Bimekizumab efficacy and safety through 2 years in patients with hidradenitis suppurativa: Results from the phase 3 BE HEARD I&II trials and open-label extension BE HEARD EXT

Christos C. Zouboulis,[1,2] Amit Garg,[3] Christopher J. Sayed,[1,4] Gregor Jemec,[1,5,6] Georgios Kokolakis,[1,7] John R. Ingram,[1,8] Akimichi Morita,[9] Pratiksha Dokhe,[10] Ingrid Pansar,[11] Robert Rolleri,[12] Christina Crater,[12] Asim Datye,[13] Alexa B. Kimball[14]

[1]European Hidradenitis Suppurativa Foundation (EHSF) e.V., Dessau, Germany; [2]Departments of Dermatology, Venereology, Allergology and Immunology, Staedtisches Klinikum Dessau, Brandenburg Medical School Theodor Fontane and Faculty of Health Sciences Brandenburg, Dessau, Germany; [3]Northwell, New Hyde Park, New York, USA; [4]Department of Dermatology, University of North Carolina School of Medicine, Chapel Hill, North Carolina, USA; [5]Department of Dermatology, Zealand University Hospital, Roskilde, Denmark; [6]Department of Clinical Medicine, Faculty of Health and Medical Science, University of Copenhagen, Copenhagen, Denmark; [7]Psoriasis Research and Treatment Center, Clinic of Dermatology, Venereology, and Allergology, Charité-Universitätsmedizin Berlin, corporate member of Freie Universität Berlin and Humboldt-Universität zu Berlin, Berlin, Germany; [8]Department of Dermatology & Academic Wound Healing, Division of Infection and Immunity, Cardiff University, Cardiff, UK; [9]Department of Geriatric and Environmental Dermatology, Nagoya City University Graduate School of Medical Sciences, Nagoya, Japan; [10]UCB, Slough, UK; [11]UCB, Brussels, Belgium; [12]UCB, Morrisville, North Carolina, USA; [13]UCB, Oakville, Ontario, Canada; [14]Beth Israel Deaconess Medical Center and Harvard Medical School, Boston, Massachusetts, USA

To access the presentation, scan the QR code or visit:
UCBposters.com/EADV2024

Link expiration: 27 December 2024

EADV 2024 | Amsterdam, The Netherlands | 25–28 September 2024

Presentation number: 7925

Disclosures & Acknowledgements

Disclosures

CCZ: Received institution grants as a clinical and research investigator for AstraZeneca, Boehringer Ingelheim, Brandenburg Medical School Theodor Fontane, EADV, European Union, German Federal Ministry of Education and Research, GSK, InflaRx, MSD, Novartis, Relaxera and UCB; received honoraria as a consultant for Almirall, Boehringer Ingelheim, Eli Lilly and Company, Idorsia, Incyte, L'Oréal, MSD, NAOS-BIODERMA, Novartis, Pfizer, PPM, Sanofi and UCB; received lecture fees from Almirall, Amgen, Biogen, Novartis, Pfizer and UCB; President of the EHSF e.V., and the Deutsches Register Morbus Adamantiades-Behçet e.V., coordinator of the ALLOCATE Skin group of the ERN Skin, chair of the ARHS Task Force group of the EADV and board member of the International Society for Behçet's Disease; Editor of the EADV News; co-copyright holder of IHS4 on behalf of the EHSF e.V.

AG: Receives honoraria as an advisor for AbbVie, Boehringer Ingelheim, Incyte, Insmed, Novartis, Pfizer, Sonoma Biotherapeutics, UCB, Union Therapeutics; receives research grants from AbbVie, CHORD COUSIN Collaboration (C3) and UCB.

CJS: Investigator for AbbVie, AstraZeneca, ChemoCentryx, Incyte, InflaRx, Novartis and UCB; consultancy fees from AbbVie, Alumis, AstraZeneca, InflaRx, Incyte, Logical Images, Sandoz, Sonoma Biotherapeutics and UCB; speaker for AbbVie and Novartis.

GJ: Honoraria from AbbVie, Boehringer Ingelheim, ChemoCentryx, Incyte, Janssen-Cilag, LEO Pharma, Novartis and UCB for participation on advisory boards; investigator for AbbVie, CSL, InflaRx, Janssen-Cilag, LEO Pharma, Novartis, Regeneron, Sanofi and UCB; speaker honoraria from AbbVie and Novartis; research grants from LEO Pharma and Novartis.

GK: Received travel grants or honoraria, has been a consultant member of advisory boards and speaker bureaus or has served as investigator for AbbVie, Actelion, Almirall, Amgen, Basilea, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Hexal-Sandoz, Janssen, LEO Pharma, MSD, Novartis, Pfizer, Sanofi, Takeda 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; his department receives income from copyright of the Dermatology Life Quality Instrument (DLQI) and related instruments.

AM: Research grants, consulting fees and/or speaker's fees from AbbVie, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eisai, Eli Lilly and Company, Janssen, Kyowa Hakko Kirin, LEO Pharma, Maruho, Mitsubishi Tanabe Pharma, Nichi-Iko, Nippon Kayaku, Novartis, Pfizer, Sun Pharma, Taiho Pharmaceutical, Torii Pharmaceutical, UCB and Ushio.

PD, IP, RR, CC, AD: Employees and shareholders of UCB.

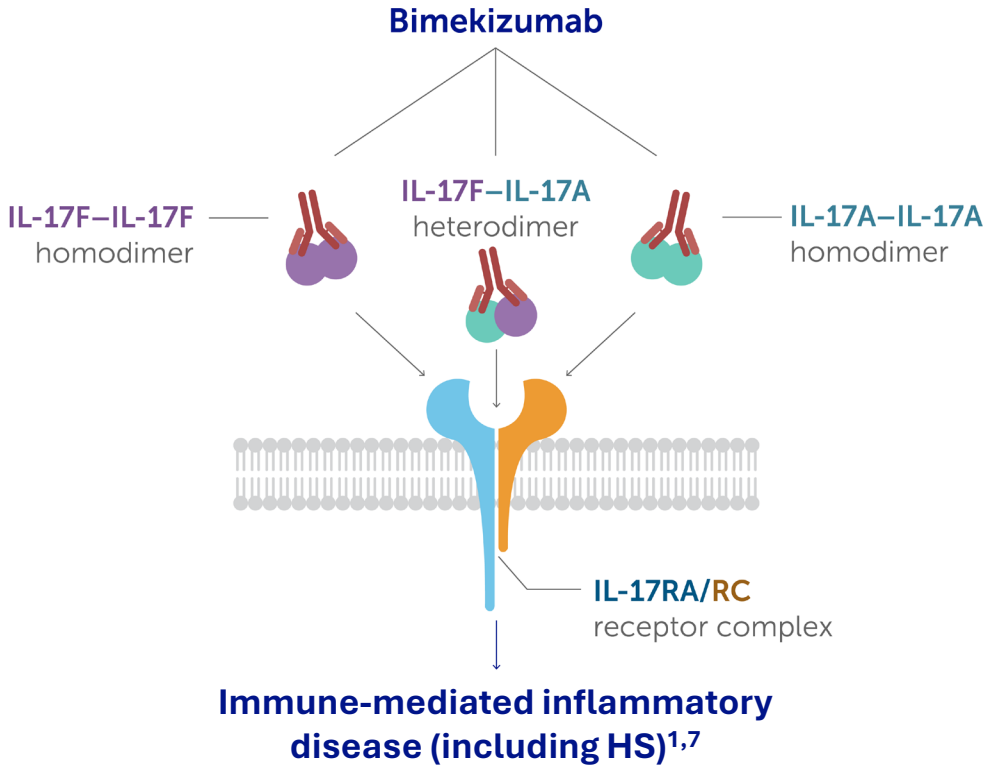
ABK: ABK's institution received grants from AbbVie, Admirx, AnaptysBio, Aristea, Bristol Myers Squibb, Eli Lilly and Company, Incyte, Janssen, MoonLake Immunotherapeutics, Novartis, Pfizer, Prometheus, Sonoma Biotherapeutics and UCB; she received consulting fees from AbbVie, Alumis, Avalo, Bayer, Boehringer Ingelheim, Eli Lilly and Company, Janssen, MoonLake Immunotherapeutics, Novartis, Pfizer, Priovant, Sanofi, Sonoma Biotherapeutics, Target RWE, UCB, Union Therapeutics and Ventyx; serves on the board of directors of Almirall.

Acknowledgements

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, and Jonathan Loh, BSc, Costello Medical, Singapore for medical writing and editorial assistance. All costs associated with the development of this presentation were funded by UCB.

Background

- **Hidradenitis suppurativa (HS)** is a chronic and debilitating inflammatory skin disease.[1]
- Interleukin (IL)-17F and IL-17A are **highly expressed in HS lesional skin** and play a role in disease immunopathogenesis.[2–4]
- **Bimekizumab (BKZ)**, a humanised IgG1 monoclonal antibody that selectively inhibits IL-17F in addition to IL-17A, has previously demonstrated **clinically meaningful improvements** in patients with moderate to severe HS.[5,6]

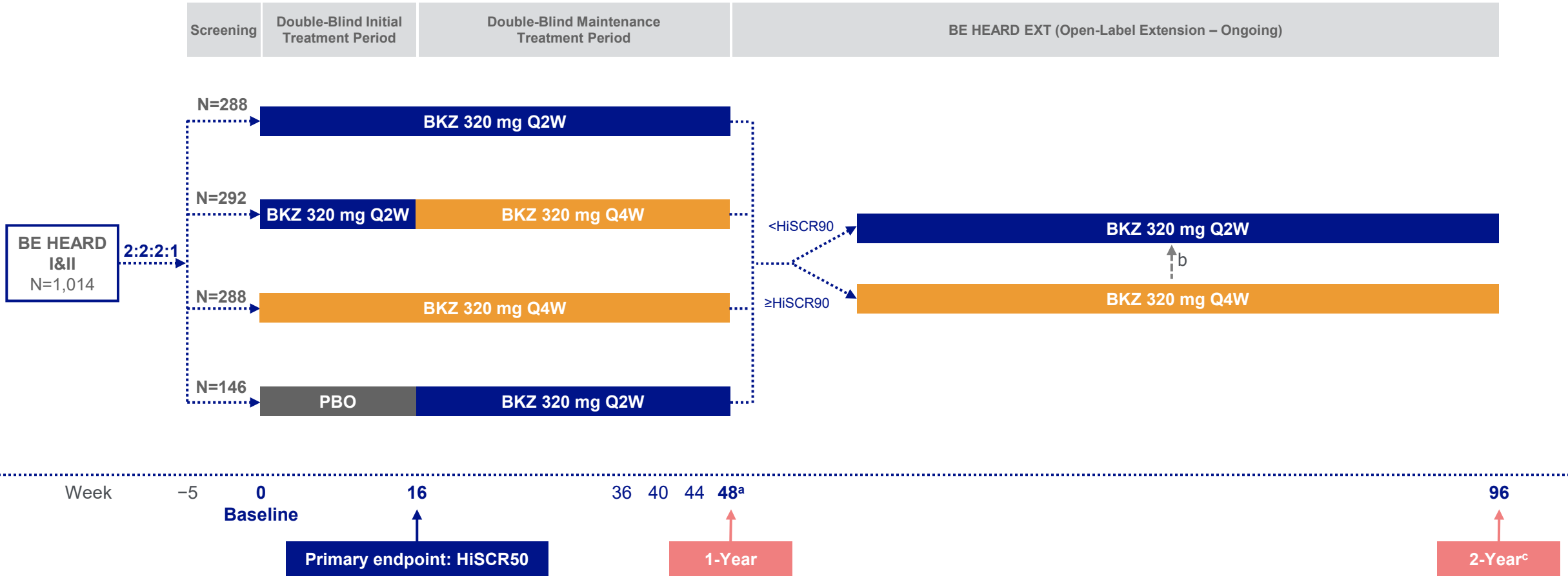


OBJECTIVE: To report efficacy and safety data of BKZ in patients with HS over 2 years for the pooled phase 3 BE HEARD I&II trials and the open-label extension (OLE) BE HEARD EXT.[6,8]

1. Zouboulis CC et al. Exp Dermatol 2020;29:1154–70; **2.** Skelton A et al. J Invest Dermatol 2023;143:S87; **3.** Kimball AB et al. Exp Dermatol 2022;31:1522–32; **4.** Zouboulis VA et al. Pharmaceutics 2021;14:44; **5.** Adams R et al. Front Immunol 2020;11:1894; **6.** Kimball AB et al. Lancet 2024;403:2504–19 (NCT04242446, NCT04242498); **7.** Figure adapted from: Patel DD et al. Ann Rheum Dis 2013;72(Suppl 2):ii116–23; **8.** BE HEARD EXT: https://clinicaltrials.gov/study/NCT04901195.
BKZ: bimekizumab; HS: hidradenitis suppurativa; Ig: immunoglobulin; IL: interleukin; OLE: open-label extension; RA: receptor A; RC: receptor C.

Methods – 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]** 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. 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; OLE: open-label extension; Q2W: every two weeks; Q4W: every four weeks.

Methods – Outcomes

- We report the following **efficacy outcomes** to **Week 96** (2 years) for patients randomised to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT (BKZ Total group):
  - ≥50/75/90/100% HS Clinical Response (HiSCR50/75/90/100) rates;
  - Percentage change from baseline in International HS Severity Score System (IHS4);
  - Percentage change from baseline in total draining tunnel (DT) count;
  - Dermatology Life Quality Index (DLQI) 0/1 response rates.

- We also present an overview of **treatment-emergent adverse events (TEAEs) and other safety outcomes over 1 year (Weeks 0–48) and over 2 years (Week 0–96)** for patients who received ≥1 dose of BKZ.

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; IHS4: International HS Severity Score System; TEAE: treatment-emergent adverse event.

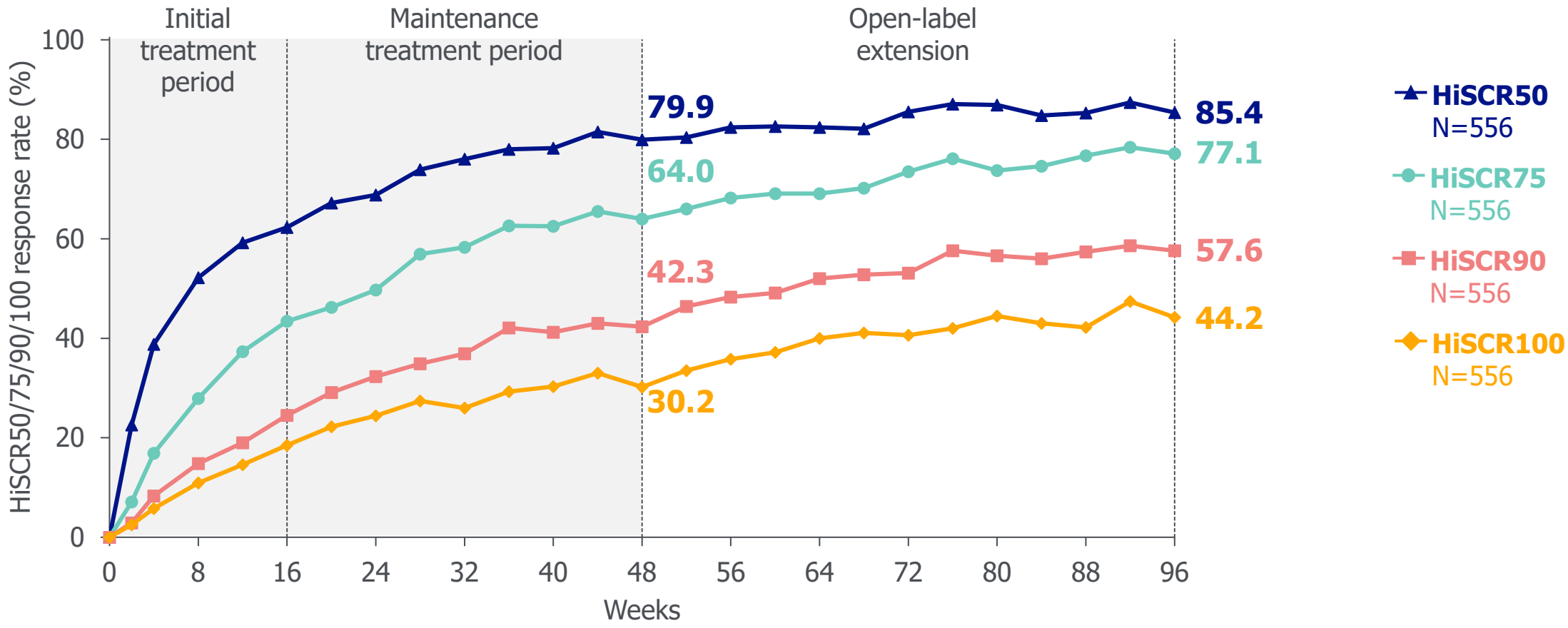
Baseline Characteristics

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

	BKZ Total[a] N=556
Age, years, mean ± SD	36.3 ± 12.2
Sex, female, n (%)	299 (53.8)
Racial group, White, n (%)	448 (80.6)
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)
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; included only patients who entered BE HEARD EXT at Week 48. **[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. AN: abscess and inflammatory nodule; BKZ: bimekizumab; BMI: body mass index; DLQI: Dermatology Life Quality Index; DT: draining tunnel; OLE: open-label extension; SD: standard deviation.

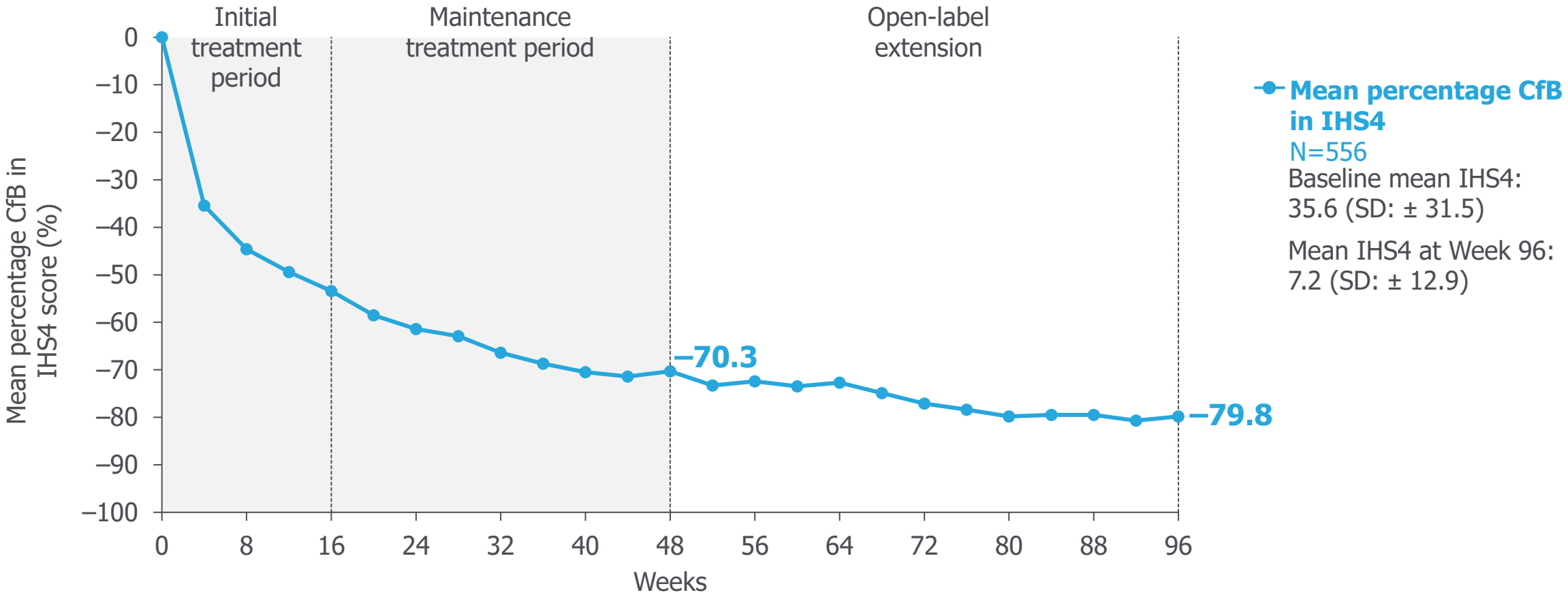
HiSCR Rates over Time in BKZ Total Group (OC)



Clinically meaningful improvements at 1 year were maintained to 2 years across HiSCR50/75/90/100.

OLE set: N=657; included only patients who entered BE HEARD EXT at Week 48. 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: HiSCR50, 444/556; HiSCR75, 356/556; HiSCR90, 235/556; HiSCR100, 168/556; Week 96 n/N: HiSCR50, 381/446; HiSCR75, 344/446; HiSCR90, 257/446; HiSCR100, 197/446. OC, n/N: denominator represents number of patients with a non-missing lesion count assessment in the given week, and percentages are calculated accordingly (i.e. where data recorded after an intercurrent event are included as recorded). 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; OC: observed case; OLE: open-label extension.

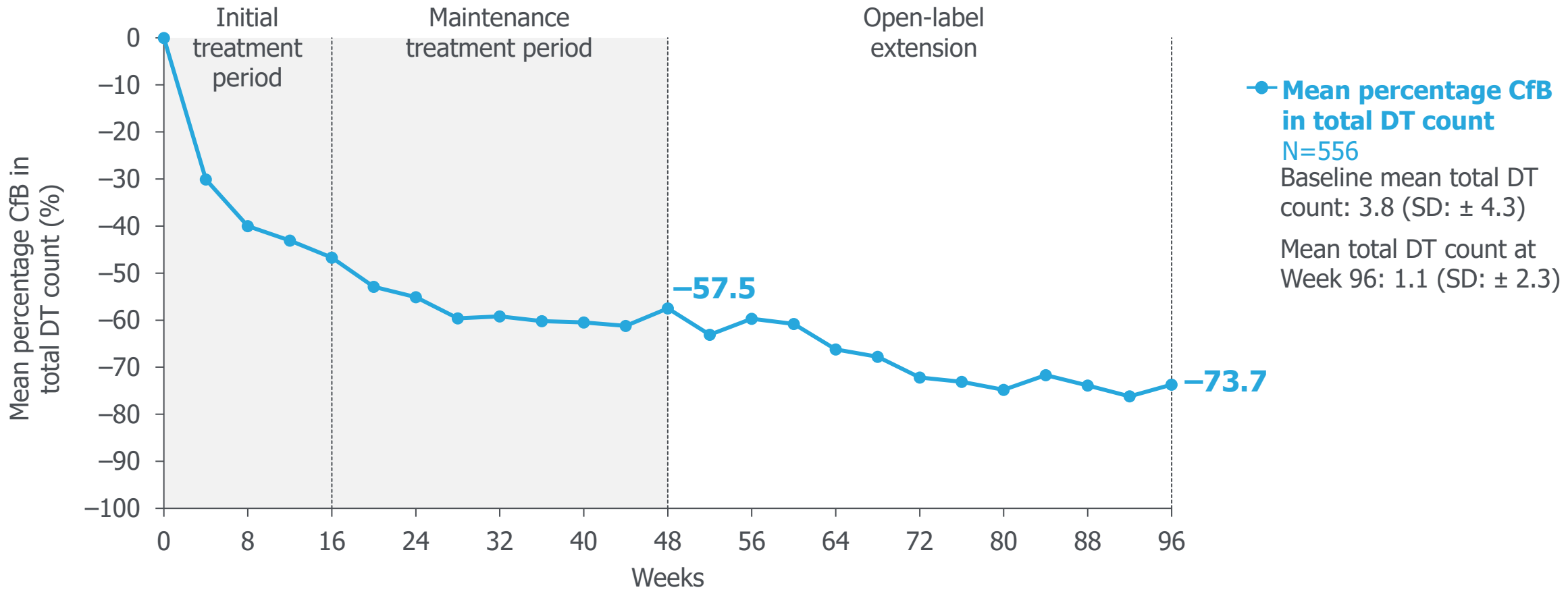
Mean Percentage CfB in IHS4 Score over Time in BKZ Total Group (OC)



Substantial reductions in IHS4 score at 1 year were maintained to 2 years.

OLE set: N=657; included only patients who entered BE HEARD EXT at Week 48. 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: 556/556, Week 96 n/N: 446/556. OC, n/N: denominator represents number of patients with a non-missing lesion count assessment in the given week, and percentages are calculated accordingly (i.e. where data recorded after an intercurrent event are included as recorded). BKZ: bimekizumab; CfB: change from baseline; HS: hidradenitis suppurativa; IHS4: International HS Severity Score System; OC: observed case; OLE: open-label extension; SD: standard deviation.

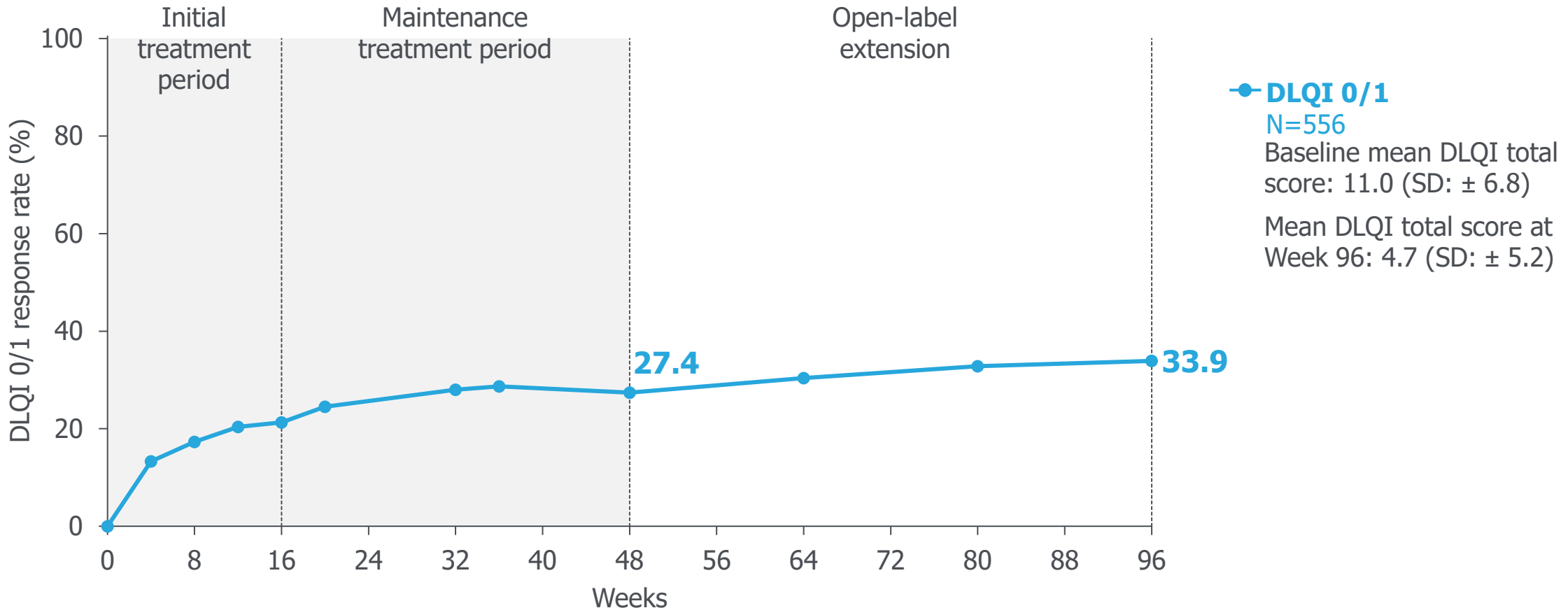
Mean Percentage CfB in Total DT Count over Time in BKZ Total Group (OC)



Clinically meaningful reductions in total DT count at 1 year were further reduced to 2 years.

OLE set: N=657; included only patients who entered BE HEARD EXT at Week 48. 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: 425/556, Week 96 n/N: 350/556. OC, n/N: denominator represents number of patients with a non-missing draining tunnel count assessment in the given week, and percentages are calculated accordingly (i.e. where data recorded after an intercurrent event are included as recorded). BKZ: bimekizumab; CfB: change from baseline; DT: draining tunnel; OC: observed case; OLE: open-label extension; SD: standard deviation.

DLQI Total Score 0/1 Response Rates over Time in BKZ Total Group (OC)



DLQI total score 0/1 response rates at 1 year were maintained to 2 years.

OLE set: N=657; included only patients who entered BE HEARD EXT at Week 48. 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: 149/439. OC, n/N: denominator represents number of patients with a DLQI assessment in the given week, and percentages are calculated accordingly (i.e. where data recorded after an intercurrent event are included as recorded). BKZ: bimekizumab; DLQI: Dermatology Life Quality Index; OC: observed case; OLE: open-label extension; SD: standard deviation.

Overview of Safety Outcomes over 1 Year and 2 Years[a]

EAIR/100 PY (95% CI)	Patients with ≥1 dose BKZ N=995	
	Over 1 year (Weeks 0–48)[b] Total exposure: 8.1 per 100 PY	Over 2 years (Weeks 0–96) Total exposure: 17.7 per 100 PY
Any TEAE	287.0 (267.9, 307.1)	248.9 (233.0, 265.5)
Serious TEAEs	8.1 (6.3, 10.4)	7.2 (6.0, 8.6)
Severe TEAEs	10.4 (8.2, 12.9)	7.7 (6.4, 9.2)
TEAEs leading to discontinuation	8.5 (6.6, 10.8)	6.3 (5.1, 7.6)
All deaths[c]	0.1 (0.0, 0.7)	0.1 (0.0, 0.4)
Most common TEAEs		
Hidradenitis	25.7 (22.1, 29.6)	20.5 (18.2, 23.0)
Coronavirus infection	14.0 (11.4, 16.9)	15.3 (13.4, 17.4)
Oral candidiasis[d]	14.7 (12.1, 17.7)	10.5 (8.9, 12.2)
Serious infections	2.0 (1.1, 3.2)	1.9 (1.3, 2.6)
Fungal infections	34.2 (30.0, 38.9)	24.4 (21.8, 27.2)
Any malignancies	0.5 (0.1, 1.3)	0.7 (0.4, 1.3)
Any hepatic events	5.6 (4.1, 7.5)	4.7 (3.7, 5.8)
Adjudicated suicidal ideation and behaviour[e]	0.6 (0.2, 1.4)	0.7 (0.4, 1.3)
Definite or probable adjudicated IBD		
With history of IBD (n=8)	0 (N/A)	14.2 (1.7, 51.2)
No history of IBD (n=987)	0.9 (0.4, 1.8)	0.5 (0.2, 0.9)

TEAEs were coded using MedDRA v19.0 and reported using EAIRs per 100 PY. **[a]** TEAEs for all patients who received ≥1 BKZ dose over 1 (Weeks 0–48) and 2 years (Weeks 0–96), including patients who switched at Week 16 from placebo to BKZ 320 mg Q2W (n=134; for these patients, events are reported after the switch to BKZ and for 80 weeks of BKZ treatment); **[b]** Data originally presented at EADV 2023: Bechara FG et al. P0087; **[c]** Across 2 years, 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; **[d]** The majority of oral candidiasis cases were mild to moderate and were resolved/recovering with standard anti-fungal therapy; **[e]** There were no events of completed suicide. BKZ: bimekizumab; CI: confidence interval; EAIR: exposure-adjusted incidence rate; HS: hidradenitis suppurativa; IBD: inflammatory bowel disease; N/A: not applicable; Q2W: every two weeks; PY: patient-years; TEAE: treatment-emergent adverse event.

Conclusions

- This is the first presentation of 2-year bimekizumab data from the phase 3 BE HEARD I&II trials and the open-label extension BE HEARD EXT.[1,2]
- Efficacy and health-related quality of life outcomes were **maintained through 2 years** of treatment.
- **No new safety signals** were observed with bimekizumab and the **safety profile over 2 years was consistent** with findings from BE HEARD I&II and studies of bimekizumab in other indications.[1,3–5]

These data highlight the **durability and consistency of bimekizumab** treatment in patients with moderate to severe HS.

To access the presentation, scan the QR code or visit:
UCBposters.com/EADV2024
Number: 7925

1. Kimball AB. Lancet 2024;403:2504–19 (NCT04242446, NCT04242498); **2.** BE HEARD EXT: https://clinicaltrials.gov/study/NCT04901195; **3.** Reich K. N Engl J Med 2021;385:142–52; **4.** Merola JF. Lancet 2023;401:38–48; **5.** van der Heijde D. Ann Rheum Dis 2023;82:515–26. BKZ: bimekizumab; HS: hidradenitis suppurativa.