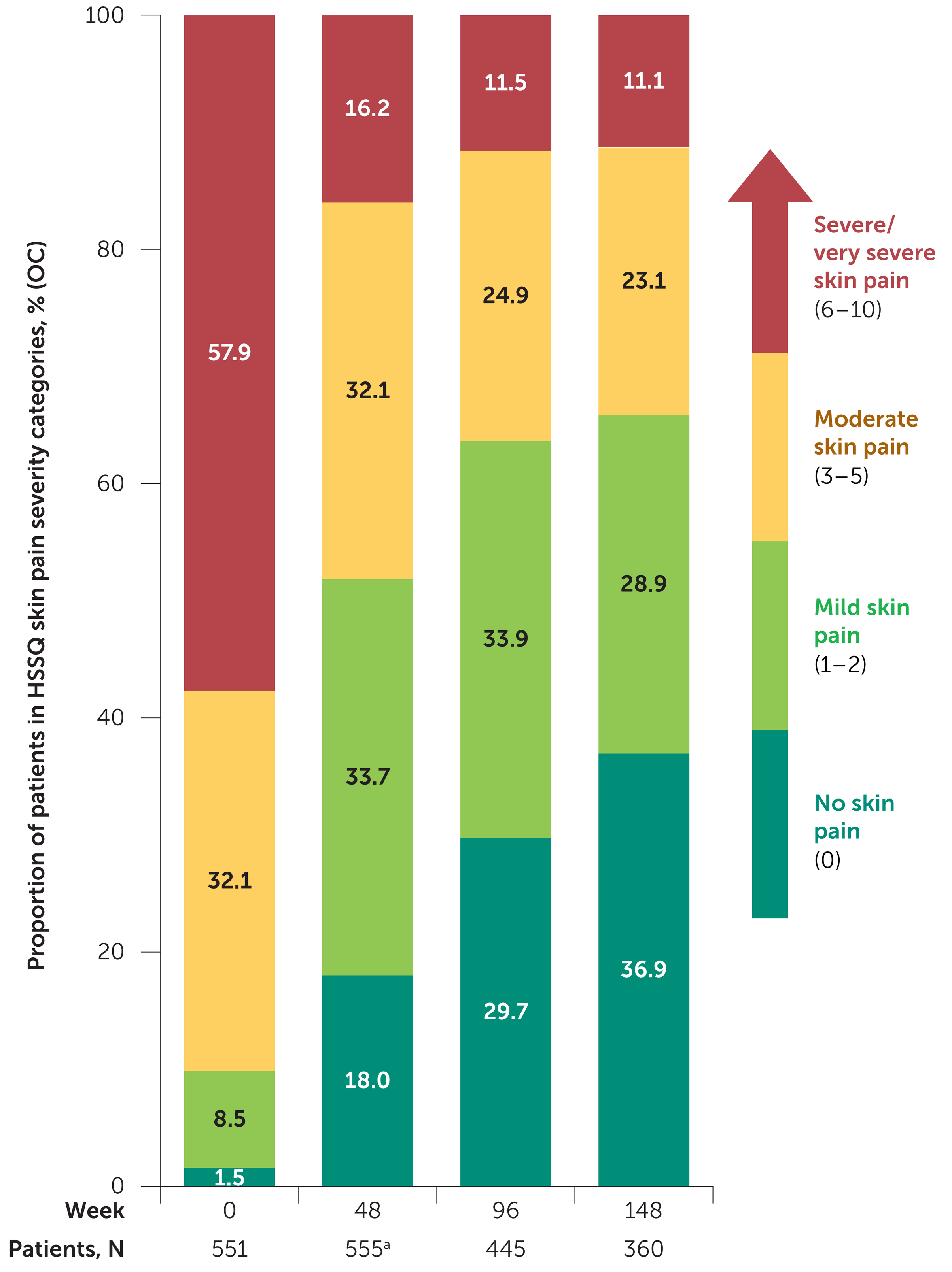
Figure 2 HSSQ skin pain response over 3 years



Week	48	96	148
Proportion of patients, % (**mNRI**)[b]	72.2%	72.1%	71.1%

OC, n/N: n represents patients achieving skin pain response at the given week, defined as a 30% reduction and ≥1-point reduction in patients with a baseline score of ≥3; N represents the total number of patients reporting on skin pain at the given week. [a] The requirement of a visit at Week 48 to enter the OLE resulted in an increase in N number at Week 48; [b] For mNRI, N=496.

Figure 3 Distribution of HSSQ skin pain severity categories over 3 years



Week	0	48	96	148
None (0) [**MI**][b]	1.5%	18.0%	27.4%	31.9%
Mild (1–2) [**MI**][b]	8.5%	33.7%	32.7%	29.1%
Moderate (3–5) [**MI**][b]	32.2%	32.1%	27.7%	27.2%
Severe/very severe (6–10) [**MI**][b]	57.8%	16.2%	12.3%	11.8%

OC, n represents patients reporting skin pain of each severity in the given week; N represents the total number of patients reporting on skin pain at the given week. [a] The requirement of a visit at Week 48 to enter the OLE resulted in an increase in N number at Week 48; [b] For MI, N=556.

AN: abscess and inflammatory nodule; **BKZ:** bimekizumab; **BMI:** body mass index; **CfB:** change from baseline; **DLQI:** dermatology life quality index; **DT:** draining tunnel; **HiSQOL:** hidradenitis suppurativa quality of life questionnaire; **HS:** hidradenitis suppurativa; **HSSQ:** hidradenitis suppurativa symptom questionnaire; **IL:** interleukin; **MI:** multiple imputation; **mNRI:** modified non-responder imputation; **MTP:** maintenance treatment period; **OC:** observed case; **OLE:** open-label extension; **SD:** standard deviation.

References: [1]Garg A et al. J Am Acad Dermatol 2020:82;366–76; [2]Adams R et al. Front Immunol 2020;11:1894; [3]Orenstein LAV et al. Presented at SHSA 2024; 3000238; [4]Kimball AB et al. Lancet 2024;403:2504–19; [5]BE HEARD EXT: www.clinicaltrials.gov/study/NCT04901195; [6]Ingram JR et al. Dermatol Ther (Heidelb) 2025;15:1093–111.
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