Bimekizumab efficacy and safety through 3 years in patients with hidradenitis suppurativa: Results from the phase 3 BE HEARD I&II trials and their open-label extension BE HEARD EXT

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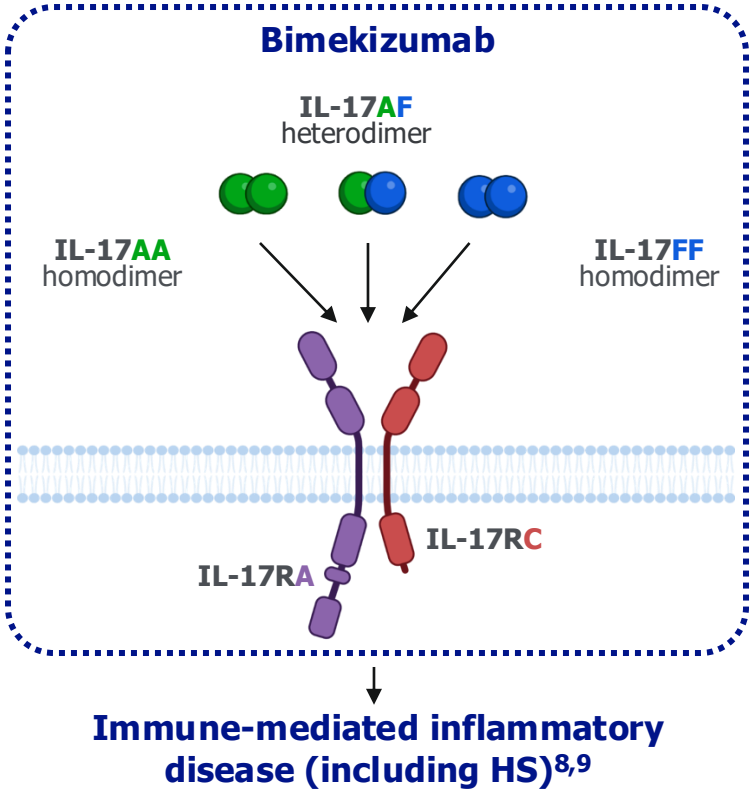
Background

- **Hidradenitis suppurativa (HS)** is a chronic, relapsing, inflammatory skin disease, characterised by painful lesions which cause disability and diminish patients' health-related quality of life (HRQoL).[1–3]
- **Long-term disease control** is essential to prevent irreversible damage and disease progression.[4]
- **Bimekizumab (BKZ)** is a humanised monoclonal IgG1 antibody that selectively inhibits IL-17A and F; BKZ has demonstrated **clinically meaningful improvements** in patients with HS **over 2 years** of treatment.[5–7]

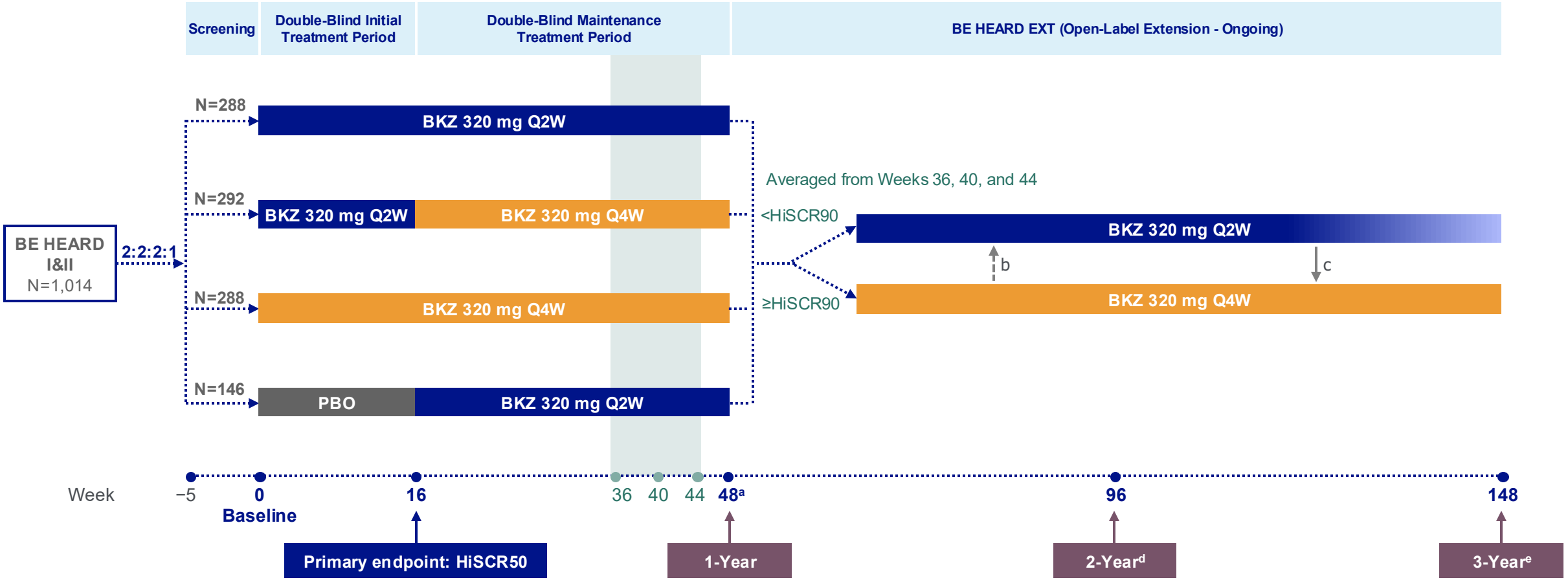


OBJECTIVE: To report **efficacy** and **safety** of BKZ in patients with moderate to severe HS **up to 3 years** (148 weeks) for the pooled phase 3 BE HEARD I&II trials and the open-label extension (OLE) BE HEARD EXT.[6,10]

1. Garg A *et al*. J Am Acad Dermatol 2020;82:366–76; **2**. Kaur AP *et al*. Skin Health Dis 2023;3:e214; **3.** Montero-Vilchez T *et al*. Int J Environ Res Public Health 2021;18:6709; **4.** Ramos FJM *et al*. ACTAS Dermosifiliogr 2024;115:213–14; **5.** Adams R *et al*. Front Immunol 2020;11:1894; **6.** Kimball AB *et al*. Lancet 2024;403:2504–19; **7.** Zouboulis CC. EADV 2024; Presentation 7925; **8.** Figure adapted from: Patel DD et al. Ann Rheum Dis 2013;72(Suppl 2):ii116–23; **9**. Zouboulis CC et al. Exp Dermatol 2020;29:1154–70; **10.** BE HEARD EXT: https://clinicaltrials.gov/study/NCT04901195. BKZ: bimekizumab; HRQoL: health-related quality of life; HS: hidradenitis suppurativa; IL: interleukin; IL-17R: interleukin-17 receptor; OLE: open-label extension; RA: receptor A; RC: receptor C.

Study Design

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



[a] Patients who completed Week 48 of BE HEARD I&II could enrol 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]** Patients receiving bimekizumab 320 mg Q4W in BE HEARD EXT who could not sustain an average improvement from baseline in AN count of >90% over any 8-week period or achieve >75% improvement from baseline in AN count at any single visit, could have their dose increased to Q2W at investigator discretion. **[c]** Following approval of a protocol amendment in the third year, all BE HEARD EXT patients were to receive BKZ Q4W. **[d]** Cumulative 2-year data (48 weeks in BE HEARD I&II and 48 weeks in BE HEARD EXT). **[e]** Cumulative 3-year data (48 weeks in BE HEARD I&II and 96 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. AN: abscesses and inflammatory nodules; 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; PBO; placebo; Q2W: every two weeks; Q4W: every four weeks.

Outcomes

Efficacy

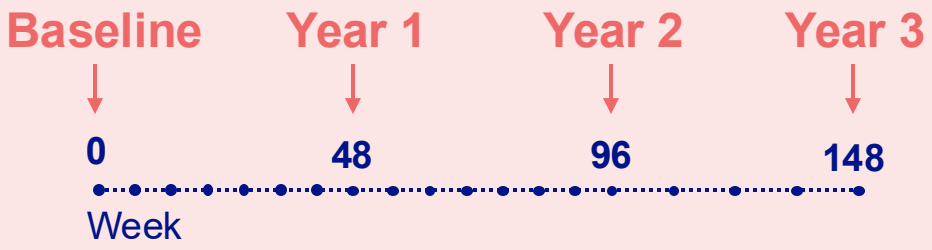
- **Efficacy set**: Patients **randomised to BKZ 320 mg** at baseline in BE HEARD I&II who then entered BE HEARD EXT (BKZ Total).

≥50/75/90/100% HS Clinical Response (HiSCR50/75/90/100) rates

Dermatology Life Quality Index (DLQI) 0/1 response rates[a]

Absolute change from baseline in draining tunnel (DT) count

- Timepoints: Over time to Year 3

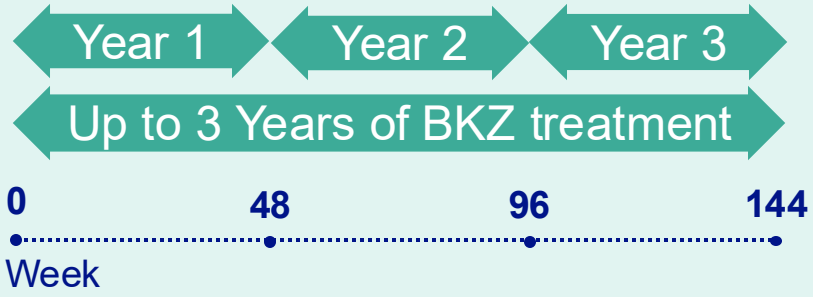


Safety

- **Safety set**: Patients who received **≥1 dose** of BKZ.

Treatment-emergent adverse events (TEAEs)

- Time periods:



[a] DLQI score ranges 0–30, DLQI 0/1 response defined as total score of 0 or 1 (no effect at all on patients' life). BKZ: bimekizumab; DLQI: Dermatology Life Quality Index; DT: draining tunnel; HiSCR: Hidradenitis Suppurativa Clinical Response; HiSCR50/75/90/100: ≥50%/75%/90%/100% reduction from baseline in the total abscess and inflammatory nodule count with no increase from baseline in abscess or draining tunnel count; HS: hidradenitis suppurativa; TEAE: treatment-emergent adverse event.

Imputation Methods

Observed case (OC)

Patients who discontinued for **any reason**: left as **MISSING**

Patients who did not discontinue: For visits with missing data, patients were left as **MISSING**

Modified non-responder imputation (mNRI)[a]

Patients who discontinued due to **adverse events** or **lack of efficacy**: imputed as **NON-RESPONSE**

Patients who did not discontinue: For visits with missing data, a **MULTIPLE IMPUTATION** model was applied

[a] For mNRI, discontinuation due to adverse event or lack of efficacy constitutes as an intercurrent event. Intermittent missing data were imputed using multiple imputation with Markov Chain Monte Carlo (MCMC) method followed by monotone regression for monotone missing data. Lesion counts were imputed and then dichotomised to obtain the response status. Patients who experienced an intercurrent event were treated as non-responders following the intercurrent event.
MCMC: Markov Chain Monte Carlo; mNRI: modified non-responder imputation; OC: observed case.

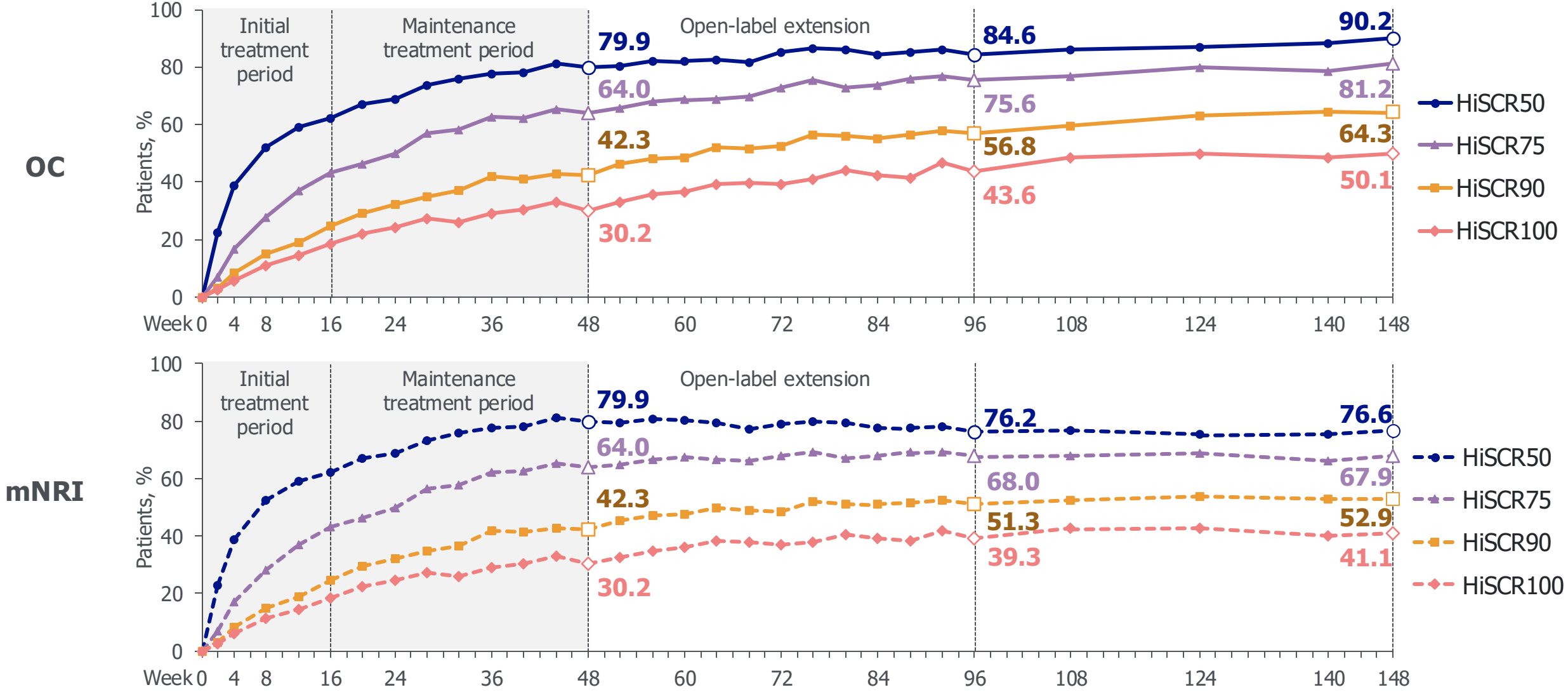
Baseline Characteristics

- Of 1,014 total patients, **556 patients** randomised to BKZ at baseline in BE HEARD I&II completed Week 48 and entered BE HEARD EXT; of these, 367 completed Week 148.
- Population was consistent with moderate to severe HS patient populations seen in clinical trials.[1–3]

	BKZ Total[a] (Efficacy set) N=556	Patients with ≥1 dose BKZ (Safety set) N=995
Age, years, mean (SD)	36.3 (12.2)	36.7 (12.2)
Sex, female, n (%)	299 (53.8)	564 (56.7)
Racial group, White, n (%)	448 (80.6)	796 (80.0)
BMI, kg/m², mean (SD)	32.5 (7.8)	33.0 (8.1)
Duration of disease, years, mean (SD)	7.4 (7.1)	8.0 (7.8)
Hurley stage, n (%)		
II	303 (54.5)	553 (55.6)
III	253 (45.5)	442 (44.4)
DLQI total score, mean (SD)	11.0 (6.8)	11.2 (6.9)
Prior biologic use,[b] n (%)	112 (20.1)	192 (19.3)
Baseline antibiotic use, n (%)	54 (9.7)	83 (8.3)

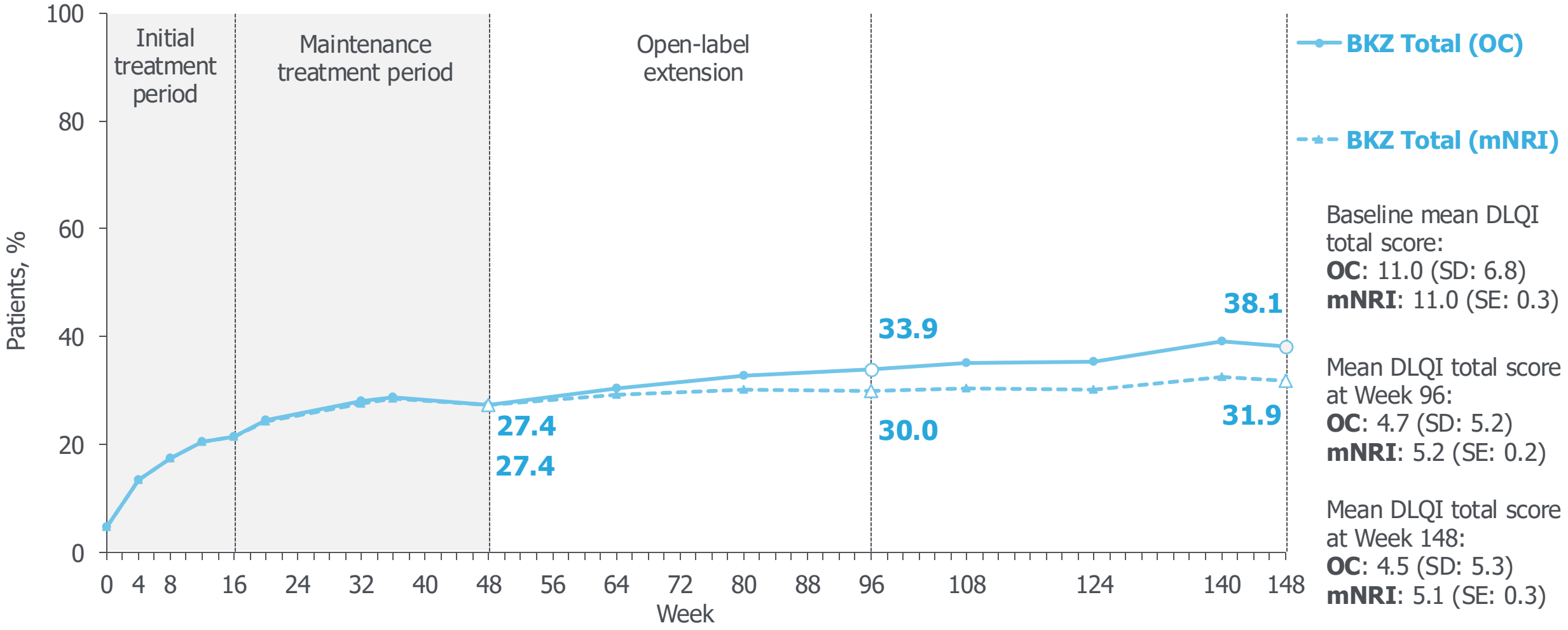
OLE set for efficacy set; Pool S3 for safety set. **[a]** BKZ Total comprised patients randomised to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT; **[b]** Patients received prior biologic therapy for any indication. **1.** Glatt S *et al*. JAMA Dermatol 2021;157:1279–88; **2.** Kimball AB *et al*. N Engl J Med 2016;375:422–34; **3.** Kimball AB *et al*. Lancet 2023;401:747–61. BKZ: bimekizumab; BMI: body mass index; DLQI: Dermatology Life Quality Index; HS: hidradenitis suppurativa; OLE: open-label extension; SD: standard deviation.

HiSCR in BKZ Total (OC, mNRI)



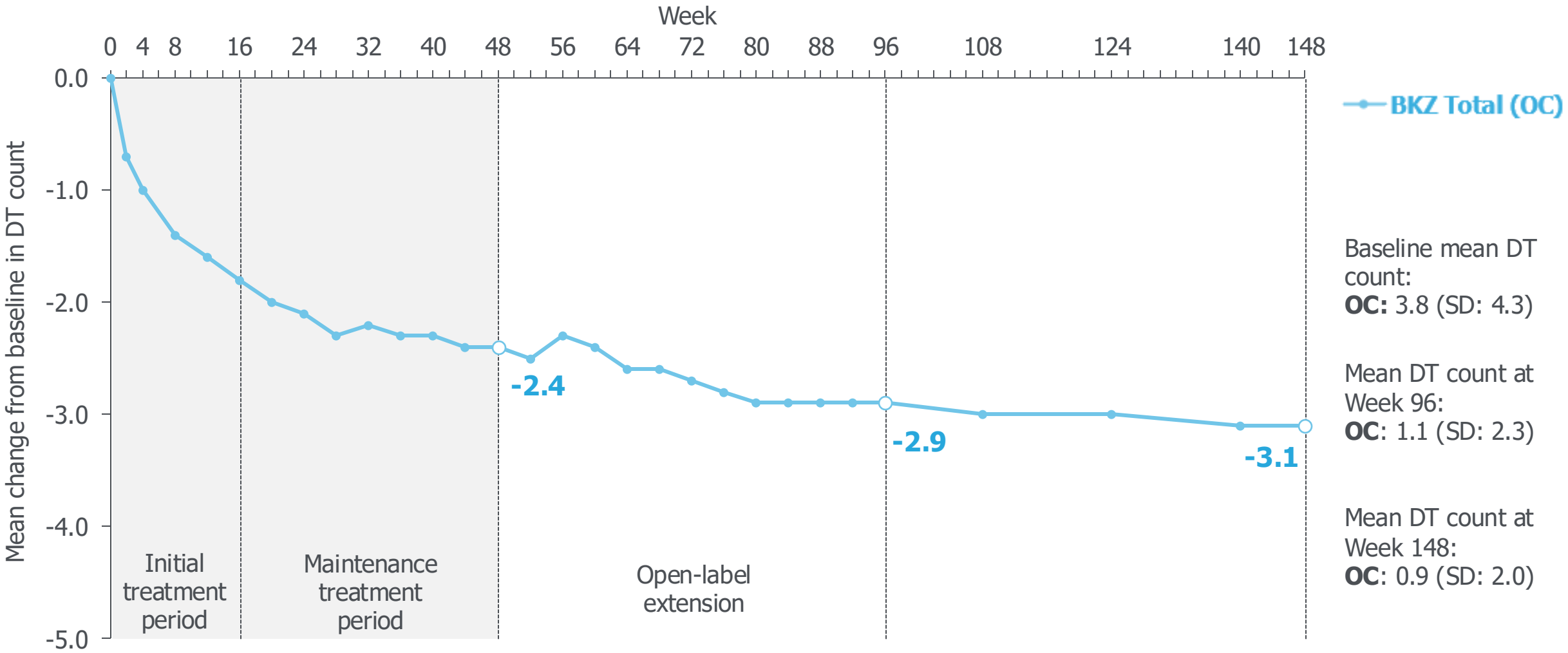
OLE set. Data for patients in BKZ Total are presented. BKZ Total comprised patients randomised to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT. OC, n/N: denominator represents number of patients with a lesion assessment in the given week, and percentages are calculated accordingly. Week 48 n/N: HiSCR50, 444/556; HiSCR75, 356/556; HiSCR90, 235/556; HiSCR100, 168/556; Week 96 n/N: HiSCR50, 378/447; HiSCR75, 338/447; HiSCR90, 254/447; HiSCR100, 195/447; Week 148 n/N: HiSCR50, 331/367; HiSCR75, 298/367; HiSCR90, 236/367; HiSCR100, 184/367. Of the 146 patients who were randomised to placebo at baseline in BE HEARD I&II, the proportions achieving Week 16 HiSCR thresholds were: HiSCR50: 48/135; HiSCR75: 25/135; HiSCR90: 13/35; HiSCR100: 8/135. For mNRI, discontinuation due to adverse event or lack of efficacy constituted an intercurrent event. Patients who experienced an intercurrent event were treated as non-responders following the intercurrent event. BKZ: bimekizumab HiSCR: Hidradenitis Suppurativa Clinical Response; HiSCR50/75/90/100: ≥50%/75%/90%/100% reduction from baseline in the total abscess and inflammatory nodule count with no increase from baseline in abscess or draining tunnel count; mNRI: modified non-responder imputation; OC: observed case; OLE: open-label extension.

DLQI 0/1 Response Rates[a] in BKZ Total (OC, mNRI)



OLE set. Data for patients in BKZ Total are presented. BKZ Total comprised patients randomised to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT. Week 48 n/N: 151/551, Week 96 n/N: 151/445, Week 148 n/N: 137/360. OC, n/N: denominator represents number of patients with a DLQI assessment in the given week, and percentages are calculated accordingly. For mNRI, discontinuation due to adverse event or lack of efficacy constituted an intercurrent event. Patients who experienced an intercurrent event were treated as non-responders following the intercurrent event. **[a]** DLQI 0/1 response defined as total score of 0 or 1 (no effect at all on patients' life); DLQI score ranges 0–30.
BKZ: bimekizumab; DLQI: Dermatology Life Quality Index; mNRI: modified non-responder imputation; OC: observed case; OLE: open-label extension; SD: standard deviation; SE: standard error.

Mean Absolute Change from Baseline in DT Count in BKZ Total (OC)



OLE set. Data for patients in BKZ Total are presented. BKZ Total comprised patients randomised to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT. Week 48 n: 556, Week 96 n: 447, Week 148 n: 367. OC, n: represents number of patients with a non-missing lesion count assessment in the given week and a non-zero baseline lesion count assessment. Baseline mean total abscess and inflammatory nodule count (SD): 16.9 (18.5). BKZ: bimekizumab; DT: draining tunnel; OC: observed case; OLE: open-label extension; SD: standard deviation.

Incidence of TEAEs per 100 Patient-Years

EAIR/100 PY (95% CI)	Patients with ≥1 dose BKZ N=995			
	Year 1 (Week 0–48) Total exposure: 7.8 per 100 PY	Year 2 (Week >48–96) Total exposure: 5.9 per 100 PY	Year 3 (Week >96–144) Total exposure: 4.7 per 100 PY	Up to 3 Years (Week 0–144) Total exposure: 18.4 per 100 PY
Any TEAE	261.9 (244.5, 280.3)	237.2 (218.3, 257.2)	168.3 (152.2, 185.6)	226.8 (212.4, 242.0)
Serious TEAEs	8.2 (6.3, 10.5)	7.9 (5.7, 10.5)	7.9 (5.5, 10.9)	7.2 (6.0, 8.6)
Severe TEAEs	10.4 (8.2, 12.9)	7.2 (5.2, 9.8)	7.0 (4.8, 9.9)	7.7 (6.4, 9.1)
TEAEs leading to discontinuation	8.7 (6.8, 11.1)	4.8 (3.2, 7.0)	3.0 (1.7, 5.1)	6.0 (5.0, 7.3)
Any TEAE leading to death[a]	0.1 (0.0, 0.7)	0.3 (0.0, 1.2)	0	0.2 (0.0, 0.5)
Most common TEAEs[b]				
Hidradenitis	25.5 (21.9, 29.5)	27.4 (23.1, 32.2)	18.2 (14.4, 22.7)	20.7 (18.5, 23.2)
Coronavirus infection	13.6 (11.1, 16.5)	23.7 (19.7, 28.2)	7.5 (5.2, 10.5)	15.3 (13.4, 17.4)
Oral candidiasis	15.2 (12.5, 18.2)	12.3 (9.5, 15.6)	10.3 (7.5, 13.8)	10.4 (8.9, 12.1)
Serious infections	1.9 (1.1, 3.2)	1.7 (0.8, 3.2)	3.2 (1.8, 5.3)	2.0 (1.4, 2.8)
Fungal infections	34.8 (30.5, 39.6)	25.0 (20.9, 29.7)	22.3 (18.0, 27.2)	24.4 (21.9, 27.1)
Any malignancies	0.5 (0.1, 1.3)	1.0 (0.4, 2.2)	0.6 (0.1, 1.9)	0.7 (0.4, 1.2)
Any hepatic events	6.0 (4.4, 8.0)	5.8 (4.0, 8.2)	4.6 (2.8, 7.0)	4.7 (3.8, 5.9)
Adjudicated suicidal ideation and behaviour[c]	0.8 (0.3, 1.7)	0.9 (0.3, 2.0)	0.4 (0.1, 1.6)	0.7 (0.4, 1.2)
Definite or probable adjudicated IBD[d]	0.9 (0.4, 1.8)	0.5 (0.1, 1.5)	0.2 (0.0, 1.2)	0.5 (0.3, 1.0)

Data presented relates to the initial treatment and maintenance periods of BE HEARD I&II, and the open-label extension BE HEARD EXT (total of 3 years). TEAEs were coded using MedDRA v19.0 and reported for up to 3 years of BKZ treatment using EAIRs per 100 participant-years. **[a]** Up to 3 years, three patients died; one patient with significant cardiovascular history died due to congestive heart failure, one patient died due to possible central nervous system infection in the context of deteriorating HS and one patient with history of gynaecological cancer died of leiomyosarcoma; **[b]** The three most common TEAEs are organised in descending order based on the Up to 3 Years data; **[c]** There were no events of completed suicide; **[d]** Among the eight patients with a history of IBD, two patients experienced flares up to 3 years. BKZ: bimekizumab; CI: confidence interval; EAIR: exposure-adjusted incidence rate; HS: hidradenitis suppurativa; IBD: inflammatory bowel disease; MedDRA: Medical Dictionary for Regulatory Activities; PY: patient-years; TEAEs: treatment-emergent adverse events.

Conclusions

Clinical improvements at Year 1 were **maintained** or **further improved** through **3 years** of treatment.

Draining tunnel and **health-related quality of life** improvements were also **maintained** through **3 years**.

Bimekizumab was **well-tolerated** and **no new safety signals** were identified.

These data highlight the **depth and durability of response** to bimekizumab treatment in patients with moderate to severe hidradenitis suppurativa.

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