

Bimekizumab efficacy on IHS4 response levels and draining tunnels by HS disease duration over 3 years: Data from BE HEARD EXT

Thrasylvoulos Tzellos,^{1–3} Christopher J. Sayed,⁴ Christos C. Zouboulis,^{3,5} Valentina Dini,^{3,6} Irina Turchin,^{7–9} Koremasa Hayama,¹⁰ Bartosz Lukowski,¹¹ Christina Crater,¹² Nicola Tilt,¹³ Afsaneh Alavi^{3,14}

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¹Department of Dermatology, Nordland Hospital Trust, Bodø, Norway; ²Department of Clinical Medicine, Faculty of Health Sciences, UiT – The Arctic University of Norway, Tromsø, Norway; ³European Hidradenitis Suppurativa Foundation (EHSF) e.V., Dessau, Germany; ⁴Department of Dermatology, University of North Carolina School of Medicine, Chapel Hill, North Carolina, USA; ⁵Department of Dermatology, Venereology and Immunology, Universitaetsklinikum Ruppin-Brandenburg, Brandenburg Medical School Theodor Fontane and Faculty of Health Sciences Brandenburg, Neuruppin, Germany; ⁶Department of Clinical and Experimental Medicine, University of Pisa, Pisa, Italy; ⁷Brunswick Dermatology Center, Fredericton, New Brunswick, Canada; ⁸Probit Medical Research, Waterloo, Ontario, Canada; ⁹Department of Medicine, Dalhousie University, Halifax, Nova Scotia, Canada; ¹⁰Division of Cutaneous Science, Department of Dermatology, Nihon University School of Medicine, Tokyo, Japan; ¹¹Vedim/UCB, Warsaw, Poland; ¹²UCB, Morrisville, North Carolina, USA; ¹³UCB, Slough, United Kingdom; ¹⁴Department of Dermatology, Mayo Clinic College of Medicine and Science, Rochester, Minnesota, USA

Objective

To report the impact of disease duration since diagnosis on International Hidradenitis Suppurativa Severity Score System (IHS4) outcomes and draining tunnels (DTs) in patients with moderate to severe hidradenitis suppurativa (HS) treated with bimekizumab over 3 years.

Background

- HS is a progressive relapsing, inflammatory disease characterised by recurrent painful nodules, abscesses and tunnels.¹
- Patients with HS face delayed diagnosis, resulting in disease or symptom progression and suboptimal treatment outcomes.^{2,3}
- Early diagnosis and biologic treatment are crucial to prevent disease progression.^{2,3}
- Interleukin (IL)-17F and IL-17A are highly expressed in patients with HS, with IL-17F more abundant in HS serum and lesional skin than IL-17A.^{4,5} IL-17F expression is significantly upregulated in lesions, with the highest expression in DTs.⁶
- Bimekizumab, a humanised IgG1 monoclonal antibody that selectively inhibits IL-17F in addition to IL-17A, demonstrated clinically meaningful lesion resolution in patients with moderate to severe HS.^{7,8}

Methods

- Data were pooled from the phase 3 BE HEARD I&II trials (NCT04242446, NCT04242498) and BE HEARD EXT (NCT04901195), for patients with moderate to severe HS.^{8,9}
- Data are reported for patients randomised to bimekizumab 320 mg from baseline in BE HEARD I&II who subsequently entered BE HEARD EXT and continued to receive bimekizumab (BKZ Total).
- IHS4-55, IHS4-75, IHS4-90 and IHS4-100 responses are defined as ≥55%, ≥75%, ≥90% or 100% improvement from baseline in IHS4 total score, respectively.¹⁰
- Outcomes include:
 - IHS4 responses at Year 1 (Week 48), Year 2 (Week 96) and Year 3 (Week 148) by lowest and highest quartiles of baseline disease duration since HS diagnosis;
 - The proportion of patients achieving DT categories (0, 1–2, 3–5, >5) by baseline disease duration quartiles over 3 years.
- Data are reported as observed case (OC).

Results

- Of the 1,014 patients in the BE HEARD I&II trials, 868 were randomised to bimekizumab at baseline; 556 patients completed Year 1 and entered BE HEARD EXT.
- Baseline characteristics for the lowest (<2.38 years) and highest (≥10.74 years) disease duration quartiles are presented in **Table 1**.
 - Patients in the lowest disease duration quartile tended to be younger, and there was a greater proportion of males and non-smokers versus those in the highest quartile.
 - The proportion of patients with prior biologic use was greater in the highest disease duration quartile.
 - Mean abscess and inflammatory nodule (AN) count and mean IHS4 score were also greater in the highest disease duration quartile.
- The proportions of patients achieving IHS4-55/75/90/100 at Years 1, 2 and 3 are presented in **Figure 1**.
 - From Year 1 to Year 3, IHS4-55/75/90/100 responses were maintained or increased in both lowest and highest disease duration quartiles.
 - At Year 1, proportions of patients achieving IHS4-55/75/90/100 were greater in the lowest disease duration quartile compared to the highest disease duration quartile.
 - At Year 3, proportions of patients achieving IHS4-75/90/100 were greater in the lowest disease duration quartile compared to the highest disease duration quartile; the proportions of patients achieving IHS4-55 were similar in both disease duration quartiles.
- The proportions of patients with 0, 1–2, 3–5, >5 DTs over 3 years are presented in **Figure 2**.
 - Proportions of patients with 0 DTs at baseline were similar in the lowest and highest disease duration quartiles.
 - While improvements were seen for patients in both disease duration quartiles, the proportion of patients achieving 0 DTs was greater in the lowest disease duration quartile over 3 years.
 - The proportion of patients with >5 DTs was reduced at Year 1 in both disease duration quartiles; this was maintained to Year 3.

Conclusions

Bimekizumab demonstrated sustained clinically meaningful improvements in IHS4 and DT outcomes over 3 years, regardless of disease duration.

Patients with shorter disease duration since HS diagnosis generally had better outcomes than those with longer disease duration, emphasising the benefit of earlier treatment with bimekizumab.

Shorter disease duration had the greatest impact on improving clinical outcomes at 3 years, particularly at the highest thresholds such as IHS4-100 and 0 DTs.

Summary

The impact of disease duration since diagnosis in patients with hidradenitis suppurativa receiving bimekizumab was assessed for IHS4 responses and draining tunnel counts over 3 years.

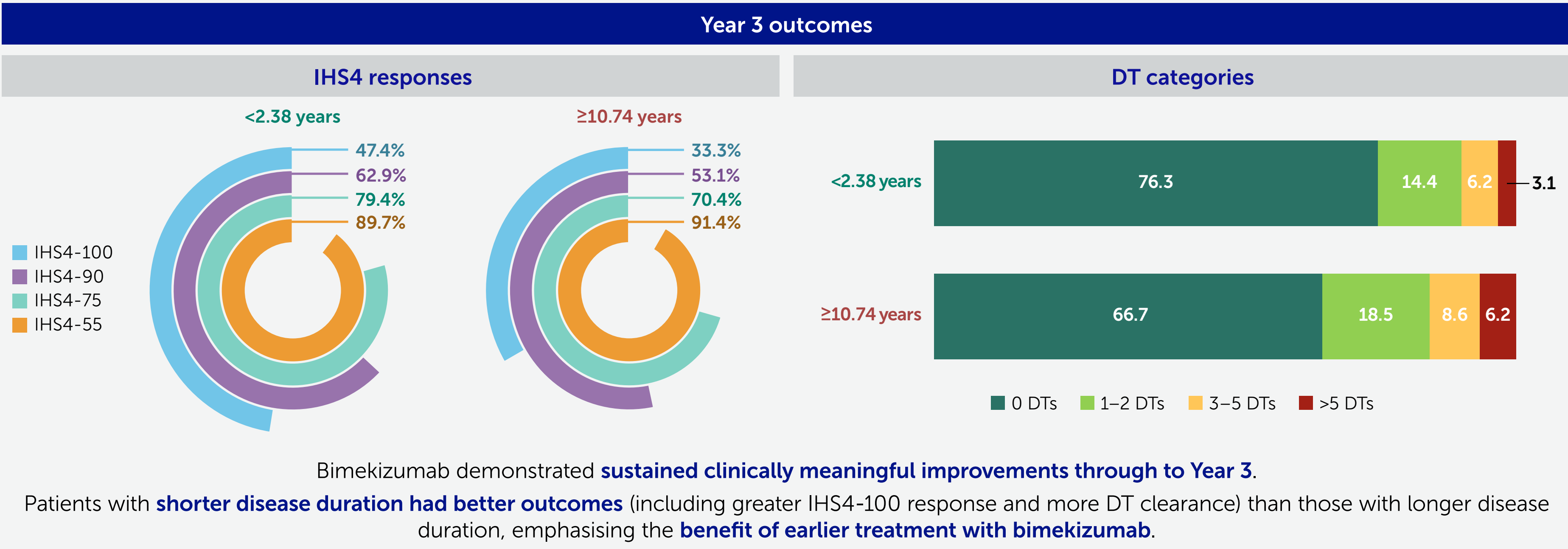
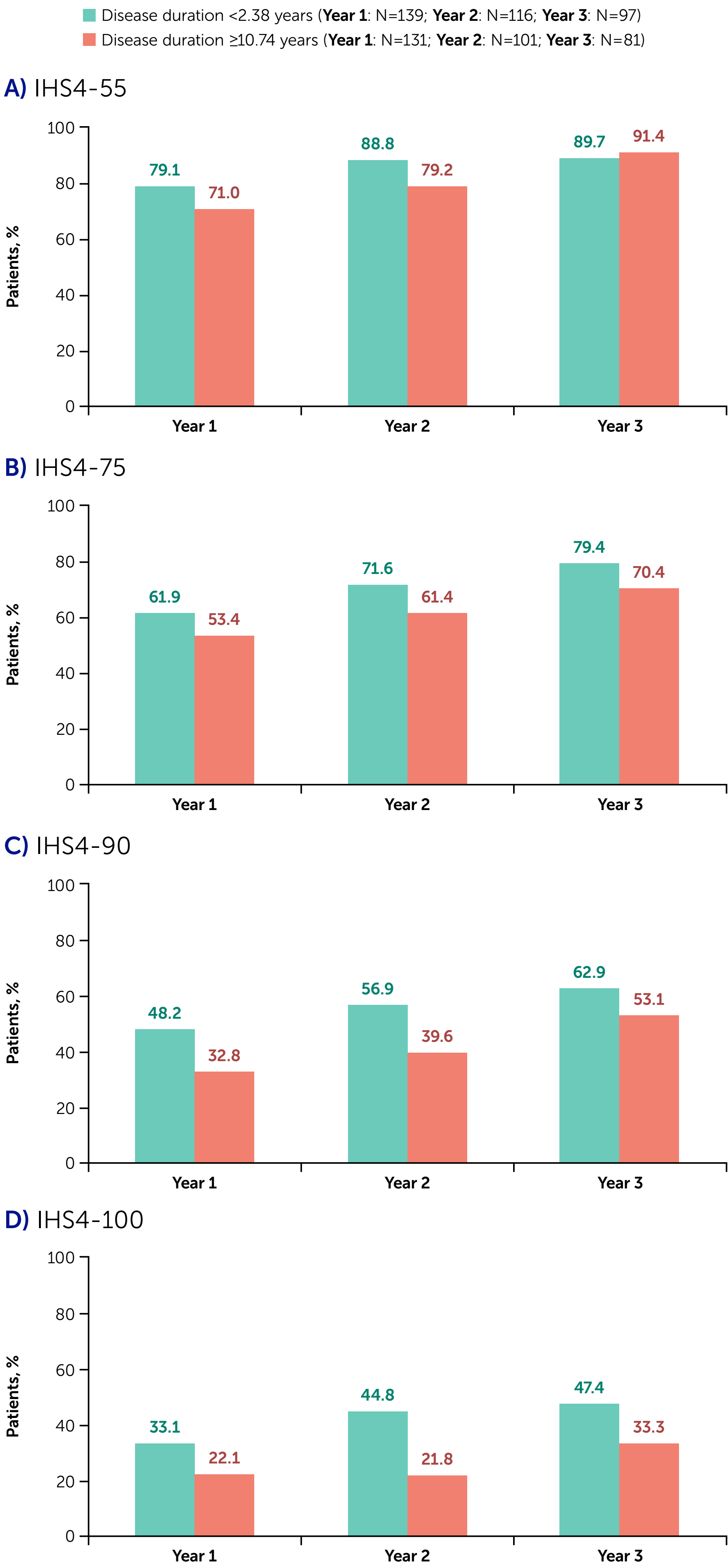


Figure 1 IHS4 response levels by lowest and highest quartiles of baseline disease duration since HS diagnosis over 3 years



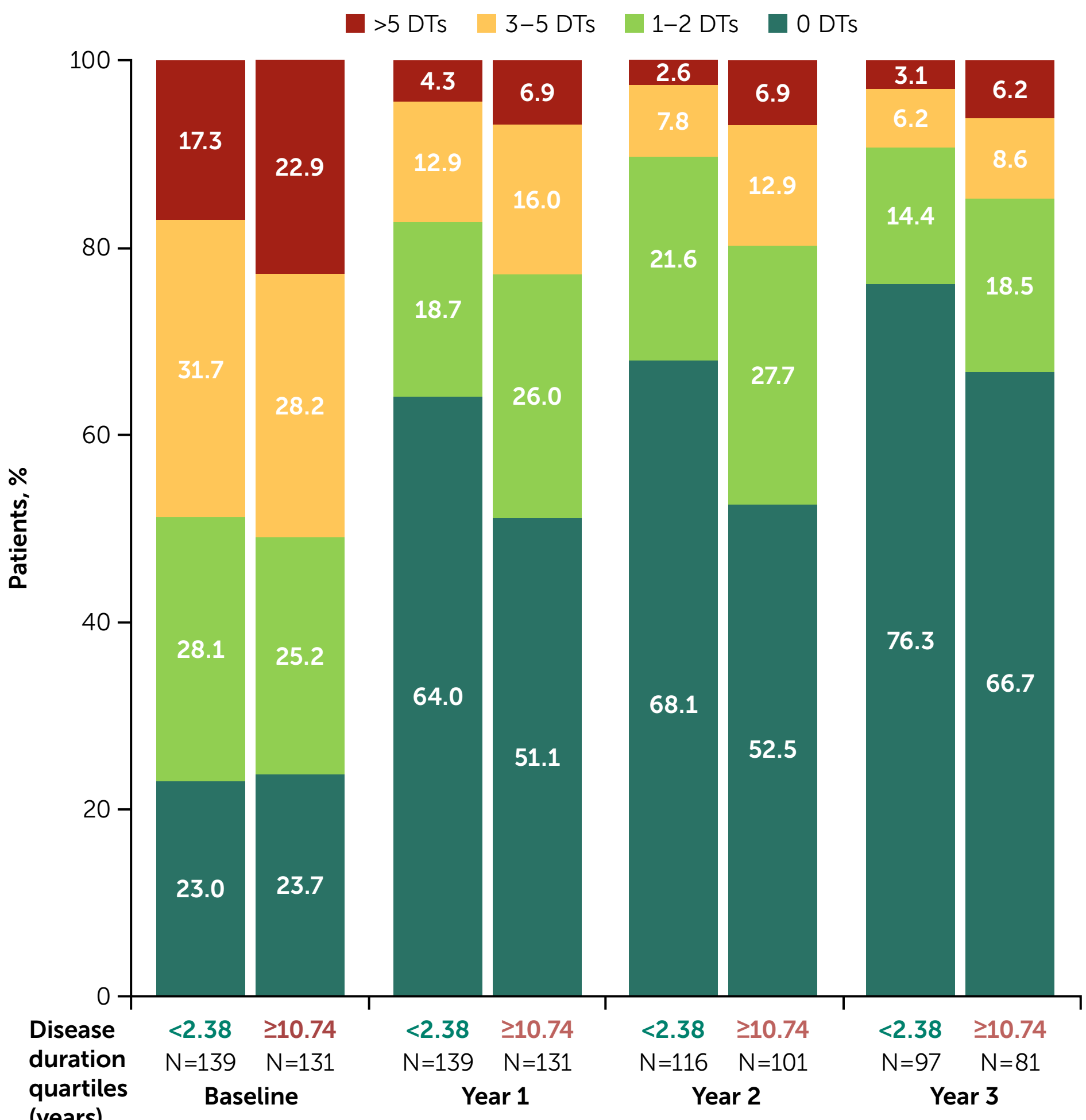
OC, n/N: N represents number of patients with a non-missing lesion count assessment in the given week, and percentages are calculated accordingly.

Table 1 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 or African American	6 (4.3)	13 (9.9)
Asian	13 (9.4)	3 (2.3)
Other/missing	9 (6.5)	6 (4.6)
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, ^a n (%)		
II	82 (59.0)	75 (57.3)
III	57 (41.0)	56 (42.7)
Prior biologic use, ^b n (%)	11 (7.9)	29 (22.1)
Baseline antibiotic use, n (%)	13 (9.4)	15 (11.5)

^(a) Derived Hurley stage for each patient is the worst overall Hurley stage derived from the Hurley stages recorded across all anatomical regions; ^(b) Patients received prior biologic therapy for HS.

Figure 2 Draining tunnel categories by lowest and highest quartiles of baseline disease duration since HS diagnosis over 3 years



OC, n/N: N represents number of patients with a non-missing DT count assessment in the given week, and percentages are calculated accordingly. Percentages may not sum to 100 due to rounding.

AN: abscess and inflammatory nodule; BKZ: bimekizumab; BMI: body mass index; DT: draining tunnel; HS: hidradenitis suppurativa; IL: interleukin; IHS4: International HS Severity Score System; IHS4-55/75/90/100: ≥55%/≥75%/≥90%/100% improvement from baseline in IHS4 total score; OC: observed case; SD: standard deviation.

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