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 for BE HEARD I and 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 BKZ-randomized patients.

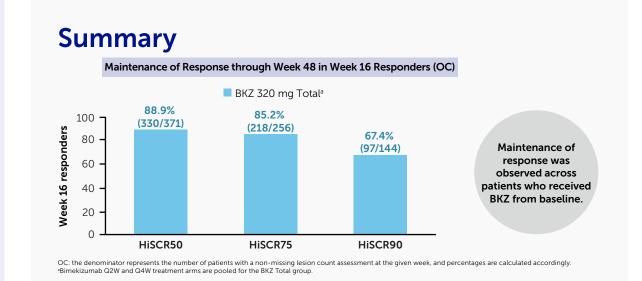
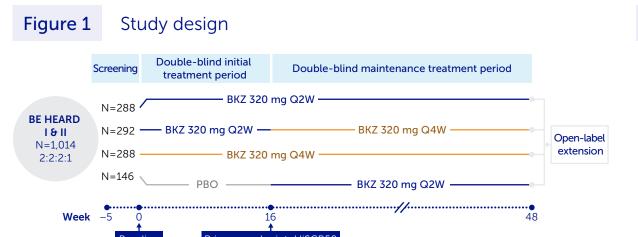


Table 1 Baseline characteristics

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	PBO/BKZ 320 mg Q2W	BKZ 320 mg Q4W/Q4W	BKZ 320 mg Q2W/Q4W	BKZ 320 mg Q2W/Q2W	BKZ 320 mg Total ^a			
	(N=146)	(N=288)	(N=292)	(N=288)	(N=868)			
Age, years , mean (SD)	37.3 (12.8)	35.8 (11.6)	37.0 (12.4)	36.8 (12.4)	36.5 (12.1)			
Sex, female, n (%)	75 (51.4)	175 (60.8)	174 (59.6)	152 (52.8)	501 (57.7)			
BMI, kg/m², mean (SD)	33.1 (8.3)	33.8 (7.9)	32.7 (7.9)	32.7 (8.6)	33.1 (8.1)			
Duration of HS, years, mean (SD)	9.8 (9.4)	7.3 (7.3)	8.3 (7.7)	7.6 (7.4)	7.7 (7.4)			
Baseline AN count, mean (SD)	14.4 (10.0)	17.7 (20.9)	17.2 (16.8)	14.7 (11.6)	16.6 (16.9)			
Hurley stage, n (%)				1	1			
II	79 (54.1)	160 (55.6)	160 (54.8)	166 (57.6)	486 (56.0)			
III	67 (45.9)	128 (44.4)	132 (45.2)	122 (42.4)	382 (44.0)			
DLQI total score, mean (SD)	12.2 (7.1)	11.7 (7.4)	10.8 (6.7)	11.2 (6.5)	11.2 (6.9)			
Prior biologic use, n (%)	29 (19.9)	47 (16.3)	57 (19.5)	60 (20.8)	164 (18.9)			
Baseline antibiotic use, n (%)	11 (7.5)	18 (6.3)	28 (9.6)	29 (10.1)	75 (8.6)			
	•	We	ek 16 HiSCR50 Respond	ders				
	PBO/BKZ 320 mg Q2W	BKZ 320 mg Q4W/Q4W	BKZ 320 mg Q2W/Q4W	BKZ 320 mg Q2W/Q2W	BKZ 320 mg Total ^a			
Age years maan (CD)	(n=48)	(n=152)	(n=155)	(n=160)	(n=467)			
Age, years, mean (SD)	36.4 (11.9)	34.8 (11.8)	36.7 (12.2)	36.2 (12.8)	35.9 (12.3)			
Sex, female, n (%)	27 (56.3)	93 (61.2)	91 (58.7)	89 (55.6)	273 (58.5)			
BMI, kg/m², mean (SD)	32.7 (9.0)	34.2 (8.4)	31.9 (7.0)	31.9 (8.3)	32.7 (8.0)			
Duration of HS, years, mean (SD)	8.8 (9.3)	6.4 (6.3)	7.8 (6.8)	6.9 (7.1)	7.0 (6.7)			
Baseline AN count, mean (SD)	13.1 (8.0)	18.6 (24.9)	15.5 (13.3)	14.5 (10.5)	16.2 (17.3)			
Hurley stage, n (%)			1	 	I I			
II	25 (52.1)	86 (56.6)	95 (61.3)	99 (61.9)	280 (60.0)			
III	23 (47.9)	66 (43.4)	60 (38.7)	61 (38.1)	187 (40.0)			
DLQI total score, mean (SD)	10.7 (6.6)	10.4 (6.6)	10.6 (6.6)	10.9 (6.2)	10.6 (6.5)			
Prior biologic use, n (%)	8 (16.7)	23 (15.1)	28 (18.1)	35 (21.9)	86 (18.4)			
Baseline antibiotic use, n (%)	1 (2.1)	7 (4.6)	10 (6.5)	18 (11.3)	35 (7.5)			
	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/Q2W (n=104)	BKZ 320 mg Total ^a (n=290)			
Age, years, mean (SD)	34.1 (10.2)	34.6 (11.8)	38.1 (12.4)	36.5 (12.9)	36.5 (12.5)			
Sex, female, n (%)	16 (53.3)	56 (64.4)	55 (55.6)	52 (50.0)	163 (56.2)			
BMI, kg/m², mean (SD)	31.8 (9.3)	33.8 (8.6)	32.2 (6.9)	31.6 (8.1)	32.4 (7.9)			
Duration of HS, years, mean (SD)	9.0 (8.6)	6.4 (6.7)	7.7 (6.9)	6.4 (7.0)	6.8 (6.9)			
Baseline AN count, mean (SD)	9.2 (4.6)	11.1 (10.0)	9.8 (6.4)	9.7 (5.5)	10.2 (7.4)			
Hurley stage, n (%)	1		1	1	1			
II	17 (56.7)	55 (63.2)	72 (72.7)	72 (69.2)	199 (68.6)			
 III	13 (43.3)	32 (36.8)	27 (27.3)	32 (30.8)	91 (31.4)			
DLQI total score, mean (SD)	9.1 (5.5)	9.5 (6.6)	9.5 (6.4)	10.4 (6.2)	9.8 (6.4)			
Prior biologic use, n (%)	3 (10.0)	13 (14.9)	15 (15.2)	20 (19.2)	48 (16.6)			
	1 (20.0)	4 (4.6)	8 (8.1)	13 (12.5)	25 (8.6)			



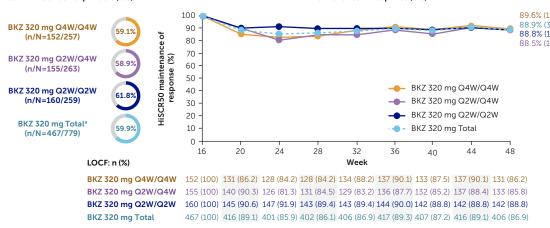
At baseline, 1,014 patients with moderate to severe HS were randomized 2:2:2:1 to BKZ 320 mg Q2W to Week 48, BKZ 320 mg Q4W to Week 48, BKZ 320 mg Q2W to Week 48 bKZ 320 mg Q4W to Week 48, BKZ 320 mg Q2W to Week 48 bKZ 320 mg Q4W to Week 48 bKZ 320 mg

Table 2 Maintenance of response through Week 48 (OC, LOCF)

		BKZ 320 mg Q4W/Q4W		BKZ 320 mg Q2W/Q4W		BKZ 320 mg Q2W/Q2W		BKZ 320 mg Total ^a	
		OC n/N (%)	LOCF n (%)	OC n/N (%)	LOCF n (%)	OC n/N (%)	LOCF n (%)	OC n/N (%)	LOCF n (%)
Week 16 HiSCR50 responders	Week 32	116/131 (88.5)	134 (88.2)	120/141 (85.1)	129 (83.2)	121/135 (89.6)	143 (89.4)	357/407 (87.7)	406 (86.9)
	Week 48	103/115 (89.6)	131 (86.2)	116/131 (88.5)	133 (85.8)	111/125 (88.8)	142 (88.8)	330/371 (88.9)	406 (86.9)
Week 16 HiSCR75 responders	Week 32	70/82 (85.4)	79 (84.9)	79/99 (79.8)	85 (78.0)	77/92 (83.7)	91 (82.7)	226/273 (82.8)	255 (81.7)
	Week 48	63/73 (86.3)	75 (80.6)	83/94 (88.3)	92 (84.4)	72/89 (80.9)	88 (80.0)	218/256 (85.2)	255 (81.7)
Week 16 HiSCR90 responders	Week 32	32/49 (65.3)	37 (67.3)	39/55 (70.9)	41 (68.3)	32/45 (71.1)	39 (69.6)	103/149 (69.1)	117 (68.4)
	Week 48	31/46 (67.4)	36 (65.5)	36/52 (69.2)	39 (65.0)	30/46 (65.2)	37 (66.1)	97/144 (67.4)	112 (65.5)
·		BKZ 320 mg Q4W/Q4W		BKZ 320 mg Q2W/Q4W		BKZ 320 mg Q2W/Q2W		BKZ 320 mg Total ^a	
Week 16 AN count of 0, 1, or 2		OC n/N (%)	LOCF n (%)	OC n/N (%)	LOCF n (%)	OC n/N (%)	LOCF n (%)	OC n/N (%)	LOCF n (%)
	Week 32	58/75 (77.3)	68 (78.2)	75/87 (86.2)	82 (82.8)	75/88 (85.2)	89 (85.6)	208/250 (83.2)	239 (82.4)
	Week 48	57/66 (86.4)	72 (82.8)	73/83 (88.0)	82 (82.8)	69/84 (82.1)	85 (81.7)	199/233 (85.4)	239 (82.4)

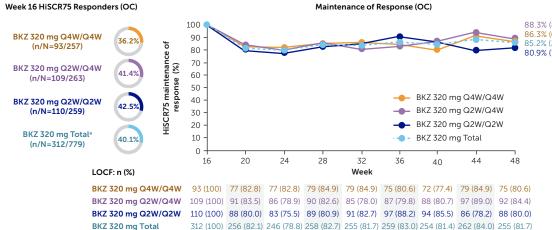
andomized set; OC: the denominator represents the number of patients with a non-missing lesion count assessment at the given week, and percentages are calculated accordingly; The

gure 2 HiSCR50 maintenance of response (OC, LOCF)



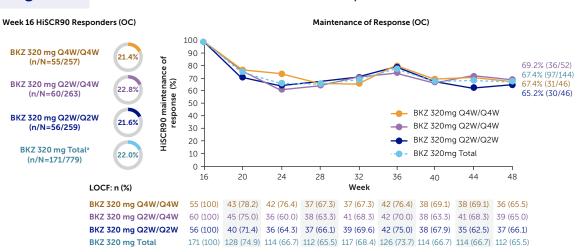
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Figure 3 HiSCR75 maintenance of response (OC, LOCF)



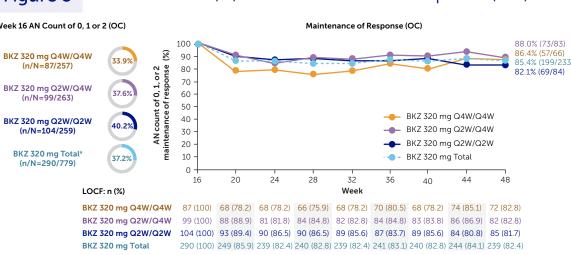
landomized set; OC: the denominator represents the number of patients with a non-missing lesion count assessment at the given week, and percentages are calculated accordingly; The OCF value is used when a patient has missing data at the wist or discontinues the study prior to the visit; +Bimekizumab Q2W and Q4W treatment arms are pooled for the BKZ Total group.

Figure 4 HiSCR90 maintenance of response (OC, LOCF)



domized set; OC: the denominator represents the number of patients with a non-missing lesion count assessment at the given week, and percentages are calculated accordingly; Tealure is used when a patient has missing data at the visit or discontinues the study prior to the visit. Phimekizumah Q2W and Q4W treatment arms are pooled for the BK7 Total gro

Figure 5 AN count of 0, 1, or 2 maintenance of response (OC, LOCF)



andomized set; OC: the denominator represents the number of patients with a non-missing lesion count assessment at the given week, and percentages are calculated accordingly; The OCF value is used when a patient has missing data at the visit or discontinues the study prior to the visit; Bimekizumab O2W and O4W treatment arms are pooled for the BKZ Total group

It: interleukin; IDCF: last observation carried forward; N/A: not applicable; OC: observed case; PBO: placebo; Q2W: every 2 weeks; Q4W: every 4 weeks; Q4W: every 4 weeks; SD: standard deviation.

Week 16 HiSCR50 Responders (OC

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