

Bimekizumab response maintenance to 48 weeks in patients with moderate to severe hidradenitis suppurativa: Pooled responder analysis from the phase 3, double-blind, placebo-controlled, randomized clinical trials BE HEARD I & II

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Synopsis

- Hidradenitis suppurativa (HS) is a chronic, relapsing, and painful inflammatory skin disease associated with significant comorbidities and poor quality of life.¹
- However, treatment options are limited.²
- Bimekizumab (BKZ), a monoclonal immunoglobulin G1 antibody which selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated efficacy in patients with moderate to severe HS.²
- Here, we report maintenance of response through Week 48 from BE HEARD I & II.^{3,4}

Objective

To report maintenance of response over 48 weeks in patients with moderate to severe HS who achieved clinical responses after 16 weeks of BKZ treatment from the phase 3 BE HEARD I & II studies.

Methods

- Data were pooled from BE HEARD I & II.^{3,4} These randomized, double-blinded, placebo-(PBO)-controlled phase 3 studies were comprised of an initial (Weeks 0–16) and a maintenance (Weeks 16–48) treatment period (Figure 1).
- Maintenance of response is reported respectively as a) the percentage of BKZ-treated patients who achieved 50/75/90% HS Clinical Response (HiSCR50/75/90) or b) an abscess and inflammatory nodule (AN) count of 0, 1, or 2 at both Week 16 and Week 48.
- Data are reported as observed cases (OC) throughout; last observation carried forward (LOCF) data are provided in Table 2.

Results

Baseline Characteristics

- Baseline demographics were comparable across treatment arms (Table 1).

Week 48 Responders

- Among Week 16 HiSCR50 responders, 88.5–89.6% of patients maintained this response through Week 48, across treatment regimens (Table 2; Figure 2).
- Among Week 16 HiSCR75 responders, 80.9–88.3% of patients maintained this response through Week 48, across treatment regimens (Table 2; Figure 3).
- Among Week 16 HiSCR90 responders, 65.2–69.2% of patients maintained this response through Week 48, across treatment regimens (Table 2; Figure 4).
- Among patients with an AN count of 0, 1, or 2 at Week 16, 82.1%–88.0% of patients maintained this response through Week 48, across treatment regimens (Table 2; Figure 5).

Conclusions

Maintenance of response among Week 16 responders was high across the primary endpoint (HiSCR50) and more stringent clinical outcome measures for bimekizumab-randomized patients.

Summary

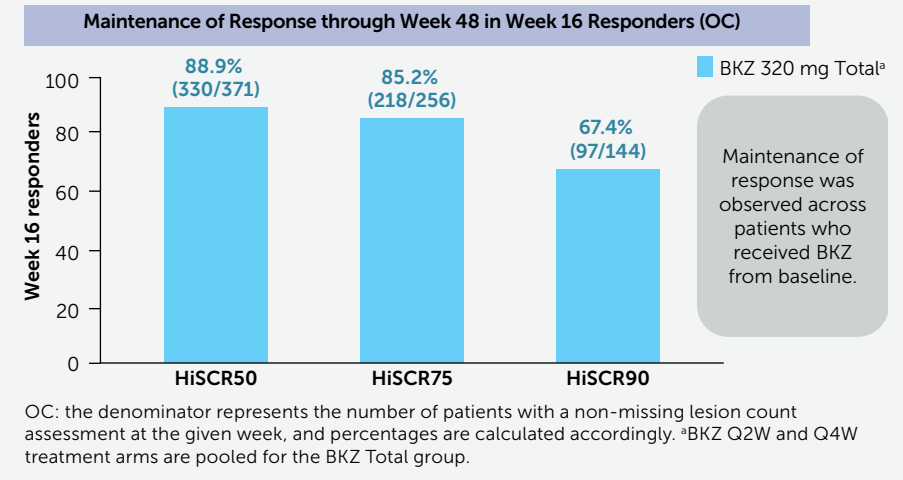


Figure 1 Study design

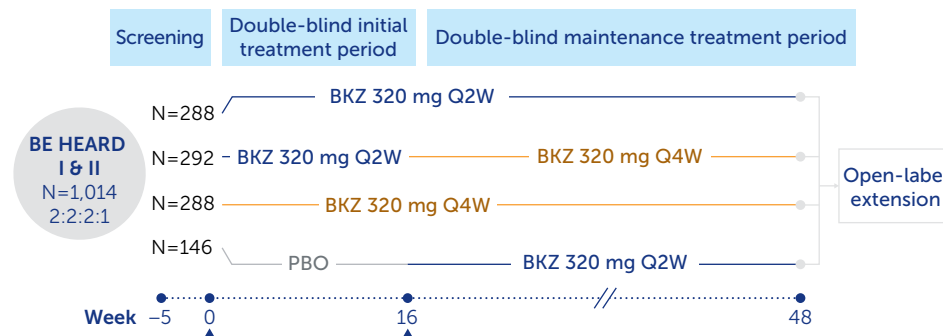


Figure 2 HiSCR50 maintenance of response (OC, LOCF)

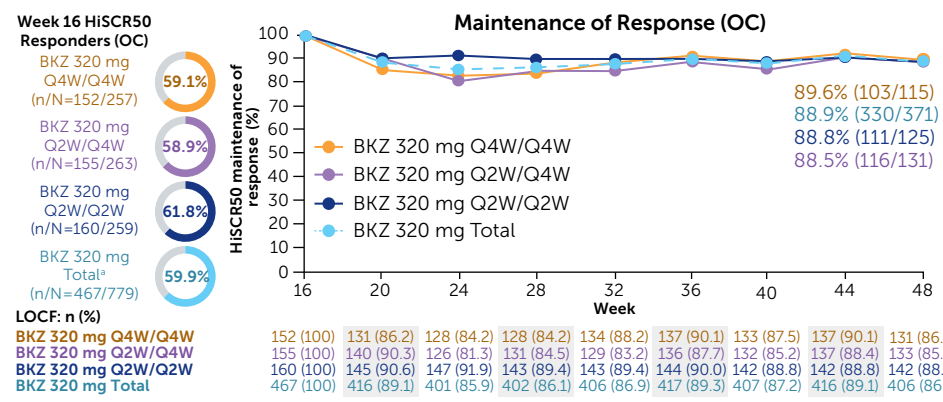


Figure 3 HiSCR75 maintenance of response (OC, LOCF)

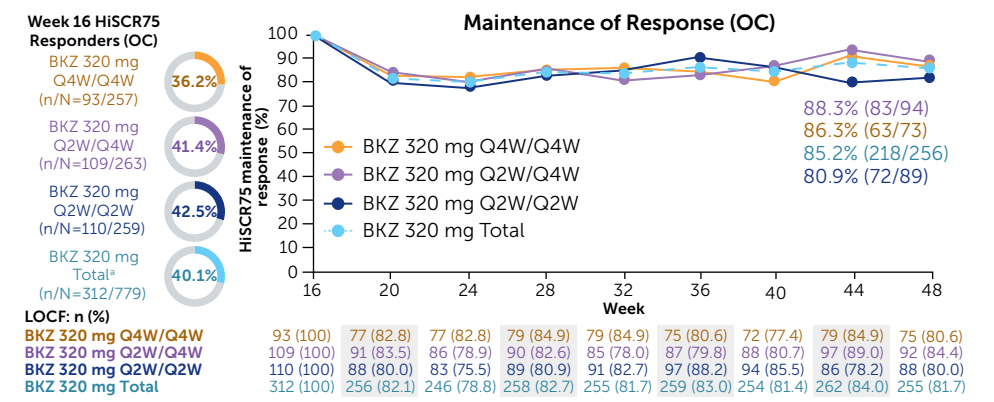


Table 1 Baseline characteristics

	PBO/BKZ 320 mg Q2W (N=146)		BKZ 320 mg Q4W/Q4W (N=288)		Overall (N=292)		BKZ 320 mg Q2W/Q4W (N=288)		BKZ 320 mg Total (N=868)	
	Age, years, mean (SD)	37.3 (12.8)	35.8 (11.6)	37.0 (12.4)	36.8 (12.4)	36.5 (12.4)	36.5 (12.4)	36.5 (12.4)	36.5 (12.4)	36.5 (12.4)
Sex, female, n (%)	75 (51.4)	75 (51.4)	175 (60.8)	175 (60.8)	174 (59.6)	174 (59.6)	152 (52.8)	152 (52.8)	501 (57.7)	501 (57.7)
BMI, kg/m ² , mean (SD)	33.1 (8.3)	33.1 (8.3)	33.8 (7.9)	33.8 (7.9)	32.7 (7.9)	32.7 (7.9)	32.7 (8.6)	32.7 (8.6)	33.1 (8.1)	33.1 (8.1)
Duration of HS, years, mean (SD)	9.8 (9.4)	9.8 (9.4)	7.3 (7.3)	7.3 (7.3)	8.3 (7.7)	8.3 (7.7)	7.6 (7.4)	7.6 (7.4)	7.7 (7.4)	7.7 (7.4)
Baseline AN count, mean (SD)	14.4 (10.0)	14.4 (10.0)	17.7 (20.9)	17.7 (20.9)	17.2 (16.8)	17.2 (16.8)	14.7 (11.6)	14.7 (11.6)	16.6 (16.9)	16.6 (16.9)
Hurley stage, n (%)										
II	79 (54.1)	79 (54.1)	160 (55.6)	160 (55.6)	160 (54.8)	160 (54.8)	166 (57.6)	166 (57.6)	486 (56.0)	486 (56.0)
III	67 (45.9)	67 (45.9)	132 (44.4)	132 (44.4)	132 (45.2)	132 (45.2)	122 (42.4)	122 (42.4)	382 (44.0)	382 (44.0)
DLQI total score, mean (SD)	12.2 (7.1)	12.2 (7.1)	11.7 (7.4)	11.7 (7.4)	10.8 (6.7)	10.8 (6.7)	11.2 (6.5)	11.2 (6.5)	11.2 (6.9)	11.2 (6.9)
Prior biologic use, n (%)	29 (19.9)	29 (19.9)	47 (16.3)	47 (16.3)	60 (20.8)	60 (20.8)	60 (20.8)	60 (20.8)	164 (18.9)	164 (18.9)
Baseline antibiotic use, n (%)	11 (7.5)	11 (7.5)	18 (6.3)	18 (6.3)	28 (9.6)	28 (9.6)	29 (10.1)	29 (10.1)	75 (8.6)	75 (8.6)
	Week 16 HiSCR50 Responders									
	PBO/BKZ 320 mg Q2W (n=48)	BKZ 320 mg Q4W/Q4W (n=152)	BKZ 320 mg Q2W/Q4W (n=155)	BKZ 320 mg Q2W/Q4W (n=160)	BKZ 320 mg Q2W/Q4W (n=160)	BKZ 320 mg Q2W/Q4W (n=160)	BKZ 320 mg Q2W/Q4W (n=160)	BKZ 320 mg Q2W/Q4W (n=160)	BKZ 320 mg Q2W/Q4W (n=160)	BKZ 320 mg Total (n=467)
Age, years, mean (SD)	36.4 (11.9)	34.8 (11.8)	36.7 (12.2)	36.2 (12.8)	36.2 (12.8)	36.2 (12.8)	36.2 (12.8)	36.2 (12.8)	36.2 (12.8)	36.2 (12.8)
Sex, female, n (%)	27 (56.3)	93 (61.2)	91 (58.7)	89 (55.6)	89 (55.6)	89 (55.6)	89 (55.6)	89 (55.6)	89 (55.6)	89 (55.6)
BMI, kg/m ² , mean (SD)	32.7 (9.0)	34.2 (8.4)	31.9 (7.0)	31.9 (8.3)	31.9 (8.3)	31.9 (8.3)	31.9 (8.3)	31.9 (8.3)	31.9 (8.3)	31.9 (8.3)
Duration of HS, years, mean (SD)	8.8 (9.3)	6.4 (6.3)	7.8 (6.8)	6.9 (7.1)	6.9 (7.1)	6.9 (7.1)	6.9 (7.1)	6.9 (7.1)	6.9 (7.1)	6.9 (7.1)
Baseline AN count, mean (SD)	13.1 (8.0)	18.6 (24.9)	15.5 (13.3)	14.5 (10.5)	14.5 (10.5)	14.5 (10.5)	14.5 (10.5)	14.5 (10.5)	14.5 (10.5)	14.5 (10.5)
Hurley stage, n (%)										
II	25 (52.1)	86 (56.6)	95 (61.3)	99 (61.9)	99 (61.9)	99 (61.9)	99 (61.9)	99 (61.9)	99 (61.9)	99 (61.9)
III	23 (47.9)	66 (43.4)	60 (38.7)	61 (38.1)	61 (38.1)	61 (38.1)	61 (38.1)	61 (38.1)	61 (38.1)	61 (38.1)
DLQI total score, mean (SD)	10.7 (6.6)	10.4 (6.6)	10.4 (6.6)	10.6 (6.5)	10.6 (6.5)	10.6 (6.5)	10.6 (6.5)	10.6 (6.5)	10.6 (6.5)	10.6 (6.5)
Prior biologic use, n (%)	8 (16.7)	23 (15.1)	28 (18.1)	35 (21.9)	35 (21.9)	35 (21.9)	35 (21.9)	35 (21.9)	35 (21.9)	35 (21.9)
Baseline antibiotic use, n (%)	1 (2.1)	7 (4.6)	10 (6.5)	18 (11.3)	18 (11.3)	18 (11.3)	18 (11.3)	18 (11.3)	18 (11.3)	18 (11.3)
	Week 16 AN Count of 0, 1, or 2									
	PBO/BKZ 320 mg Q2W (n=30)	BKZ 320 mg Q4W/Q4W (n=87)	BKZ 320 mg Q2W/Q4W (n=99)	BKZ 320 mg Q2W/Q4W (n=104)	BKZ 320 mg Q2W/Q4W (n=104)	BKZ 320 mg Q2W/Q4W (n=104)	BKZ 320 mg Q2W/Q4W (n=104)	BKZ 320 mg Q2W/Q4W (n=104)	BKZ 320 mg Q2W/Q4W (n=104)	BKZ 320 mg Total (n=290)
Age, years, mean (SD)	34.1 (10.2)	34.6 (11.8)	38.1 (12.4)	36.5 (12.9)	36.5 (12.9)	36.5 (12.9)	36.5 (12.9)	36.5 (12.9)	36.5 (12.9)	36.5 (12.9)
Sex, female, n (%)	16 (53.3)	56 (64.4)	55 (55.6)	52 (50.0)	52 (50.0)	52 (50.0)	52 (50.0)	52 (50.0)	52 (50.0)	52 (50.0)
BMI, kg/m ² , mean (SD)	31.8 (9.3)	33.8 (8.6)	32.2 (6.9)	31.6 (8.1)	31.6 (8.1)	31.6 (8.1)	31.6 (8.1)	31.6 (8.1)	31.6 (8.1)	31.6 (8.1)
Duration of HS, years, mean (SD)	9.0 (8.6)	6.4 (6.7)	7.7 (6.9)	6.4 (7.0)	6.4 (7.0)	6.4 (7.0)	6.4 (7.0)	6.4 (7.0)	6.4 (7.0)	6.4 (7.0)
Baseline AN count, mean (SD)	9.2 (4.6)	11.1 (10.0)	9.8 (6.4)	9.7 (5.5)	9.7 (5.5)	9.7 (5.5)	9.7 (5.5)	9.7 (5.5)	9.7 (5.5)	9.7 (5.5)
Hurley stage, n (%)										
II	17 (56.7)	55 (63.2)	72 (72.7)	72 (69.2)	72 (69.2)	72 (69.2)	72 (69.2)	72 (69.2)	72 (69.2)	72 (69.2)
III	13 (43.3)	32 (36.8)	27 (27.3)	32 (30.8)	32 (30.8)	32 (30.8)	32 (30.8)	32 (30.8)	32 (30.8)	32 (30.8)
DLQI total score, mean (SD)	9.1 (5.5)	9.5 (6.6)	9.5 (6.4)	10.4 (6.2)	10.4 (6.2)	10.4 (6.2)	10.4 (6.2)	10.4 (6.2)	10.4 (6.2)	10.4 (6.2)
Prior biologic use, n (%)	3 (10.0)	13 (14.9)	15 (15.2)	20 (19.2)	20 (19.2)	20 (19.2)	20 (19.2)	20 (19.2)	20 (19.2)	20 (19.2)
Baseline antibiotic use, n (%)	0	4 (4.6)	8 (8.1)	13 (12.5)	13 (12.5)	13 (12.5)	13 (12.5)	13 (12.5)	13 (12.5)	13 (12.5)

Pooled set; baseline characteristics evaluated at Week 0; *BKZ Q2W and Q4W treatment arms are pooled for the BKZ Total group.

AN: abscess and inflammatory nodule; BKZ: bimekizumab; BMI: body mass index; DLQI: Dermatology Life Quality Index; HiSCR: HS clinical response; HiSCR50/75/90: >50/75/90% 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; LOCF: last observation carried forward; OC: observed case; PBO: placebo; Q2W: every 2 weeks; Q4W: every 4 weeks; SD: standard deviation.

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References: Dufour DN, et al. Postgrad Med J 2014;90:216–21; Glatt S, et al. JAMA Dermatol 2021;157:1279–88; BE HEARD I: <https://clinicaltrials.gov/ct2/show/NCT04242446>; BE HEARD II: <https://clinicaltrials.gov/ct2/show/NCT04242448>. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: JRI, MP, RC, EBBG, FGB, HF, WG, EM, MB, RR, RB, JSK. Drafting of the publication, or reviewing it critically for important intellectual content: JRI, MP, RC, EBBG, FGB, HF, WG, EM, MB, RR, RB, JSK. 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