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Bimekizumab Impact on Draining Tunnels Over 2 Years in HS: Data from BE HEARD EXT

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Objective

To report the impact of bimekizumab (BKZ) on the number of draining tunnels (DTs; fistulas/sinus tracts) over 2 years across the BE HEARD I&II and open-label BE HEARD EXT phase 3 trials.

Background

- DTs negatively impact quality of life in patients with hidradenitis suppurativa (HS) and lead to potentially long-term, severe sequelae.[1,2]
- BKZ is a humanized lgG1 antibody which selectively inhibits interleukin (IL)-17F in addition to IL-17A.[3] BKZ has previously demonstrated clinical efficacy, including reduction in DTs, in phase 3 clinical trials of patients with HS.[4]

Methods

- Data were pooled from the BE HEARD I&II studies and the open-label extension, BE HEARD EXT.[4,5] Week 48 BE HEARD I&II completers could enroll in BE HEARD EXT and receive open-label BKZ 320 mg every 2 weeks (Q2W) or every 4 weeks (Q4W) based on ≥90% HS Clinical Response (HiSCR90; averaged from BE HEARD I&II Weeks 36, 40, and 44) (**Figure 1**).
- Data are reported for patients randomized to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT (BKZ Total).
- Here, we report mean absolute change from baseline (CfB) in DT count for all BKZ Total patients, and achievement of ≥3 DT reductions in patients with baseline DT count ≥5 to Week 96.
- Data are reported as observed case (OC).

Results

- At baseline, 1,014 patients were randomized, and 72.8% of these patients had DTs. Among the 657 BE HEARD I&II Week 48 completers who entered BE HEARD EXT, 556 patients received continuous BKZ from baseline.
- Of the 556 patients randomized to BKZ (with and without DTs), mean DT count at baseline was 3.8 ± standard deviation (SD): 4.3 (**Table 1**).
- Mean absolute CfB was reduced at Week 48 to -2.4 ± 3.4, in the BKZ Total group for patients with or without DTs at baseline. This reduction was maintained to Week 96 (-2.9 ± 3.7) (**Figure 2**).
- Of patients with ≥5 DTs at baseline in the BKZ Total group (n=177), the proportion of patients with ≥3 DT reductions were 84.7% (150/177) at Week 48 and 88.1% (133/151) at Week 96 (**Figure 3**).

Conclusions

A large proportion of patients treated with bimekizumab experienced a decrease in the number of DTs after 1 year, with a reduction of ≥3 DTs observed in most patients with ≥5 DTs at baseline. Improvements in DTs were maintained throughout the second year of treatment.

Plain Language Summary

Why was this study needed?
Hidradenitis suppurativa (HS) is a long-term skin condition. Painful lesions can occur, which may itch or ooze, these are called draining tunnels. These lesions can severely impact patients' lives.

What did this study show?
Bimekizumab is a new drug in development for HS. Treatment with bimekizumab reduced the number of draining tunnels over two years.

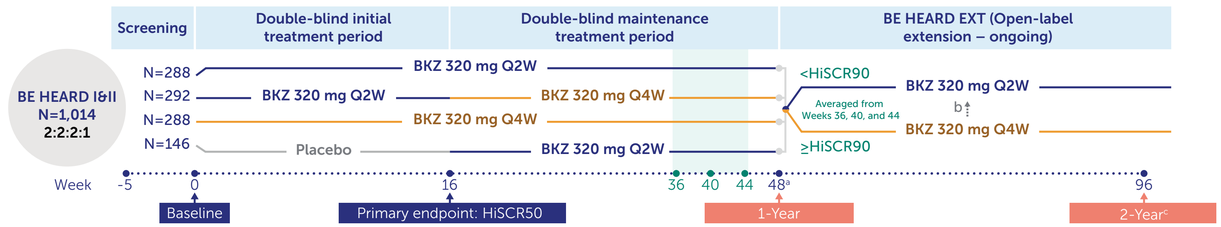
Why is this important?
The symptoms caused by draining tunnels impact the lives of patients with HS. Bimekizumab reduces these draining tunnels and may help ease these symptoms.

Table 1 Baseline characteristics

	BKZ Total N=556
Age (years), mean ± SD	36.3 ± 12.2
Sex, female, n (%)	299 (53.8)
Racial group, n (%)	
White	448 (80.6)
Black or African American	55 (9.9)
BMI (kg/m²), mean ± SD	32.5 ± 7.8
Smoking status, current, n (%)	260 (46.8)
Duration of HS (years), mean ± SD	7.4 ± 7.1
AN count, mean ± SD	16.9 ± 18.5
DT count, mean ± SD	3.8 ± 4.3
Hurley stage, n (%)	
II	303 (54.5)
III	253 (45.5)
DLQI total score, mean ± SD	11.0 ± 6.8
HiSQOL total score, mean ± SD	24.6 ± 12.8
Prior biologic use,[a] n (%)	112 (20.1)
Baseline antibiotic use, n (%)	54 (9.7)

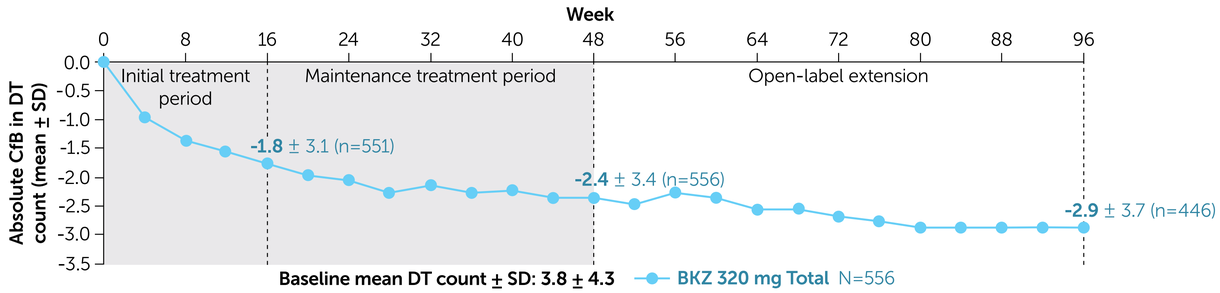
OLE set; only included patients who entered BE HEARD EXT at Week 48. BKZ Total (N=556) comprised patients randomized to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT and continued to receive BKZ. **[a]** Patients received prior biologic therapy for any indication.

Figure 1 Study design



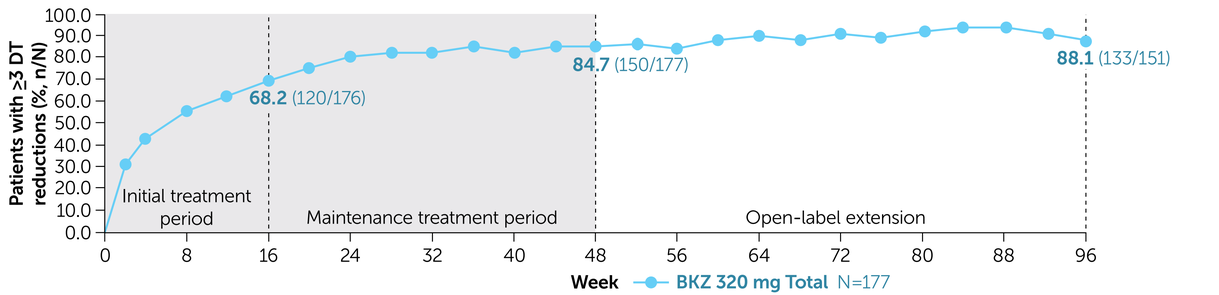
At baseline, 1,014 patients with moderate to severe HS were randomized 2:2:2:1 to BKZ 320 mg Q2W to Week 48, BKZ 320 mg Q2W to Week 16 then BKZ 320 mg Q4W to Week 48, BKZ 320 mg Q4W to Week 48, or placebo to Week 16 then BKZ 320 mg Q2W to Week 48. **[a]** Patients who completed Week 48 of BE HEARD I&II 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).

Figure 2 Mean absolute CfB in DT count to Week 96 (OC)



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: represents number of patients with a non-missing lesion count assessment in the given week.

Figure 3 Proportion of patients with ≥3 DT reductions to Week 96 in patients with ≥5 DTs at baseline (OC)



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.

Abbreviations: AN: abscess and inflammatory nodule; **BKZ:** bimekizumab; **BMI:** body mass index; **CfB:** change from baseline; **DLQI:** Dermatology Life Quality Index; **DT:** draining tunnels; **HISCR50/90:** ≥50%/90% reduction from baseline in the total AN count with no increase from baseline in abscess or DT count; **HiSQOL:** Hidradenitis Suppurativa Qualit of Life; **HS:** hidradenitis suppurativa; **IL:** interleukin; **OC:** observed case; **OLE:** open-label extension; **SD:** standard deviation; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks.

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