Bimekizumab Efficacy and Safety Over 4 Years in Patients with Moderate to Severe HS: Results from the BE HEARD EXT OLE2 in 4 Countries

Falk G. Bechara,[1,2] Christopher J. Sayed,[3,] Amit Garg,[4] Ziad Reguiaï,[5] Sylke Schneider-Burrus,[6] Andreas Pinter,[7] Shinichi Imafuku,[8] Jose Manuel Lopez Pinto,[9] Delphine Deherder,[10] Christina Crater,[11] Tom Vaux,[11] Haley B. Naik[12]

[1]Department of Dermatology, Venereology, and Allergology, St. Josef-Hospital, Ruhr-University Bochum, Bochum, Germany; [2]ICH – International Center for Hidradenitis Suppurativa / Acne Inversa, Ruhr-University Bochum, Bochum, Germany; [3]Department of Dermatology, University of North Carolina School of Medicine, Chapel Hill, NC, USA; [4]Northwell, New Hyde Park, NY, USA; [5]Dermatology Department, Polyclinique Courlancy-Bezannes, Reims, France; [6]Center for Skin Surgery, Havelklinik, Berlin, Germany; [7]University Hospital Frankfurt, Frankfurt am Main, Germany; [8]Department of Dermatology, Faculty of Medicine, Fukuoka University, Fukuoka, Japan; [9]UCB, Madrid, Spain; [10]UCB, Braine-l'Alleud, Belgium; [11]UCB, Morrisville, NC, USA; [12]Department of Dermatology, University of California, San Francisco, CA, USA

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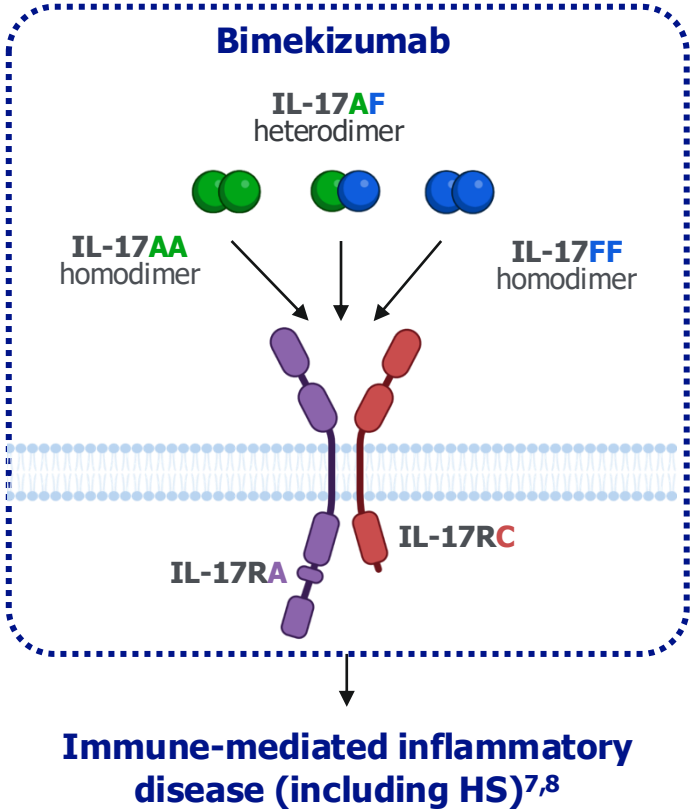
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Background

- **Hidradenitis suppurativa (HS)**, a chronic, progressive skin disease associated with substantial impairment of **health-related quality of life (HRQoL)**, requires effective and safe long-term control with treatments that may prevent disease progression.[1,2]
- **Bimekizumab (BKZ)** selectively inhibits interleukin (IL)-17F in addition to IL-17A and has demonstrated **clinically meaningful improvements** and a **favorable safety profile** in moderate to severe HS over 3 years of treatment.[3–6]
- Data were pooled across the **BE HEARD** clinical development program and included only patients who enrolled in the second open-label extension (**OLE2**), which was conducted to provide continued access to BKZ in **France**, **Germany**, **Japan**, and the **United States**.[4,5]

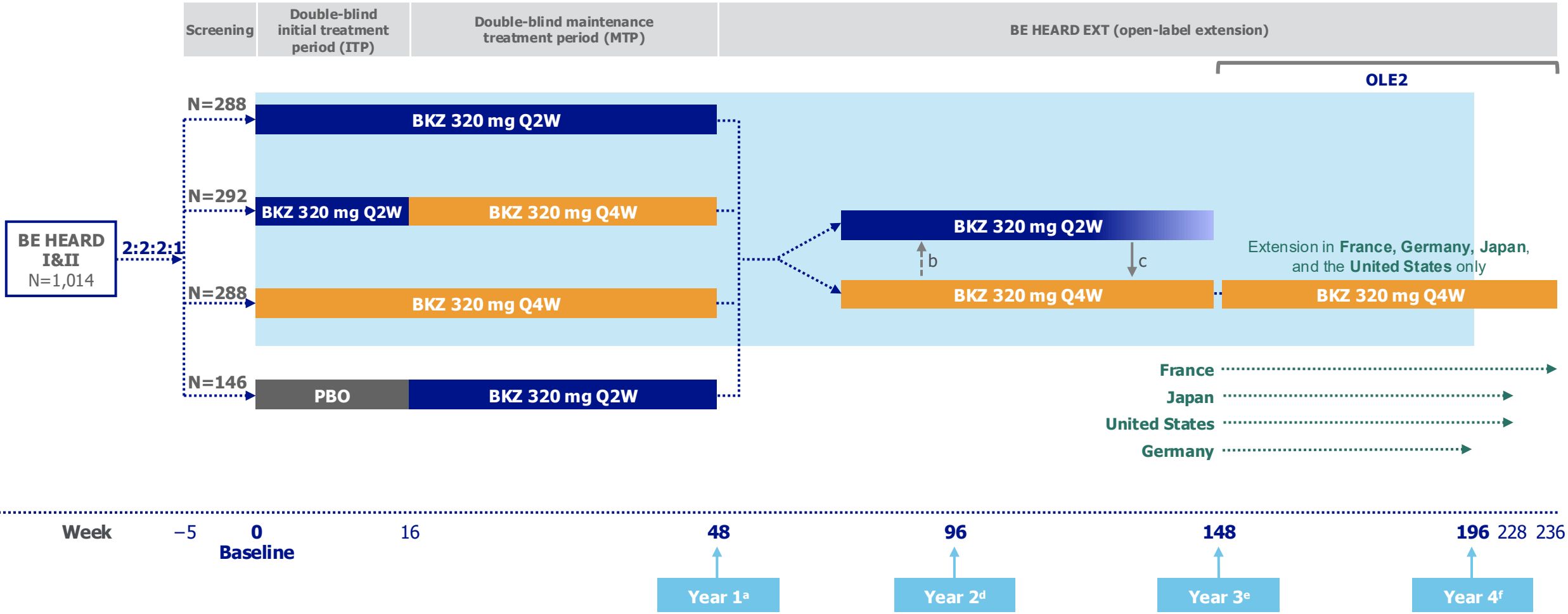


Objective: To report the long-term **efficacy** and **safety** of bimekizumab treatment over 4 years in patients with moderate to severe HS who completed the phase 3 BE HEARD I&II trials, entered BE HEARD EXT, and were enrolled in the OLE2 in four countries (OLE2 cohort).[4,5]

1. Sabat R et al. Lancet 2025;405:420–38; **2.** Tehrani MD et al. J Eur Acad Dermatol Venereol 2025;39:1395–409; **3.** Adams R. et al. Front Immunol 2020;11:1894; **4.** Kimball AB et al. Lancet 2024;403:2504–19; **5.** Sayed CJ et al. J Am Acad Dermatol 2026;94:867–78; **6.** Ingram JR et al. Presented at EADV 2025; D1T01.2E; **7.** Figure adapted from: Patel DD et al. Ann Rheum Dis 2013;72(Suppl 2):ii116–23; **8**. Zouboulis CC et al. Exp Dermatol 2020;29:1154–70. **BKZ:** bimekizumab; **HRQoL:** health-related quality of life; **HS:** hidradenitis suppurativa; **Ig:** immunoglobulin; **IL:** interleukin; **OLE:** open-label extension; **RA:** receptor A; **RC:** receptor C.

BE HEARD Study Design Over 4 Years: OLE2 Efficacy Set

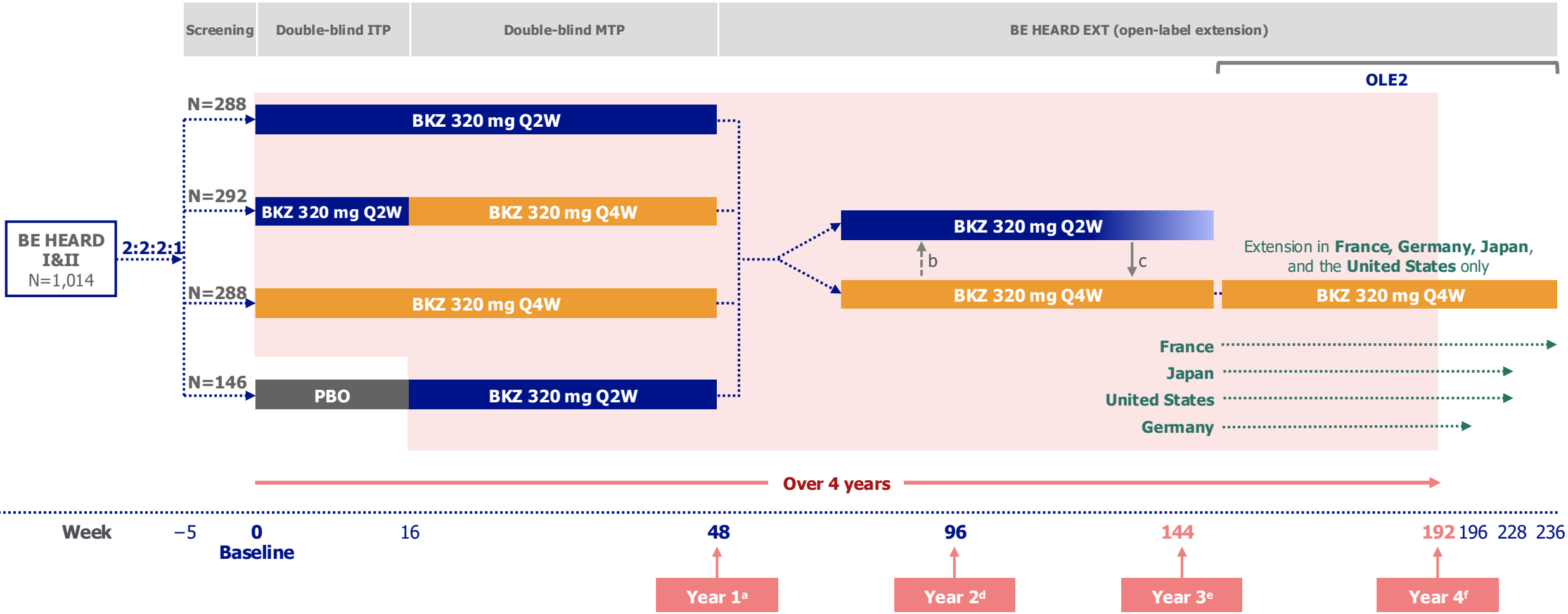
Patients randomized to BKZ at baseline who continued to receive BKZ in OLE2



The OLE2 was conducted in France, Germany, Japan, and the United States only. **[a]** Patients who completed Week 48 (Year 1) 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 (<HiSCR90: BKZ Q2W; ≥HiSCR90: BKZ Q4W) using the average lesion counts from Week 36, Week 40, and Week 44 of BE HEARD I&II; **[b]** Patients receiving BKZ 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 100 weeks in BE HEARD EXT). **[f]** Cumulative 4-year data (48 weeks in BE HEARD I&II and 148 weeks in BE HEARD EXT [including 48 weeks in OLE2]). **AN:** abscesses and inflammatory nodules; **BKZ:** bimekizumab; **HiSCR:** Hidradenitis Suppurativa Clinical Response; **HiSCR50/90:** ≥50%/90% reduction from baseline in the total AN count with no increase from baseline in abscess or draining tunnel count; **ITP:** initial treatment period; **MTP:** maintenance treatment period; **OLE:** open-label extension; **PBO;** placebo; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks.

BE HEARD Study Design Over 4 Years: OLE2 Safety Set

Patients with ≥1 BKZ dose, including patients initially randomized to PBO



The OLE2 was conducted in France, Germany, Japan, and the United States only. **[a]** Patients who completed Week 48 (Year 1) 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 (<HiSCR90: BKZ Q2W; ≥HiSCR90: BKZ Q4W) using the average lesion counts from Week 36, Week 40, and Week 44 of BE HEARD I&II; **[b]** Patients receiving BKZ 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); **[f]** Cumulative 4-year data (48 weeks in BE HEARD I&II and 144 weeks in BE HEARD EXT [including 44 weeks in OLE2]). **AN:** abscesses and inflammatory nodules; **BKZ:** bimekizumab; **HiSCR:** Hidradenitis Suppurativa Clinical Response; **HiSCR50/90:** ≥50%/90% reduction from baseline in the total AN count with no increase from baseline in abscess or draining tunnel count; **ITP:** initial treatment period; **MTP:** maintenance treatment period; **OLE:** open-label extension; **PBO;** placebo; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks.

Outcomes

Efficacy

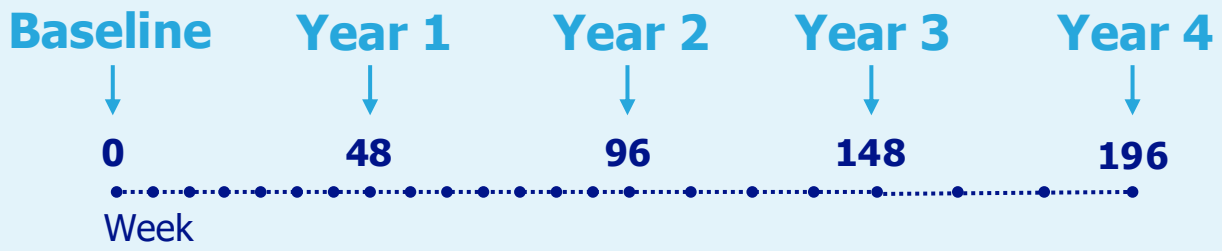
- **Efficacy set:** Patients **randomized to BKZ 320 mg** at baseline in BE HEARD I&II who continued to receive BKZ during BE HEARD EXT and entered the OLE2 (N=152)

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

Absolute change from baseline (CfB) in draining tunnel (**DT**) count

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

- Data are reported as observed case (OC)
- Timepoints: Over time to Year 4

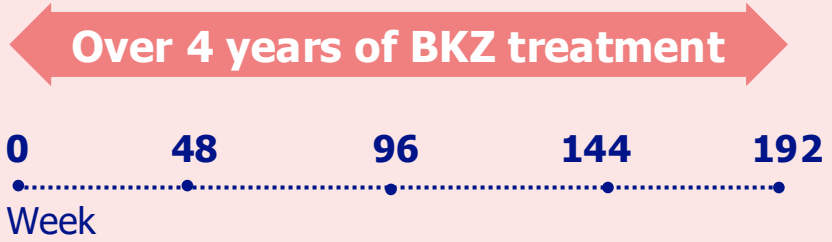


Safety

- **Safety set:** Patients in the OLE2 who received **≥1 dose of BKZ**[b] (N=184)

Exposure-adjusted incidence rates (**EAIRs**)[c] of the most common treatment-emergent adverse events (**TEAEs**) and safety topics of interest

- Time period:



[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); **[b]** Includes patients who were initially randomized to placebo at baseline; **[c]** EAIRs were calculated as the number of patients experiencing the event divided by the total PY at risk, providing a measure of event occurrence that accounts for patient-level differences in treatment exposure duration. **BKZ:** bimekizumab; **CfB:** change from baseline; **DLQI:** Dermatology Life Quality Index; **DT:** draining tunnel; **EAIR:** exposure-adjusted incidence rate; **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; **OC:** observed case; **OLE:** open-label extension; **PY**: patient-year; **TEAE:** treatment-emergent adverse event.

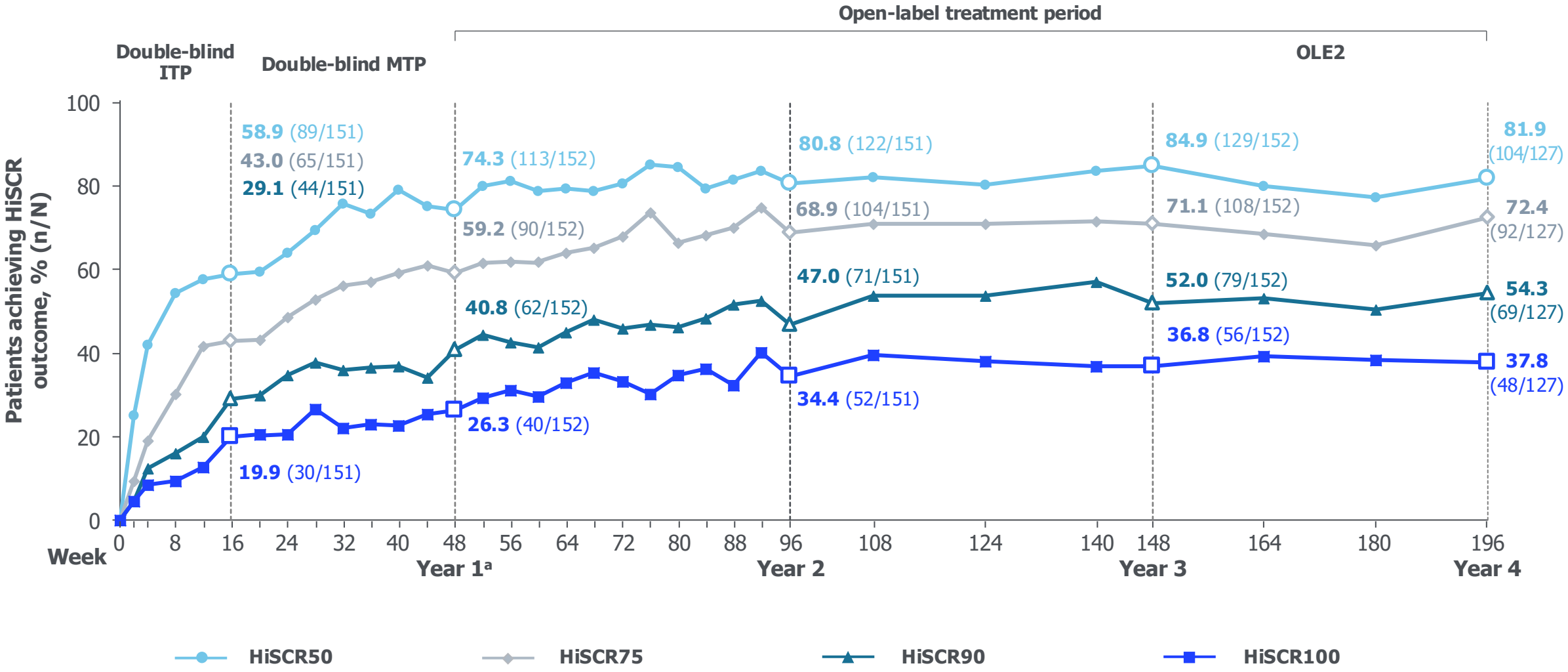
Baseline Characteristics

	OLE2 efficacy set[a] N=152	OLE2 safety set[b] N=184
Age, years, mean (SD)	36.8 (11.4)	36.7 (11.6)
Sex, female, n (%)	90 (59.2)	108 (58.7)
Racial group, n (%)		
White	94 (61.8)	116 (63.0)
Black or African American	24 (15.8)	28 (15.2)
Asian	20 (13.2)	24 (13.0)
Other	10 (6.6)	12 (6.5)
Missing	4 (2.6)	4 (2.2)
BMI, kg/m^2, mean (SD)	34.1 (9.1)	33.8 (9.0)
Country, n (%)		
France	38 (25.0)	42 (22.8)
Germany	20 (13.2)	28 (15.2)
Japan	20 (13.2)	24 (13.0)
United States	74 (48.7)	90 (48.9)
Duration of HS, years, mean (SD)	8.7 (7.9)	8.9 (7.9)
Hurley stage,[c] n (%)		
II	82 (53.9)	97 (52.7)
III	70 (46.1)	87 (47.3)
AN count, mean (SD)	18.3 (16.8)	17.3 (15.7)
DT count, mean (SD)	3.5 (4.3)	3.6 (4.3)
DLQI total score, mean (SD)	11.4 (7.3)	11.4 (7.3)
Prior biologic use,[d] n (%)	30 (19.7)	39 (21.2)

Results should be interpreted within the context of this selected population, which comprised OLE2-eligible patients from four countries and may therefore be subject to selection and regional bias.

[a] OLE2 efficacy set comprised patients randomized to BKZ from baseline in BE HEARD I&II who continued to receive BKZ during BEHEARD EXT including OLE2; **[b]** OLE2 safety set comprised patients who received ≥1 BKZ dose, including patients who were initially randomized to placebo at baseline; **[c]** Derived Hurley stage for each participant is the worst overall Hurley stage derived from the Hurley stages recorded across all anatomical regions; **[d]** Patients received prior biologic therapy for any indication. **AN:** abscess and inflammatory nodule; **BKZ:** bimekizumab; **BMI:** body mass index; **DLQI:** Dermatology Life Quality Index; **DT:** draining tunnel; **HS:** hidradenitis suppurativa; **OLE:** open-label extension; **SD:** standard deviation.

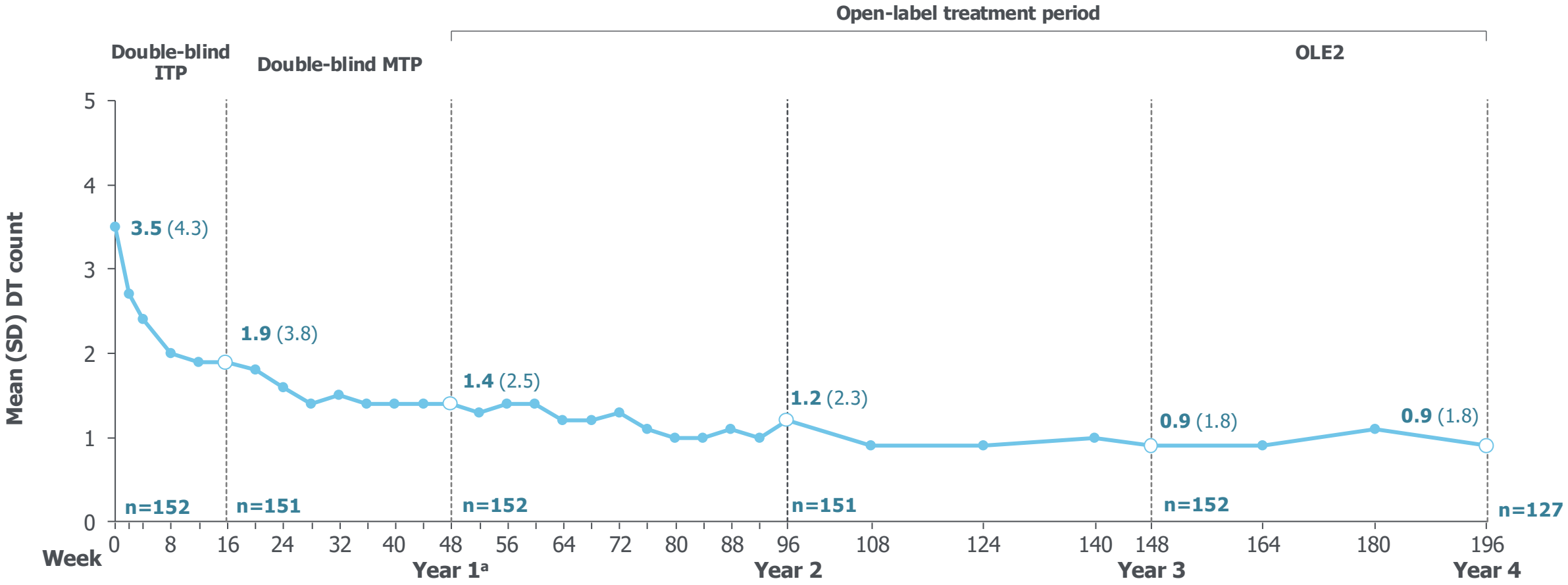
HiSCR50/75/90/100 Over 4 Years in the OLE2 Cohort



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OC, n/N: denominator represents number of patients with a non-missing lesion assessment in the given week, and percentages are calculated accordingly. OLE2 efficacy set comprised patients randomized to BKZ from baseline in BE HEARD I&II who continued to receive BKZ during BE HEARD EXT including OLE2. **[a]** The requirement of a visit at Year 1 to enter the OLE resulted in an increase in n number at Year 1. **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; **ITP:** initial treatment period; **MTP:** maintenance treatment period; **OC:** observed case; **OLE:** open-label extension.

Mean (SD) DT Count Over 4 Years in the OLE2 cohort

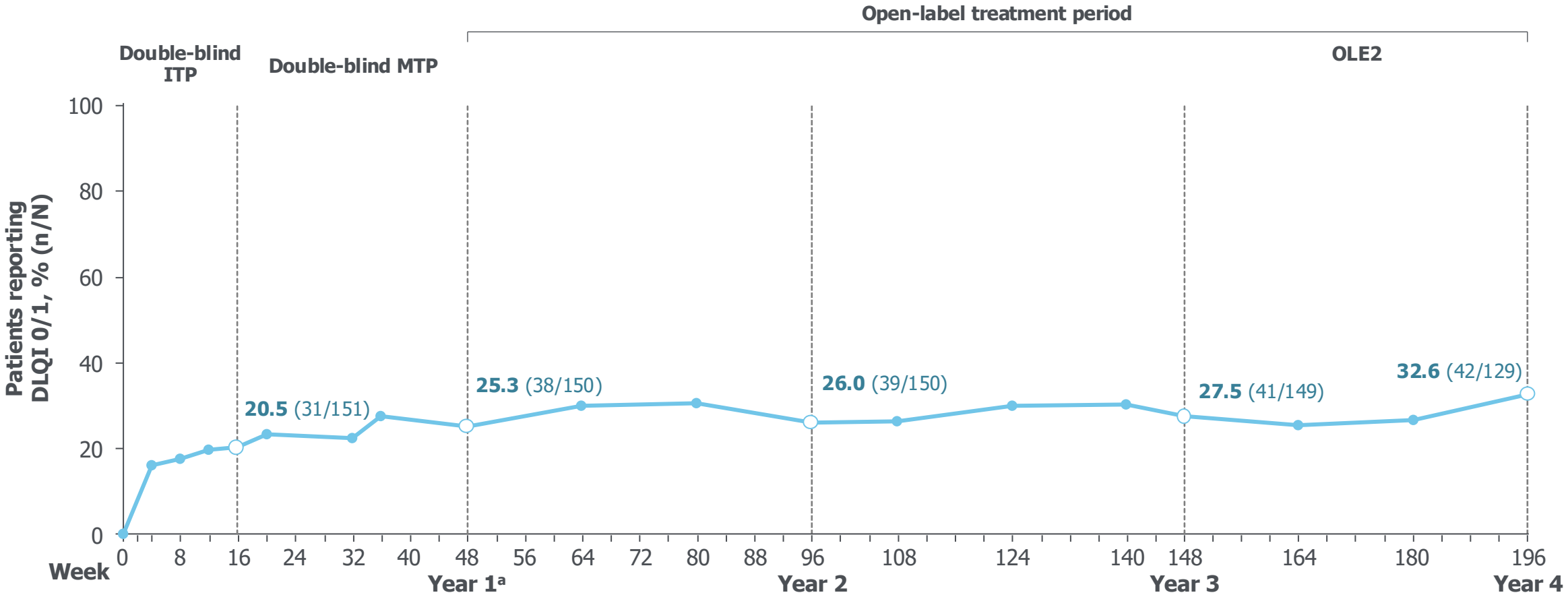


	Mean (SD) CfB in DT count
Year 1	−2.1 (3.6); n=152
Year 4	−2.9 (4.0); n=127

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OC, n represents the number of patients with a non-missing lesion count assessment in the given week and percentages are calculated accordingly. OLE2 efficacy set comprised patients randomized to BKZ from baseline in BE HEARD I&II who continued to receive BKZ during BE HEARD EXT including OLE2. **[a]** The requirement of a visit at Week 48 to enter the OLE resulted in an increase in n number at Week 48. **BKZ:** bimekizumab; **CfB:** change from baseline; **DT:** draining tunnel; **ITP:** initial treatment period; **MTP:** maintenance treatment period; **OC:** observed case; **OLE:** open-label extension; **SD:** standard deviation.

DLQI 0/1 Response Rates Over 4 Years in the OLE2 Cohort



	Mean (SD) DLQI total score
Baseline	11.4 (7.3); n=150
Year 4	4.9 (5.4); n=129

OC, n/N: denominator represents number of patients with a non-missing DLQI assessment in the given week, and percentages are calculated accordingly. DLQI 0/1 response was defined as total score of 0 or 1 (no effect at all of skin disease on patients' life); DLQI score ranges 0–30. OLE2 efficacy set comprised patients randomized to BKZ from baseline in BE HEARD I&II who continued to receive BKZ during BE HEARD EXT including OLE2. **[a]** The requirement of a visit at Year 1 to enter the OLE resulted in an increase in n number at Year 1. **BKZ:** bimekizumab; **DLQI:** Dermatology Life Quality Index; **ITP:** initial treatment period; **MTP:** maintenance treatment period; **OC:** observed case; **OLE:** open-label extension; **SD:** standard deviation.

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Incidence of TEAEs per 100 PY Over 4 Years

EAIR/100 PY (95% CI)	OLE2 safety set N=184; 100 PY=6.62
Any TEAE	169.9 (145.8, 196.8)
Serious TEAEs	4.4 (2.9, 6.4)
Severe TEAEs	3.7 (2.4, 5.6)
TEAEs leading to discontinuation in OLE2[a]	0.6 (0.2, 1.6)
Any TEAE leading to death in OLE2[a]	0
Most common TEAEs[b]	
Hidradenitis	19.9 (16.0, 24.4)
Corona virus infection	13.4 (10.4, 16.9)
Nasopharyngitis	9.8 (7.3, 12.8)

EAIR/100 PY (95% CI)	OLE2 safety set N=184; 100 PY=6.62
Hypersensitivity reactions[c,d]	19.9 (16.0, 24.5)
Dermatitis and eczema	15.8 (12.5, 19.8)
Dermatitis	1.1 (0.4, 2.2)
Eczema	5.6 (3.9, 7.9)
Serious hypersensitivity reactions	0
Serious infections	1.7 (0.9, 3.1)
Fungal infections	17.8 (14.2, 22.1)
Candida infections	7.8 (5.6, 10.4)
Oral candidiasis	5.4 (3.7, 7.6)
Any malignancies	0.2 (0.0, 0.8)
Any hepatic events	3.8 (2.4, 5.7)
Adjudicated definite or probable inflammatory bowel disease	0.3 (0.0, 1.1)
Adjudicated suicidal ideation and behavior events	0

OLE2 safety set comprised patients who received ≥1 BKZ dose, including patients who were initially randomized to placebo at baseline. Over 4 years: Weeks 0–192. TEAEs were coded using MedDRA v19.0 and reported using EAIRs per 100 PY. **[a]** Only discontinuations and deaths that occurred due to TEAEs in the OLE2 are shown; **[b]** The three TEAEs with the highest incidence over 4 years are presented, per the MedDRA Preferred Terms; **[c]** Hypersensitivity reactions are identified using the Standardised MedDRA Query (SMQ) 'Hypersensitivity' narrow terms; **[d]** There was one non-serious pustular rash reported over 4 years. **BKZ:** bimekizumab; **CI:** confidence interval; **EAIR:** exposure-adjusted incidence rate; **HS:** hidradenitis suppurativa; **IBD:** inflammatory bowel disease; **MedDRA:** Medical Dictionary for Regulatory Activities; **OLE:** open-label extension; **PY:** patient-years; **TEAEs:** treatment-emergent adverse events.

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Conclusions

In patients included in the OLE2 cohort from **four countries**, **efficacy** and **HRQoL** outcome **improvements** observed with bimekizumab were **maintained over 4 years**.

Bimekizumab was **well tolerated to Year 4** in the OLE2 cohort, with a safety profile consistent with previous analyses and overall study population.[1–3]

Limitation: Although these results support the **sustained long-term benefit of bimekizumab**, the analyses are limited to patients who continued into the OLE2 from **four countries**, which may introduce selection and regional bias.

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Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **FGB**, **CJS**, **AG**, **ZR**, **SSB**, **AP**, **SI**, **JMLP**, **DD**, **CC**, **TV**, **HBN**; drafting of the publication, or reviewing it critically for important intellectual content: **FGB**, **CJS**, **AG**, **ZR**, **SSB**, **AP**, **SI**, **JMLP**, **DD**, **CC**, **TV**, **HBN**; final approval of the publication: **FGB**, **CJS**, **AG**, **ZR**, **SSB**, **AP**, **SI**, **JMLP**, **DD**, **CC**, **TV**, **HBN**.

1. Kimball AB et al. Lancet 2024;403:2504–19; **2.** Sayed CJ et al. J Am Acad Dermatol 2026;94:867–78; **3.** Ingram JR et al. Presented at EADV 2025; D1T01.2E. **HRQoL:** health-related quality of life; **OLE:** open-label extension.