Bimekizumab Leads to Sustained Flare-Free Status in Moderate to Severe Hidradenitis Suppurativa: 3-Year Data from BE HEARD EXT

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Objectives

To assess **flare outcomes**[a,b] in all, or baseline Hurley stage II or III patients, with moderate to severe **hidradenitis suppurativa** (HS) treated with **bimekizumab** (BKZ) over 3 years (148 weeks).

Background

- **HS** is characterized by nodules, abscesses, and draining tunnels, with acute exacerbations of symptoms known as "**flares**".[1,2]
- Timely, effective **disease management** is important to reduce the frequency of flares.[1]
- **BKZ** is a humanized IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17A and IL-17F.[3]

Methods

- Data were pooled from BE HEARD I&II and their open-label extension BE HEARD EXT (full study design available via QR code).[4,5]
- Patients randomized to receive **BKZ 320 mg** from baseline in BE HEARD I&II who entered BE HEARD EXT were included (**BKZ Total group**); data also reported by baseline **Hurley stage**.
- Flare data were collected at scheduled clinic visits. Data are reported as observed case (OC).

Flare: ≥25% increase in abscess and inflammatory nodule (AN) count versus baseline with an absolute increase in AN count of ≥2.

Flare outcomes reported to **Year 3**:

- The cumulative proportion of patients who **remained flare-free**.[a]
- The proportion of patients with a **flare** at a given visit.[b]

[**a**] No observed flares at any visit up to and including the given timepoint; [**b**] Flare rates reported at a single point. **1.** Masson R et al. Skin Appendage Disord 2024;10:224–8; **2.** Kirby JS et al. Br J Dermatol 2020;182:24–8; **3.** Adams R et al. Front Immunol 2020;11:1894; **4.** Kimball AB et al. Lancet. 2024;403:2504–19 (NCT04242446, NCT04242498); **5.** BE HEARD EXT (NCT04901195): www.clinicaltrials.gov/study/NCT04901195; AN: abscess and inflammatory nodule; BKZ: bimekizumab; HS: hidradenitis suppurativa; IL: interleukin; OC: observed case.

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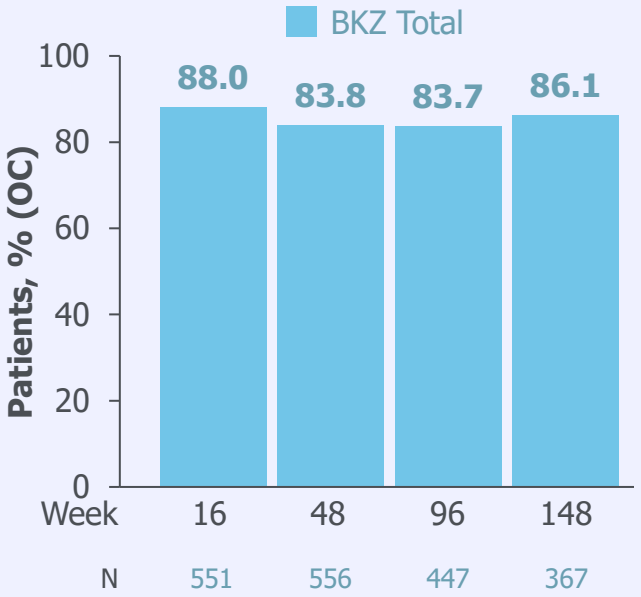
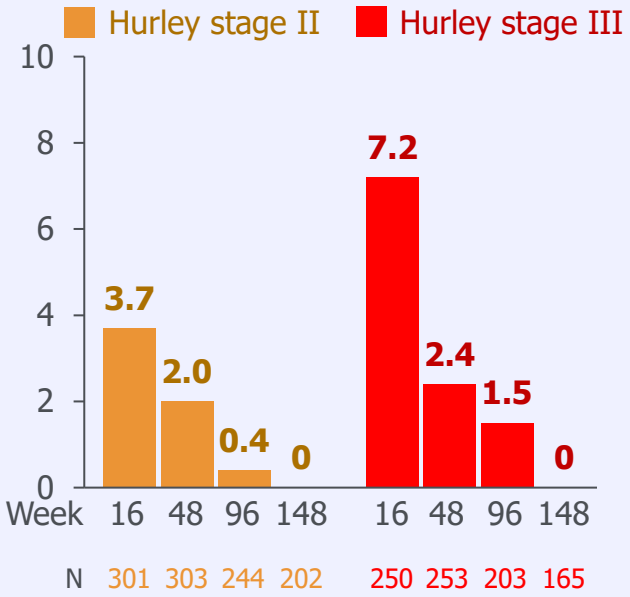
Summary

Flare outcomes were assessed in patients with **moderate to severe HS** treated with **bimekizumab** over 3 years.

Cumulative proportion of patients remaining **flare-free**[a]



Proportion of patients experiencing a **flare**[b]



Most **bimekizumab-treated** patients **remained flare-free** at scheduled clinic visits through 3 years and **did not experience a flare** at Year 3, regardless of baseline Hurley stage.

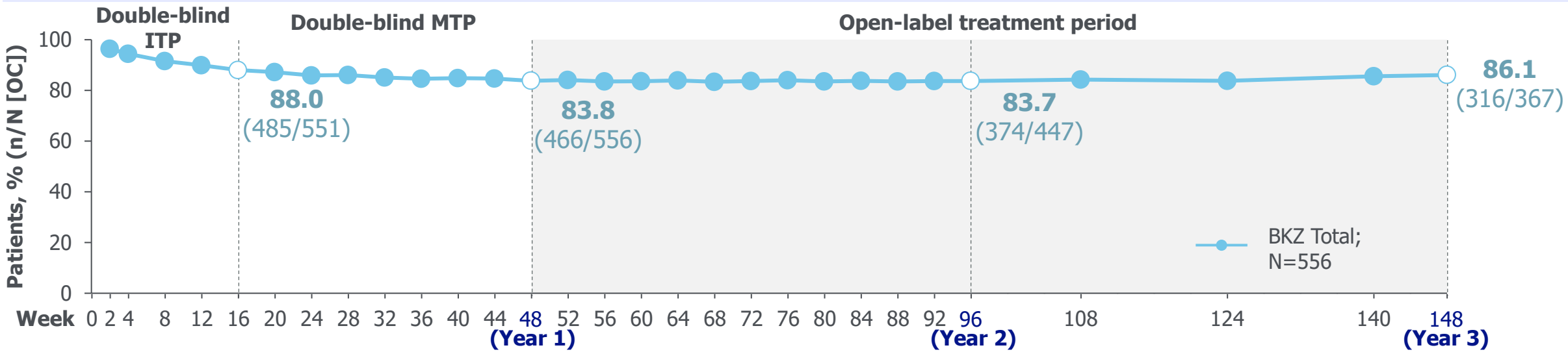
Baseline Characteristics

	BKZ Total N=556	Hurley stage II[c] N=303	Hurley stage III[c] N=253
Age (years), mean, SD	36.3 (12.2)	36.5 (12.3)	36.1 (12.0)
Sex, female, n (%)	299 (53.8)	172 (56.8)	127 (50.2)
Racial group, White, n (%)	448 (80.6)	258 (85.1)	190 (75.1)
Smoking status, current, n (%)	260 (46.8)	145 (47.9)	115 (45.5)
BMI (kg/m²), mean (SD)	32.5 (7.8)	32.6 (8.1)	32.5 (7.5)
Duration of HS (years), mean (SD)	7.4 (7.1)	7.3 (7.4)	7.5 (6.9)
DLQI total score, mean (SD)	11.0 (6.8)	10.1 (6.5)	12.2 (7.0)
AN count, mean (SD)	16.9 (18.5)	14.7 (18.8)	19.6 (17.9)
DT count, mean (SD)	3.8 (4.3)	2.0 (2.3)	5.9 (5.1)
Hurley stage[d], n (%)			
II	303 (54.5)	303 (100.0)	0 (0)
III	253 (45.5)	0 (0)	253 (100)

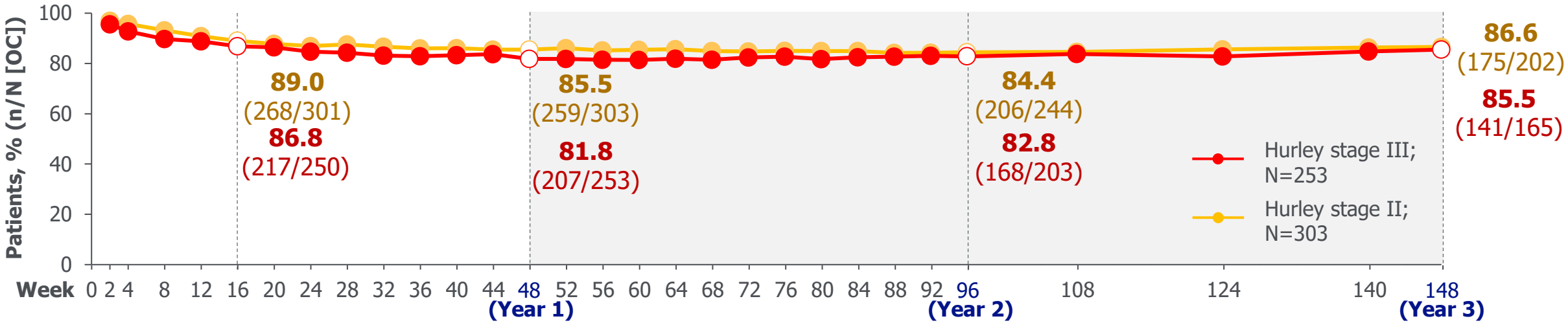
[**a**] No observed flares at any visit up to and including the given timepoint; [**b**] Flare rates reported at a single point; [**c**] Refers to baseline Hurley stage; [**d**] This refers to the worst overall Hurley stage derived from the Hurley stages recorded across all anatomical regions. AN: abscess and inflammatory nodule; BKZ: bimekizumab; BMI: body mass index; DLQI: Dermatology Life Quality Index; DT: draining tunnel; HS: hidradenitis suppurativa; OC: observed case; SD: standard deviation.

The Cumulative Proportion of Patients Remaining Flare-Free Was High Through 3 Years[a]

BKZ Total



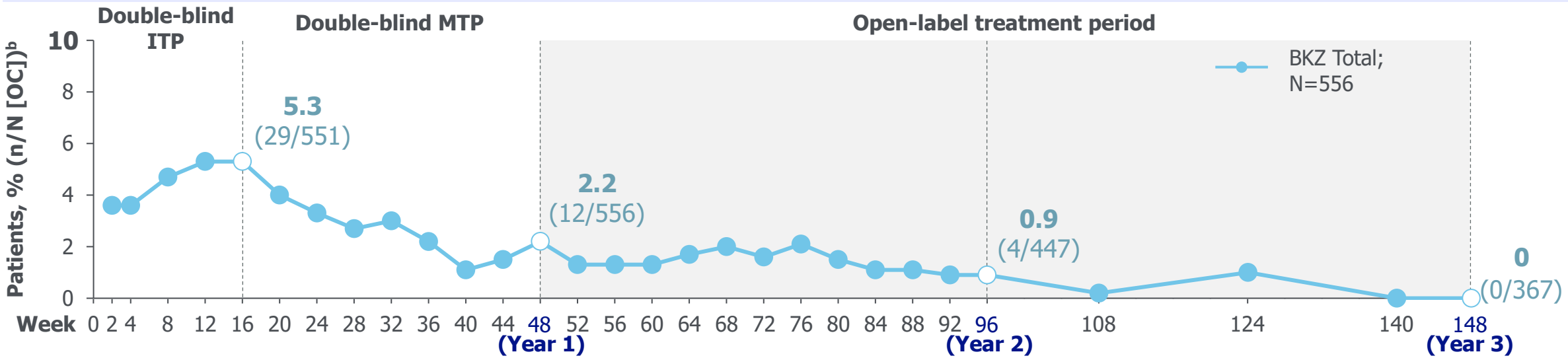
BKZ Total Reported by Baseline Hurley Stage II and III



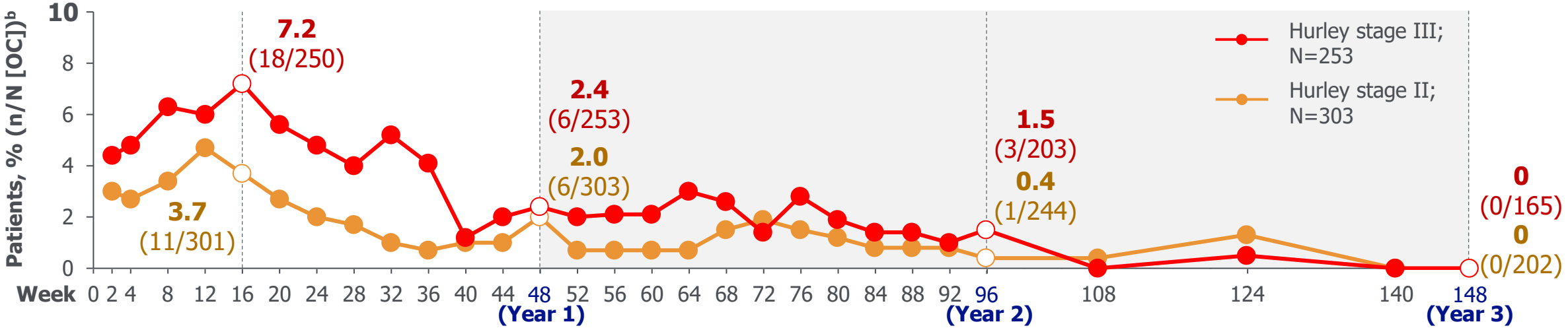
Remaining flare-free: no observed flares at any visit up to and including the given timepoint. The requirement of a visit at Week 48 to enter the open-label extension resulted in an increase in N number at Week 48. OC, n/N: the denominator represents the number of patients with non-missing scores at the given week, and percentages are calculated accordingly. [**a**] Patients who did not complete the trial from Week 48 to Week 148 may have affected results (n=189). Patients withdrawing due to lack of efficacy: n=23. Patients who experienced more flares may have been more likely to withdraw. BKZ: bimekizumab; ITP: initial treatment period; MTP: maintenance treatment period; OC: observed case.

The Proportion of Patients Experiencing a Flare at a Given Visit Remained Low to Year 3[a]

BKZ Total



BKZ Total Reported by Baseline Hurley Stage II and III



Flare rates reported at a single point. The requirement of a visit at Week 48 to enter the open-label extension resulted in an increase in N number at Week 48. OC, n/N: the denominator represents the number of patients with non-missing scores at the given week, and percentages are calculated accordingly. [**a**] Patients who did not complete the trial from Week 48 to Week 148 may have affected results (n=189). Patients withdrawing due to lack of efficacy: n=23. Patients who experienced more flares may have been more likely to withdraw; [**b**] Due to the small range of percentage values, the Y-axis range is 0–10%. BKZ: bimekizumab; ITP: initial treatment period; MTP: maintenance treatment period; OC: observed case.

Conclusions

Most patients treated with bimekizumab who stayed in the study remained flare-free at all visits through 3 years.

Bimekizumab-treated patients who were Hurley stage II experienced numerically lower flare rates through Year 1 versus those who were Hurley stage III. In Year 3, low flare rates were achieved by all patients remaining in the study, regardless of Hurley stage.

These data suggest that initiating bimekizumab therapy in Hurley stage II patients may result in more rapid control of inflammatory flares.

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