Bimekizumab impact on draining tunnels in patients with moderate to severe hidradenitis suppurativa: Pooled 48-week data from BE HEARD I & II

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OBJECTIVE:

- To report the effect of bimekizumab (BKZ) treatment on draining tunnel (DT) outcomes to Week 16 and Week 48 in patients with hidradenitis suppurativa (HS) in the phase 3 BE HEARD trials.

Background:

- HS is a chronic, recurrent inflammatory skin disease that impacts patients' quality of life.[1,2] HS is characterized by **painful** skin lesions and **DTs** (fistulas and sinus tracts) in folds of the skin.[1,3]
- BKZ is a monoclonal immunoglobulin G1 antibody which selectively inhibits IL-17F in addition to IL-17A.[4]
- Here we evaluate the effect of BKZ on DTs in patients with moderate to severe HS.

Methods:

- Data were pooled across patients with moderate to severe HS enrolled in BE HEARD I and BE HEARD II.[5,6]
- Missing data were addressed using modified non-responder imputation (mNRI), multiple imputation (MI) and observed case (OC).

DT Outcomes:

- Absolute and percentage change from baseline (CfB) in DT count
- Week 16 least-square (LS) mean CfB and nominal p values (ANCOVA model)
- Proportions of patients achieving ≥3 DT reductions (baseline count ≥5)
- Proportions of patients achieving 0 DTs (overall and baseline count >5)

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.** Navrazhina K et al. J Allergy Clin Immunol 2021;147:6; **4.** Adams R et al. Front Immunol 2020;11:1894; **5.** BE HEARD I: www.clinicaltrials.gov/study/NCT04242446; **6.** BE HEARD II: www.clinicaltrials.gov/study/NCT04242498. ANCOVA: analysis of covariance; BKZ: bimekizumab; CfB: change from baseline; DT: draining tunnel; HS: hidradenitis suppurativa; IL: interleukin; LS: least-squares; MI: multiple imputation; mNRI: modified non-responder imputation; OC: observed case.

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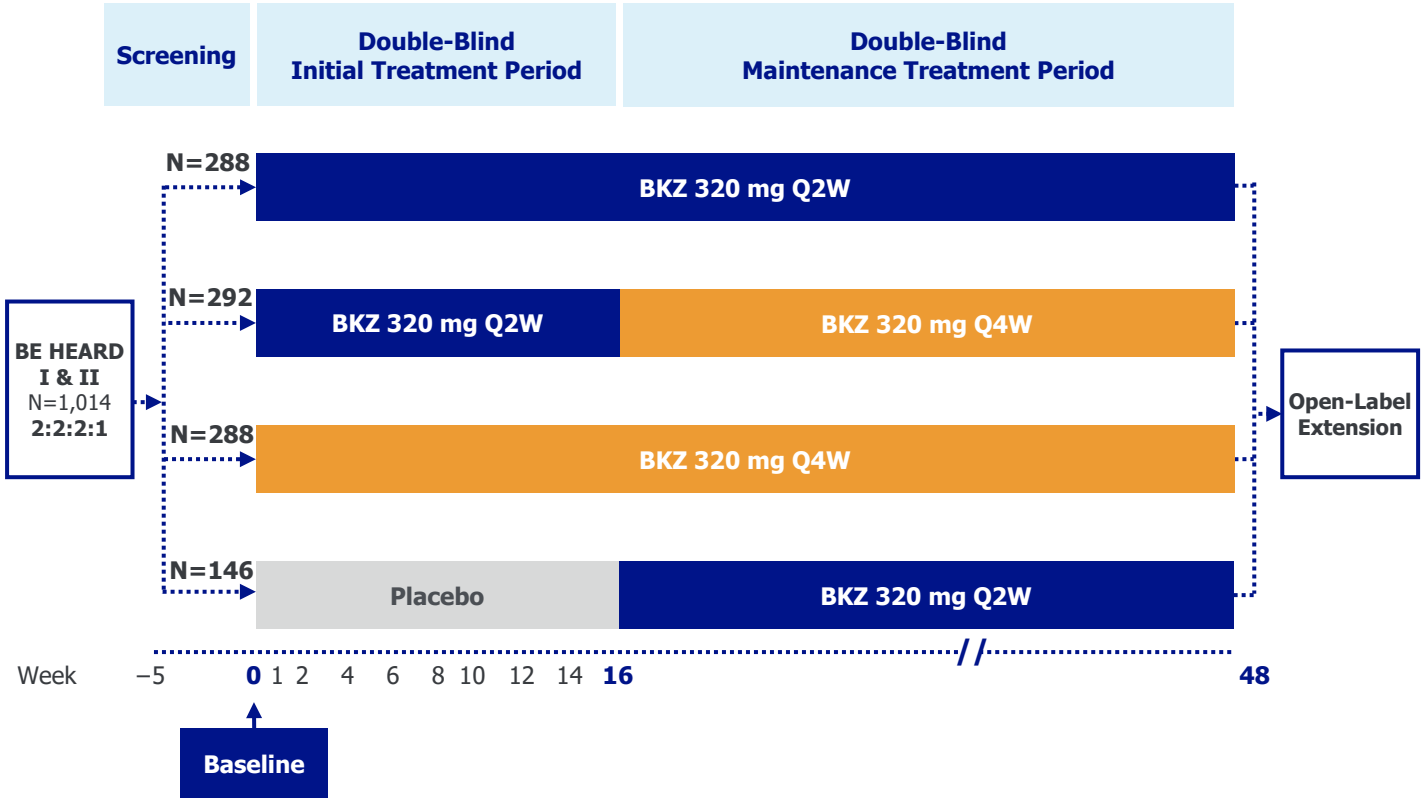
BE HEARD Study Design[1,2]



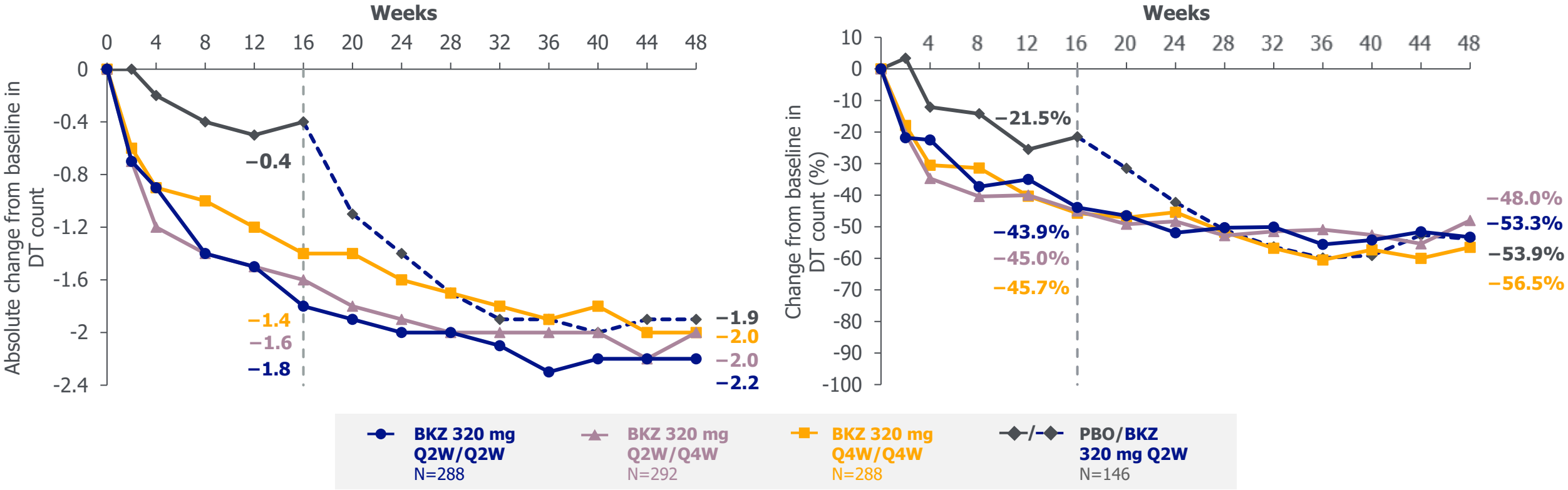
- For Week 16 analyses (ANCOVA model), all patients randomized to receive BKZ 320 mg Q2W at baseline were pooled in the BKZ 320 mg Q2W Total group.
- At baseline, **72.8% of patients had DTs**, with DT count comparable across regimens.

Baseline Characteristics

	BKZ 320 mg Q2W/Q2W N=288	BKZ 320 mg Q2W/Q4W N=292	BKZ 320 mg Q4W/Q4W N=288	PBO/BKZ 320 mg Q2W N=146
Age, years, mean ± SD	36.8 ± 12.4	37.0 ± 12.4	35.8 ± 11.6	37.3 ± 12.8
Sex, female, n (%)	152 (52.8)	174 (59.6)	175 (60.8)	75 (51.4)
Racial group, White, n (%)	232 (80.6)	233 (79.8)	224 (77.8)	119 (81.5)
BMI, kg/m^2, mean ± SD	32.7 ± 8.6	32.7 ± 7.9	33.8 ± 7.9	33.1 ± 8.3
Duration of disease, years, mean ± SD	7.6 ± 7.4	8.3 ± 7.7	7.3 ± 7.3	9.8 ± 9.4
AN count, mean ± SD	14.7 ± 11.6	17.2 ± 16.8	17.7 ± 20.9	14.5 ± 10.0
DT count, mean ± SD Patients with ≥5 DT at baseline (n)	3.8 ± 4.4 8.7 ± 4.1 (101)	3.8 ± 4.4 9.8 ± 4.6 (76)	3.3 ± 4.1 8.4 ± 4.1 (85)	3.4 ± 3.8 8.3 ± 3.3 (43)
Hurley Stage, n (%) II III	 166 (57.6) 122 (42.4)	 160 (54.8) 132 (45.2)	 160 (55.6) 128 (44.4)	 79 (54.1) 67 (45.9)
Prior biologic use, n (%)	59 (20.5)	56 (19.2)	47 (16.3)	29 (19.9)
Baseline antibiotic use, n (%)	29 (10.1)	28 (9.6)	18 (6.3)	11 (7.5)

Randomized set. **1.** BE HEARD I: www.clinicaltrials.gov/study/NCT04242446; **2.** BE HEARD II: www.clinicaltrials.gov/study/NCT04242498. AN: abscess and inflammatory nodules; BKZ: bimekizumab; BMI: body mass index; DT: draining tunnel; PBO: placebo; SD: standard deviation; Q2W: every 2 weeks, Q4W: every 4 weeks.

Absolute and Percentage Change from Baseline in DT Count to Week 48 (MI)



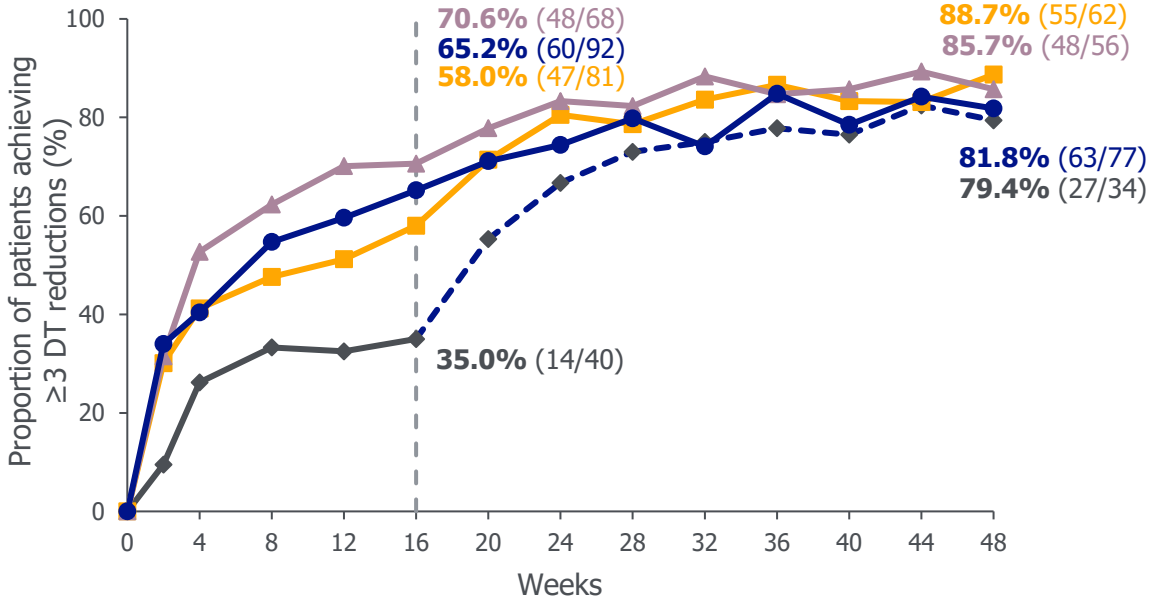
Change from Baseline to Week 16 in Draining Tunnel Count

Statistic (ANCOVA)	BKZ 320 mg Q2W Total N=580	BKZ 320 mg Q4W N=288	PBO N=146
LS mean (95% CI)	−1.453 (−1.760, −1.146)	−1.399 (−1.779, −1.019)	−0.370 (−0.849, 0.109)
Nominal p value[a]	<0.001	<0.001	-

Absolute and percentage change from baseline score in DT count are shown for all patients randomized at baseline, pooled across trials. LS mean, 95% CIs, and nominal p value are based on an analysis of covariance (ANCOVA) with fixed effects of treatment, Hurley Stage at baseline, baseline antibiotic use, and feeder study; baseline value is included as a covariate. All patients randomized to receive BKZ 320 mg Q2W at baseline were pooled in the BKZ 320 mg Q2W Total group. **[a]** Nominal p<0.001 versus PBO. ANCOVA: analysis of covariance; BKZ: bimekizumab; CI: confidence interval; DT: draining tunnel; LS: least-squares; MI: multiple imputation; PBO: placebo; Q2W: every 2 weeks, Q4W: every 4 weeks.

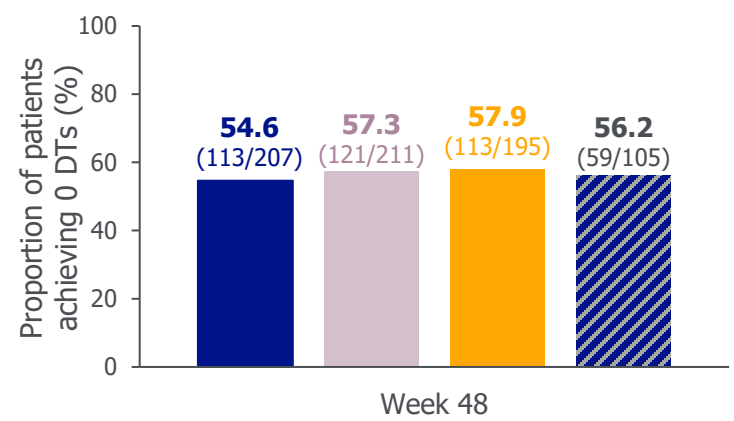
Proportions of Patients Achieving ≥3 DT Reduction or 0 DTs to Week 48

Patients with ≥5 DTs at baseline achieving ≥3 DT reduction (OC)[a]



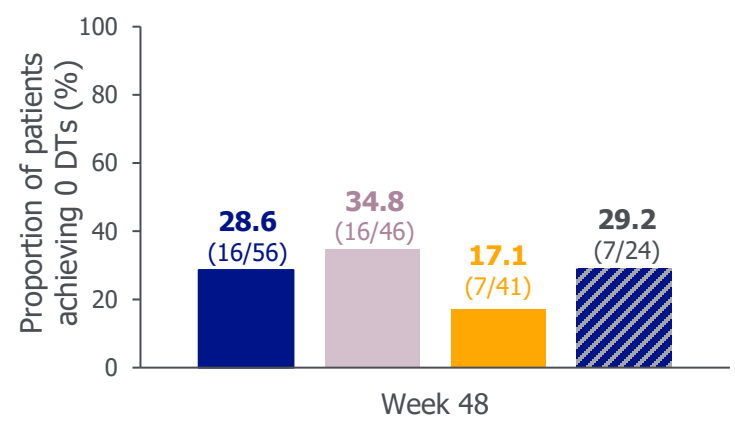
mNRI, % (95% CI)	Week 16	Week 48
BKZ 320 mg Q2W/Q2W	61.6 (56.1, 67.2)	66.1 (59.4, 72.8)
BKZ 320 mg Q2W/Q4W	61.0 (54.6, 67.5)	66.2 (58.5, 74.0)
BKZ 320 mg Q4W/Q4W	57.2 (49.7, 64.7)	67.5 (60.4, 74.6)
PBO/BKZ 320 mg Q2W	30.5 (16.7, 44.4)	59.5 (44.6, 74.4)

Overall patients achieving 0 DTs (OC)



mNRI, % (95% CI)	Week 48
BKZ 320 mg Q2W/Q2W	42.6 (36.4, 48.8)
BKZ 320 mg Q2W/Q4W	44.3 (38.3, 50.4)
BKZ 320 mg Q4W/Q4W	44.0 (38.0, 50.1)
PBO/BKZ 320 mg Q2W	43.9 (35.3, 52.5)

Patients with >5 DTs at baseline achieving 0 DTs (OC)[b]



mNRI, % (95% CI)	Week 48
BKZ 320 mg Q2W/Q2W	20.5 (11.0, 30.0)
BKZ 320 mg Q2W/Q4W	21.7 (11.3, 32.1)
BKZ 320 mg Q4W/Q4W	13.1 (3.7, 22.5)
PBO/BKZ 320 mg Q2W	17.7 (3.8, 31.5)

[a] Included patients had a baseline DT count ≥5; **[b]** Included patients had a baseline DT count >5. mNRI: patients who discontinued due to lack of efficacy/adverse events, or received systemic antibiotics identified as rescue medication for HS by the principal investigator, were considered non-responders; multiple imputation was used for all other missing data. 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; HS: hidradenitis suppurativa; mNRI: modified non-responder imputation; OC: observed case; PBO: placebo; Q2W: every 2 weeks; Q4W: every 4 weeks.

CONCLUSIONS:

- Patients treated with bimekizumab demonstrated **greater draining tunnel reductions** versus placebo to Week 16. Results with bimekizumab were either sustained or improved to Week 48.
- Patients who **switched from placebo to bimekizumab Q2W** at Week 16 demonstrated **draining tunnel count improvements** comparable to patients who received **continuous bimekizumab** to Week 48.
- The **majority** of patients with ≥5 draining tunnels at baseline achieved a **≥3 draining tunnel reduction** over 48 weeks, regardless of bimekizumab dosing regimen.
- **Over 50%** of patients achieved **0 draining tunnels** at Week 48 and achievement in patients with >5 draining tunnels at baseline increased by Week 48, regardless of bimekizumab dosing regimen. These data highlight bimekizumab efficacy in patients with high draining tunnel burden.

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