

# UCB VIRTUAL BRIEFING

BIMZELX® (bimekizumab) in  
Hidradenitis Suppurativa

Capital Market Call  
22 September 2025



Inspired by **patients.**  
Driven by **science.**





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This document contains forward-looking statements, including, without limitation, statements containing the words “potential”, “believes”, “anticipates”, “expects”, “intends”, “plans”, “seeks”, “estimates”, “may”, “will”, “continue” and similar expressions. These forward-looking statements are based on current plans, estimates and beliefs of management. All statements, other than statements of historical facts, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, arbitration, political, regulatory or clinical results or practices and other such estimates and results. By their nature, such forward-looking statements are not guaranteeing future performance and are subject to known and unknown risks, uncertainties, and assumptions which might cause the actual results, financial condition, performance or achievements of UCB, or industry results, to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements contained in this document.

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# Agenda







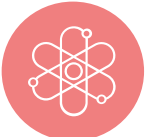


<b>Antje Witte</b> Head of Investor Relations, UCB	<b>Welcome</b>
<b>Fiona du Monceau</b> Executive Vice President, Head of Patient Evidence	<b>Introduction</b>
<b>Professor John Ingram</b> MA MSc DM(Oxon) FRCP(Derm) FAcadMED, Clinical Professor & Consultant Dermatologist Division of Infection & Immunity Cardiff University	<b>Bimekizumab Efficacy and Safety Through 3 Years in Patients With Hidradenitis Suppurativa</b>
<b>Dr Amit Garg</b> Professor & Founding Chair, Department of Dermatology, Zucker School of Medicine at Hofstra/Northwell   Professor, Center for Health Innovations & Outcomes Research, Feinstein Institutes for Medical Research	<b>BE HEARD I&amp;II HS Lesion Intervention Over Time BE HEARD I&amp;II IHS4 by Disease Duration</b>
<b>All</b>	<b>Q&amp;A Session</b>

# BIMEKIZUMAB (BIMZELX®) first and only approved IL-17A and IL-17F inhibitor

## PERFORMANCE ACROSS INDICATIONS

<div>5</div> <div>distinct indications approved<sup>1</sup></div>	<div>&gt;50</div> <div>countries approved with 21 regulatory authorities</div>	<div>&gt;82k</div> <div>patients reached<sup>2</sup></div>	<div>&gt;100k</div> <div>patient years of exposure<sup>2</sup></div>	<div>4</div> <div>additional indications under study<sup>3</sup></div>
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## BUILDING LEADERSHIP IN HIDRADENITIS SUPPURATIVA (HS)

<div>Securing HS approvals</div> <div><div></div><div>April 2024</div></div> <div><div></div><div>September 2024</div></div> <div><div></div><div>November 2024</div></div>	<div>Gaining market share</div> <div><div></div><div>Total Biologic Dynamic patient share &gt;35%</div></div> <div><div></div><div>Total Biologic Dynamic patient share &gt;65%</div></div> <div><div></div><div>Dynamic patient share &gt;25% in 4 months</div></div>	<div>Core pillars to drive progress in HS</div> <div><div></div><div><div>Revolutionize Science</div><div>Advance community knowledge of HS and its pathways, triggers, and treatment, through science.</div></div></div> <div><div></div><div><div>Redefine Care</div><div>Ensure earlier diagnosis and optimal treatment to reduce progression and control symptoms.</div></div></div> <div><div></div><div><div>Restore Humanity</div><div>Put an end to the shame, stigma, and inhumanity that currently surrounds HS patients and their treatment.</div></div></div>
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1. psoriasis (PsO), hidradenitis suppurativa (HS) psoriatic arthritis (PsA), axial spondyloarthritis (AxSpA) [including Ankylosing Spondylitis (AS) and non-radiographic Axial Spondyloarthritis (nr-axSpA)], 2. As of June 2025, 3. Palmoplantar Pustulosis (PPP), PSO in children and adolescents, HS in children and adolescents, Juvenile idiopathic arthritis.



## **Professor John Ingram**

MA MSc DM(Oxon) FRCP(Derm)  
FACadMED, Clinical Professor &  
Consultant Dermatologist Division  
of Infection & Immunity Cardiff  
University

## **Bimekizumab Efficacy and Safety Through 3 Years in Patients With Hidradenitis Suppurativa**

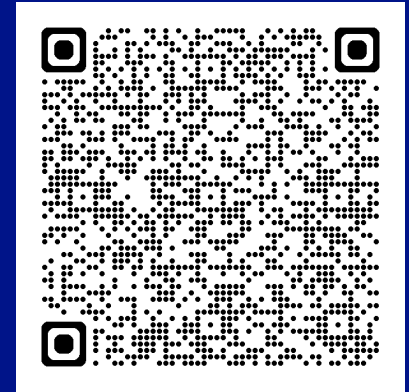
# Disclosures

Speaker 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, Cantargia, ChemoCentryx, Citryll, Elasmogen, Engitix, Incyte, Indero, Insmad, Kymera Therapeutics, MoonLake Immunotherapeutics, Novartis, UCB, UNION Therapeutics and Viela Bio; co-copyright holder of HiSQOL©, HS Patient global assessment, and HS-IGA; his department receives income from copyright of the Dermatology Life Quality Instrument (DLQI) and related instruments.

# 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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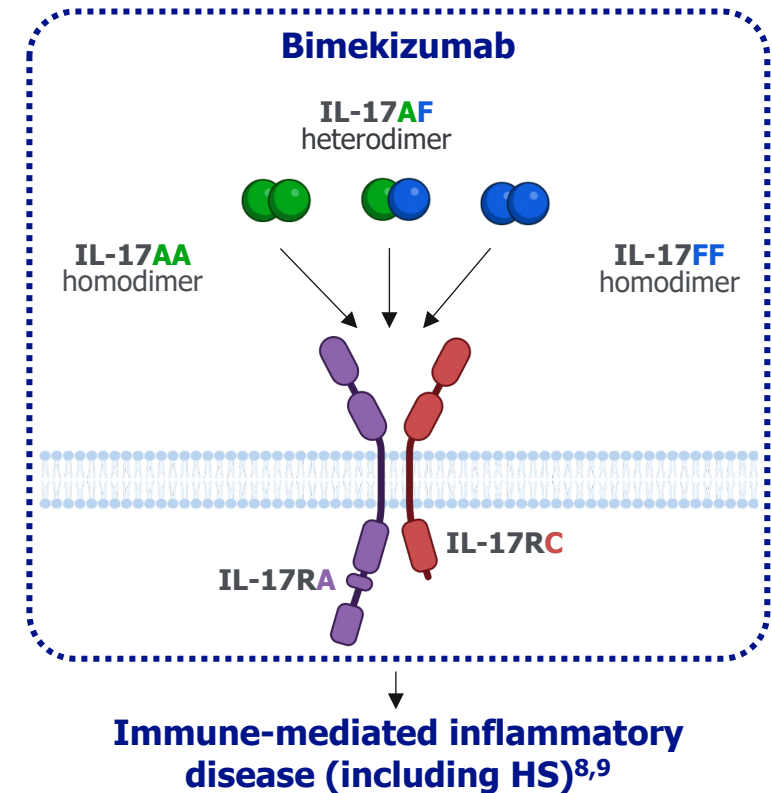


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# Background

- **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).<sup>1–3</sup>
- **Long-term disease control** is essential to prevent irreversible damage and disease progression.<sup>4</sup>
- **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.<sup>5–7</sup>

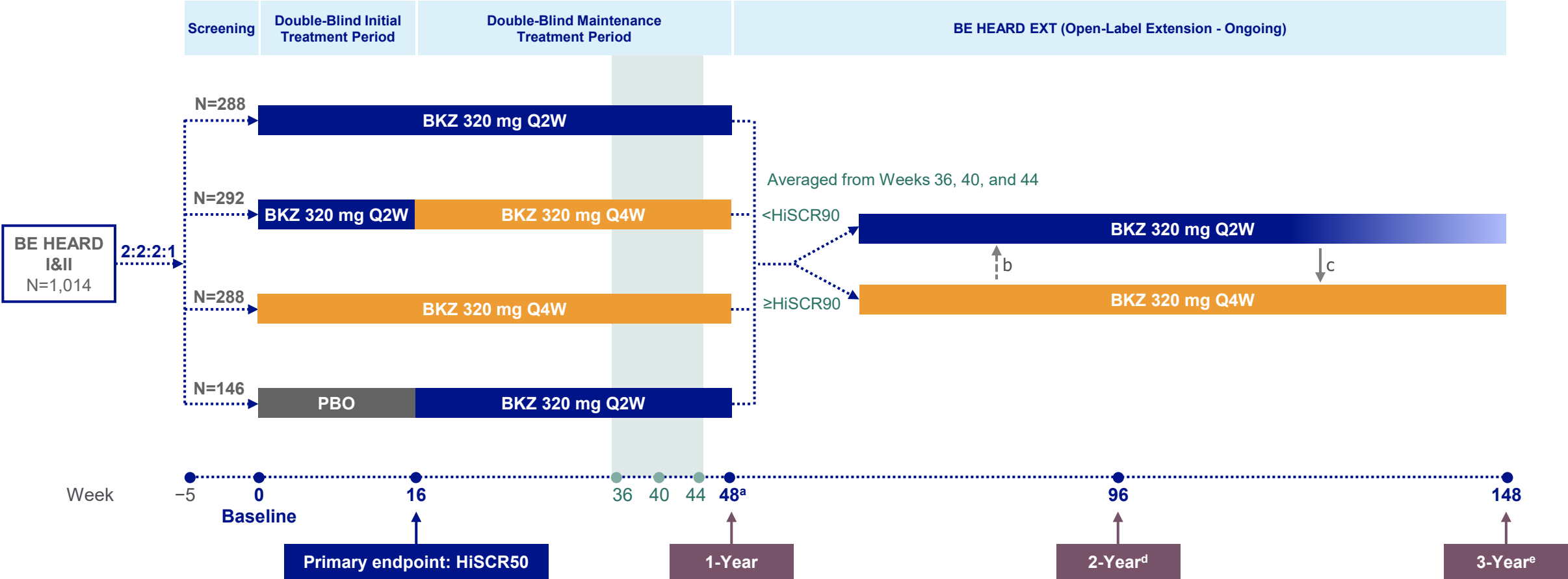


**OBJECTIVE:** To report **efficacy** and **safety** of BKZ in patients with moderate to severe HS **up to 3 years** (148 weeks) for the pooled phase 3 BE HEARD I&II trials and the open-label extension (OLE) BE HEARD EXT.<sup>6,10</sup>



# Study Design

- The phase 3 BE HEARD I&II and BE HEARD EXT study designs:<sup>1,2</sup>



**[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

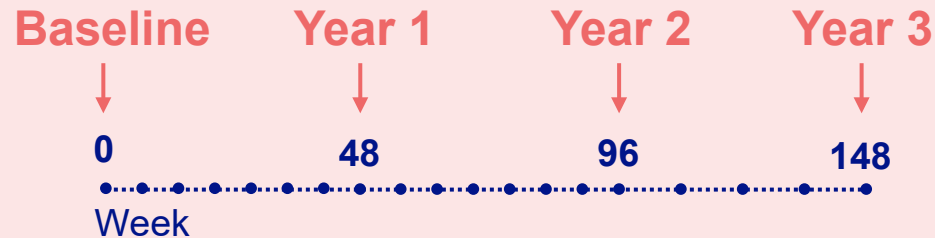
- **Efficacy set:** Patients **randomised to BKZ 320 mg** at baseline in BE HEARD I&II who then entered BE HEARD EXT (BKZ Total).

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

Dermatology Life  
Quality Index (DLQI)  
0/1 response rates<sup>a</sup>

Absolute change  
from baseline in  
draining tunnel  
(DT) count

- Timepoints: Over time to Year 3

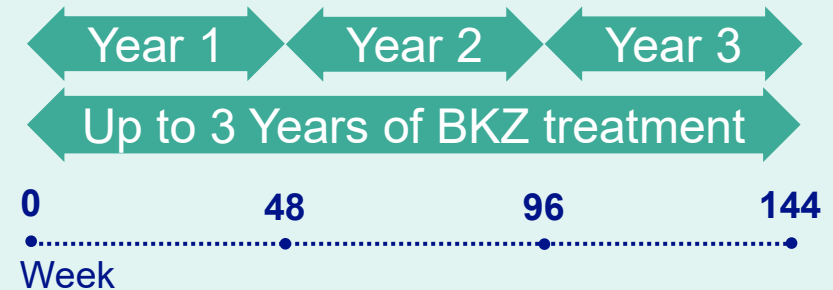


## Safety

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

Treatment-emergent  
adverse events  
(TEAEs)

- Time periods:



<sup>[a]</sup> 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**

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## Modified non-responder imputation (mNRI)<sup>a</sup>



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

<sup>[a]</sup> 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.

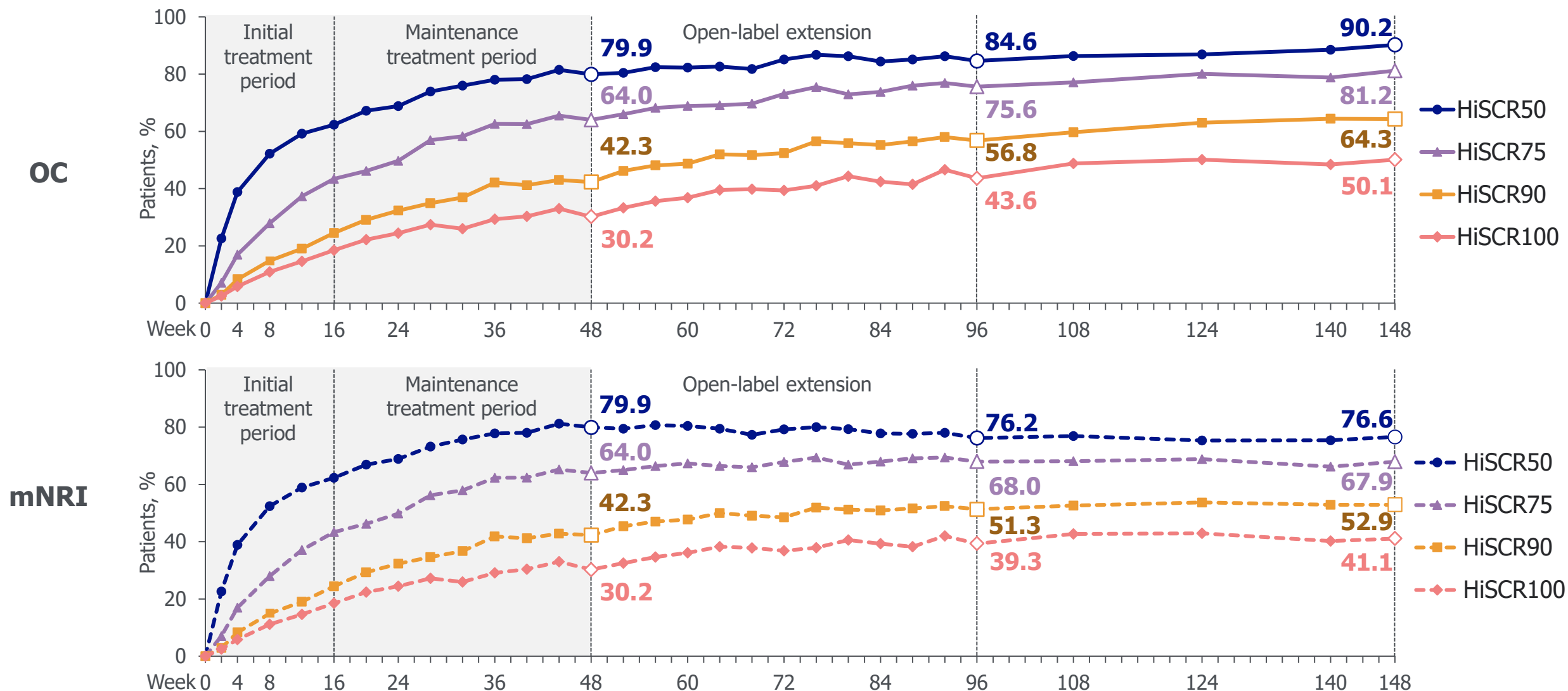
# Baseline Characteristics

- 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.<sup>1–3</sup>

	<b>BKZ Total<sup>a</sup></b> <b>(Efficacy set)</b> N=556	<b>Patients with ≥1 dose BKZ</b> <b>(Safety set)</b> N=995
<b>Age, years</b> , mean (SD)	36.3 (12.2)	36.7 (12.2)
<b>Sex, female</b> , n (%)	299 (53.8)	564 (56.7)
<b>Racial group, White</b> , n (%)	448 (80.6)	796 (80.0)
<b>BMI, kg/m<sup>2</sup></b> , mean (SD)	32.5 (7.8)	33.0 (8.1)
<b>Duration of disease, years</b> , mean (SD)	7.4 (7.1)	8.0 (7.8)
<b>Hurley stage</b> , n (%)		
II	303 (54.5)	553 (55.6)
III	253 (45.5)	442 (44.4)
<b>DLQI total score</b> , mean (SD)	11.0 (6.8)	11.2 (6.9)
<b>Prior biologic use,<sup>b</sup> n (%)</b>	112 (20.1)	192 (19.3)
<b>Baseline antibiotic use</b> , n (%)	54 (9.7)	83 (8.3)

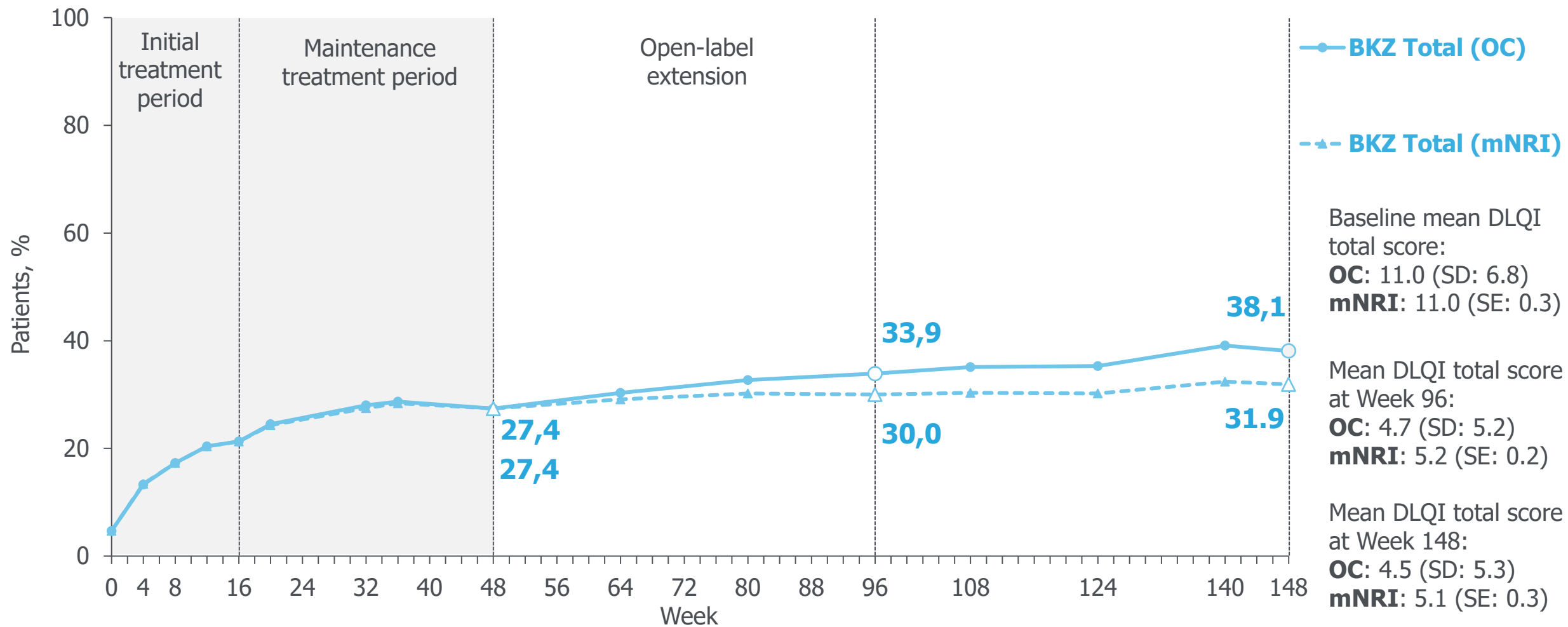


# HiSCR in BKZ Total (OC, mNRI)



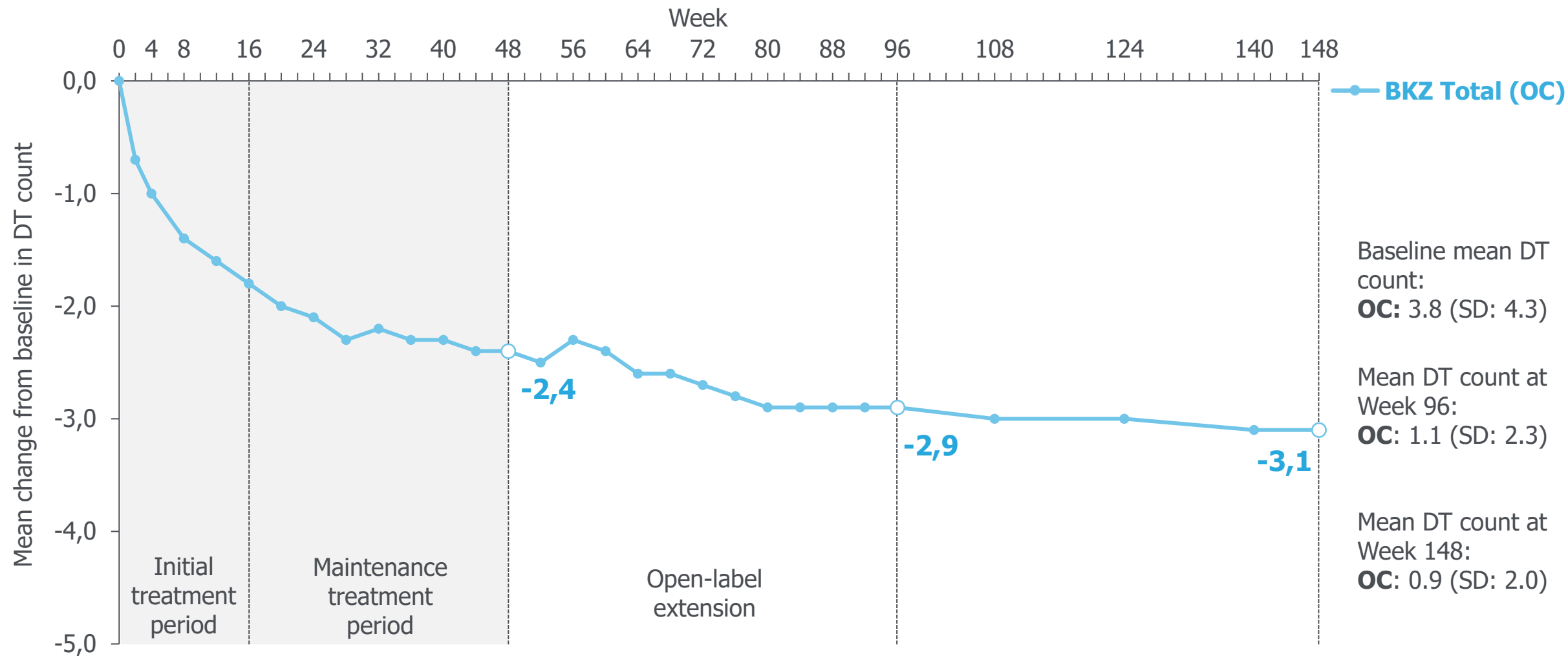
OLE set. Data for patients in BKZ Total are presented. BKZ Total comprised patients randomised to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT. OC, n/N: denominator represents number of patients with a lesion assessment in the given week, and percentages are calculated accordingly. Week 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:  $\geq 50\%/75\%/90\%/100\%$  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<sup>a</sup> 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

	Patients with ≥1 dose BKZ N=995			
EAIR/100 PY (95% CI)	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
<b>Any TEAE</b>	261.9 (244.5, 280.3)	237.2 (218.3, 257.2)	168.3 (152.2, 185.6)	226.8 (212.4, 242.0)
<b>Serious TEAEs</b>	8.2 (6.3, 10.5)	7.9 (5.7, 10.5)	7.9 (5.5, 10.9)	7.2 (6.0, 8.6)
<b>Severe TEAEs</b>	10.4 (8.2, 12.9)	7.2 (5.2, 9.8)	7.0 (4.8, 9.9)	7.7 (6.4, 9.1)
<b>TEAEs leading to discontinuation</b>	8.7 (6.8, 11.1)	4.8 (3.2, 7.0)	3.0 (1.7, 5.1)	6.0 (5.0, 7.3)
<b>Any TEAE leading to death<sup>a</sup></b>	0.1 (0.0, 0.7)	0.3 (0.0, 1.2)	0	0.2 (0.0, 0.5)
<b>Most common TEAEs<sup>b</sup></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)
<b>Serious infections</b>	1.9 (1.1, 3.2)	1.7 (0.8, 3.2)	3.2 (1.8, 5.3)	2.0 (1.4, 2.8)
<b>Fungal infections</b>	34.8 (30.5, 39.6)	25.0 (20.9, 29.7)	22.3 (18.0, 27.2)	24.4 (21.9, 27.1)
<b>Any malignancies</b>	0.5 (0.1, 1.3)	1.0 (0.4, 2.2)	0.6 (0.1, 1.9)	0.7 (0.4, 1.2)
<b>Any hepatic events</b>	6.0 (4.4, 8.0)	5.8 (4.0, 8.2)	4.6 (2.8, 7.0)	4.7 (3.8, 5.9)
<b>Adjudicated suicidal ideation and behaviour<sup>c</sup></b>	0.8 (0.3, 1.7)	0.9 (0.3, 2.0)	0.4 (0.1, 1.6)	0.7 (0.4, 1.2)
<b>Definite or probable adjudicated IBD<sup>d</sup></b>	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.

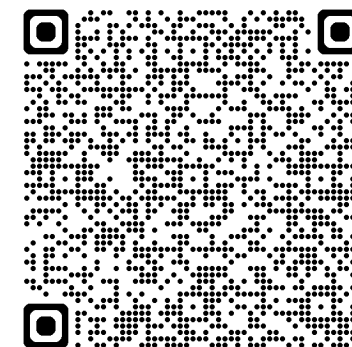
**Draining tunnel** and **health-related quality of life** improvements were also **maintained** through **3 years**.



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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## **Dr. Amit Garg**

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Medicine at Hofstra/Northwell  
| Professor, Center for Health  
Innovations & Outcomes Research,  
Feinstein Institutes for Medical Research

**BE HEARD I&II HS Lesion Intervention  
Over Time**

**BE HEARD I&II IHS4 by Disease  
Duration**

# Disclosures

Speaker receives honoraria as an advisor for AbbVie, Almirall, Boehringer Ingelheim, Engitix, Immunitas Therapeutics, Incyte, Insmad, Novartis, Pfizer, Sonoma Biotherapeutics, UCB, Union Therapeutics, Zura Bio; receives research grants from AbbVie, CHORD COUSIN Collaboration (C3) and UCB.

# Bimekizumab impact on hidradenitis suppurativa lesions over 2 years: Data from BE HEARD EXT

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Falk G. Bechara<sup>9-10</sup>

**P2839**

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# Introduction

- Hidradenitis suppurativa (HS) is an inflammatory skin disease characterised by recurrent, painful and debilitating lesions which lead to potentially long-term, severe sequelae.<sup>1,2</sup>
- The current standard measurements of lesions used in clinical trials involve reporting the percentage of patients meeting an endpoint, which does not allow for an understanding of how specific lesion types improve for individual patients, and may not capture the large amount of **within-patient variability** observed.<sup>3</sup>
- Bimekizumab (BKZ) is a humanised IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.<sup>4</sup>

# Methods

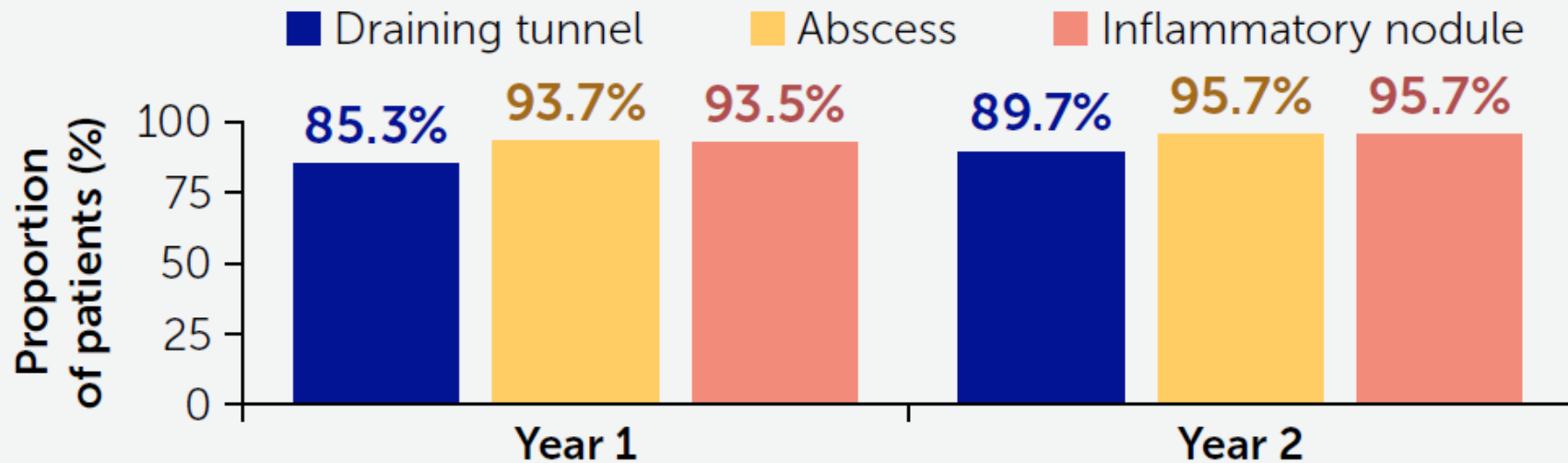
- Data were pooled from **BE HEARD I&II** studies and their open-label extension, **BE HEARD EXT** (NCT04242446, NCT04242498, NCT04901195).<sup>5,6</sup>
- Data are reported for patients randomised to receive BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT (BKZ Total group).
- **Lesion counts** are reported on **an individual patient-basis** for draining tunnels (DT), abscesses and inflammatory nodules (IN). In addition, the overall proportion of patients who had a lesion at baseline and experienced a reduction in lesion count, or no lesions at baseline and remained lesion-free, are reported at Year 1 (Week 48) and Year 2 (Week 96).
- Cumulative **2-year data** (48 weeks in BE HEARD I&II and 48 weeks in BE HEARD EXT) reported as observed case.

# Summary

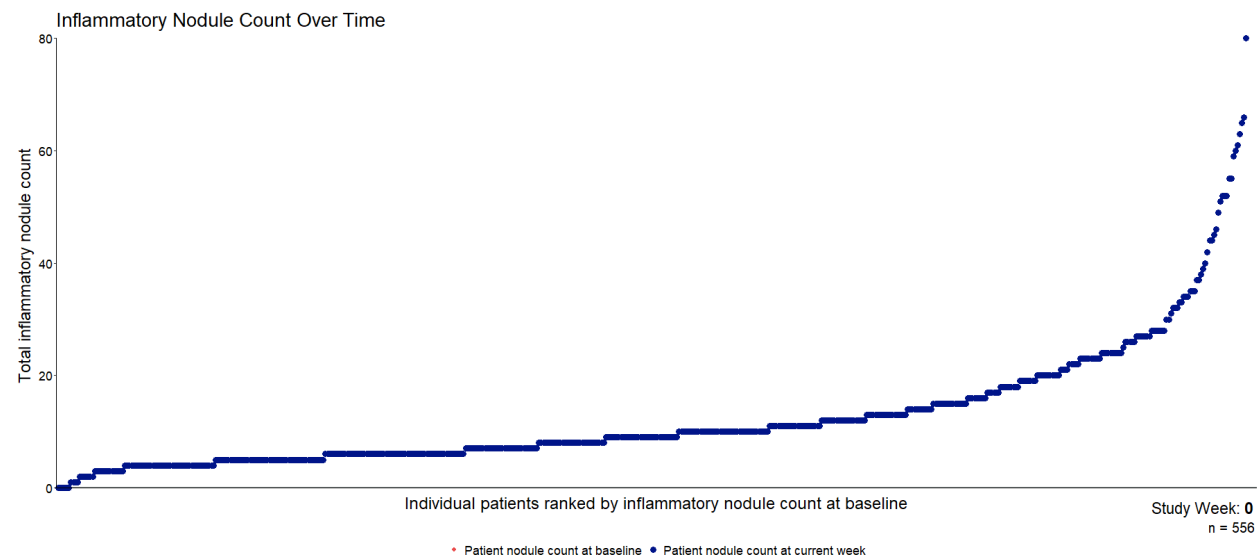
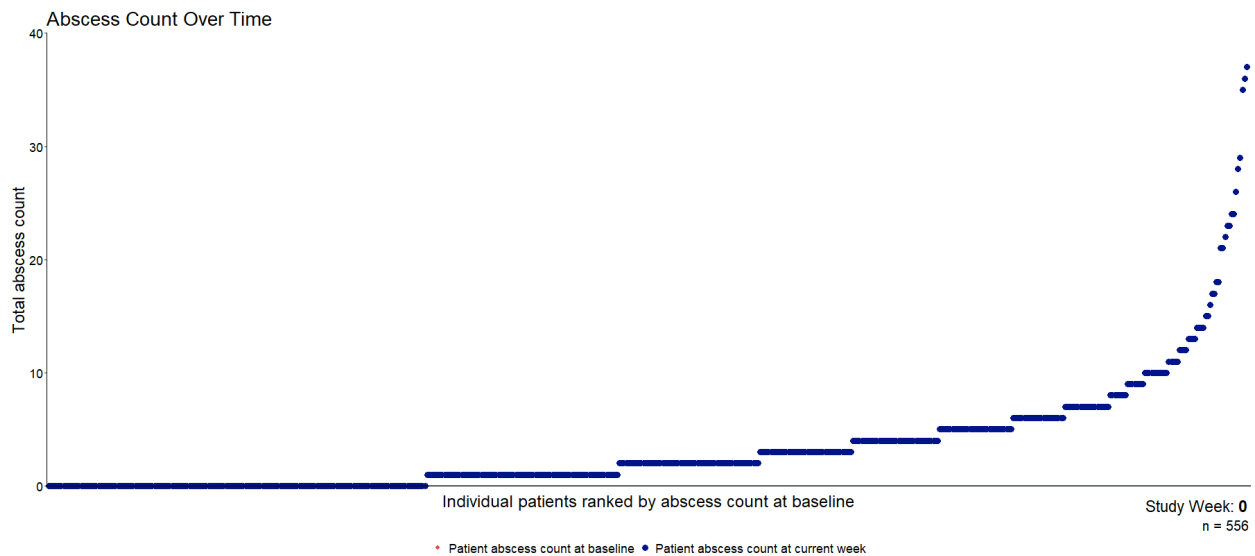
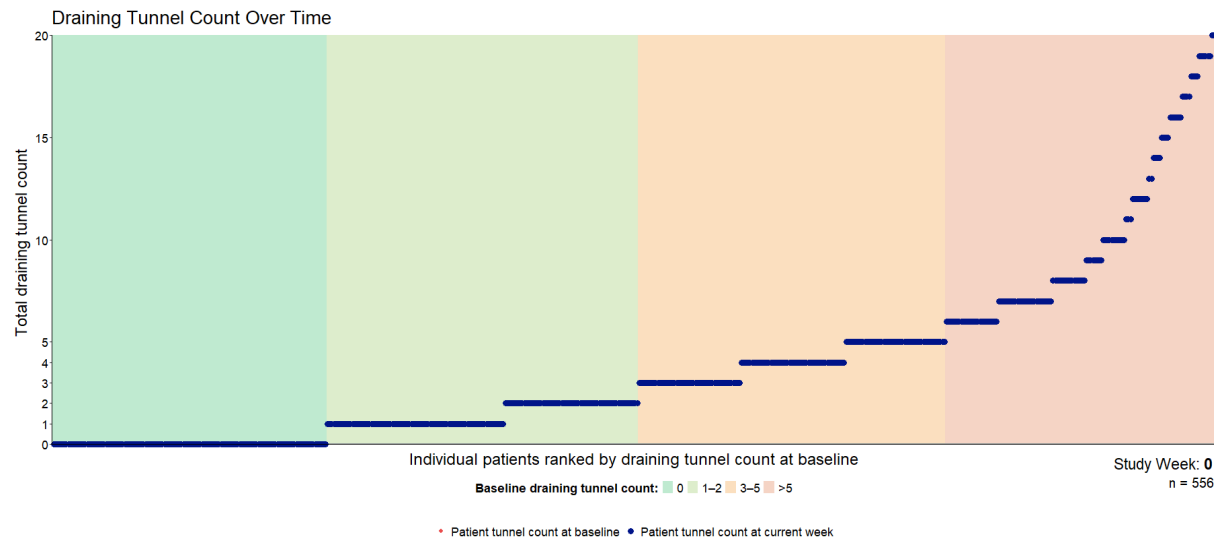
## Results

The **majority of patients saw reductions from baseline** in draining tunnel, abscess and inflammatory nodule count at Years 1 and 2.

**Proportion of patients with reductions from baseline in draining tunnel, abscess and inflammatory nodule count at Year 1 and Year 2**



# All Patient-Level Lesion Data



**Red** dots indicate IN count at baseline for each included patient, with shaded areas representing baseline quartiles, as noted in the legend. Patients are ranked by baseline lesion count. **Blue** dots indicate reported IN count for each included patient at the specified timepoint. Each patient retains their x-axis position. Four patients were omitted from the IN count due to their baseline count exceeding the y-axis maximum – IN count at baseline: 254, 91, 89, 87; Week 48: 5, 50, 24, 15; Week 96: 8, 5, 7, 13, respectively. Year 1 N=556; Year 2 N=446. IN: inflammatory nodules.

# Conclusions



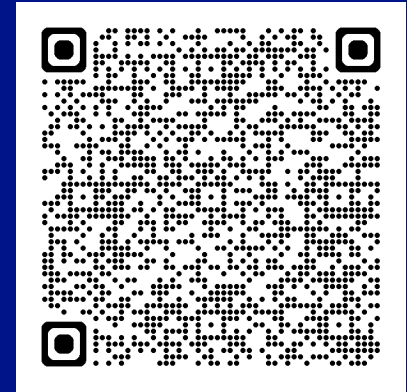
Over 2 years, bimekizumab treatment **reduced the number of HS lesions** in the majority of individuals ( $\geq 89.7\%$ ). These data show the dynamic changes in draining tunnels, abscesses and inflammatory nodules within individual patients; such data are important due to the severe **long-term sequelae** of these lesions.



# Bimekizumab efficacy on IHS4 response levels and draining tunnels by HS disease duration over 2 years: Data from BE HEARD EXT

**Thrasyvoulos Tzellos,<sup>1,2</sup> Christopher J. Sayed,<sup>1,3</sup> Christos C. Zouboulis,<sup>1,4</sup> Valentina Dini,<sup>1,5</sup> Takuya Miyagawa,<sup>6</sup> Irina Turchin,<sup>7-9</sup> Susanne Wiegatz,<sup>10</sup> Sarah Kavanagh,<sup>11</sup> Afsaneh Alavi<sup>1,12</sup>**

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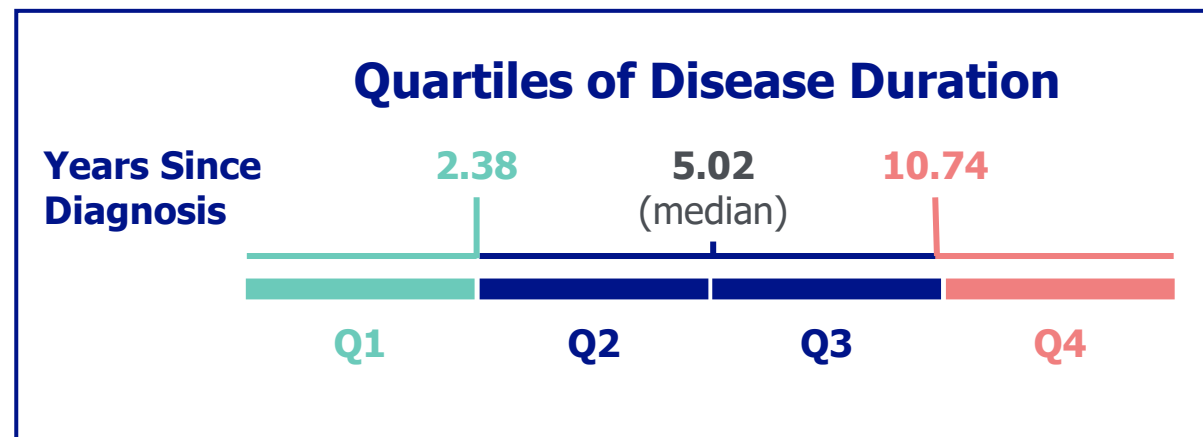


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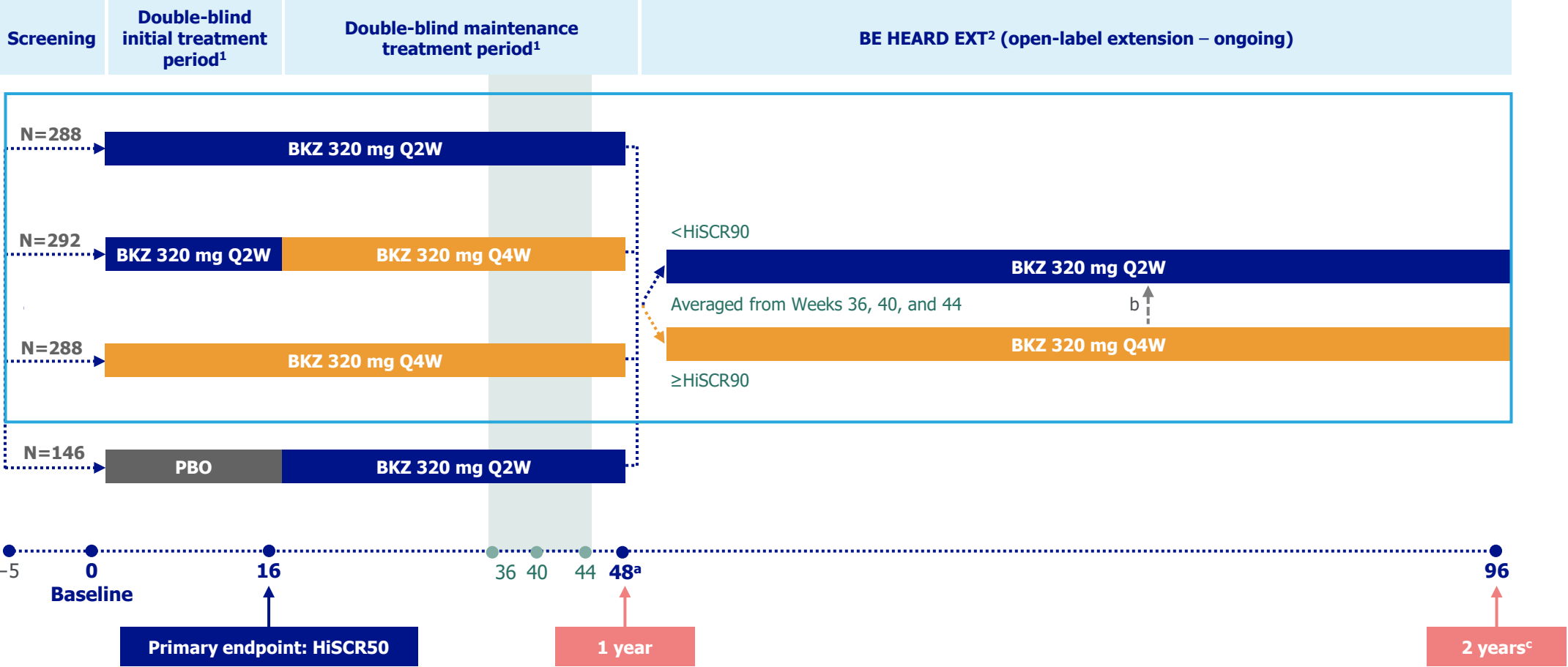
# Methods

- Data pooled from the phase 3 **BE HEARD I&II** and the open-label **BE HEARD EXTENSION**.<sup>1–4</sup>
- **IHS4 response** is reported:
  - At Year 1 (Week 48) and Year 2 (Week 96).
  - By **lowest** and **highest** quartiles of baseline **disease duration** since HS diagnosis.<sup>5</sup>
- The proportion of patients achieving **DT categories** (0, 1–2, 3–5, >5) is also reported by **disease duration** over 2 years.
- Data are reported for patients randomised to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT (OLE set; BKZ Total group).
- Observed case data are reported.



**1.** Kimball AB et al. The Lancet 2024;403:2504–19; **2.** BE HEARD I: <https://clinicaltrials.gov/study/NCT04242446>; **3.** BE HEARD II: <https://clinicaltrials.gov/study/NCT04242498>; **4.** BE HEARD EXT: [www.clinicaltrials.gov/study/NCT04901195](https://clinicaltrials.gov/study/NCT04901195); **5.** Zouboulis CC et al. Br J Dermatol 2017;177:1401–9. BKZ: bimekizumab; DT: draining tunnel; IHS4: International Hidradenitis Suppurativa Severity Score System; OLE: open-label extension.

# Study Design



**[a]** Patients who completed Week 48 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 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: [www.clinicaltrials.gov/study/NCT04901195](https://www.clinicaltrials.gov/study/NCT04901195). AN: abscess and inflammatory nodule; HiSCR50/90; BKZ: bimekizumab; HS: hidradenitis suppurativa; Hidradenitis Suppurativa Clinical Response defined as ≥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 2 weeks; Q4W: every 4 weeks.

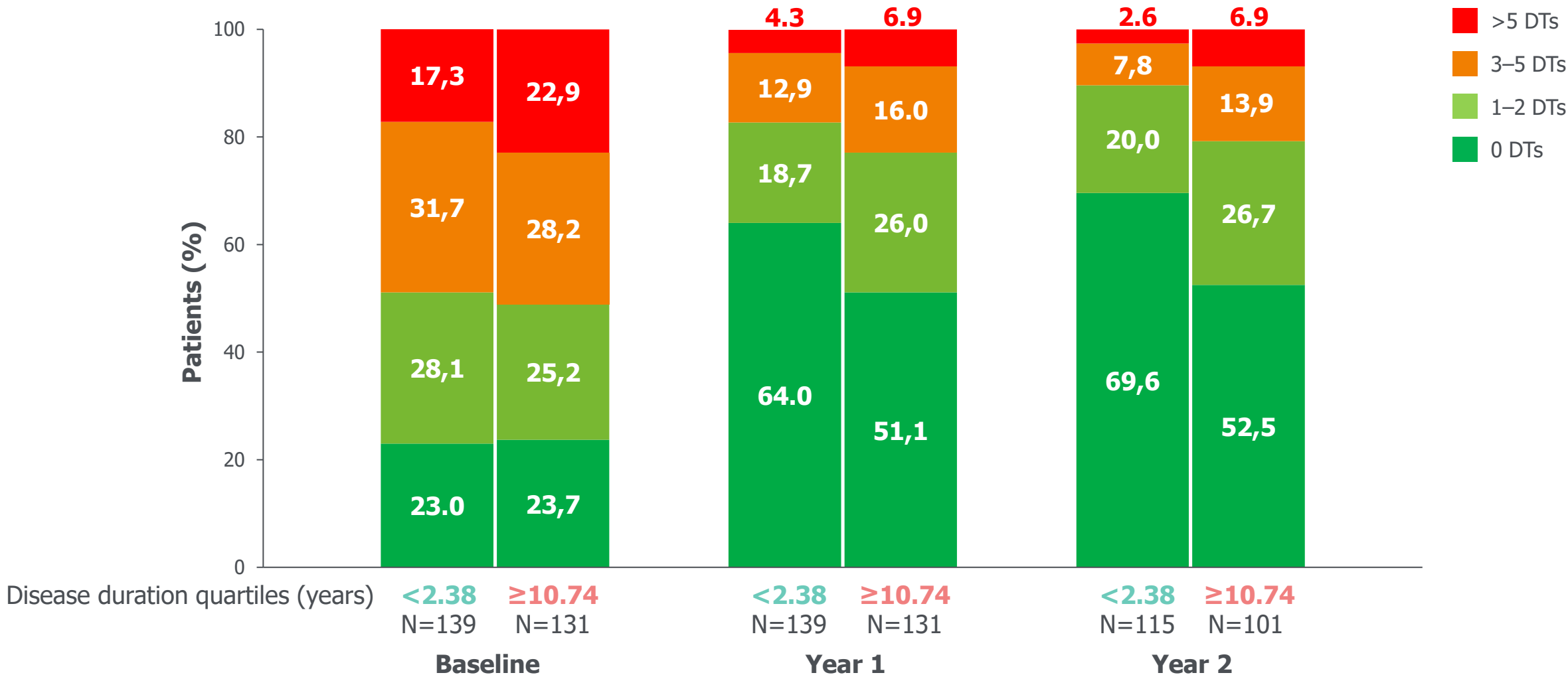
# Baseline Characteristics

	Disease duration <2.38 years BKZ 320 mg Total N=139	Disease duration ≥10.74 years BKZ 320 mg Total N=131
<b>Age (years),</b> mean (SD)	34.8 (13.5)	41.8 (10.3)
<b>Sex, female,</b> n (%)	63 (45.3)	84 (64.1)
<b>Racial group,</b> n (%)		
White	111 (79.9)	109 (83.2)
Black	6 (4.3)	13 (9.9)
Other/Missing	22 (15.8)	9 (6.9)
<b>BMI (kg/m<sup>2</sup>),</b> mean (SD)	31.2 (7.4)	33.3 (7.8)
<b>Smoking status,</b> current, n (%)	57 (41.0)	66 (50.4)
<b>AN count,</b> mean (SD)	16.1 (14.6)	19.4 (25.9)
<b>DT count,</b> mean (SD)	3.3 (3.3)	3.9 (4.6)
<b>IHS4 score,</b> mean (SD)	32.2 (22.8)	38.9 (37.0)
<b>Hurley stage,</b> n (%)		
II	82 (59.0)	75 (57.3)
III	57 (41.0)	56 (42.7)
<b>Prior biologic use,<sup>a</sup></b> n (%)	11 (7.9)	29 (22.1)
<b>Baseline antibiotic use,</b> n (%)	13 (9.4)	15 (11.5)

- Patients in the **lowest** disease duration quartile, had a higher distribution of **younger** patients, **males** and **non-smokers** versus those in the **highest** quartile.
- The distribution of patients with **prior biologic use** was higher in patients in the **highest** disease duration quartile.
- Mean **AN count** and mean **IHS4 score** were also higher in the **highest** disease duration quartile.

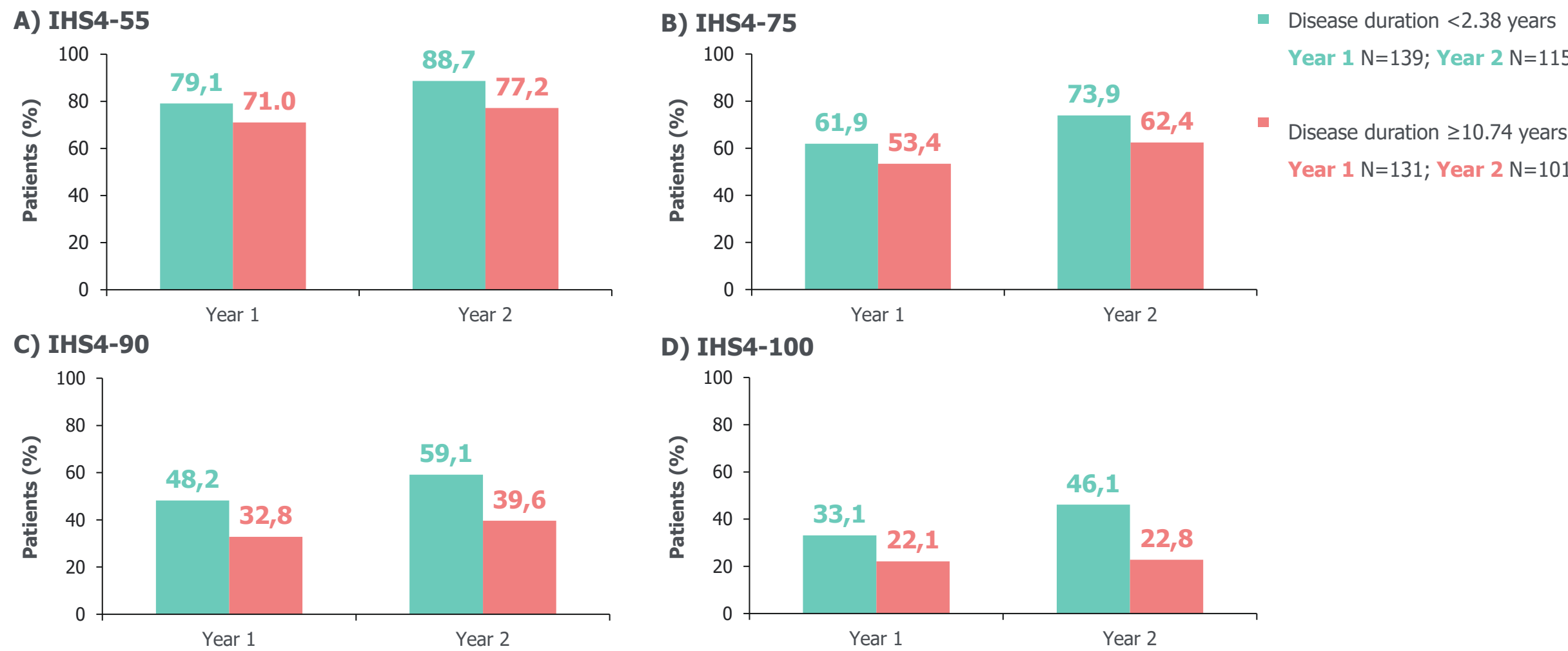
[a] Patients received prior biologic therapy for any indication. AN: abscess and inflammatory nodule; BKZ: bimekizumab; BMI: body mass index; DT: draining tunnel; IHS4: International Hidradenitis Suppurativa Severity Score System; SD: standard deviation.

# DT Categories by **Lowest** and **Highest** Baseline Disease Duration Quartiles Since HS Diagnosis



OC, n/N: denominator represents number of patients with a non-missing DT count assessment in the given week, and percentages are calculated accordingly. For 0/1-2/3 -5/>5 DTs, n=32/39/44/24; n=31/33/37/30; n=89/26/18/6; n=67/34/21/9; n=80/23/9/3; n=53/27/14/7 for Baseline, Year 1 and Year 2 lowest and highest disease duration quartiles, respectively. DT: draining tunnel; HS: hidradenitis suppurativa; OC: observed case.

# IHS4 Response Levels by Lowest and Highest Baseline Disease Duration Quartiles Since HS Diagnosis at Year 1 and 2



OC, n/N: denominator represents number of patients with a non-missing lesion count assessment in the given week, and percentages are calculated accordingly. Year 1, disease duration <2.38 years IHS4-55/75/90/100: n=110/86/67/46. Year 1, disease duration ≥10.74 years IHS4-55/75/90/100: n=93/70/43/29. Year 2, disease duration <2.38 years IHS4-55/75/90/100: n=102/85/68/53. Year 2, disease duration ≥10.74 years IHS4-55/75/90/100: n=78/63/40/23. IHS4: International Hidradenitis Suppurativa Severity Score System; IHS4-55/75/90/100: ≥55%/≥75%/≥90%/100% improvement from baseline in IHS4 total score; HS: hidradenitis suppurativa; OC: observed case.



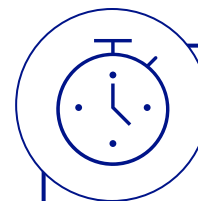
# Conclusions



**Bimekizumab** treatment demonstrated **clinically meaningful improvements**, regardless of disease duration.



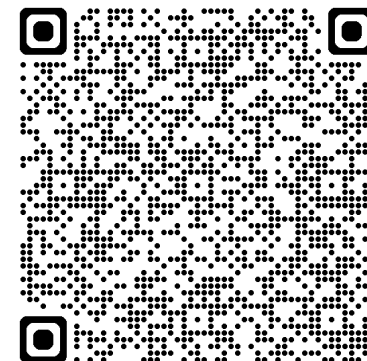
The **biggest impact** of short **disease duration** on clinical outcomes were seen at **high thresholds** (IHS4-100, 0 DTs) at 2 years.



Bimekizumab-treated patients with **shorter disease duration** had **better efficacy outcomes** than those with longer disease duration.

Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **TTz, CJS, CCZ, VD, TM, IT, SW, SK, AA**; Drafting of the publication, or reviewing it critically for important intellectual content: **TTz, CJS, CCZ, VD, TM, IT, SW, SK, AA**; Final approval of the publication: **TTz, CJS, CCZ, VD, TM, IT, SW, SK, AA**. DTs: draining tunnels; IHS4: International Hidradenitis Suppurativa Severity Score System; HS: hidradenitis suppurativa.

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## Q&A

### **Professor John Ingram**

MA MSc DM(Oxon) FRCP(Derm) FAcadMed, Clinical Professor & Consultant Dermatologist Division of Infection & Immunity Cardiff University

### **Dr. Amit Garg**

Professor & Founding Chair, Department of Dermatology, Zucker School of Medicine at Hofstra/Northwell  
Professor, Center for Health Innovations & Outcomes Research, Feinstein Institutes for Medical Research

### **Fiona du Monceau**

Executive Vice President, Head of Patient Impact and Chief Commercial Officer

# Thank you



Inspired by **patients.**  
Driven by **science.**