P0149

Bimekizumab impact on flare in patients with moderate to severe hidradenitis suppurativa: Pooled Week 48 results from BE HEARD I&II

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Objective

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

Introduction

- HS is a chronic inflammatory skin disease characterised by recurrent nodules, abscesses and skin tunnels, with patients often experiencing worsening of symptoms, known as flares.[1,2]
- Achieving disease control is important to reduce the frequency and severity of flares.[1,2]
- BKZ selectively inhibits interleukin (IL)-17F in addition to IL-17A and has previously demonstrated its efficacy in patients with HS, in the phase 3 BE HEARD I&II trials.[3,4]

Methods

- Pooled data from the randomised, double-blinded, placebo (PBO)-controlled, multicentre BE HEARD I&II trials included an initial (Weeks 0–16) and maintenance (Weeks 16–48) treatment period (**Figure 1**).
- The proportion of patients who experienced a flare at the given visit (single point) and the cumulative proportion (any visit up to and including the given timepoint) of patients who remained flare-free over 48 weeks are reported.
- Data are reported as observed case (OC).

Results

- Overall, 1,014 patients were randomised to BKZ Q2W/Q2W (N=288), BKZ Q2W/Q4W (N=292), BKZ Q4W/Q4W (N=288), or PBO/Q2W (N=146) in BE HEARD I&II (**Figure 1**).
- Baseline demographics and disease characteristics were comparable across treatment arms (**Table 1**).
- At every visit until and including Week 16, fewer BKZ-treated patients experienced flares than PBO-treated patients (**Figure 2**).
- After switching from PBO to BKZ at Week 16, the number of patients experiencing a flare decreased rapidly, to the level observed in those continuously treated with BKZ from baseline, through Week 48 (**Figure 2**).
- A substantial proportion of patients continuously treated with BKZ remained flare-free by Week 48 (**Figure 3**).
- After switching from PBO to BKZ Q2W at Week 16, the cumulative proportion of patients who remained flare-free to Week 48 was sustained (**Figure 3**).

Conclusions

Overall, patients treated with bimekizumab experienced fewer flares to Week 16 compared to patients treated with placebo. The proportion of patients who experienced flares remained low in the bimekizumab treated group to Week 48, and reduced rapidly in patients who switched from placebo to bimekizumab.

The majority of patients continuously treated with bimekizumab from baseline were flare-free at Week 16 and sustained their flare-free status to Week 48. Following switch from placebo to bimekizumab, patients experienced few new flares.

Summary

Fewer patients treated with BKZ **experienced flares** over time

Majority of patients treated with BKZ were **flare-free** at Weeks 16 and 48

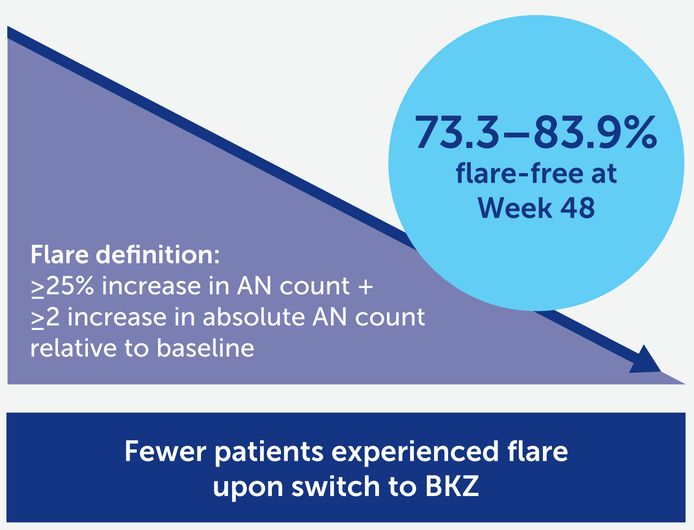
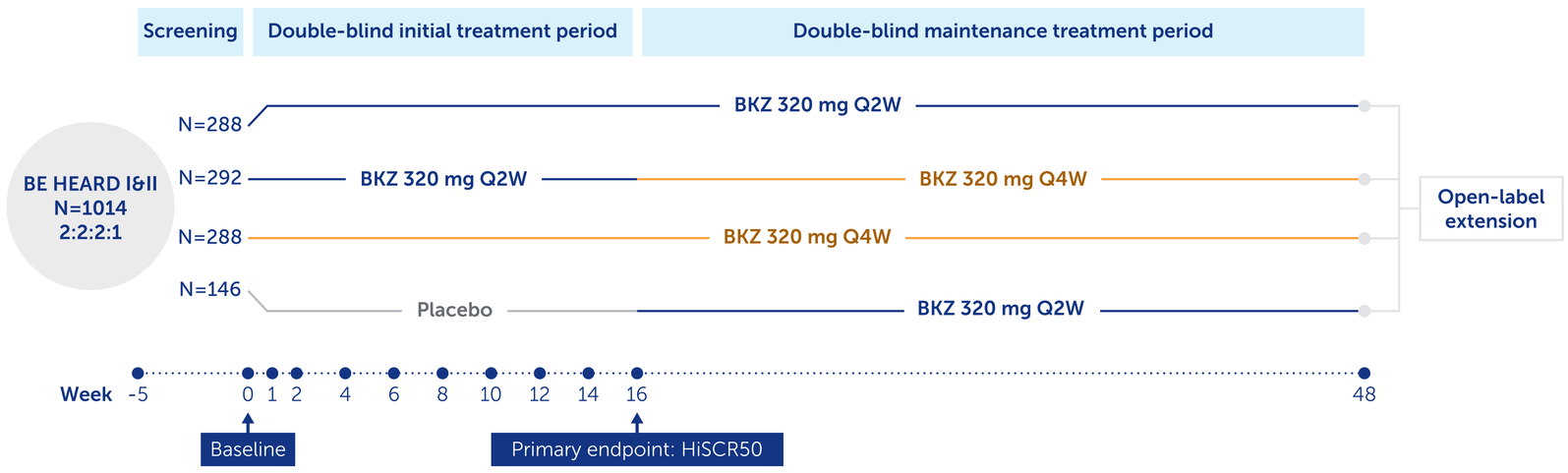


Table 1 Baseline characteristics

	BKZ Q2W/Q2W N=288	BKZ Q2W/Q4W N=292	BKZ 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)
BMI (kg/m²), mean ± SD	32.7 ± 8.6	32.7 ± 7.9	33.8 ± 7.9	33.1 ± 8.3
Duration of HS (years), mean ± SD	7.6 ± 7.4	8.3 ± 7.7	7.3 ± 7.3	9.8 ± 9.4
Baseline AN count, mean ± SD	14.7 ± 11.6	17.2 ± 16.8	17.7 ± 20.9	14.4 ± 10.0
Hurley stage, n (%)				
II	166 (57.6)	160 (54.8)	160 (55.6)	79 (54.1)
III	122 (42.4)	132 (45.2)	128 (44.4)	67 (45.9)
Baseline DT count, mean ± SD	3.8 ± 4.4	3.8 ± 4.4	3.3 ± 4.1	3.4 ± 3.8
Prior biologic use,[a] 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)

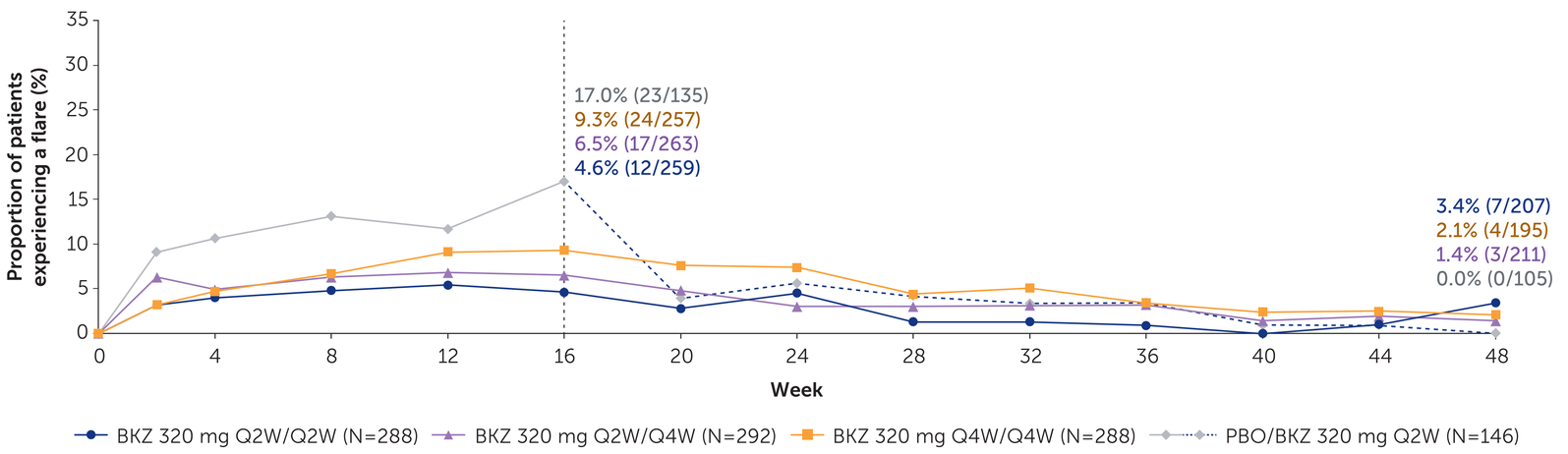
Randomised pooled set, N=1,014. **[a]** Patients received prior biologic therapy for any indication.

Figure 1 Study design



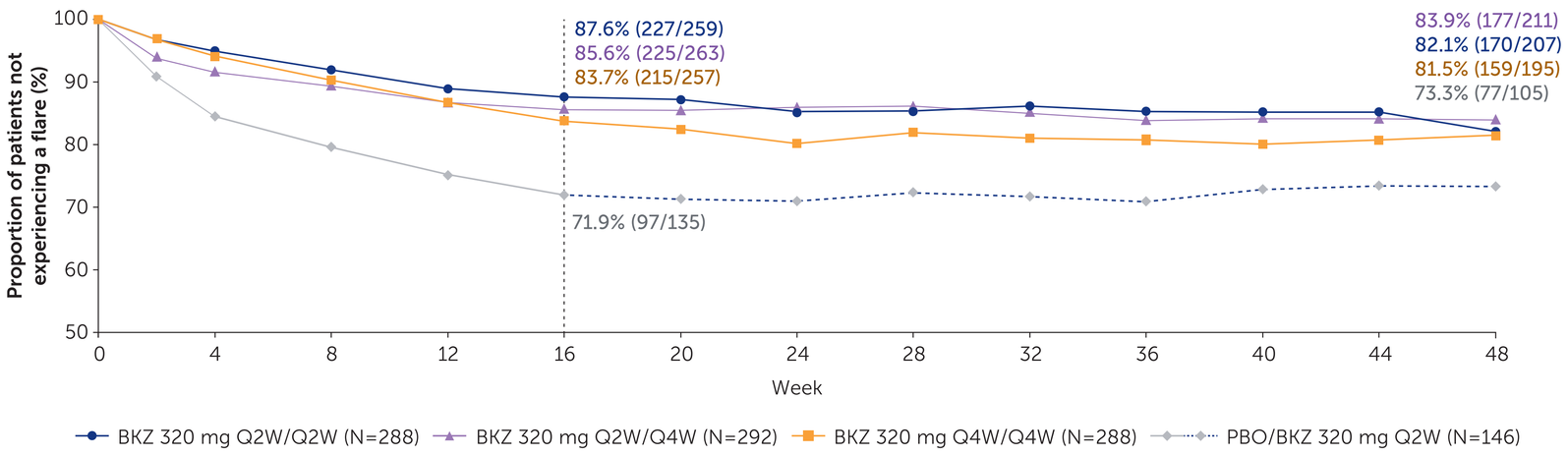
At baseline, 1,014 patients with moderate to severe HS were randomised 2:2:2:1 to BKZ 320 mg Q2W to Week 48, BKZ 320 mg Q4W to Week 48, BKZ 320 mg Q2W to Week 16 then BKZ 320 mg Q4W to Week 48, or PBO to Week 16 then BKZ 320 mg Q2W to Week 48.

Figure 2 Proportion of patients experiencing a flare at a given visit (OC)



Randomised pooled set, N=1,014. N/Nsub whereby Nsub represents the number of participants with a non-missing lesion count assessment at the given week, and percentages are calculated accordingly. Flare was defined as ≥25% increase in AN count with an absolute increase in AN count of ≥2 relative to baseline. Treatment switch after the initial treatment period for the PBO/BKZ 320 mg Q2W group started at Week 16. OC does not include patients who are missing from a given study visit (they may return after missed visits) or discontinued the study.

Figure 3 Cumulative proportion of patients remaining flare-free (OC)



Randomised pooled set, N=1,014. Proportion of patients who have not experienced a flare up to and including each visit; N/Nsub whereby Nsub represents the number of participants with a non-missing lesion count assessment at the given week, and percentages are calculated accordingly. Flare was defined as ≥25% increase in AN count with an absolute increase in AN count of ≥2 relative to baseline. Treatment switch after the initial treatment period for the PBO/BKZ 320 mg Q2W group started at Week 16. OC does not include patients who are missing from a given study visit (they may return after missed visits) or discontinued the study.

AN: abscess and inflammatory nodule; **BMI:** body mass index; **BKZ:** bimekizumab; **DT:** draining tunnels; **OC:** observed case; **PBO:** placebo; **Q2/4W:** every 2/4 weeks; **SD:** standard deviation.

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