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

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Disclosures

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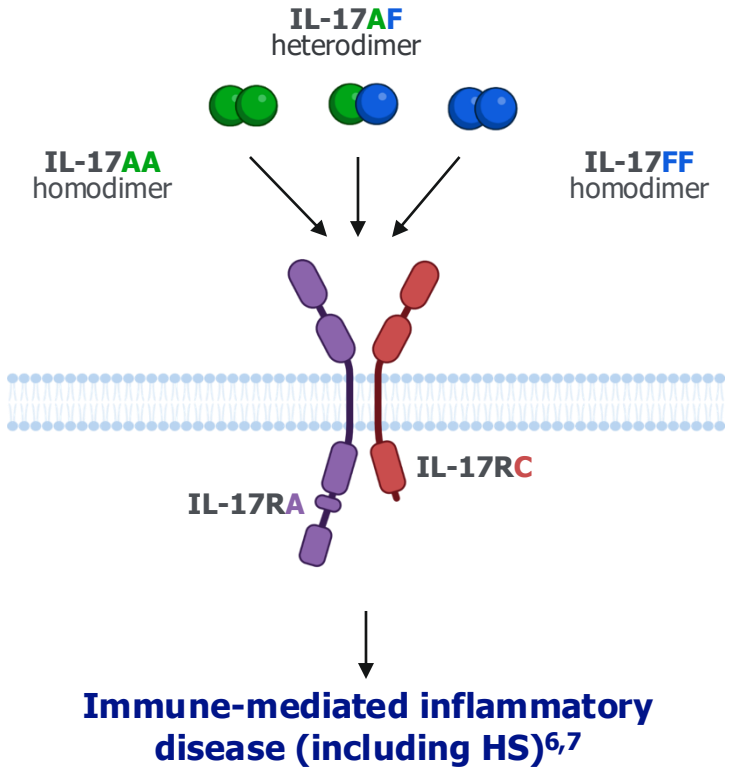
Background

- Patients with the progressive disease hidradenitis suppurativa (HS) can face **delayed diagnosis**, resulting in tunnel progression and suboptimal treatment outcome.[1,2] Early diagnosis is crucial for effective treatment.[1,2]
- **Bimekizumab** (BKZ), a humanised IgG1 monoclonal antibody, selectively inhibits interleukin (IL)-17F in addition to IL-17A.[3]
- The clinician-rated **International HS Severity Score System** (IHS4) evaluates the number of inflammatory nodules/abscesses/draining tunnels (DTs).[4,5]

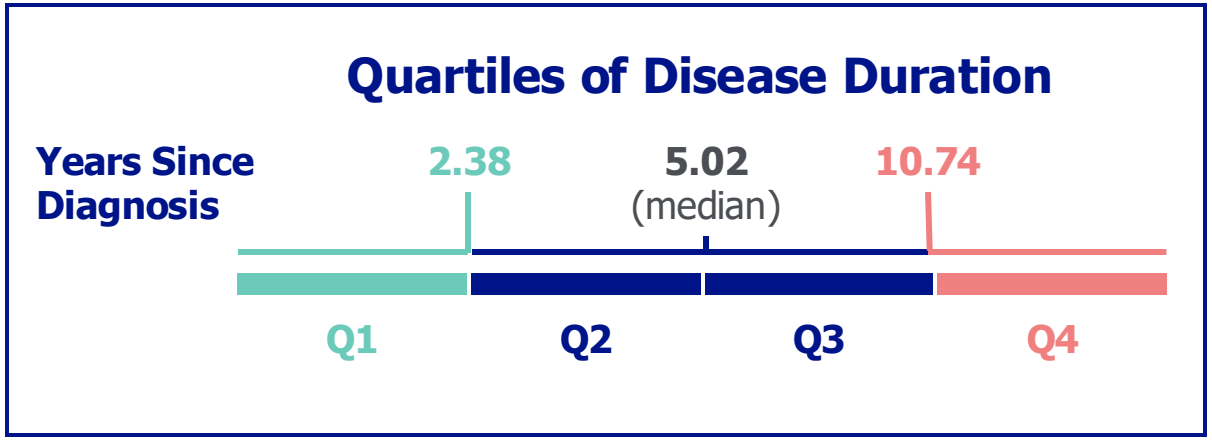


OBJECTIVE: To investigate the impact of disease duration on IHS4 outcomes and DTs in patients with moderate to severe HS treated with bimekizumab over 2 years.

1. Saunte DM et al. Br J Dermatol 2015;173:1546–9; **2.** Kokolakis G et al. Dermatol 2020;236:421–30; **3.** Adams R et al. Front Immunol 2020;11:1894; **4.** Zouboulis CC et al. Br J Dermatol 2017;177:1401–9; **5.** Tzellos T et al. J Eur Acad Dermatol Venereol 2023;37:395–401; **6.** Figure adapted from: Patel DD et al. Ann Rheum Dis 2012;0:1–8 (Fig 1); **7.** Zouboulis CC et al. Presented at EADV 2024; P7925. DT: draining tunnel; HS: hidradenitis suppurativa; IHS4: International Hidradenitis Suppurativa Severity Score System; IL: interleukin; IL-17R: interleukin-17 receptor.

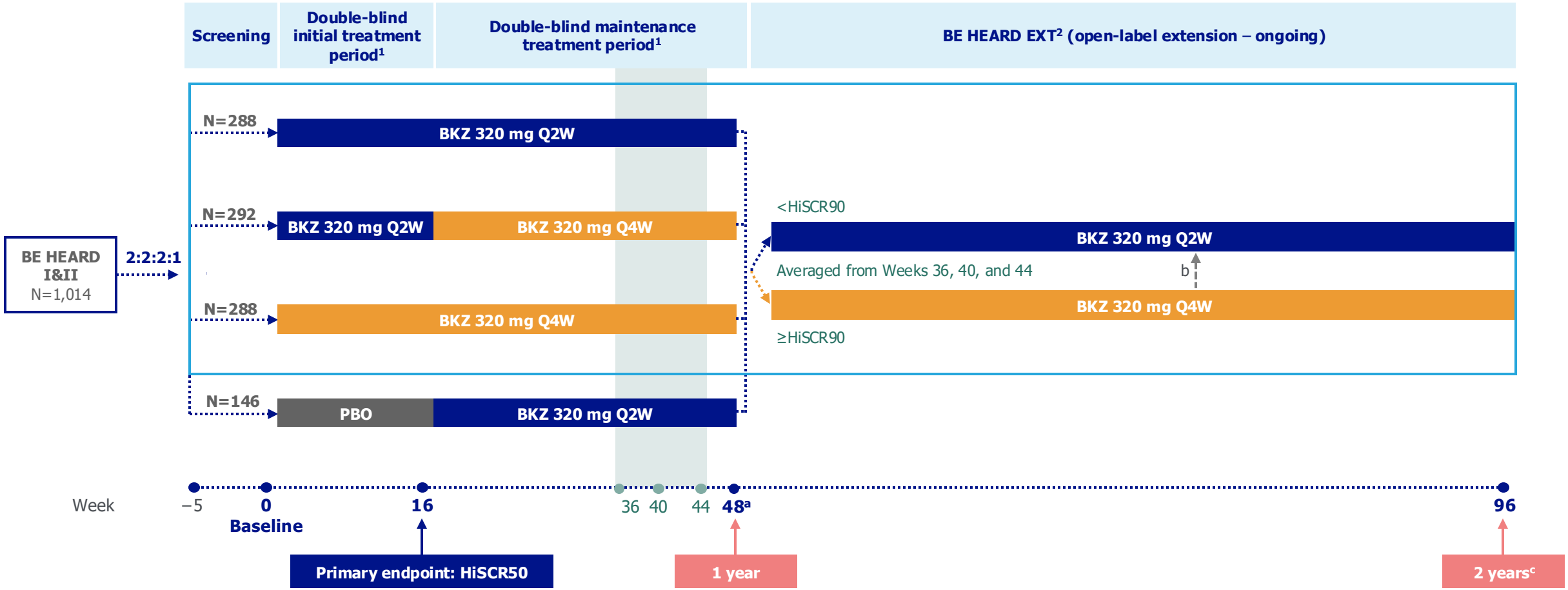
Methods

- Data pooled from the phase 3 **BE HEARD I&II** and the open-label **BE HEARD EXTENSION**.[1–4]
- **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.[5]
- 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; **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. 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.

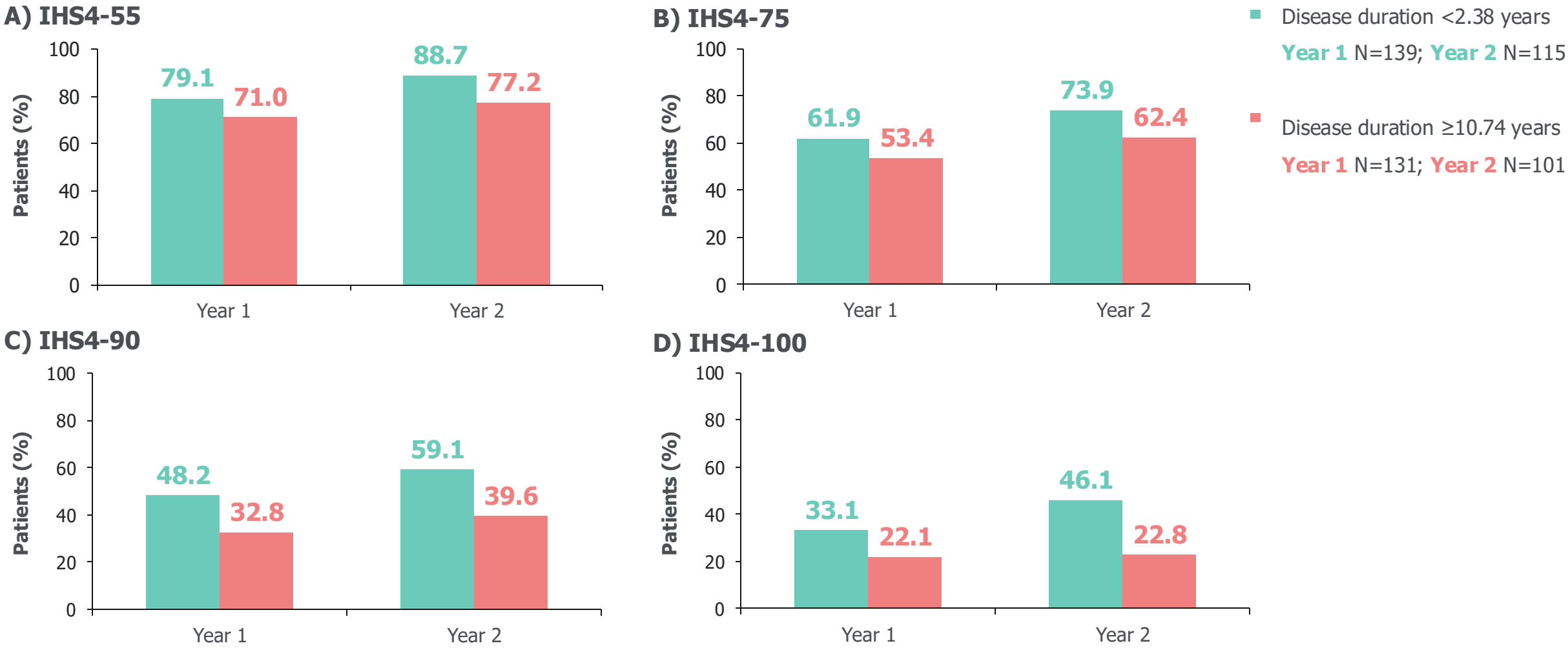
Baseline Characteristics

	Disease duration <2.38 years	Disease duration ≥10.74 years
	BKZ 320 mg Total N=139	**BKZ 320 mg Total** N=131
Age (years), mean (SD)	34.8 (13.5)	41.8 (10.3)
Sex, female, n (%)	63 (45.3)	84 (64.1)
Racial group, n (%)		
White	111 (79.9)	109 (83.2)
Black	6 (4.3)	13 (9.9)
Other/Missing	22 (15.8)	9 (6.9)
BMI (kg/m²), mean (SD)	31.2 (7.4)	33.3 (7.8)
Smoking status, current, n (%)	57 (41.0)	66 (50.4)
AN count, mean (SD)	16.1 (14.6)	19.4 (25.9)
DT count, mean (SD)	3.3 (3.3)	3.9 (4.6)
IHS4 score, mean (SD)	32.2 (22.8)	38.9 (37.0)
Hurley stage, n (%)		
II	82 (59.0)	75 (57.3)
III	57 (41.0)	56 (42.7)
Prior biologic use,[a] n (%)	11 (7.9)	29 (22.1)
Baseline antibiotic use, 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.

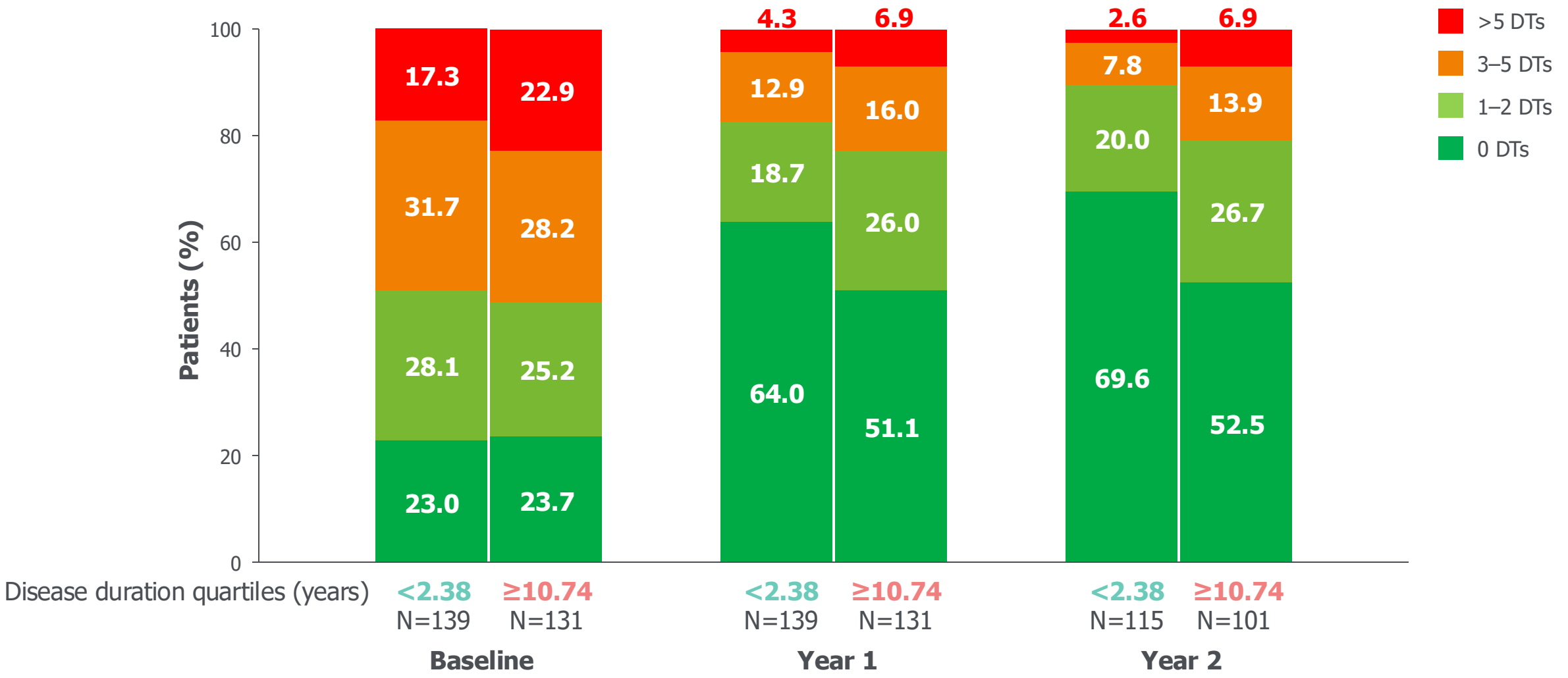
[a] Patients received prior biologic therapy for any indication. AN: abscess and inflammatory nodule; BKZ: bimekizumab; BMI: body mass index; DT: draining tunnel; IHS4: International Hidradenitis Suppurativa Severity Score System; SD: standard deviation.

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.

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.

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.

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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.