

52784

Bimekizumab impact on pain in moderate to severe hidradenitis suppurativa: Week 48 results from BE HEARD I & II



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Introduction: The majority of patients with hidradenitis suppurativa (HS) experience disease-associated pain.[1] Bimekizumab (BKZ), a humanized IgG1 monoclonal antibody, inhibits IL-17F in addition to IL-17A.[2]

Methods: Patients with moderate to severe HS received (initial/maintenance) BKZ 320mg every 2 weeks (wks; Q2W)/Q2W, BKZQ2W/Q4W, BKZQ4W/Q4W or placebo (PBO)/BKZQ2W in the pooled BE HEARD I&II phase 3 studies.[3,4] Achievement of HS Symptom Questionnaire (HSSQ; individual symptom items scored 0–10) skin pain response (30%-reduction and ≥ 1 -point reduction from baseline [baseline score ≥ 3]) and HSSQ skin pain=0 are reported (observed case [OC], modified non-responder imputation [mNRI]), alongside percentage change from baseline (multiple imputation for continuous variable), to Wk48. Patient Global Impression of Severity of Skin Pain (PGI-S-P) and Change in Severity of Skin Pain (PGI-C-S-P) are reported to Wk48 (OC).

Results: N=1,014 patients were randomized to BKZQ2W/Q2W (n=288), BKZQ2W/Q4W (n=292), BKZQ4W/Q4W (n=288), or PBO/BKZQ2W (n=146). Mean baseline HSSQ skin pain score was 5.8 across groups. PGI-S-P was rated "severe" by 28.5–33.3% and "mild" by 15.1–16.7% of patients. At Wk48, HSSQ skin pain response was achieved by 64.6–75.7% of patients (mNRI: 51.7–61.0%); HSSQ skin pain=0 was achieved by 12.7–19.8% of patients (mNRI: 11.3–15.5%). HSSQ skin pain scores reduced by 36.9–43.7% across groups from Wk0-48. At Wk48, 55.9–63.7% of patients rated their skin pain "much better" using the PGI-C-S-P; 3.9–7.8% of patients rated PGI-S-P "severe", versus 45.6–47.4% "mild".

Conclusion: BKZ-treated patients demonstrated clinically meaningful improvements in skin pain up to 48 wks across various assessed outcomes.

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51558

Bimekizumab treatment resulted in rapid and sustained improvement in total and individual Bath Ankylosing Spondylitis Disease Activity Index components in patients with psoriatic arthritis: 1-year results from two phase 3 studies



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Introduction: The patient-reported Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) can assess symptom improvement in psoriatic arthritis (PsA).[1] We report BASDAI data from two phase 3 trials of bimekizumab (BKZ), a monoclonal IgG1 antibody that selectively inhibits IL-17F in addition to IL-17A.

Methods: BE OPTIMAL (bDMARD-naïve) and BE COMPLETE (TNF inhibitor intolerance/inadequate response [TNFi-IR]), placebo (PBO)-controlled to Week (Wk)16, assessed BKZ 160mg Q4W in patients with PsA. All PBO patients switched to BKZ (PBO/BKZ) at Wk16.[2,3] Patients completing BE OPTIMAL (Wk52)/BE COMPLETE (Wk16) were eligible to enter BE VITAL (open-label extension).[4] BASDAI total scores (mean change from baseline; multiple imputation) and $\geq 50\%$ improvement (BASDAI50; non-responder imputation) are reported for patients with baseline BASDAI ≥ 4 .

Results: Patients with baseline BASDAI ≥ 4 : bDMARD-naïve BKZ 311/431 (72.2%), PBO/BKZ 213/281 (75.8%); TNFi-IR BKZ 204/267 (76.4%), PBO/BKZ 96/133 (72.2%). Mean (SE) baseline BASDAI scores were similar between treatment arms/trials (bDMARD-naïve: BKZ 6.14 [0.07], PBO/BKZ 6.19 [0.09]; TNFi-IR: BKZ 6.23 [0.09], PBO/BKZ 6.49 [0.13]). BASDAI score improved rapidly with BKZ by Wk16 (bDMARD-naïve -2.55 [0.12]; TNFi-IR -2.61 [0.15]), sustained to Wk52 (-3.21 [0.12]; -2.91 [0.16]). PBO/BKZ scores improved from Wk16 (-1.06 [0.14]; -0.74 [0.20]) to Wk52 (-2.97 [0.17]; -2.82 [0.27]). Similar improvements observed across BASDAI components, including neck, back, or hip pain. Proportion of BKZ-treated patients reaching BASDAI50 at Wk16 (bDMARD-naïve 43.7%; TNFi-IR 45.1%) sustained to Wk52 (53.4%; 45.6%). PBO/BKZ responders improved from Wk16 (16.4%; 9.4%) to Wk52 (47.4%; 40.6%).

Conclusions: PsA symptoms, assessed by BASDAI, improved rapidly and were sustained with BKZ treatment, irrespective of prior bDMARD use.

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51609

Bimekizumab treatment resulted in sustained improvements in pain and fatigue in patients with active psoriatic arthritis and baseline psoriasis: 1-year results from two phase 3 studies



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Introduction: Patients with psoriatic arthritis (PsA) identified pain and fatigue as salient symptoms of disease burden;[1] evaluating long-term bimekizumab (BKZ) treatment impact on these symptoms among patients with PsA and skin involvement is of clinical interest.

Methods: BE OPTIMAL (bDMARD-naïve) and BE COMPLETE (TNF inhibitor intolerance/inadequate response [TNFi-IR]) assessed BKZ 160mg Q4W in patients with PsA; both double-blind, placebo (PBO)-controlled to Week (Wk)16.[2,3] PBO patients switched to BKZ at Wk16 (PBO/BKZ). Patients completing BE OPTIMAL (Wk52)/BE COMPLETE (Wk16) could enter BE VITAL (open-label extension).[4] Outcomes reported to 1 year for patients with baseline psoriasis (body surface area [BSA] $\geq 3\%$): Patient's Assessment of Arthritis Pain $\geq 50\%$ improvement from baseline (PtAAP50), Functional Assessment of Chronic Illness Therapy-Fatigue minimum clinically important difference (FACIT-Fatigue MCID; ≥ 4 -point improvement in patients with baseline score ≤ 48 ; collected to Wk40 in BE COMPLETE/VITAL). Missing data imputed as non-responder.

Results: 621/1,112 (55.8%) patients had baseline psoriasis (357 bDMARD-naïve [217 BKZ; 140 PBO]; 264 TNFi-IR [176 BKZ; 88 PBO]). Clinically meaningful improvements in pain and fatigue were sustained to 1 year in bDMARD-naïve/TNFi-IR BKZ-treated patients: PtAAP50 was sustained from 51.6%/56.3% (Wk16) to 60.4%/60.2% (Wk52); FACIT-Fatigue MCID was sustained from 55.3%/63.5% (Wk16) to 55.8%/66.5% (Wk52/40). In patients who switched to BKZ (bDMARD naïve/TNFi-IR), PtAAP50 increased from 15.0%/11.4% (Wk16) to 62.9%/50.0% (Wk52); FACIT-Fatigue MCID increased from 41.4%/31.3% (Wk16) to 56.4%/48.2% (Wk52/40). Similar trends observed for overall trial populations.

Conclusions: BKZ treatment demonstrated sustained improvements in patient-reported pain and fatigue to 1 year in patients with PsA and baseline psoriasis, irrespective of prior bDMARD use.

Commercial Support: This study was funded by UCB Pharma. Medical writing support was provided by Costello Medical.

Bimekizumab impact on pain in moderate to severe hidradenitis suppurativa: Week 48 results from BE HEARD I & II

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OBJECTIVES:

- To report the skin pain response, and change from baseline in skin pain, using the Hidradenitis Suppurativa Symptom Questionnaire (HSSQ) skin pain item from Weeks 16–48.
- To report Week 48 results from the Patient Global Impression of Severity of Skin Pain (PGI-S-SP) and Change in Severity of Skin Pain (PGI-C-SP).^a

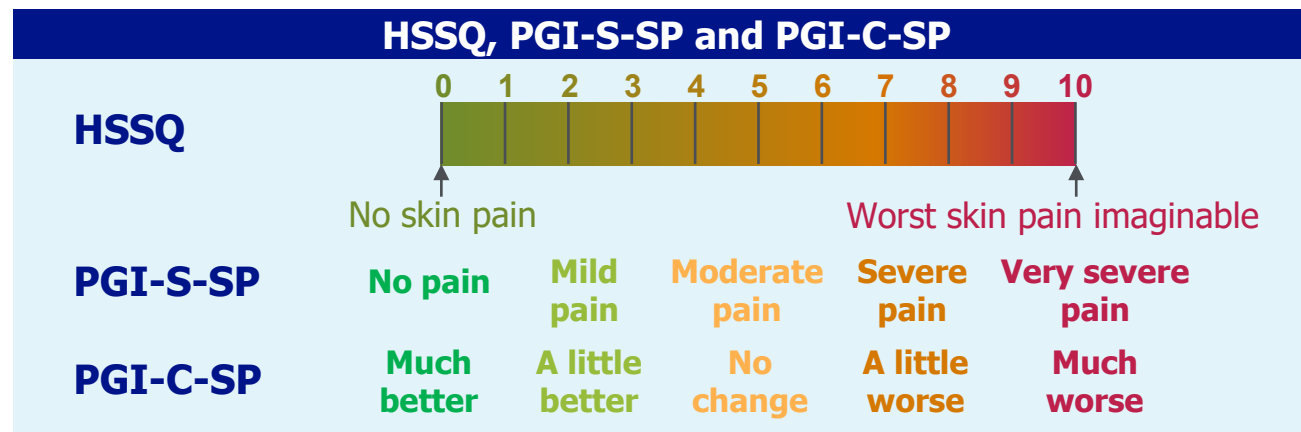
Background:

- Most patients with hidradenitis suppurativa (HS) experience **disease-associated pain**, considered one of the most important symptoms of HS impacting quality of life, which may be driven by **aberrant interleukin (IL)-17 signalling**.^{1,2}
- Bimekizumab (BKZ)**, a humanized IgG1 monoclonal antibody, inhibits IL-17F in addition to IL-17A.³

[a] PGI-S-SP and PGI-C-SP were used as anchors to derive meaningful improvement and severity thresholds for HSSQ items; [b] Clinically meaningful improvement was defined as a $\geq 30\%$ reduction and ≥ 1 -point reduction from baseline in patients with a baseline score ≥ 3 . HSSQ symptom items were scored 0–10 at baseline and every 2 weeks from Weeks 16–48; [c] Only patients with a baseline score ≥ 1 were included; [d] PGI-S-SP was assessed at baseline and Weeks 4, 16, 32 and 48; [e] PGI-C-SP was assessed at Weeks 4, 16, 32 and 48. 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. Ingram JR et al. Dermatology 2023; Epub ahead of print. BKZ: bimekizumab; HS: hidradenitis suppurativa; HSSQ: Hidradenitis Suppurativa Symptom Questionnaire; IgG1: immunoglobulin G1; IL: interleukin; MI: multiple imputation; mNRI: modified non-responder imputation; OC: observed case; PGI-C-SP: Patient Global Impression of Change in Severity of Skin Pain; PGI-S-SP: Patient Global Impression of Severity of Skin Pain.

Methods:

- HSSQ was developed to capture patient-perceived **severity of HS symptoms** over the past 7 days.⁴
- HSSQ skin pain response^b** and **HSSQ skin pain score=0^c** are reported using observed case (OC) and modified non-responder imputation (mNRI).
- Percentage** and **absolute change from baseline in HSSQ** data are reported using multiple imputation (MI).
- PGI-S-SP** and **PGI-C-SP** are reported using OC.^{a,d,e}

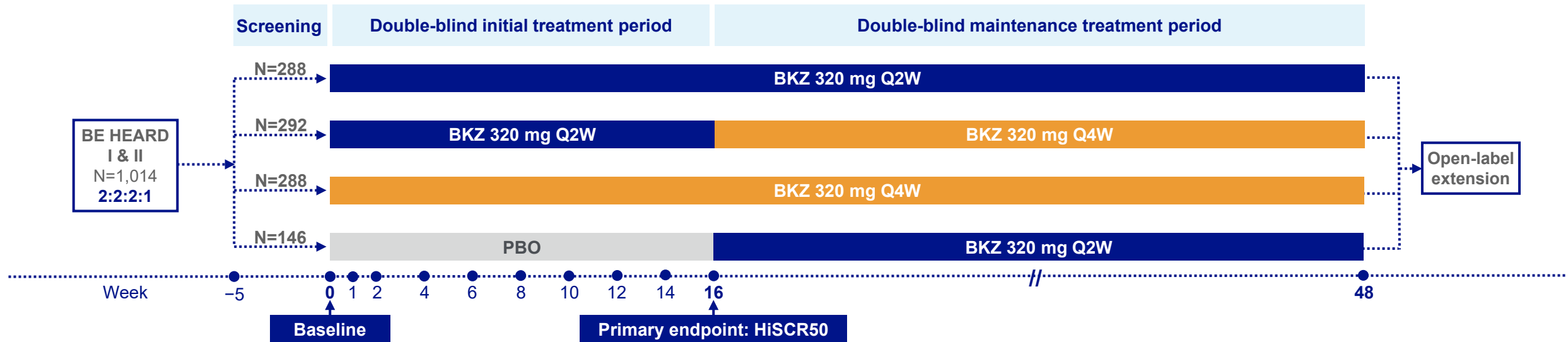


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BE HEARD I and II Study Design^{1,2}



Baseline Characteristics

n (%), unless otherwise stated

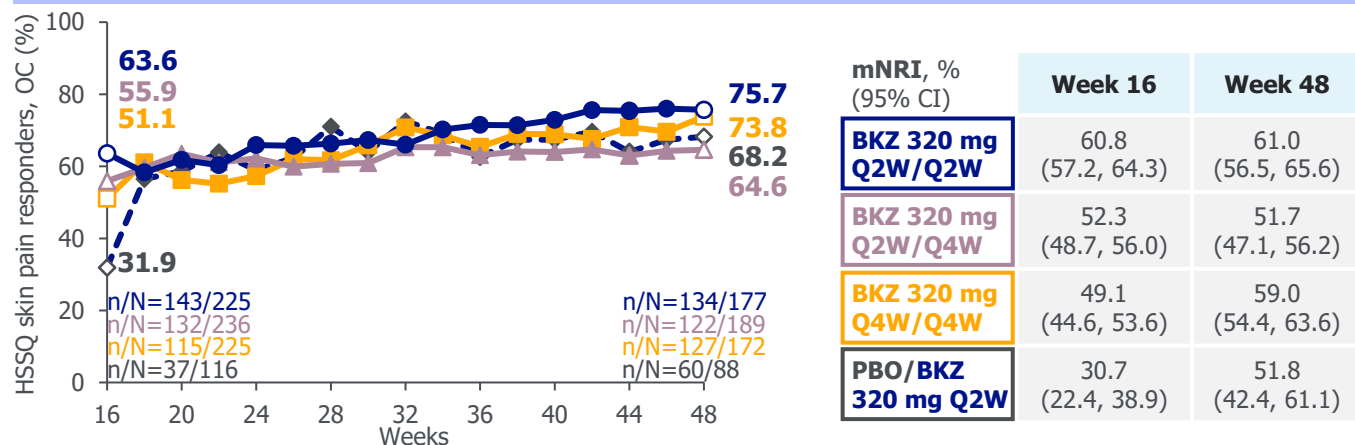
	BKZ 320 mg Q2W/Q2W (N=288)	BKZ 320 mg Q2W/Q4W (N=292)	BKZ 320 mg Q4W/Q4W (N=288)	PBO/BKZ 320 mg Q2W (N=146)
Age (years) mean ± SD	36.8 (12.4)	37.0 (12.4)	35.8 (11.6)	37.3 (12.8)
Sex, female	152 (52.8)	174 (59.6)	175 (60.8)	75 (51.4)
White	232 (80.6)	233 (79.8)	224 (77.8)	119 (81.5)
BMI (kg/m²) mean ± 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)
AN count , mean ± SD	14.7 (11.6)	17.2 (16.8)	17.7 (20.9)	14.4 (10.0)
DT count , mean ± SD	3.8 (4.4)	3.8 (4.4)	3.3 (4.1)	3.4 (3.8)
Hurley Stage				
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)
HSSQ skin pain score , mean ± SE	5.8 (0.1)	5.8 (0.1)	5.8 (0.1)	5.8 (0.2)
Prior biologic use	59 (20.5)	56 (19.2)	47 (16.3)	29 (19.9)
Baseline antibiotic use	29 (10.1)	28 (9.6)	18 (6.3)	11 (7.5)

Randomized set. At baseline, 1,014 patients with moderate to severe HS were randomized 2:2:2:1 to BKZ 320 mg Q2W to Week 48, BKZ 320 mg Q4W to Week 48, BKZ 320 mg Q2W to Week 16 then BKZ 320 mg Q4W to Week 48, or PBO to Week 16 then BKZ 320 mg Q2W to Week 48. **1.** BE HEARD I: www.clinicaltrials.gov/study/NCT04242446; **2.** BE HEARD II: www.clinicaltrials.gov/study/NCT04242498. AN: abscess and inflammatory nodule; BKZ: bimekizumab; BMI: body mass index; DT: draining tunnel; HiSCR50: ≥50% reduction from baseline in the total AN count with no increase from baseline in abscess or DT count; HS: hidradenitis suppurativa; HSSQ: Hidradenitis Suppurativa Symptom Questionnaire; PBO: placebo; Q2W: every 2 weeks; Q4W: every 4 weeks; SD: standard deviation; SE: standard error.

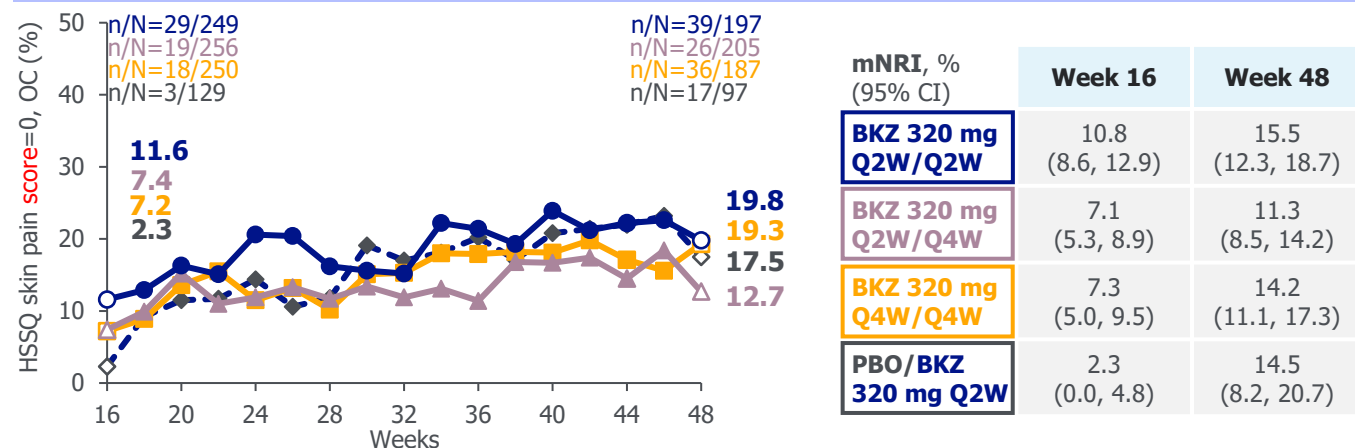
HSSQ Skin Pain Responders (OC, mNRI) and Change from Baseline Score (MI) in Week 16–48



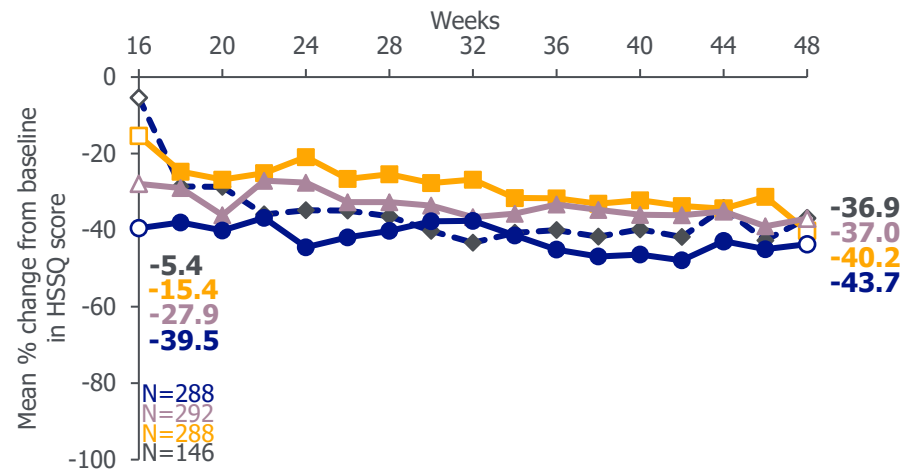
HSSQ skin pain responders^a (OC)



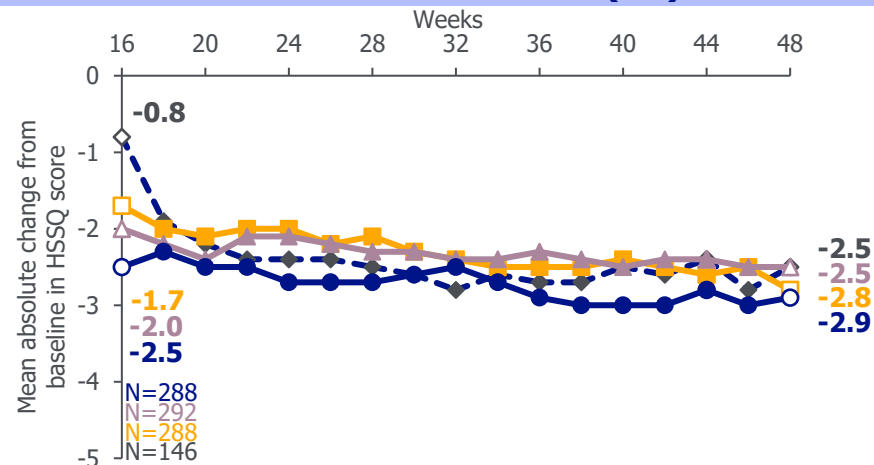
HSSQ skin pain score=0 responders^b (OC)



Percent change from baseline in HSSQ skin pain score from Week 16 (MI)

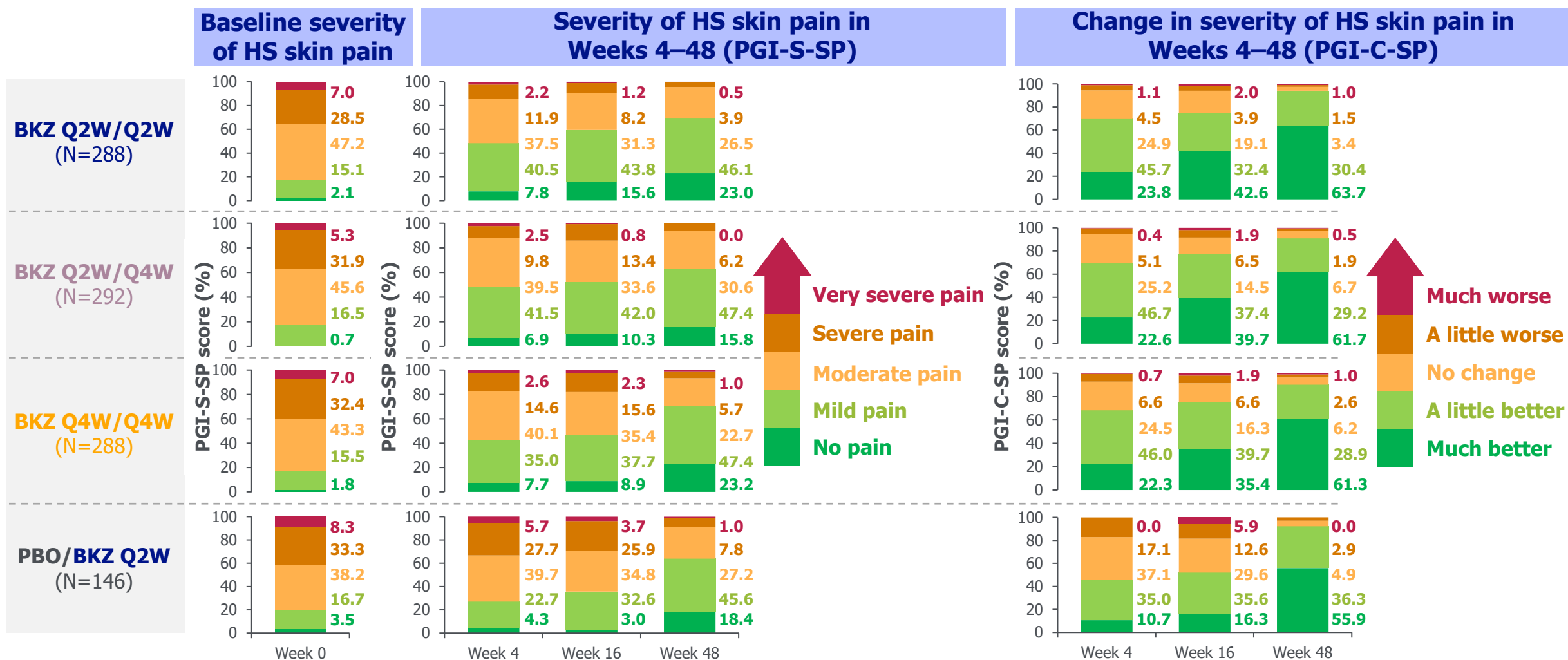


Absolute change from baseline in HSSQ skin pain score from Week 16 (MI)



Randomized set, N=1,014. [a] Clinically meaningful improvement was defined as a $\geq 30\%$ reduction and ≥ 1 -point reduction from baseline in patients with a baseline HSSQ score ≥ 3 . Individual symptom items were scored 0–10 at baseline and from Weeks 16–48; [b] Only patients with a baseline score ≥ 1 were included. mNRI: patients who discontinued due to lack of efficacy/adverse events, or received systemic antibiotics identified as rescue medication for HS by the principal investigator, were considered non-responders; MI was used for all other missing data. OC, n/N: denominator represents number of patients with a non-missing HSSQ score in the given week, and percentages were calculated accordingly. BKZ: bimekizumab; CI: confidence interval; HS: hidradenitis suppurativa; HSSQ: Hidradenitis Suppurativa Symptom Questionnaire; MI: multiple imputation; mNRI: multiple non-responder imputation; OC: observed case; PBO: placebo; Q2W: every 2 weeks; Q4W: every 4 weeks.

PGI-S-SP and PGI-C-SP to Week 48 (OC)^a



- Severity of HS skin pain **decreased over time**; most patients (>55%) indicated a '**much better**' change in severity of skin pain at Week 48.
- PBO-to-BKZ switchers saw **improvements from Week 16 after switch to BKZ**; responses were similar to continuous BKZ treatment.

Randomized set, N=1,014. [a] PGI-S-SP and PGI-C-SP were used as anchors to derive meaningful improvement and severity thresholds for HSSQ items. OC: all available data after an intercurrent event were summarized as recorded in the database, and all missing data were left missing. BKZ: bimekizumab; HS: hidradenitis suppurativa; OC: observed case; PBO: placebo; PGI-C-SP: Patient Global Impression of Change in Severity of Skin Pain; PGI-S-SP: Patient Global Impression of Severity of Skin Pain; Q2W: every 2 weeks; Q4W: every 4 weeks.

CONCLUSIONS:

- Patients treated with bimekizumab saw continuous reductions in skin pain up to 48 weeks as demonstrated by clinically meaningful improvements in skin pain across the various skin pain outcomes assessed.
- After switching to bimekizumab, patients who initially received placebo saw improvements in skin pain, with responses similar to patients receiving continuous bimekizumab treatment.
- These data support bimekizumab, which blocks IL-17F in addition to IL-17A, as a promising new therapeutic option.

Author Contributions: Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **LAVO, VS, HLT, EP, HF, JL, RR, PJ, EM, JCS**; Drafting of the publication, or reviewing it critically for important intellectual content: **LAVO, VS, HLT, EP, HF, JL, RR, PJ, EM, JCS**; Final approval of the publication: **LAVO, VS, HLT, EP, HF, JL, RR, PJ, EM, JCS**.

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