Bimekizumab impact on draining tunnel reduction over 2 years in moderate to severe hidradenitis suppurativa: Results from BE HEARD EXT

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OBJECTIVE

- To report the impact of bimekizumab (BKZ) on draining tunnels (DTs) over 2 years in patients with DTs at baseline.

Background

- For patients with hidradenitis suppurativa (HS), DTs (fistulas/sinus tracts) **highly impact their quality of life**.[1,2]
- BKZ is a humanized IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.[3]

Methods

- Data were pooled from the phase 3 trials BE HEARD I&II and their open-label extension, BE HEARD EXT.[4,5]
- Data are reported for patients **randomized to BKZ 320 mg from baseline** in BE HEARD I&II who entered **BE HEARD EXT** (BKZ Total) and continued to receive BKZ.
- Data are reported as observed case (OC).

DT outcomes over 2 years:

Proportions of patients with:

- ≥1 DTs at baseline having **0**, **1–2**, **3–5**, or **>5** DTs over time.
- **1–2**, **3–5**, or **≥5** DTs at baseline having **0** DTs over time.

1. Zouboulis CC. et al. Exp Dermatol 2020;29:1154–70; **2.** Chernyshov PV. et al. Int J Environ Res Public Health 2021;18:6131; **3.** Adams R. et al. Front Immunol 2020;11:1894; **4.** Kimball AB. et al. The Lancet 2024;403;2504–19 (NCT04242446, NCT04242498); **5.** BE HEARD EXT: www.clinicaltrials.gov/study/NCT04901195. BKZ: bimekizumab; DT: draining tunnel; HS: hidradenitis suppurativa; IL: interleukin: OC: observed case.

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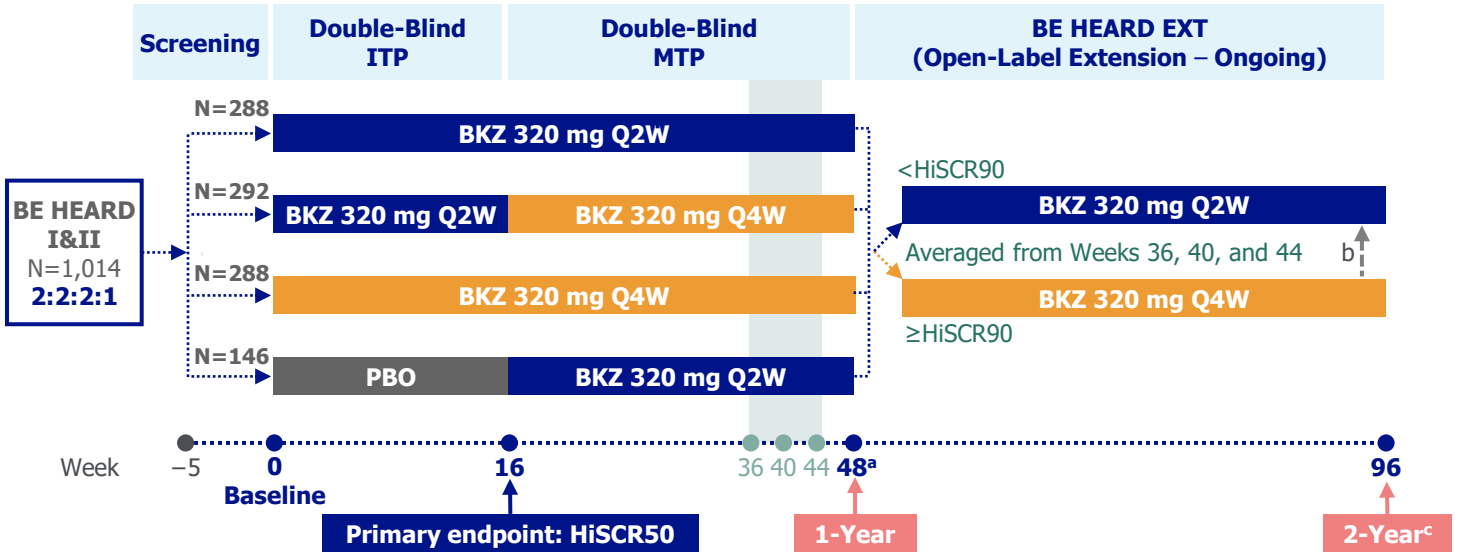
Study Design



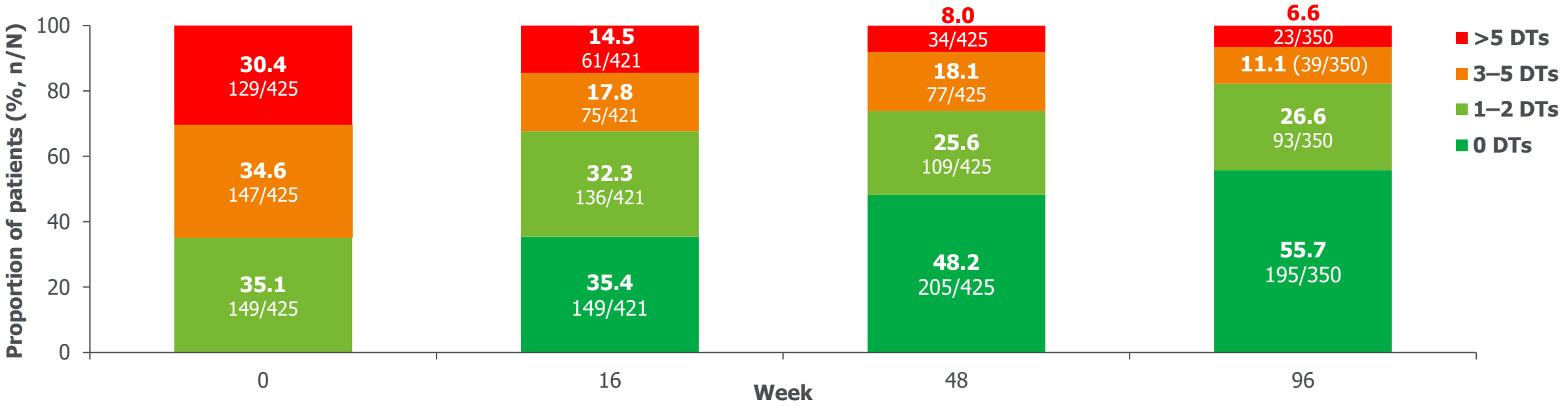
- Patients completing the 48-week BE HEARD I&II studies could enroll in BE HEARD EXT and receive open-label BKZ 320 mg every 2 weeks (Q2W) or Q4W based on HiSCR90 response averaged from Weeks 36, 40, and 44.[1,2]

Baseline Characteristics

	BKZ 320 mg Total	
	≥1 DT at baseline	**≥5 DTs at baseline**
	n=425	n=177
Age (years), mean (SD)	36.9 (12.3)	37.3 (12.3)
Sex, female, n (%)	209 (49.2)	80 (45.2)
Racial group, white, n (%)	346 (81.4)	135 (76.3)
BMI (kg/m²), mean (SD)	32.2 (7.6)	32.3 (7.7)
Duration of HS (years), mean (SD)	7.3 (6.8)	7.3 (6.7)
AN count, mean (SD)	16.6 (15.0)	20.4 (18.4)
DT count, mean (SD)	4.9 (4.3)	8.7 (4.3)
Hurley Stage, n (%)		
II	201 (47.3)	48 (27.1)
III	224 (52.7)	129 (72.9)
Prior biologic used[d], n (%)	89 (20.9)	50 (28.2)
Baseline antibiotic use, n (%)	41 (9.6)	20 (11.3)

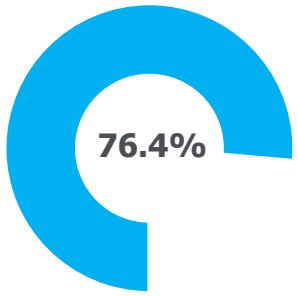
OLE set; only included patients who entered BE HEARD EXT at Week 48. BKZ Total (N=556) comprised patients randomized to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT and continued to receive BKZ. N represents the number of randomized patients. **[a]** Patients who completed Week 48 of BE 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); **[d]** Patients received prior biologic therapy for any indication. **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; BKZ: bimekizumab; BMI: body mass index; DT: draining tunnel; HiSCR50/90: ≥50%/90% reduction in the total abscess and inflammatory nodule count from baseline with no increase from baseline in abscess or draining tunnel count; ITP: initial treatment period; MTP: maintenance treatment period; PBO: placebo; Q2W: every 2 weeks; Q4W: every 4 weeks; SD: standard deviation.

Patients with ≥1 DTs at Baseline Having 0, 1–2, 3–5, and >5 DTs at Different Timepoints (OC)



Patients with ≥1 DTs at baseline

425/556



Baseline DT count, overall mean (SD):

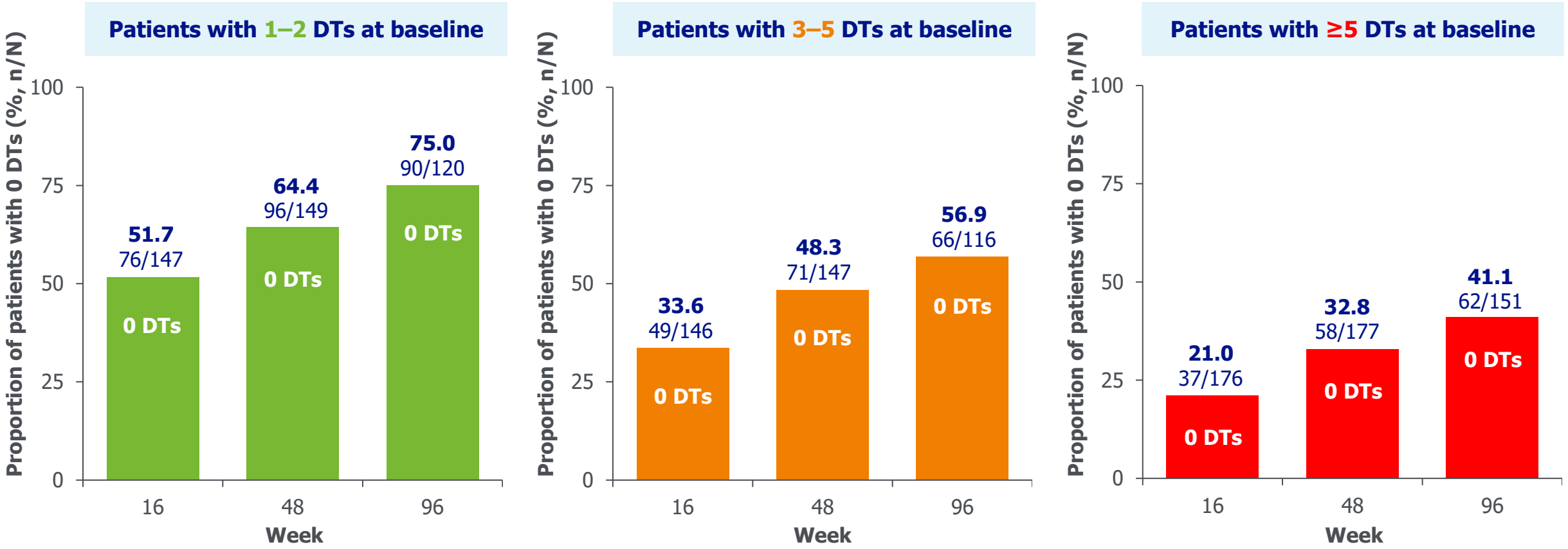
3.8 (4.3)

N=556

- The proportion of patients with ≥1 DTs at baseline who achieved **0 DTs increased to Week 96**.

OLE set; only included patients who entered BE HEARD EXT at Week 48. BKZ Total (N=556) comprised patients randomized to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT and continued to receive BKZ. Data are reported for patients in the BKZ Total group who had ≥1 DTs at baseline (n=425). OC, n/N: denominator represents number of patients with a non-missing lesion count assessment in the given week, and percentages are calculated accordingly. Due to rounding, percentages may not add up to 100%. BKZ: bimekizumab; DT: draining tunnel; OC: observed case.

Patients Having 0 DTs at Different Timepoints by Baseline DT Count (OC)

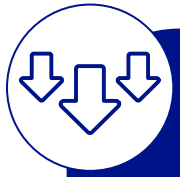


- The proportion of patients who had **0 DTs increased over time to Week 96**, regardless of their DT count at baseline.

OLE set; only included patients who entered BE HEARD EXT at Week 48. BKZ Total (N=556) comprised patients randomized to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT and continued to receive BKZ. OC, n/N: denominator represents number of patients with a non-missing lesion count assessment in the given week, and percentages are calculated accordingly.
BKZ: bimekizumab; DT: draining tunnel; OC: observed case.

CONCLUSIONS:

Patients treated with bimekizumab demonstrated **reductions of DTs** at 1 year that were further improved to 2 years.



The proportion of patients with **≥5 DTs decreased** over 2 years.

The proportion of patients treated with bimekizumab who achieved **0 DTs increased** over time to Year 2, regardless of DT count at baseline.

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Disclosures: TT: Consultancy/advisory boards/speaker fees from Abbvie, Boehringer Ingelheim, Novartis, and UCB; treasurer of the European Hidradenitis Suppurativa Foundation e.V. **CJS:** Investigator for AbbVie, AstraZeneca, ChemoCentryx, Incyte, InflaRx, Novartis, and UCB; consultancy fees from AbbVie, Alumis, AstraZeneca, InflaRx, Incyte, Logical Images, MoonLake Immunotherapeutics, Sandoz, Sanofi, Sonoma Biotherapeutics, and UCB; speaker for AbbVie and Novartis. **ABG:** Receives research/educational grants from Bristol Myers Squibb, Janssen, MoonLake Immunotherapeutics, and UCB (all paid to Mount Sinai School of Medicine); received honoraria as an advisory board member and consultant for Amgen, Eli Lilly and Company, Highlights Therapeutics, Janssen, Novartis, Sanofi, SunPharma, Takeda, Teva, UCB, and XBiotech (stock options for RA). **PAB:** Principal investigator for AbbVie, Amgen, Celgene, Eli Lilly and Company, Janssen, LEO Pharma, MSD, Novartis, Pfizer, Sanofi, and UCB; has been or is a member of expert boards or steering committees and received fees from AbbVie, Almirall, Amgen, Boeringher Ingelheim, Celgene, Eli Lilly and Company, Janssen, LEO Pharma, MSD, Novartis, Pfizer, Sanofi, and UCB. **BK:** Received research support from or has been a principal investigator (clinical trials) for AbbVie, Almirall, Janssen, Merck, MoonLake Immunotherapeutics, Novartis, Pfizer, and UCB; has been a consultant for AbbVie, Almirall, Celgene, Janssen, Merck, MoonLake Immunotherapeutics, Novartis, Pfizer, and UCB; has received honoraria from AbbVie, Almirall, Celgene, Eli Lilly and Company, Janssen, MoonLake Immunotherapeutics, Novartis, Pfizer, and UCB; and has been on scientific advisory boards for AbbVie, Almirall, Celgene, Eli Lilly and Company, Janssen, MoonLake Immunotherapeutics, Novartis, Pfizer, and UCB. **JA:** Received honoraria for consulting and/or presentations and/or sponsoring for scientific projects and/or clinical studies from AbbVie, Incyte, and UCB. **JWF:** Conducted advisory work for AbbVie, Boehringer Ingelheim, ChemoCentryx, Janssen, Kyowa Kirin, LEO Pharma, Pfizer, Regeneron, and UCB; participated in trials for Boehringer Ingelheim, CSL, Eli Lilly and Company, Pfizer, and UCB; received research support from Ortho Dermatologics, and Sun Pharma. **IP, RR, NT:** Employees and shareholders of UCB.
MP: Consultant and investigator for AbbVie, Avalo Therapeutics, Aristea Therapeutics, Eli Lilly and Company, Incyte, Janssen, MoonLake Immunotherapeutics, Novartis, Pfizer, Prometheus, Sanofi, Sonoma Biotherapeutics, and UCB; consultant for Alumis, FIDE, Trifecta Clinical/WCG, and ZuraBio; investigator for Anaptys Bio, Bayer, Bristol Myers Squibb, OASIS Pharmaceuticals, and Regeneron; received royalties from Beth Israel Deaconess Medical Center.

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