Bimekizumab 2-Year Impact on HSSQ Skin Pain in Moderate to Severe HS: Data from BE HEARD EXT

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Link expiration: 01 February 2025

SHSA 2024 | Austin, Texas | 01–03 November 2024

Presentation number: 3000238

Disclosures & Acknowledgments

Disclosures

LAVO: On the board of directors for the Hidradenitis Suppurativa Foundation (HSF); consultant and/or advisory board member for ChemoCentryx, Novartis, and UCB; received grant funding from Pfizer.

VYS: On the board of directors for the 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.

HLT: Consultant for Novartis.

EP: Consultant, advisory board member, speaker for, and received honoraria from Almirall, GSK, Janssen, MoonLake Immunotherapeutics, Novartis, and UCB; department received investigator-initiated grant support from AbbVie, Celgene, CHDR, Citryll, Janssen, Kymera, and UCB.

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, ChemoCentryx, Citryll, MoonLake Immunotherapeutics, Novartis, UCB, and Union Therapeutics, and has served on advisory boards for Insmed, Kymera Therapeutics, and Viela Bio; co-copyright holder of HiSQOL© and HS-IGA; department receives income from copyright of the Dermatology Life Quality Instrument (DLQI) and related instruments.

JWF: Conducted advisory work for AbbVie, Boehringer Ingelheim, ChemoCentryx, Janssen, Kyowa Kirin, LEO Pharma, Pfizer, Regeneron, and UCB; participated in trials for Boehringer Ingelheim, CSL, Eli Lilly, Pfizer, and UCB; received research support from Ortho Dermatologics and Sun Pharma.

HF: Received honoraria or fees for serving on advisory boards, as a speaker and as a consultant, as well as grants as an investigator from AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Daiichi Sankyo, Eisai, Eli Lilly and Company, Janssen, Japan Blood Products Organization, JMEC, Kaken Pharmaceutical, Kyowa Kirin, LEO Pharma, Maruho, Mitsubishi Tanabe, Nihon Pharmaceutical, Novartis, Otsuka Pharmaceutical, Sanofi, Sato Pharmaceutical, Sun Pharma, Taiho Pharmaceutical, Torii Pharmaceutical, UCB, and Ushio.

RR, JL, CC, LD: Employees and shareholders of UCB.

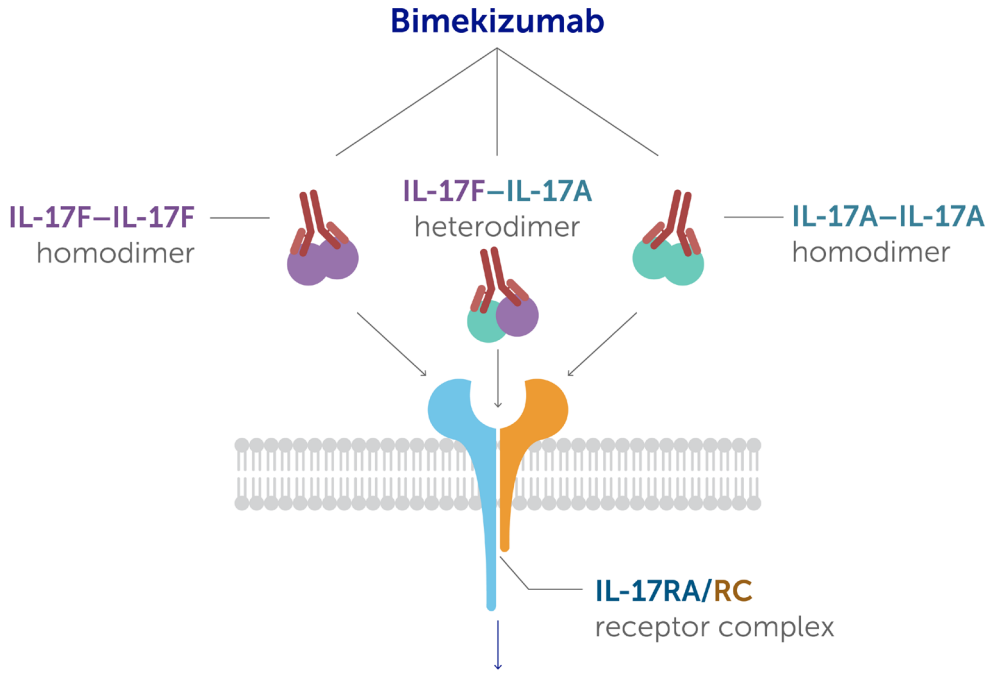
JCS: Consultant and advisory board member of AbbVie, LEO Pharma, Novartis, Pierre Fabre, Sanofi Genzyme, and Trevi Therapeutics; speaker for AbbVie, Almirall, Eli Lilly and Company, LEO Pharma, Novartis, Pfizer, Pierre Fabre, Sanofi-Genzyme, and UCB; investigator for AbbVie, Amgen, Bristol Myers Squibb, Galapagos, Galderma, Incyte, InflaRX, Janssen, Kliniksa, Kymab, Menlo Therapeutics, Merck, Novartis, Pfizer, Regereron Pharmaceuticals, Trevi Therapeutics, and UCB.

Acknowledgments

These studies were funded by UCB. We would like to thank the patients and their caregivers in addition to all the investigators and their teams who contributed to these studies. The authors acknowledge Susanne Wiegratz, MSc, UCB, Monheim am Rhein, Germany for publication coordination, Isabel Merrien, PgDip, Costello Medical, London for medical writing and editorial assistance. All costs associated with development of this presentation were funded by UCB.

Background

- **Pain** is experienced by most patients with hidradenitis suppurativa (HS) and is considered one of the most debilitating symptoms of HS impacting **quality of life.**[1] Pain may be driven by aberrant interleukin (IL)-17 signalling.[2]
- **Bimekizumab (BKZ)** is a humanized IgG1 monoclonal antibody that selectively inhibits IL-17F in addition to IL-17A.[3]



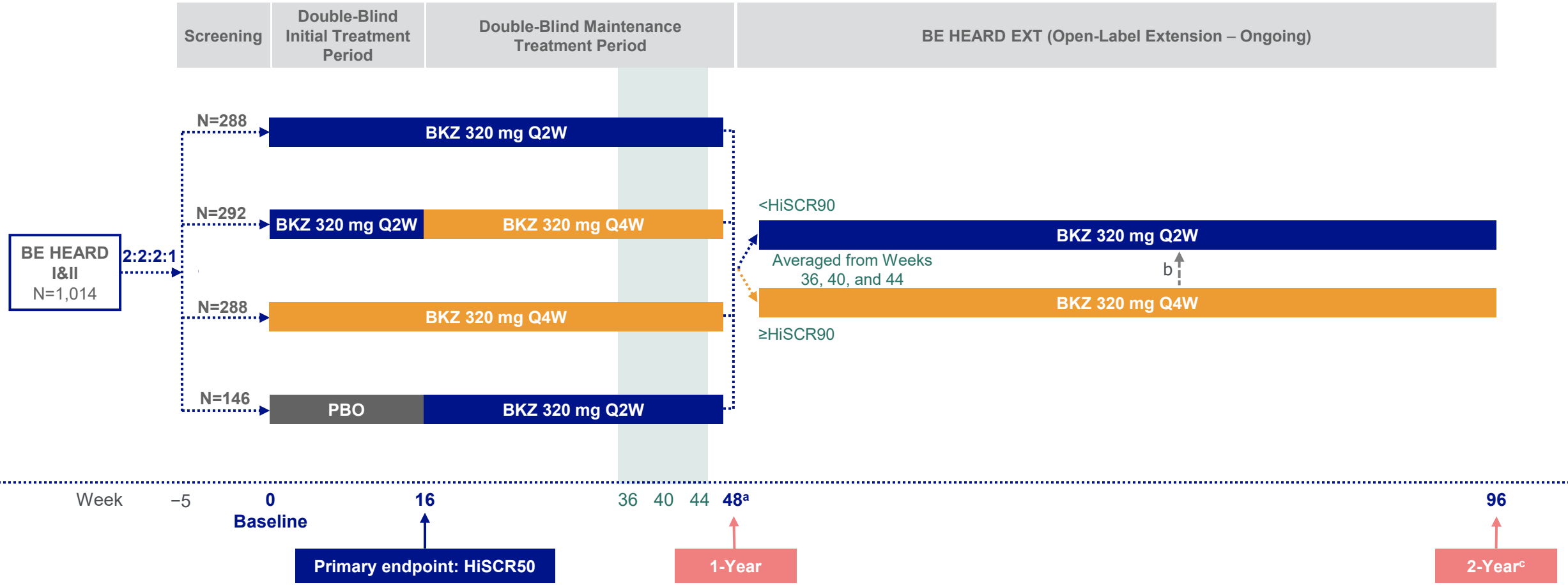
Immune-mediated inflammatory disease (including HS)[4,5]

OBJECTIVE: To report impact on pain outcomes with BKZ treatment in patients with HS through 2 years of the pooled phase 3 BE HEARD I&II trials and their open-label extension, BE HEARD EXT.

1. Garg A et al. J Am Acad Dermatol 2020;82;366–76; 2. Jiang X et al. Front Immunol 2022;13:999407; 3. Adams R et al. Front Immunol 2020;11:1894; 4. Zouboulis CC et al. Exp Dermatol 2020;29:1154–70; 5. Figure adapted from: Patel DD et al. Ann Rheum Dis 2013;72(Suppl 2):ii116–23. **Abbreviations:** BKZ: bimekizumab; HS: hidradenitis suppurativa; Ig: immunoglobulin; IL: interleukin; RA: receptor A; RC: receptor C.

Methods – Study Design

- The phase 3 BE HEARD I&II and BE HEARD EXT study designs:[1,2]



Among 657 BE HEARD I&II completers who entered BE HEARD EXT, 556 patients received BKZ from baseline. **[a]** Patients who completed Week 48 of BE HEARD I&II could enroll 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]** In the first 48 weeks of the ongoing BE HEARD EXT, dose adjustment from BKZ Q4W to BKZ Q2W was permitted based on prespecified criteria for reduction in improvement from baseline in AN count; **[c]** Cumulative 2-year data (48 weeks in BE HEARD I&II and 48 weeks in BE HEARD EXT). 1. Kimball AB et al. Lancet 2024;403:2504–19 (NCT04242446, NCT04242498); 2. BE HEARD EXT: https://clinicaltrials.gov/study/NCT04901195. **Abbreviations:** AN: abscess and inflammatory nodule; BKZ: bimekizumab; HiSCR50/90: ≥50%/90% reduction from baseline in the total AN count with no increase from baseline in abscess or draining tunnel count; Q2W: every two weeks; Q4W: every four weeks.

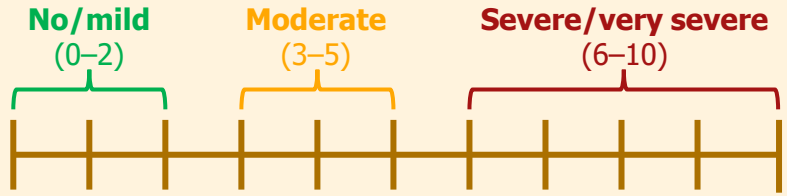
Methods – Outcomes

- We report skin pain outcomes, using the **HS Symptom Questionnaire (HSSQ)** individual skin pain item, to Week 96:
  - Skin pain response, defined as a **30% reduction and ≥1-point reduction** in participants with a baseline score of ≥3.
  - **Absolute** and **percentage change from baseline (CfB)** in skin pain score.
  - Distribution of **skin pain severity categories**.
- Data are reported for all patients randomized to BKZ 320 mg in BE HEARD I&II who enrolled in BE HEARD EXT (BKZ Total).
- Data are reported using observed case (OC).

HSSQ
(HS Symptoms)

- Items include **skin pain**, **itch**, **smell or odor**, and **drainage or oozing**.
- Items scored on an 11-point numeric rating scale. For skin pain:

Please rate your **skin pain** from your HS lesions in the past 7 days:



0
'No skin pain'

10
'Skin pain as bad as you can imagine'

HSSQ data collected at baseline, then every 2 weeks from Week 16 to Week 48, then every 16 weeks to Week 96. **Abbreviations:** BKZ: bimekizumab; CfB: change from baseline; HS: hidradenitis suppurativa; HSSQ: HS Symptom Questionnaire; OC: observed case.

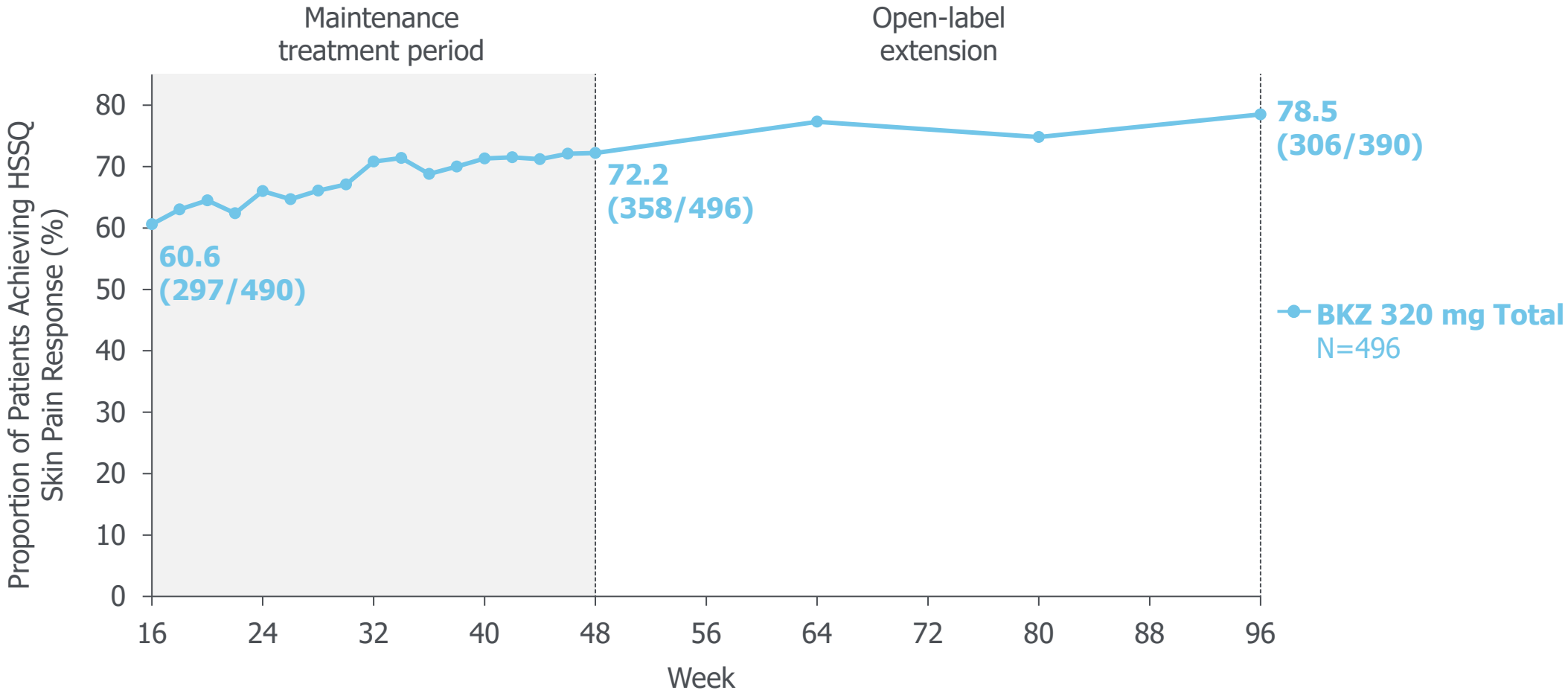
Baseline Characteristics

	BKZ 320 mg Total[a] 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, n (%)	
II	303 (54.5)
III	253 (45.5)
HSSQ skin pain score, mean ± SD	5.8 ± 2.4
DLQI total score, mean ± SD	11.0 ± 6.8
Prior biologic use,[b] n (%)	112 (20.1)
Baseline antibiotic use, n (%)	54 (9.7)

OLE set: N=657; only patients who entered BE HEARD EXT at Week 48 were included. **[a]** BKZ Total comprised patients randomized to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT; **[b]** Patients received prior biologic therapy for any indication. **Abbreviations:** AN: abscess and inflammatory nodule; BKZ: bimekizumab; BMI: body mass index; DLQI: Dermatology Life Quality Index; DT: draining tunnel; HSSQ: Hidradenitis Suppurativa Symptom Questionnaire; OLE: open-label extension; SD: standard deviation.

HSSQ Skin Pain Response from Weeks 16–96 (OC)

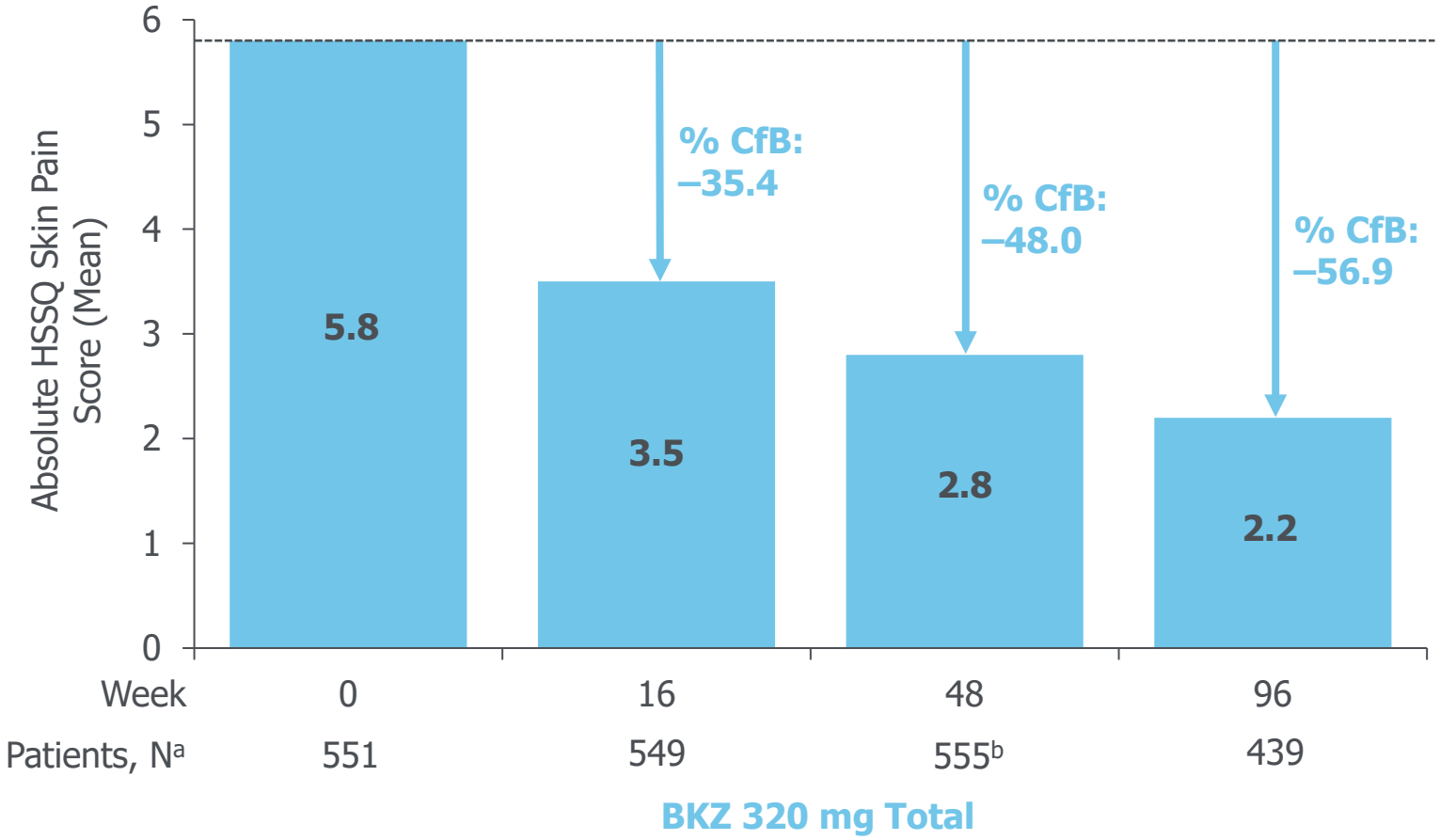
Skin pain response: ≥30% reduction and ≥1-point reduction from baseline in patients with baseline score ≥3



High levels of HSSQ **skin pain response** achieved at 1 year were **maintained** through 2 years.

OLE set; only included patients who entered BE HEARD EXT at Week 48. BKZ Total (n=556) comprised patients randomized to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT and continued to receive BKZ. Data for patients in BKZ Total who had a score of ≥3 at baseline are presented. HSSQ data collected at baseline, then every 2 weeks from Week 16 to Week 48, then every 16 weeks to Week 96. OC, n/N: N represents the number of participants with non-missing data at the given week, and percentages are calculated accordingly. **Abbreviations:** BKZ: bimekizumab; HS: hidradenitis suppurativa; HSSQ: HS symptom questionnaire; OC: observed case; OLE: open-label extension.

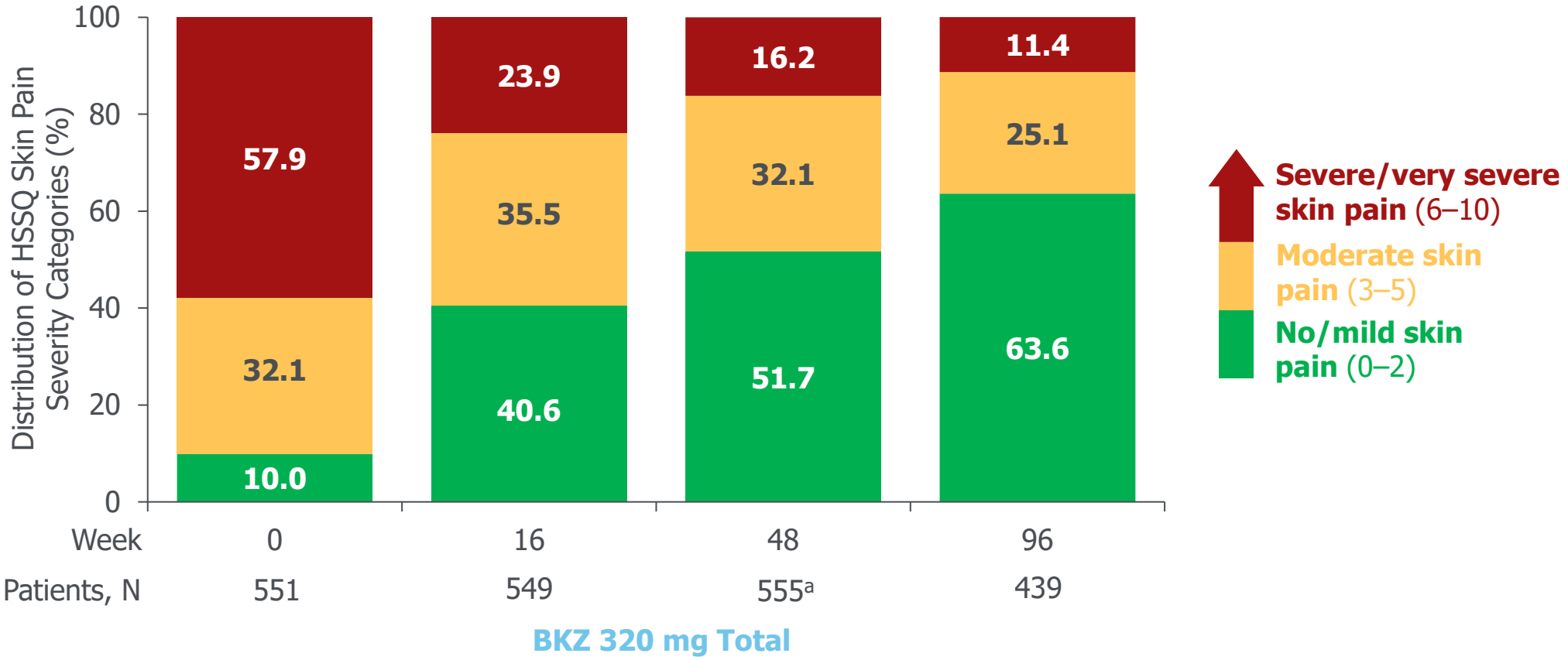
Mean Score and Percentage Change from Baseline in HSSQ Skin Pain Scores from Weeks 0–96 (OC)



Clinically meaningful reductions from baseline in HSSQ skin pain score observed over 1 year were **maintained** to 2 years.

OLE set; only included patients who entered BE HEARD EXT at Week 48. BKZ Total (n=556) comprised patients randomized to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT and continued to receive BKZ. HSSQ data collected at baseline, then every 2 weeks from Week 16 to Week 48, then every 16 weeks to Week 96. **[a]** N numbers are reported for **mean absolute HSSQ skin pain score**. **Percentage CfB in HSSQ skin pain scores, N: Week 16: 537, Week 48: 543, Week 96: 430**. **[b]** The requirement of a visit at Week 48 to enter the OLE resulted in an increase in N number at Week 48. **Abbreviations:** BKZ: bimekizumab; CfB: change from baseline; HS: hidradenitis suppurativa; HSSQ: HS symptom questionnaire; OC: observed case; OLE: open-label extension.

Distribution of HSSQ Skin Pain Severity Categories from Weeks 0–96 (OC)



Over 2 years, an **increasing** proportion of patients had **no or mild skin** pain.

OLE set; only included patients who entered BE HEARD EXT at Week 48. BKZ Total (n=556) comprised patients randomized to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT and continued to receive BKZ. HSSQ data collected at baseline, then every 2 weeks from Week 16 to Week 48, then every 16 weeks to Week 96. OC: N represents the number of participants with non-missing data at the given week, and percentages are calculated accordingly (i.e. where data recorded after an intercurrent event are included as recorded). **[a]** The requirement of a visit at Week 48 to enter the OLE resulted in an increase in N number at Week 48. **Abbreviations:** BKZ: bimekizumab; HS: hidradenitis suppurativa; HSSQ: HS symptom questionnaire; OC: observed case; OLE: open-label extension.

Conclusions

- **Clinically meaningful improvements** in skin pain observed over 1 year **were maintained over 2 years** of bimekizumab treatment across assessed HSSQ skin pain outcomes.
- **An increasing proportion** of patients reported **no or mild skin pain** over 2 years of treatment with bimekizumab.

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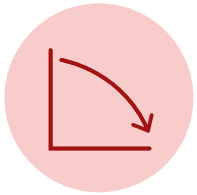
Plain Language Summary

Why was this study needed?

Hidradenitis suppurativa (HS) is a chronic skin condition which causes pain that impacts patients' quality of life. Studies have shown that the drug bimekizumab can help reduce this pain in patients with HS.



What did this study show?

Skin pain was reduced in patients treated with bimekizumab. These improvements lasted throughout two years of treatment.

Why is this important?

Pain greatly impacts the daily life of patients with HS. Bimekizumab reduces HS skin pain and may have an important, positive impact on patients' lives.