Bimekizumab impact on draining tunnel and lesion count over 2 years in hidradenitis suppurativa: Data from BE HEARD EXT

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Disclosures

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Introduction, methods and objective

Introduction:

- **Hidradenitis suppurativa** (HS) is a chronic, inflammatory skin disease, characterised by **painful lesions**, including draining tunnels (**DTs**; fistulas/sinus tracts), which negatively impact patients' **quality of life**.[1,2]
- **Bimekizumab** (BKZ) is a humanised monoclonal antibody which selectively inhibits interleukin (IL)-17F in addition to IL-17A.[3]

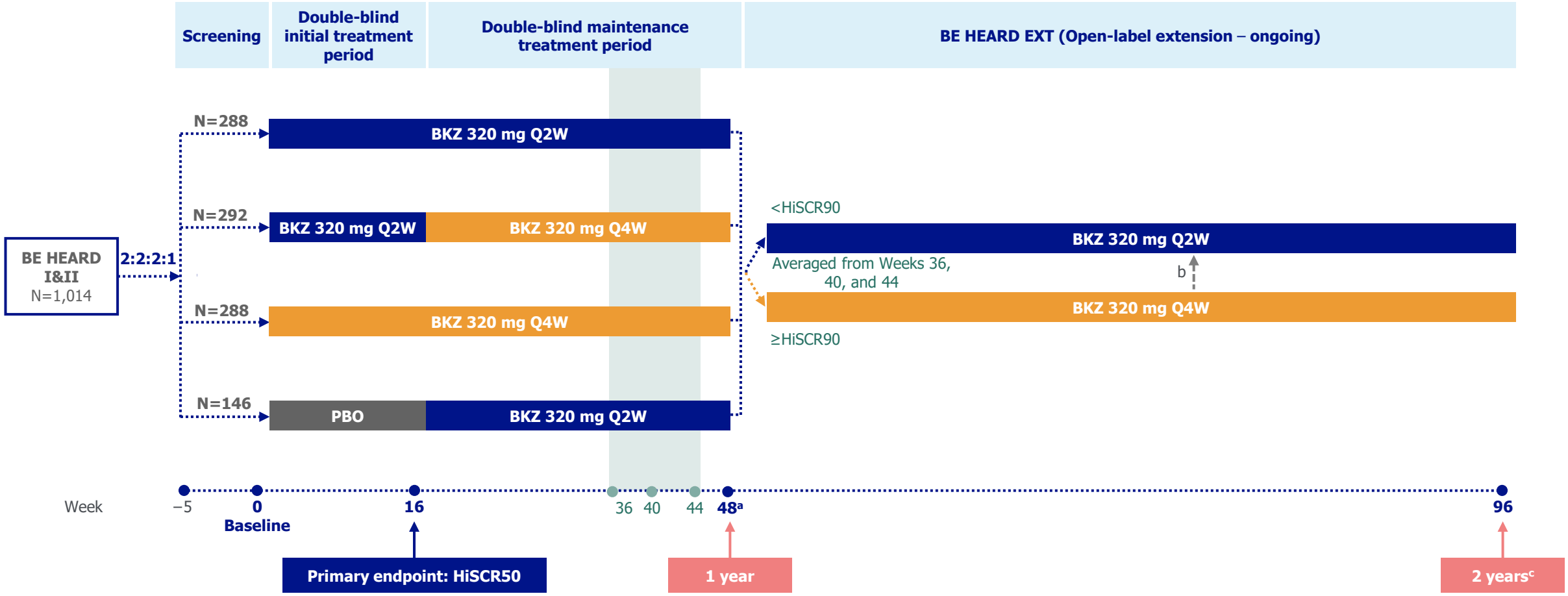
Methods:

- Data were pooled from the phase 3 BE HEARD I&II studies and the open-label BE HEARD EXT.[4,5]
- Data are reported for patients **randomised to BKZ at baseline** in BE HEARD I&II who enrolled in **BE HEARD EXT** (BKZ 320 mg Total).
- Data are reported as observed case (OC).

OBJECTIVE: To report the impact of BKZ on DT and HS lesion count over time.

1. Zouboulis CC. et al. Exp Dermatol 2020;29:1154–70; **2.** Margesson LJ. et al. Best Pract Res Clin Obstet Gynaecol 2014;1013–27; **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: www.clinicaltrials.gov/study/NCT04901195. BKZ: bimekizumab; DT: draining tunnel; HS: hidradenitis suppurativa; IL: interleukin; OC: observed case.

Study design



[a] Patients who completed Week 48 of BE HEARD I&II could enrol 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). AN: abscess and inflammatory nodule; BKZ: bimekizumab; HiSCR50/90: ≥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 two weeks; Q4W: every four weeks.

Outcomes reported

Over 2 years (BKZ Total):

All patients:

- **Mean abscess and inflammatory nodule** (AN) **count**.

Patients with **0 DTs at baseline** and **>0 DTs at baseline**:

- **Mean DT count**.
- **Absolute change from baseline** (CfB) **in DT count**.

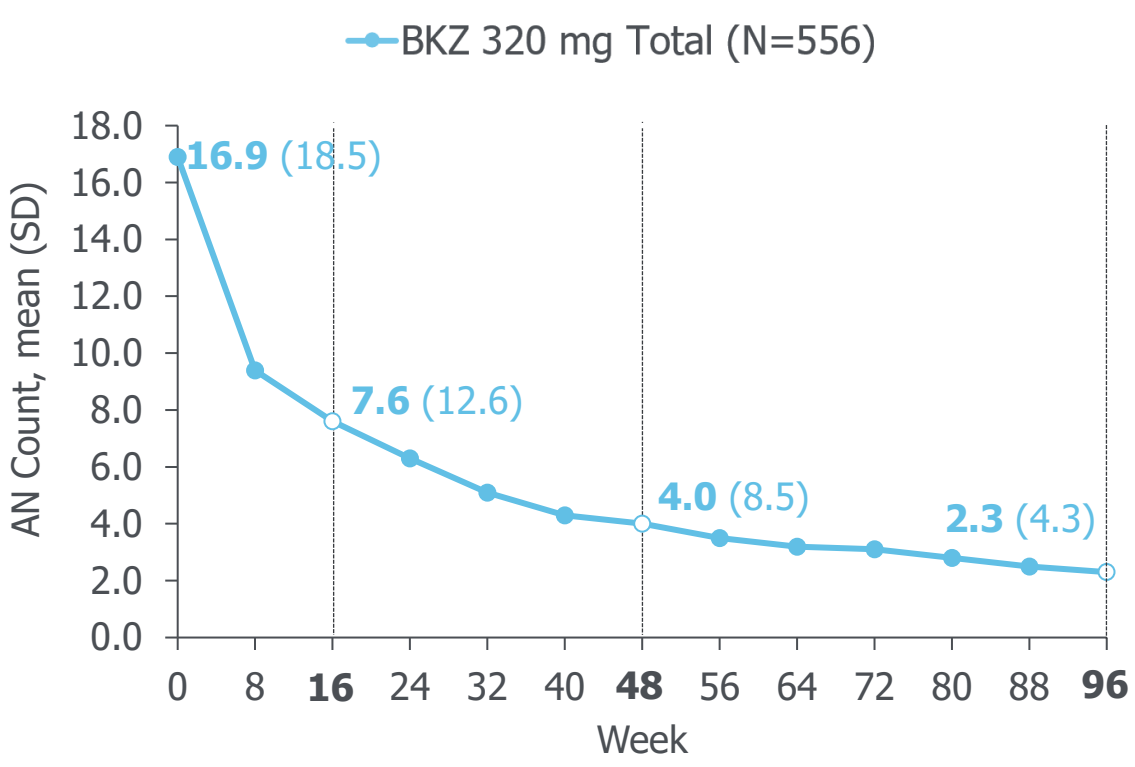
Baseline characteristics

n (%) unless otherwise stated	BKZ Total N=556	BKZ Total, 0 DTs at baseline N=131	BKZ Total, >0 DTs at baseline N=425
Age (years), mean (SD)	36.3 (12.2)	34.4 (11.4)	36.9 (12.3)
Sex, female	299 (53.8)	90 (68.7)	209 (49.2)
Racial group			
White	448 (80.6)	102 (77.9)	346 (81.4)
Black	55 (9.9)	17 (13.0)	38 (8.9)
BMI (kg/m^2), mean (SD)	32.5 (7.8)	33.6 (8.4)	32.2 (7.6)
Duration of HS (years), mean (SD)	7.4 (7.1)	7.9 (8.0)	7.3 (6.8)
AN count, mean (SD)	16.9 (18.5)	17.8 (27.1)	16.6 (15.0)
DT count, mean (SD)	3.8 (4.3)	0 (0.0)	4.9 (4.3)
Non-draining tunnel count, mean (SD)	3.8 (6.7)	1.8 (3.5)	4.4 (7.3)
Hurley stage			
II	303 (54.5)	102 (77.9)	201 (47.3)
III	253 (45.5)	29 (22.1)	224 (52.7)
Prior biologic use	112 (20.1)	23 (17.6)	89 (20.9)
Baseline antibiotic use	54 (9.7)	13 (9.9)	41 (9.6)

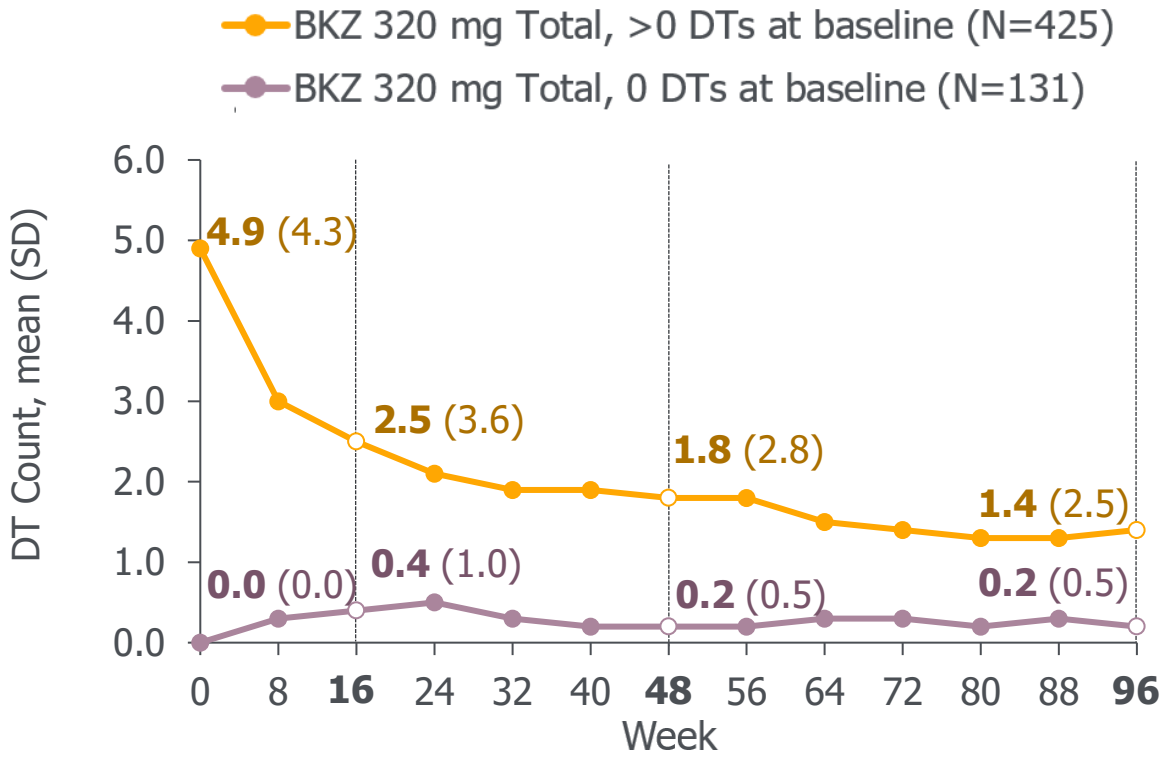
OLE set; included patients who entered BE HEARD EXT at Week 48. BKZ Total (N=556) comprised patients randomised to BKZ from baseline in BE HEARD I&II (NCT04242446, NCT04242498) who entered BE HEARD EXT (NCT04901195) and continued to receive BKZ. N represents the number of randomised patients. AN: abscess and inflammatory nodule; BKZ: bimekizumab; BMI: body mass index; CfB: change from baseline; DT: draining tunnel; HS: hidradenitis suppurativa; SD: standard deviation.

Mean AN and DT count to Week 96 (OC)

AN count



DT count



Number of patients with a non-missing lesion assessment at each week:

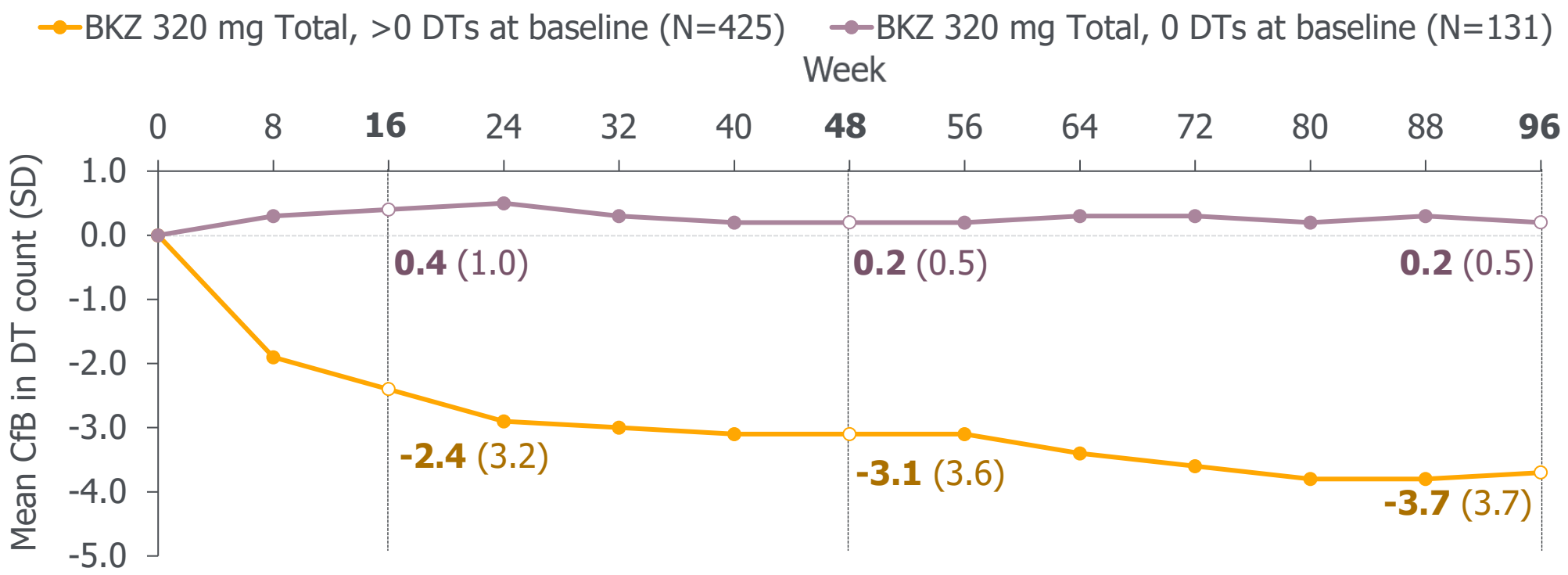
Week	0	8	16	24	32	40	48	56	64	72	80	88	96
BKZ 320 mg Total, n	556	548	551	545	542	541	556	534	517	490	472	455	446
>0 DTs at baseline, n	425	420	421	417	414	412	425	408	398	378	367	359	350
0 DTs at baseline, n	131	128	130	128	128	129	131	126	119	112	105	96	96

OLE set; included patients who entered BE HEARD EXT at Week 48. BKZ Total (N=556) comprised patients randomised to BKZ from baseline in BE HEARD I&II (NCT04242446, NCT04242498) who entered BE HEARD EXT (NCT04901195) and continued to receive BKZ. AN: abscess and inflammatory nodule; BKZ: bimekizumab; DT: draining tunnel; OC: observed case; OLE: open-label extension; SD: standard deviation.

Mean absolute change from baseline in DT count to Week 96 (OC)

Baseline mean (SD) DT count:

>0 DTs at baseline: 4.9 (4.3)



Number of patients with a non-missing lesion assessment at each week:

>0 DTs at baseline, n	425	420	421	417	414	412	425	408	398	378	367	359	350
0 DTs at baseline, n	131	128	130	128	128	129	131	126	119	112	105	96	96

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Conclusions

For patients randomised to bimekizumab at baseline, **clinically important reductions in AN count** were observed at Year 1 and **maintained** through Year 2.

In patients **with DTs at baseline**, clinically important **reductions** in DT count observed at Year 1 were **maintained** through Year 2.

In patients with **no DTs** at baseline, DT count **minimally increased** to Year 2.

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