Bimekizumab in Patients with Moderate to Severe Hidradenitis Suppurativa: A Focus on Patient Quality of Life and Depth of Responses from BE HEARD I & II to Week 48

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Objective

To investigate whether achieving more stringent clinical responses to bimekizumab (BKZ) treatment translates into greater health-related quality of life (HRQoL) benefits for patients with moderate to severe hidradenitis suppurativa (HS), from the post-hoc analysis of the phase 3 BE HEARD I & II studies.

Background

- The HS Quality of Life (QoL) questionnaire (HiSQOL) is a reliable patient-reported tool measuring HS-specific HRQoL, one of the six domains of the core outcome set established for HS by the HIdradenitis SuppuraTiva cORe outcomes set International Collaboration (HISTORIC).[1,2] HiSQOL addresses the need for an instrument that specifically measures HS-specific HRQoL.[1,3]
- HiSQOL is comprised of 17 items that are separated into three subscales (symptoms, psychosocial, and activities-adaptations) which can be reported independently or as a total score. Each item is scored from 0 (not at all) to 4 (extremely) and summed to produce the HiSQOL total score which ranges from 0–68, with higher scores indicating a more severe impact on HRQoL.[3]
- BKZ is a humanised IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A and has shown clinical efficacy in patients with HS.[4–6]

Methods

- Data were pooled from BE HEARD I & II, randomised, double-blind, placebo-controlled phase 3 studies assessing the efficacy and safety of BKZ.[5,6] The trials included an initial (Weeks 0–16) and maintenance (Weeks 16–48) period (**Figure 1**). Only those randomised to BKZ at baseline are included in this analysis.
- Clinical response to treatment was measured using Hidradenitis Suppurativa Clinical Response of ≥50% (HiSCR50) and increasingly stringent ≥75% (HiSCR75) and ≥90% (HiSCR90) at Week 16 and Week 48.
- Benefit to HRQoL was assessed by reporting the proportions of patients with None/Mild impact on HRQoL as indicated by a HiSQOL total score ≤14. Those proportions were compared for the three treatment arms randomised to BKZ at baseline: BKZ every 2 weeks (Q2W) to Week 48, BKZ every 4 weeks (Q4W) to Week 48, BKZ Q2W to Week 16 then BKZ Q4W to Week 48 (Q2W/Q4W).
- Data were analysed using observed case (OC) and modified non-responder imputation (mNRI).

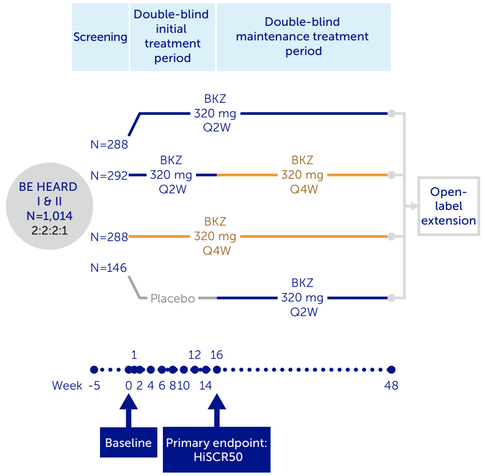
Results

- At baseline, 1,014 patients were randomised (**Figure 1**).
- Demographics and baseline characteristics were generally balanced across treatment groups (**Table 1**). Mean HiSQOL total scores at baseline were comparable across treatment regimens (**Table 1**).
- At Week 16, of patients who achieved HiSCR50, 69.5–74.8% (OC range) reported a HiSQOL rating of None/Mild (**Figure 2**). A numerically higher proportion of patients reported a HiSQOL rating of None/Mild at Week 16 if they achieved HiSCR75 (OC range; 77.2–84.3%; **Figure 2**) or HiSCR90 (OC range; 80.0–89.3%; **Figure 2**). A similar trend was also observed for Week 16 HiSCR50/75/90 responders to Week 48 (**Table 2**).
- Despite results being more similar across Week 48 HiSCR response levels, some slight numerical differences were observed for more stringent treatment response (HiSCR75/90) than HiSCR50 at Week 48 (**Figure 3**).

Conclusions

Achieving stringent levels of clinical responses observed with BKZ treatment translated into greater benefits for HRQoL in patients with HS, as defined by None/Mild impact of HS on QoL.

Figure 1 BE HEARD I & II study design



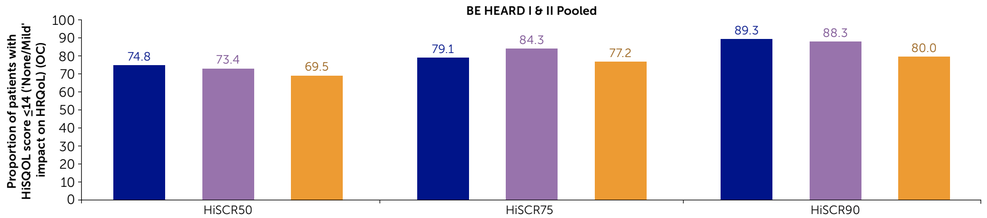
At baseline, patients with moderate to severe HS were randomised 2:2:2:1 to BKZ 320 mg Q2W to Week 48, BKZ 320 mg Q4W to Week 48, BKZ 320 mg Q2W to Week 16 then BKZ 320 mg Q4W to Week 48, or placebo to Week 16 then BKZ 320 mg Q2W to Week 48.

Table 1 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/m², mean ± SD	32.7 ± 8.5	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	9.7 ± 9.4
AN count, mean ± SD	14.7 ± 11.6	17.2 ± 16.8	17.7 ± 20.9	14.4 ± 10.0
DT count, mean ± SD	3.8 ± 4.4	3.8 ± 4.4	3.3 ± 4.1	3.4 ± 3.8
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)
HiSQOL total score, mean ± SD	24.8 ± 12.7	24.5 ± 13.1	25.8 ± 13.9	26.4 ± 14.1
Proportion of patients with 'None/Mild' impact on HRQoL, n/N (%)[a]	60/284 (21.1)	80/285 (28.1)	71/285 (24.9)	35/144 (24.3)
Prior biologic use, n (%)[b]	60 (20.8)	57 (19.5)	47 (16.3)	29 (19.9)
Baseline antibiotic use, n (%)	29 (10.1)	28 (9.6)	18 (6.3)	11 (7.5)

Randomised set (N=1,014). [a] For HiSQOL Total Score: None = 0 to 4; Mild = 5 to 14; Moderate = 15 to 21; Severe = 22 to 23 and Very Severe ≥ 24. [b] Patients received prior biologic therapy for any indication.

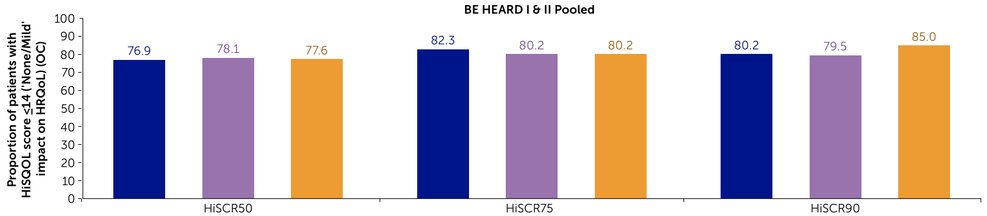
Figure 2 Week 16 HiSCR50/75/90 responders with HiSQOL score ≤14 ('None/Mild' impact on HRQoL) at Week 16 (OC, mNRI)



	HiSCR50			HiSCR75			HiSCR90		
	BKZ Q2W/Q2W (N=160)	BKZ Q2W/Q4W (N=155)	BKZ Q4W/Q4W (N=152)	BKZ Q2W/Q2W (N=110)	BKZ Q2W/Q4W (N=109)	BKZ Q4W/Q4W (N=93)	BKZ Q2W/Q2W (N=56)	BKZ Q2W/Q4W (N=60)	BKZ Q4W/Q4W (N=55)
OC: n/N	119/159	113/154	105/151	87/110	91/108	71/92	50/56	53/60	44/55
mNRI (95% CI)	73.1 (66.2, 79.9)	72.7 (65.7, 79.7)	67.1 (59.6, 74.6)	76.4 (NC, NC)	83.2 (76.1, 90.3)	73.1 (64.1, 82.1)	87.5 (NC, NC)	88.3 (NC, NC)	76.4 (NC, NC)

Randomised set (N=1,014). OC: percentages are calculated using the number of patients with a non-missing HiSQOL total score in the given week. 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 at subsequent timepoints; multiple imputation was used for all other missing data.

Figure 3 Week 48 HiSCR50/75/90 responders with HiSQOL score ≤14 ('None/Mild' impact on HRQoL) at Week 48 (OC, mNRI)



	HiSCR50			HiSCR75			HiSCR90		
	BKZ Q2W/Q2W (N=159)	BKZ Q2W/Q4W (N=170)	BKZ Q4W/Q4W (N=155)	BKZ Q2W/Q2W (N=126)	BKZ Q2W/Q4W (N=127)	BKZ Q4W/Q4W (N=128)	BKZ Q2W/Q2W (N=82)	BKZ Q2W/Q4W (N=88)	BKZ Q4W/Q4W (N=82)
OC: n/N	120/156	132/169	118/152	102/124	101/126	101/126	65/81	70/88	68/80
mNRI (95% CI)	70.9 (63.7, 78.0)	69.8 (62.9, 76.7)	71.1 (64.0, 78.3)	75.7 (68.1, 83.2)	73.8 (66.1, 81.5)	73.2 (65.5, 80.9)	73.0 (63.3, 82.6)	75.0 (NC, NC)	79.0 (70.1, 87.8)

Randomised set (N=1,014). OC: percentages are calculated using the number of patients with a non-missing HiSQOL total score in the given week. 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 at subsequent timepoints; multiple imputation was used for all other missing data.

Table 2 Week 16 HiSCR50/75/90 responders with HiSQOL score ≤14 ('None/Mild' impact on HRQoL) at Week 48 (OC, mNRI)

	HiSCR50			HiSCR75			HiSCR90		
	BKZ Q2W/Q2W (N=160)	BKZ Q2W/Q4W (N=155)	BKZ Q4W/Q4W (N=152)	BKZ Q2W/Q2W (N=110)	BKZ Q2W/Q4W (N=109)	BKZ Q4W/Q4W (N=93)	BKZ Q2W/Q2W (N=56)	BKZ Q2W/Q4W (N=60)	BKZ Q4W/Q4W (N=55)
OC: n/N (%)	91/123 (74.0)	100/130 (76.9)	89/114 (78.1)	70/87 (80.5)	77/93 (82.8)	60/71 (84.5)	41/45 (91.1)	46/52 (88.5)	36/44 (81.8)
mNRI (95% CI)	64.6 (56.7, 72.4)	66.7 (59.1, 74.4)	63.9 (56.0, 71.8)	70.4 (61.4, 79.4)	74.3 (65.8, 82.8)	68.8 (59.2, 78.4)	78.3 (67.0, 89.7)	80.0 (69.4, 90.5)	67.9 (55.3, 80.4)

Randomised set (N=1,014). OC: percentages are calculated using the number of patients with a non-missing HiSQOL total score in the given week. 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 at subsequent timepoints; multiple imputation was used for all other missing data.

AN: abscess and inflammatory nodule; **BKZ:** bimekizumab; **CI:** confidence interval; **DT:** draining tunnel; **HiSCR:** Hidradenitis Suppurativa Clinical Response; **HiSCR50/75/90:** ≥50%/≥75%/≥90% reduction from baseline in the total abscess and inflammatory nodule count with no increase from baseline in abscess or draining tunnel count; **HiSQOL:** Hidradenitis Suppurativa Quality of Life questionnaire; **HISTORIC:** HIdradenitis SuppuraTiva cORe outcomes set International Collaboration; **HRQoL:** health-related quality of life; **HS:** hidradenitis suppurativa; **IL:** interleukin; **mNRI:** modified non-responder imputation; **NC:** not calculable; **OC:** observed case; **PBO:** placebo; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks; **QoL:** quality of life; **SD:** standard deviation.

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