

Supplementary Material

Bimekizumab Pain Outcomes in Patients with Hidradenitis Suppurativa: Pooled 48-Week Results from BE HEARD I&II Phase 3 Randomized Clinical Trials

Pain and Therapy

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Supplementary Fig. 1 Frequency and timings of HSSDD and HSSQ assessments

Supplementary Fig. 2 Responder rates over time to Week 16: HSSDD worst ([A] ≥ 4 -point reduction from baseline [OC], [B] ≥ 4 -point reduction from baseline [mNRI], [C] ≥ 3 -point reduction from baseline [mNRI] and [D] 30% improvement and ≥ 1 -point reduction from baseline [mNRI]) and average ([E] 30% improvement and ≥ 1 -point reduction from baseline [mNRI]) skin pain

Supplementary Fig. 3 Responder rates over time to Week 48: HSSQ skin pain (30% improvement and ≥ 1 -point reduction from baseline [mNRI])

Supplementary Fig. 4 Mean absolute scores for (A) HSSDD worst skin pain, (B) HSSDD average skin pain and (C) HSSQ skin pain over time (MI)

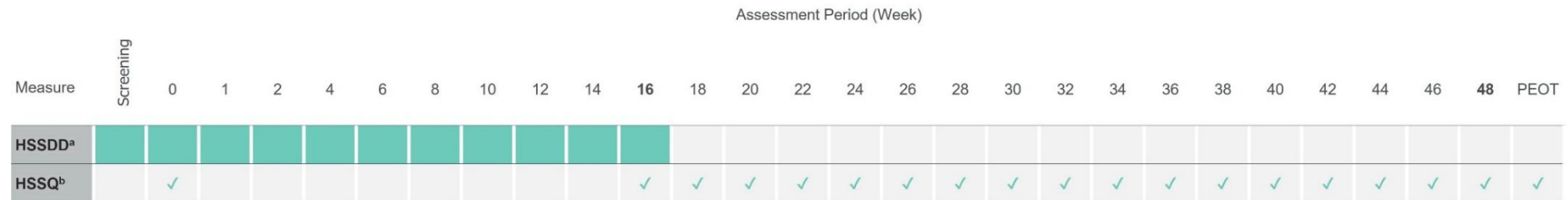
Supplementary Fig. 5 Change in HSSQ skin pain categories from baseline to Week 16, and Week 16 to Week 48 (OC)

Supplementary Fig. 6 Change in HSSQ skin pain categories from baseline to Week 48 (OC)

Supplementary Fig. 7 HSSQ skin pain score distribution at (A) baseline, (B) Week 16 and (C) Week 48 (OC)

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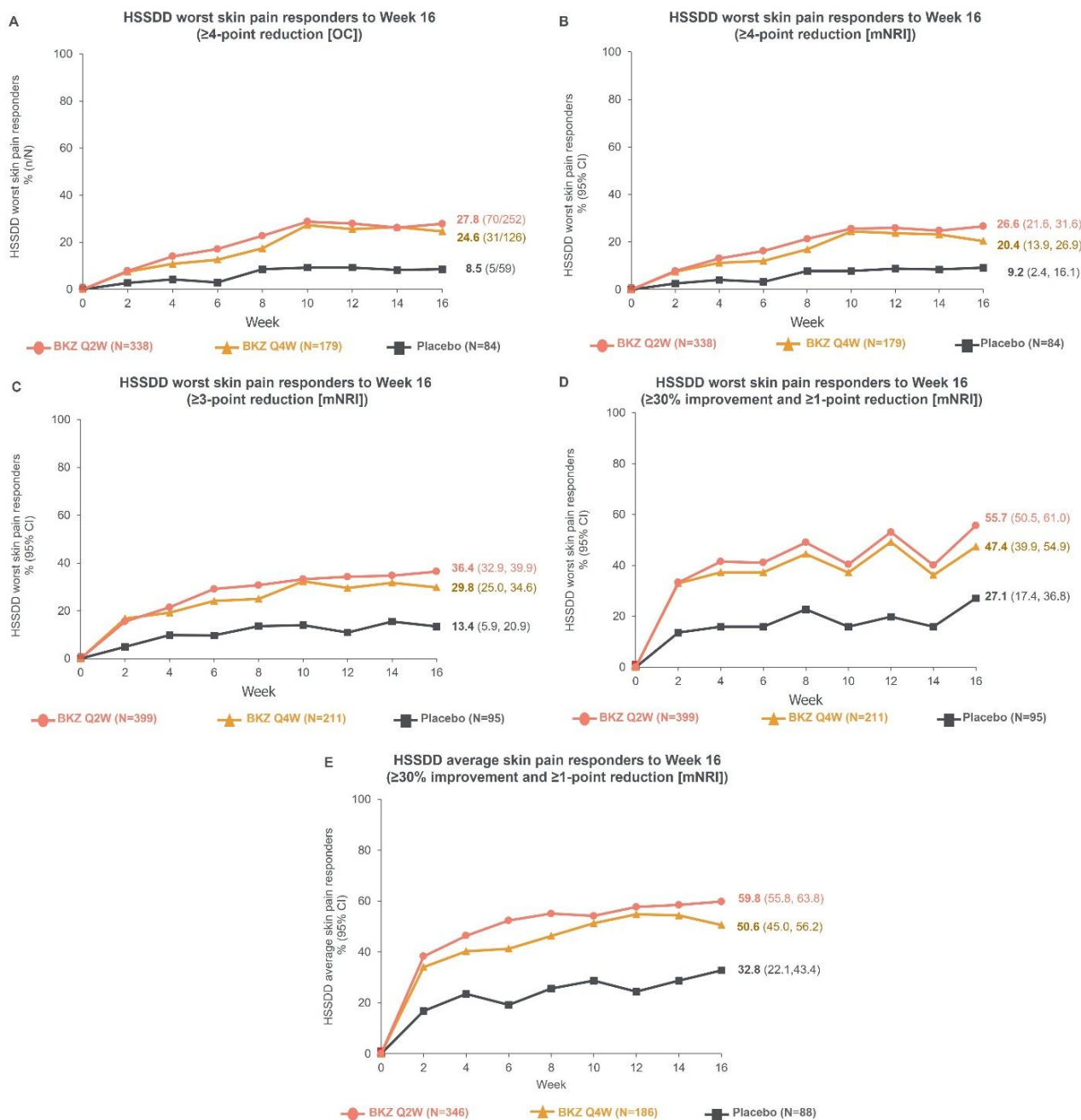
Supplementary Fig. 1 Frequency and timings of HSSDD and HSSQ assessments



^aHSSDD was assessed daily, shown by colored squares. HSSDD worst skin pain assessed patients' pain perception in the past 24 hours using the prompt "please rate your skin pain from your HS lesions at its worst in the past 24 hours". HSSDD average skin pain assessed patients' pain perception in the past 24 hours using the prompt "please rate your skin pain from your HS lesions on an average in the past 24 hours". ^bHSSQ was assessed at baseline and then every other week from Weeks 16–48, shown by tick marks. HSSQ skin pain assessed patients' pain perception in the last 7 days using the prompt "please rate your skin pain from your HS lesions in the past 7 days". Abbreviations: HS: hidradenitis suppurativa; HSSDD: Hidradenitis Suppurativa Symptom Daily Diary; HSSQ: Hidradenitis Suppurativa Symptom Questionnaire; PEOT: premature end of treatment.

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Supplementary Fig. 2 Responder rates over time to Week 16: HSSDD worst ([A] ≥ 4 -point reduction from baseline [OC], [B] ≥ 4 -point reduction from baseline [mNRI], [C] ≥ 3 -point reduction from baseline [mNRI] and [D] 30% improvement and ≥ 1 -point reduction from baseline [mNRI]) and average ([E] 30% improvement and ≥ 1 -point reduction from baseline [mNRI]) skin pain

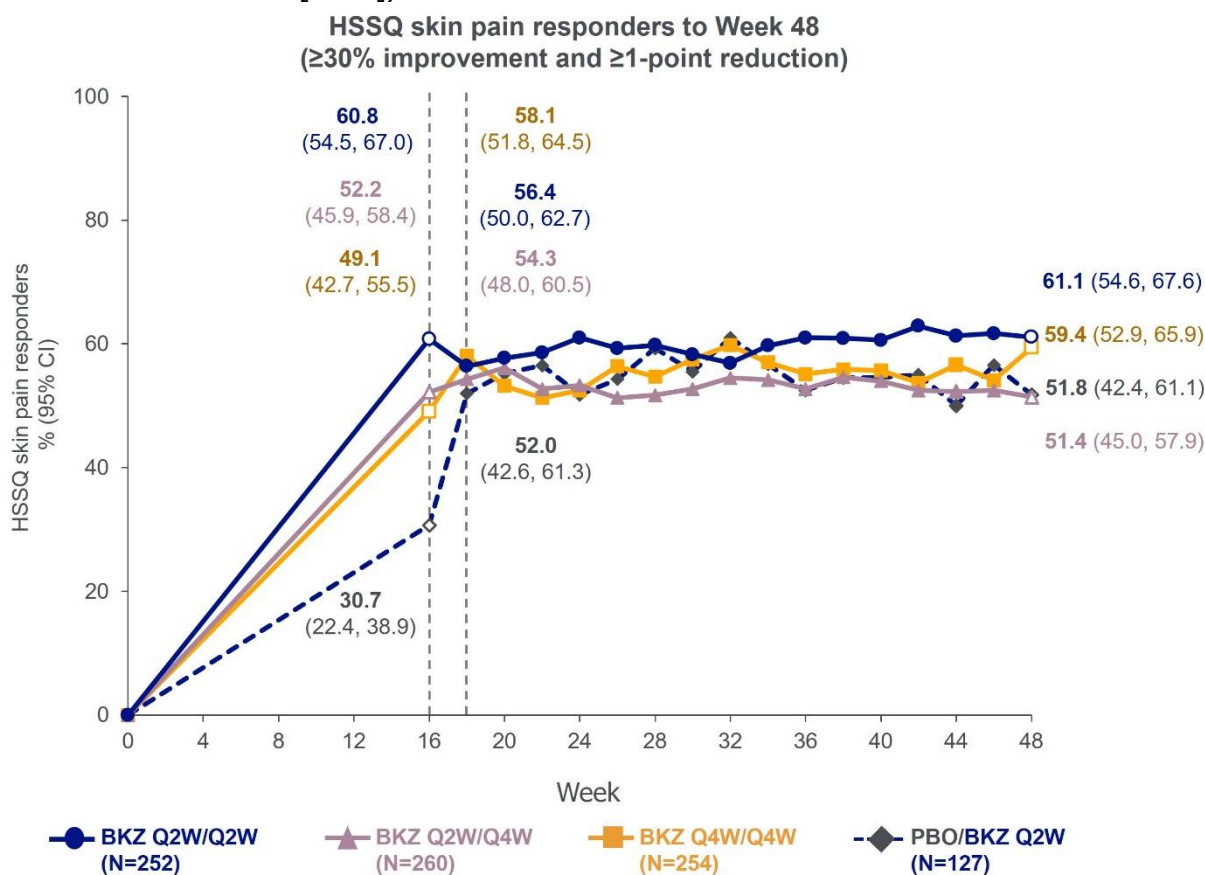


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Randomized set, N=1,014. Patients included in this analysis had a baseline HSSDD worst or average skin pain score of ≥ 3 , except for the ≥ 4 -point reduction graph, for which patients had baseline HSSDD worst skin pain score of ≥ 4 . HSSDD worst skin pain response, defined as a ≥ 3 -point reduction from a baseline HSSDD worst skin pain score of ≥ 3 , is a statistically controlled ranked secondary endpoint, all others were exploratory. 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 the number of patients with non-missing HSSDD data at the visit, and percentages are calculated accordingly. Abbreviations: BKZ: bimekizumab; HSSDD: Hidradenitis Suppurativa Symptom Daily Diary; mNRI: modified non-responder imputation; OC: observed case; Q2W: every 2 weeks; Q4W: every 4 weeks.

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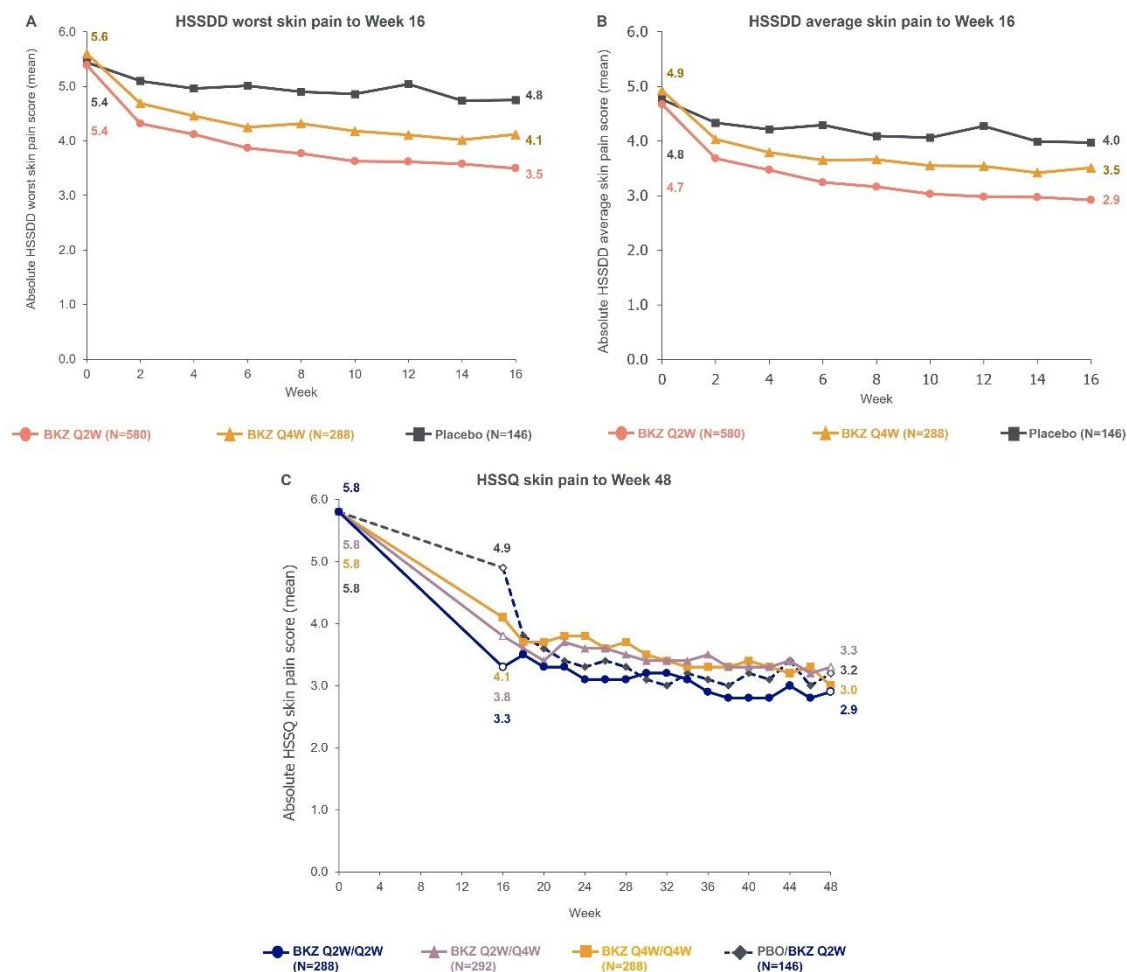
Supplementary Fig. 3 Responder rates over time to Week 48: HSSQ skin pain (30% improvement and ≥ 1 -point reduction from baseline [mNRI])



Randomized set, N=1,014. 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. HSSQ skin pain responder analysis was an exploratory endpoint. 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. Abbreviations: BKZ: bimekizumab; CI: confidence interval; HSSQ: Hidradenitis Suppurativa Symptom Questionnaire; mNRI: modified non-responder imputation; PBO: placebo; Q2W: every 2 weeks; Q4W: every 4 weeks.

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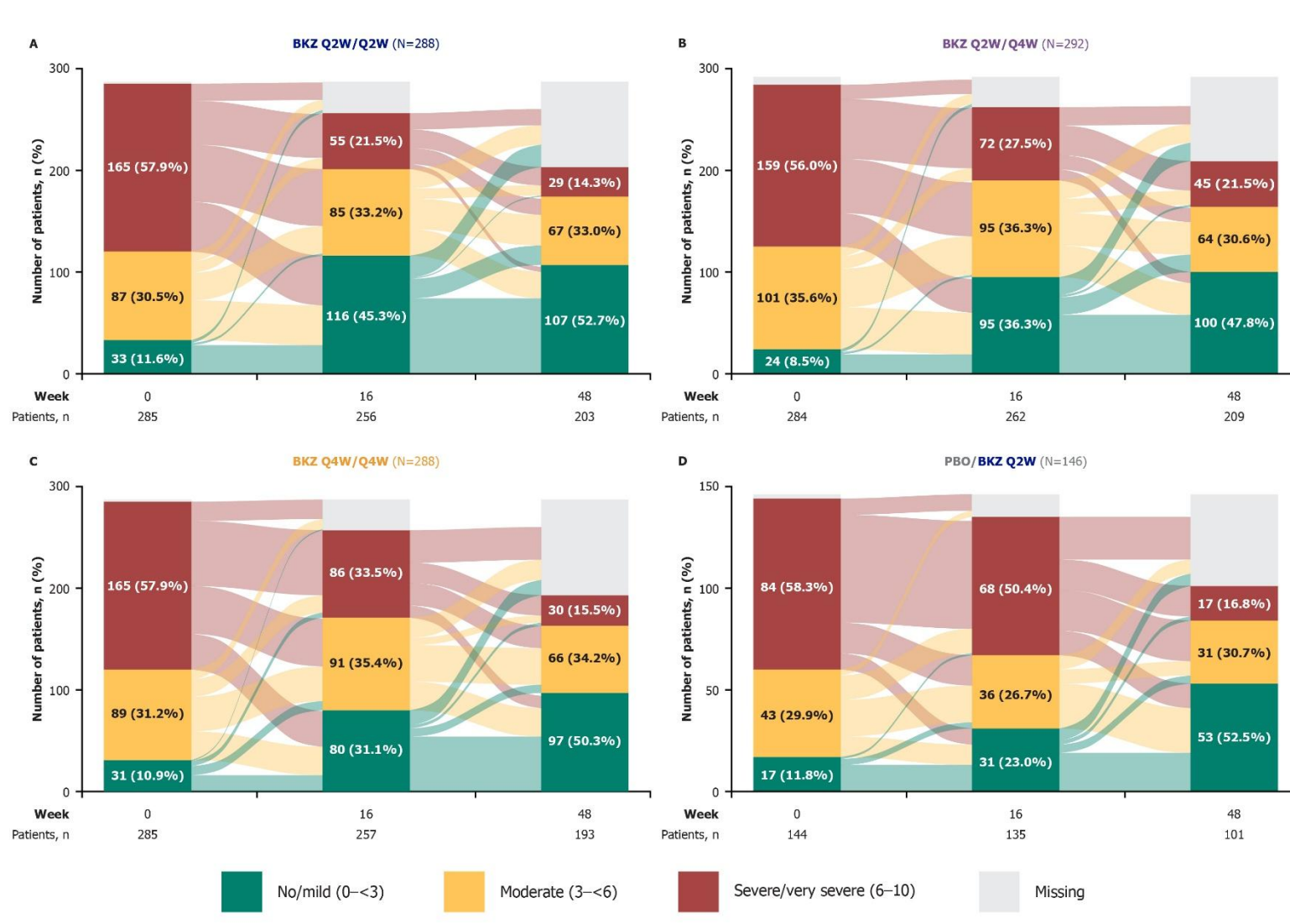
Supplementary Fig. 4 Mean absolute scores for (A) HSSDD worst skin pain, (B) HSSDD average skin pain and (C) HSSQ skin pain over time (MI)



Randomized set, N=1,014. MI: patients who discontinued study treatment due to lack of efficacy or adverse events, or who took systemic antibiotics as rescue medication for HS as defined by the principal investigator, were set to missing and subsequently imputed using MI. HSSDD absolute change from baseline in worst skin pain score at Week 16 is a statistically controlled ranked secondary endpoint for BE HEARD I and II, all others are exploratory endpoints. Abbreviations: BKZ: bimekizumab; HSSDD: Hidradenitis Suppurativa Symptom Daily Diary; MI: multiple imputation; PBO: placebo; Q2W: every 2 weeks; Q4W: every 4 weeks.

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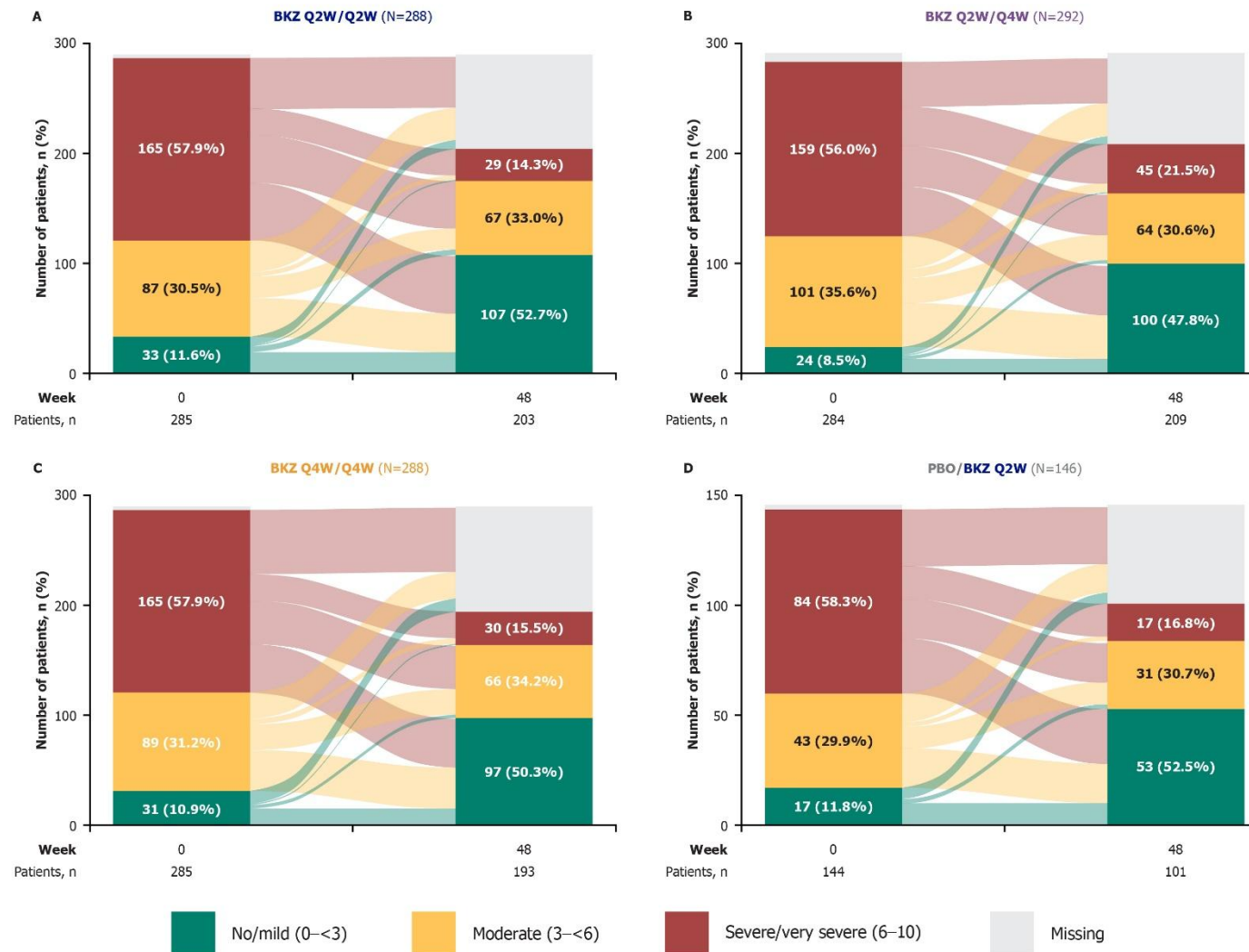
Supplementary Fig. 5 Change in HSSQ skin pain categories from baseline to Week 16, and Week 16 to Week 48 (OC)



Percentages are calculated using the number of patients with any assessment at each visit. BKZ: bimekizumab; HSSQ: Hidradenitis Suppurativa Symptom Questionnaire; OC: observed case; PBO: placebo; Q2W: every 2 weeks; Q4W: every 4 weeks.

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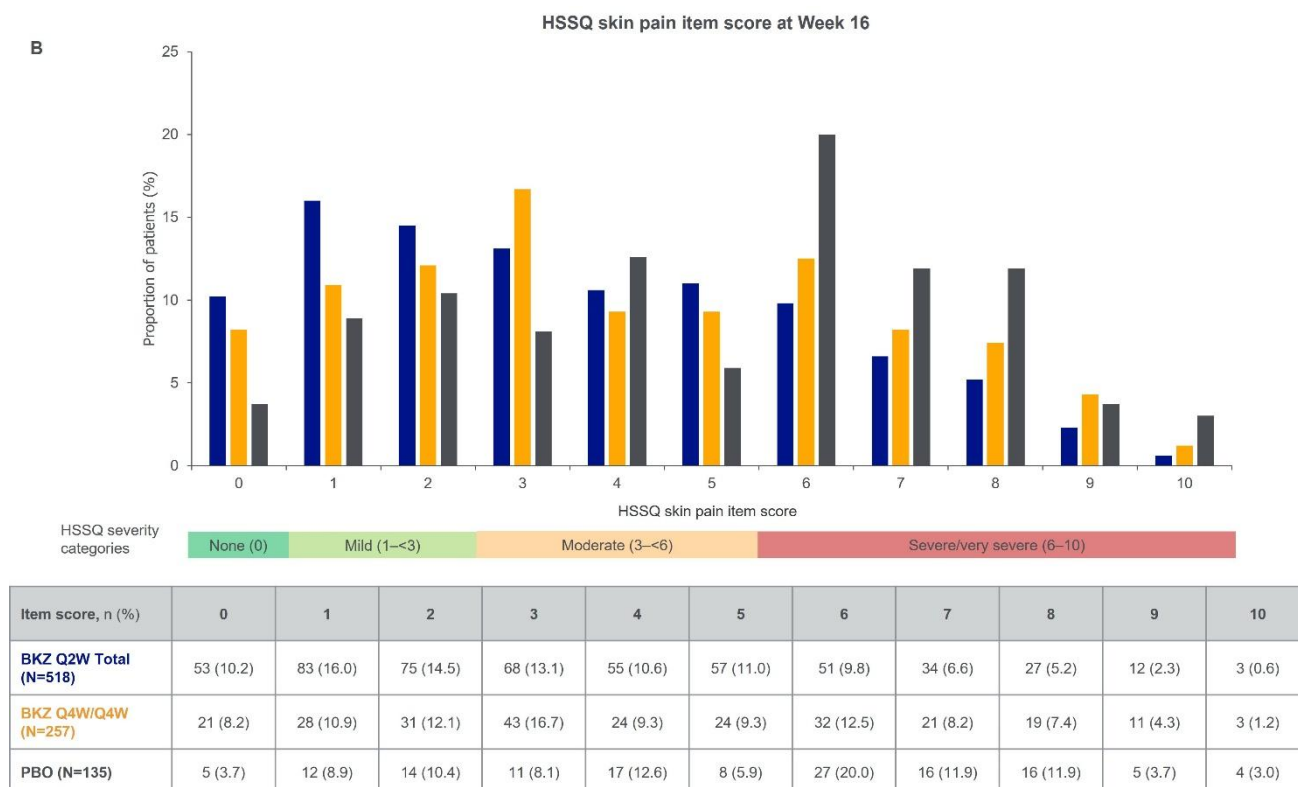
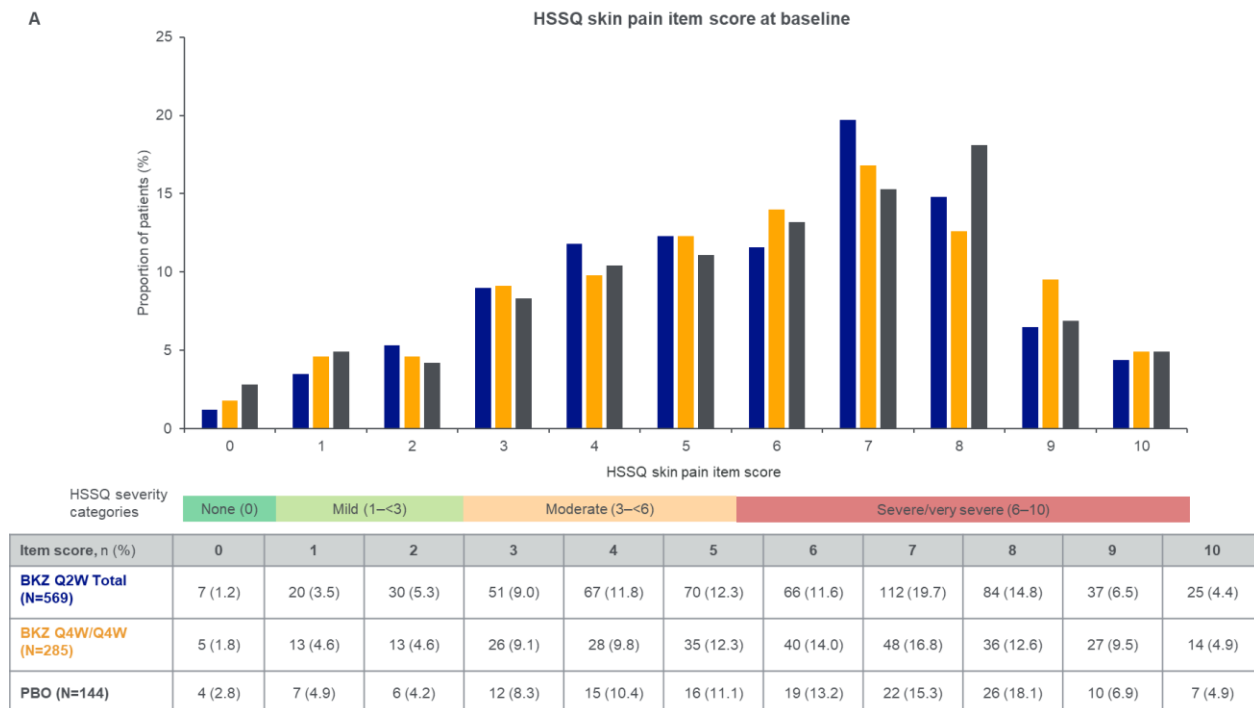
Supplementary Fig. 6 Change in HSSQ skin pain categories from baseline to Week 48 (OC)



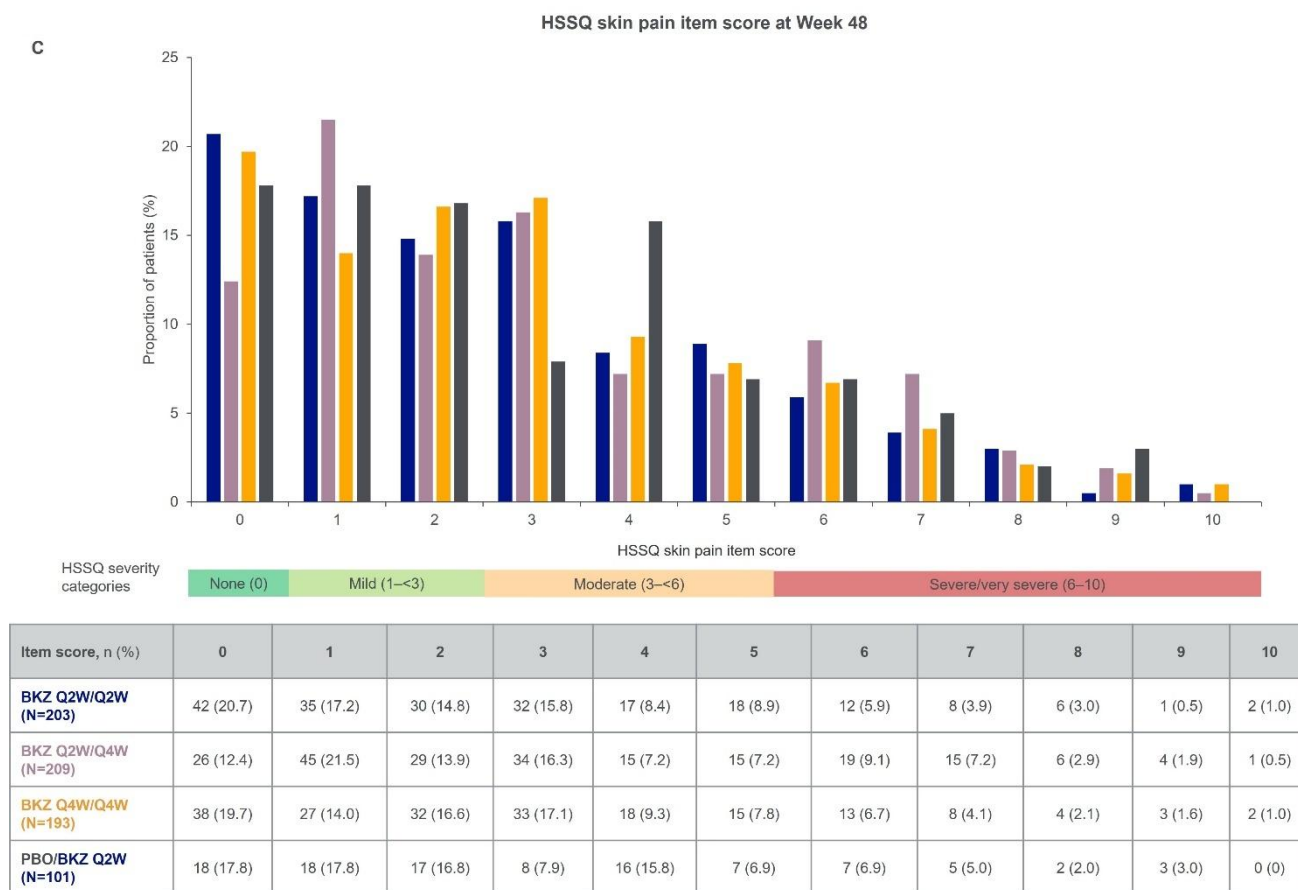
Percentages are calculated using the number of patients with any assessment at each visit. BKZ: bimekizumab; HSSQ: Hidradenitis Suppurativa Symptom Questionnaire; OC: observed case; PBO: placebo; Q2W: every 2 weeks; Q4W: every 4 weeks.

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Supplementary Fig. 7 HSSQ skin pain score distribution at (A) baseline, (B) Week 16 and (C) Week 48 (OC)



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BKZ Q2W Total includes all patients randomized to receive BKZ Q2W from baseline. HSSQ skin pain score distribution was an exploratory endpoint. Abbreviations: BKZ; bimekizumab; HSSQ: Hidradenitis Suppurativa Symptom Questionnaire; OC: observed case; PBO: placebo; Q2W: every 2 weeks; Q4W: every 4 weeks.