P0138

Bimekizumab impact on draining tunnels: A dynamic assessment in patients with moderate to severe HS using pooled Week 48 results from BE HEARD I&II

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Objective

To assess the effect of bimekizumab (BKZ) on draining tunnels (DTs) over 48 weeks in adult patients with moderate to severe hidradenitis suppurativa (HS) from the phase 3 BE HEARD I&II studies.

Introduction

- HS is a recurrent, inflammatory skin disease characterised by painful lesions in the folds of the skin and deep, dermal abscesses that join to form DTs, also known as fistulas and sinus tracts.[1–4]
- DTs may be a large contributor to the significant impact of HS on a patient's quality of life.[3,5]
- BKZ is a humanised IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, which are both abundant in lesional skin.[6,7]
- Here, we dynamically assess the effect of BKZ on DT outcomes over 48 weeks in BE HEARD I&II.[8]

Methods

- Pooled data from the randomised, double-blind, placebo (PBO)-controlled, multicentre BE HEARD I&II trials included an initial (Week 0–16) and maintenance (Week 16–48) treatment period (**Figure 1**).
- Here, we report the proportions of patients with ≥1 and ≥3 DTs at baseline achieving 0, 1–2, 3–5 or >5 DTs to Week 48.
- Data are reported as observed case (OC).

Results

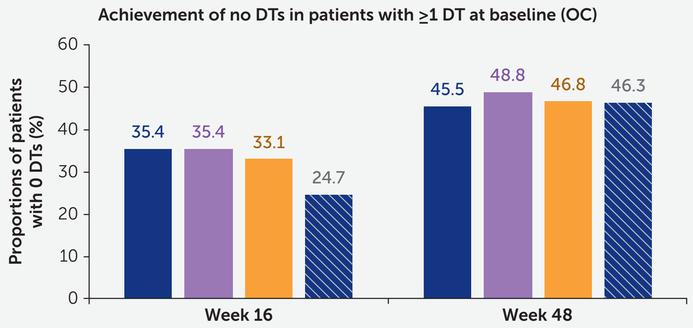
- At baseline, 1,014 patients were randomised (**Figure 1**).
- Baseline demographics were comparable across treatment arms, although higher proportions of Hurley Stage III disease were seen in patients with ≥3 DTs at baseline vs those with ≥1 DT at baseline (**Table 1**).
- At Week 16, a higher proportion of patients with ≥1 DT at baseline receiving BKZ achieved 0 DTs vs the PBO group (**Figure 2**).
- At Week 48, the proportion of patients with ≥1 DT at baseline receiving continuous BKZ that achieved 0 DTs notably increased; a similar proportion was seen in patients who switched from PBO to BKZ at Week 16 (**Figure 2**).
- Patients with ≥3 DTs at baseline showed similar results. At Week 16, a higher proportion of patients receiving BKZ had no DTs vs the PBO group. By Week 48, the proportions of patients receiving continuous BKZ that had no DTs notably increased (**Figure 3**).
- Among the patients with ≥3 DTs at baseline, similar proportions of patients receiving continuous BKZ and PBO to BKZ Q2W switchers had no DTs at Week 48. There was a more favourable increase from Week 16 to Week 48 compared with the PBO to BKZ Q2W switchers with ≥1 DT at baseline (**Figures 2** and **3**).
- The proportion of patients with >5 DTs decreased from baseline to Week 48, regardless of treatment arm, in both patients with ≥1 and ≥3 DTs at baseline (**Figures 2** and **3**).

Conclusions

Patients treated with bimekizumab demonstrated clinically meaningful reductions in DT count to 48 weeks.

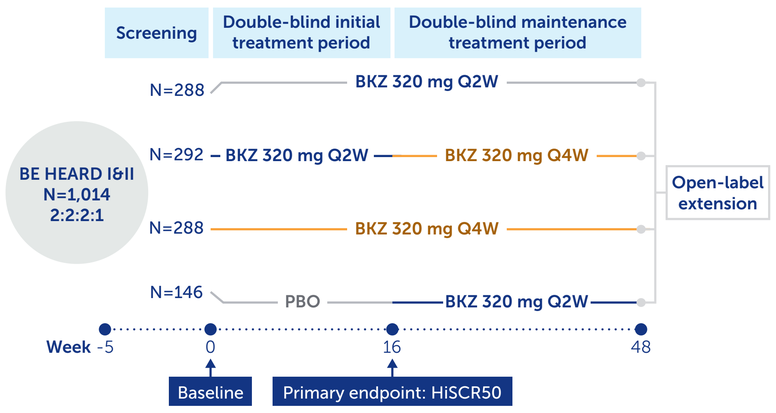
From baseline to Week 48, the proportion of patients with no DTs increased, while the proportion of patients with >5 DTs decreased.

Summary



BKZ treatment led to **large increases** in proportions of patients with **no DTs over 1 year**

Figure 1 Study design



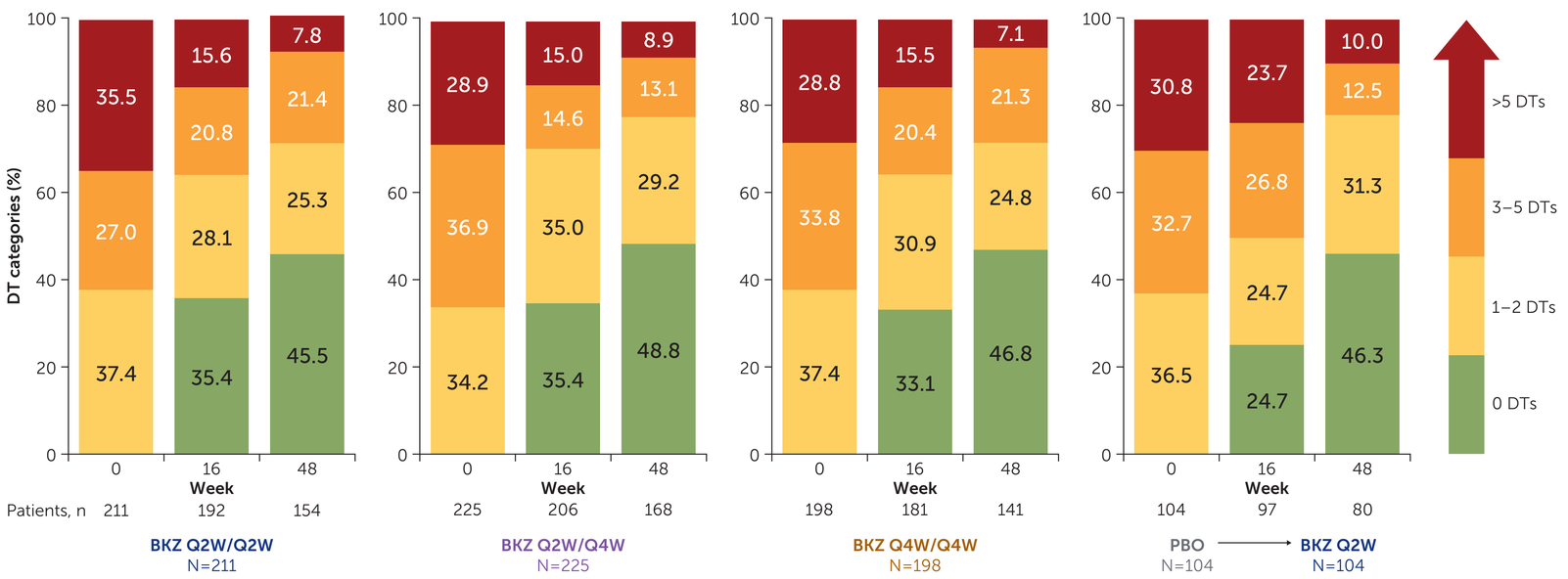
At baseline, 1,014 patients with moderate to severe HS were randomised 2:2:2:1 to BKZ 320 mg Q2W to Week 48, BKZ 320 mg Q4W to Week 48, BKZ 320 mg Q2W to Week 16 then BKZ 320 mg Q4W to Week 48, or PBO to Week 16 then BKZ 320 mg Q2W to Week 48.

Table 1 Baseline characteristics

	Patients with ≥1 DT at baseline				Patients with ≥3 DTs at baseline			
	BKZ Q2W/Q2W N=211	BKZ Q2W/Q4W N=225	BKZ Q4W/Q4W N=198	PBO/BKZ Q2W N=104	BKZ Q2W/Q2W N=132	BKZ Q2W/Q4W N=148	BKZ Q4W/Q4W N=124	PBO/BKZ Q2W N=66
Age (years), mean ± SD	37.5 ± 12.1	37.4 ± 12.8	36.8 ± 11.9	36.7 ± 12.9	38.6 ± 12.0	37.4 ± 13.1	36.1 ± 11.5	36.3 ± 13.1
Sex, female, n (%)	98 (46.4)	128 (56.9)	105 (53.0)	50 (48.1)	59 (44.7)	83 (56.1)	64 (51.6)	28 (42.4)
BMI, kg/m², mean ± SD	32.6 ± 8.4	32.4 ± 7.7	33.4 ± 7.7	32.8 ± 8.2	32.4 ± 8.9	32.3 ± 8.1	33.6 ± 7.6	31.7 ± 8.1
Duration of HS (years), mean ± SD	7.5 ± 7.2	8.2 ± 7.1	7.1 ± 6.9	9.0 ± 9.4	7.7 ± 7.2	8.7 ± 7.4	6.5 ± 6.4	8.7 ± 9.2
Baseline AN count, mean ± SD	14.7 ± 10.6	18.0 ± 17.8	18.1 ± 15.1	14.6 ± 10.1	16.4 ± 11.3	21.5 ± 20.3	21.1 ± 15.7	16.5 ± 11.5
Baseline DT count, mean ± SD	5.2 ± 4.4	4.9 ± 4.5	4.8 ± 4.2	4.7 ± 3.8	7.5 ± 4.2	6.7 ± 4.6	6.8 ± 4.1	6.6 ± 3.5
Hurley stage, n (%)								
II	103 (48.8)	101 (44.9)	91 (46.0)	49 (47.1)	47 (35.6)	48 (32.4)	36 (29.0)	24 (36.4)
III	108 (51.2)	124 (55.1)	107 (54.0)	55 (52.9)	85 (64.4)	100 (67.6)	88 (71.0)	42 (63.6)
DLQI total score, mean ± SD	11.7 ± 6.4	11.0 ± 6.7	11.3 ± 7.2	13.2 (7.2)	12.6 ± 6.6	11.3 ± 6.3	12.0 ± 7.3	13.6 ± 7.1
Prior biologic use,[a] n (%)	45 (21.3)	49 (21.8)	36 (18.2)	20 (19.2)	39 (29.5)	36 (24.3)	25 (20.2)	16 (24.2)
Baseline antibiotic use, n (%)	21 (10.0)	20 (8.9)	12 (6.1)	8 (7.7)	13 (9.8)	14 (9.5)	10 (8.1)	5 (7.6)

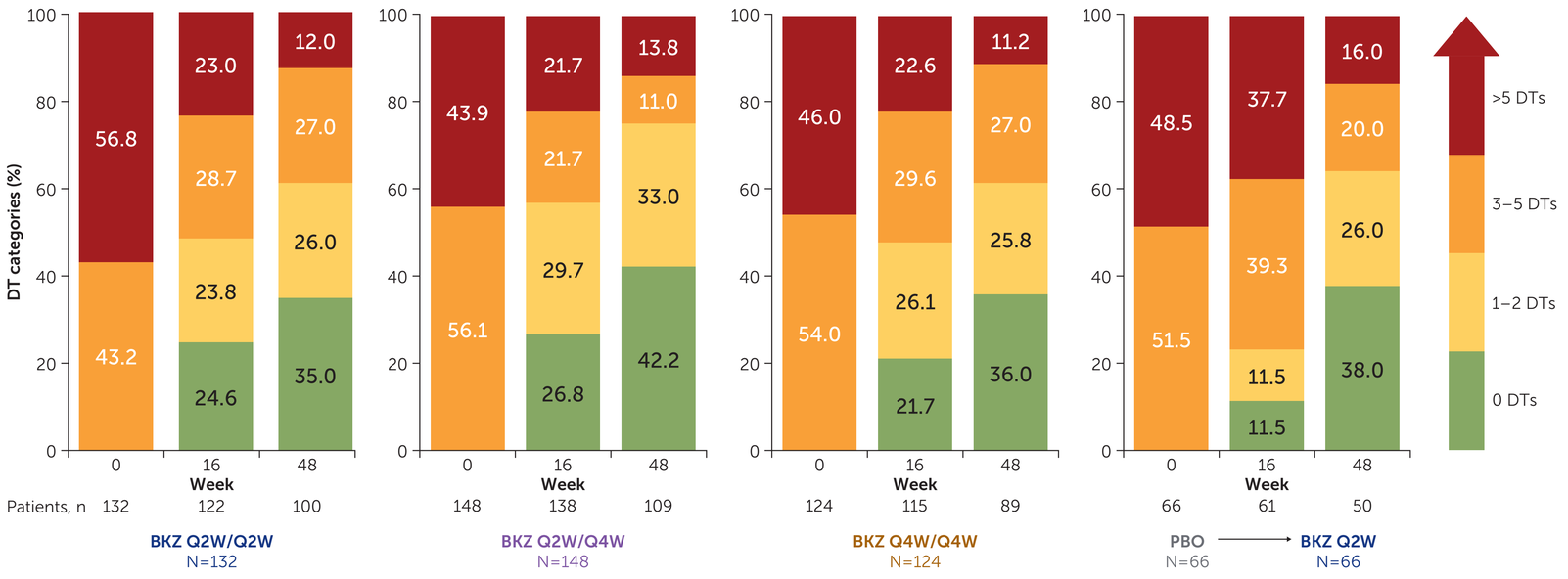
Randomised pooled set; baseline characteristics evaluated at Week 0. **[a]** Patients received prior biologic therapy for any indication.

Figure 2 Baseline DT count ≥1: DT categories to Week 48 (OC)



Randomised pooled set, N=1,014; included patients had a baseline DT count ≥1. Treatment switch after the initial treatment period for the PBO/BKZ 320mg Q2W group started at Week 16.

Figure 3 Baseline DT count ≥3: DT categories to Week 48 (OC)



Randomised pooled set, N=1,014; included patients had a baseline DT count ≥3. Treatment switch after the initial treatment period for the PBO/BKZ 320mg Q2W group started at Week 16.

AN: abscess and inflammatory nodule; **BKZ:** bimekizumab; **BMI:** body mass index; **DLQI:** Dermatology Life Quality Index; **DT:** draining tunnel; **HRQoL:** health-related quality of life; **HiSCR:** HS Clinical Response; HiSCR50: 50% reduction in the total abscess and inflammatory nodule count with no increase from baseline in abscess or draining tunnel count; **HS:** hidradenitis suppurativa; **IL:** interleukin **OC:** observed case; **PBO:** placebo; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks; **SD:** standard deviation.

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