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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Objective

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

Background

- 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]
- 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 & II.[3,4]

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**).

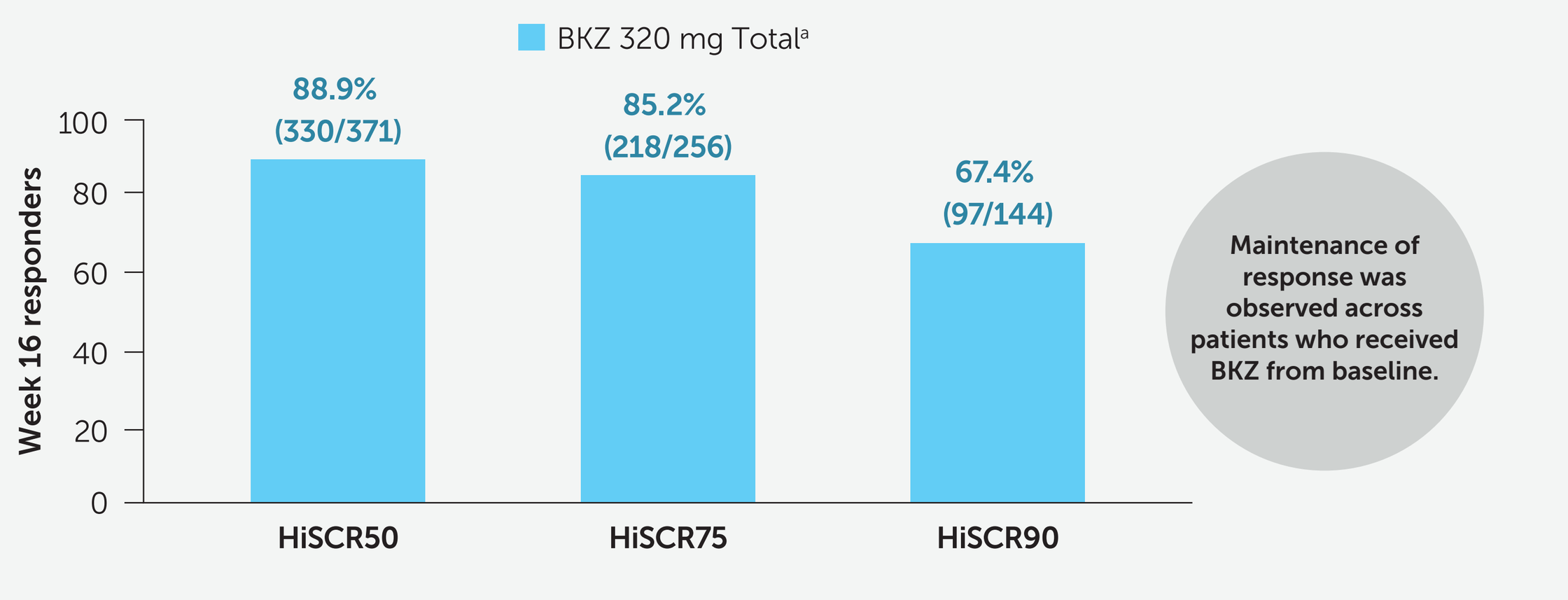
Week 48 Responders

- 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



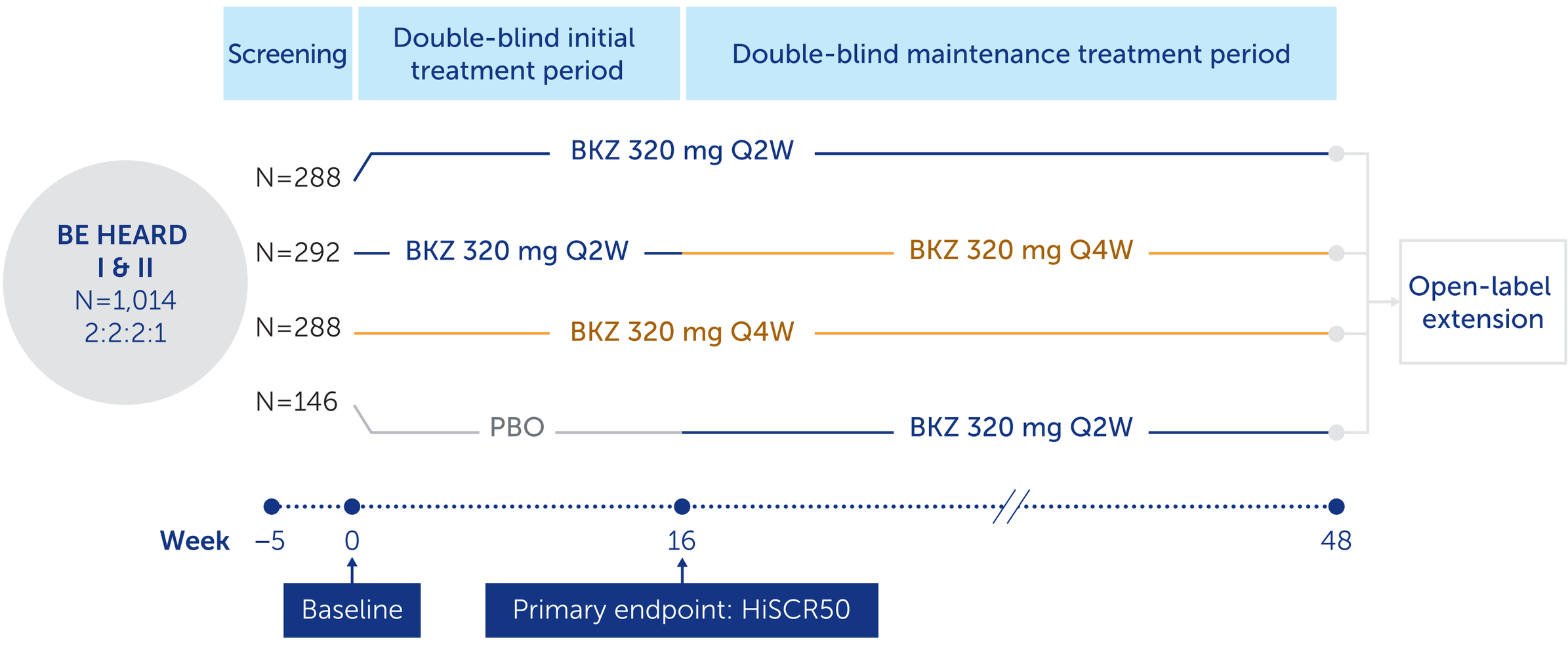
OC: the denominator represents the number of patients with a non-missing lesion count assessment at the given week, and percentages are calculated accordingly. [a]BKZ Q2W and Q4W treatment arms are pooled for the BKZ Total group.

Table 1 Baseline characteristics

	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]
Overall	(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 (%)					
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)
Week 16 HiSCR50 Responders	(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 (%)					
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	(n=30)	(n=87)	(n=99)	(n=104)	(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 (%)					
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)
Baseline antibiotic use, n (%)	0	4 (4.6)	8 (8.1)	13 (12.5)	25 (8.6)

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

Figure 1 Study design



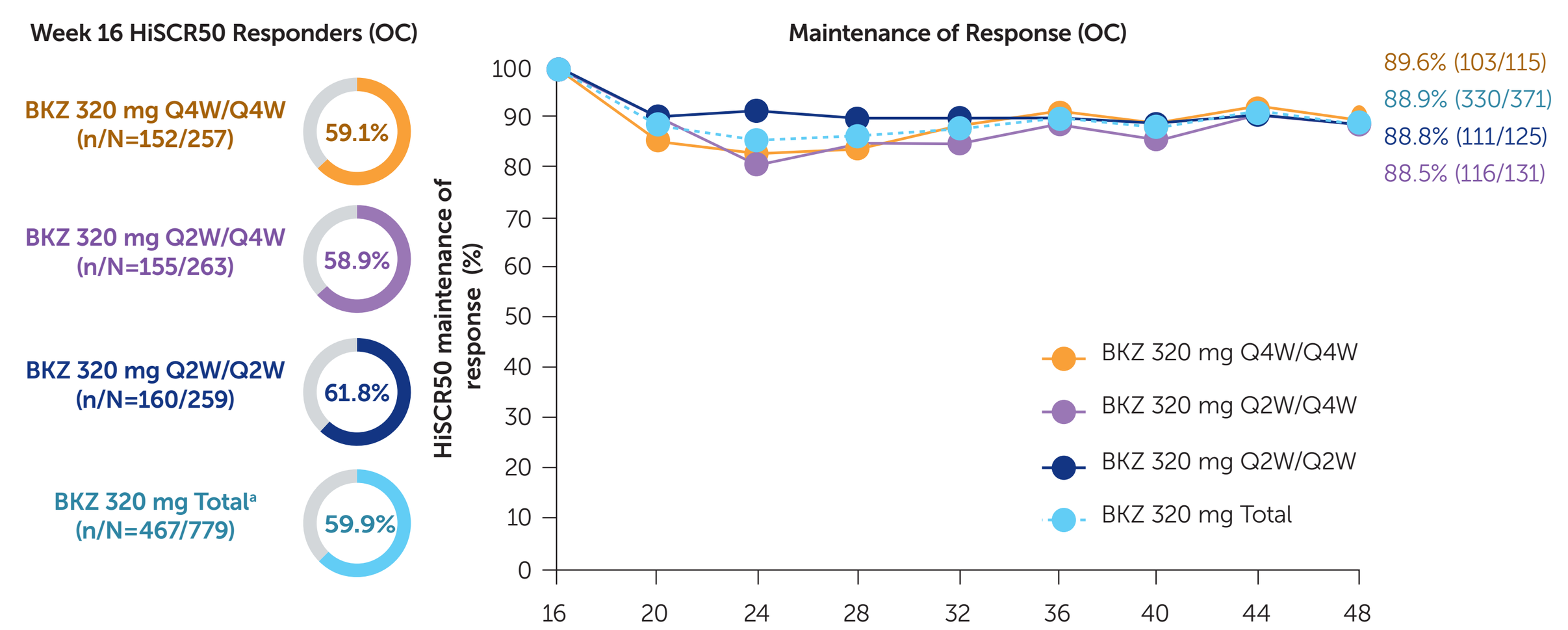
At baseline, 1,014 patients with moderate to severe HS were randomized 2:2:2:1 to BKZ 320 mg Q2W to Week 48, BKZ 320 mg Q4W to Week 48, BKZ 320 mg Q2W to Week 16 then BKZ 320 mg Q4W to Week 48, or PBO to Week 16 then BKZ 320 mg Q2W to Week 48.

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

		BKZ 320 mg Q4W/Q4W OC n/N (%)	BKZ 320 mg Q4W/Q4W LOCF n (%)	BKZ 320 mg Q2W/Q4W OC n/N (%)	BKZ 320 mg Q2W/Q4W LOCF n (%)	BKZ 320 mg Q2W/Q2W OC n/N (%)	BKZ 320 mg Q2W/Q2W LOCF n (%)	BKZ 320 mg Total[a] OC n/N (%)	BKZ 320 mg Total[a] 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)
Week 16 AN count of 0, 1, or 2	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)

Randomized 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 LOCF value is used when a patient has missing data at the visit or discontinues the study prior to the visit; [a]BKZ Q2W and Q4W treatment arms are pooled for the BKZ Total group.

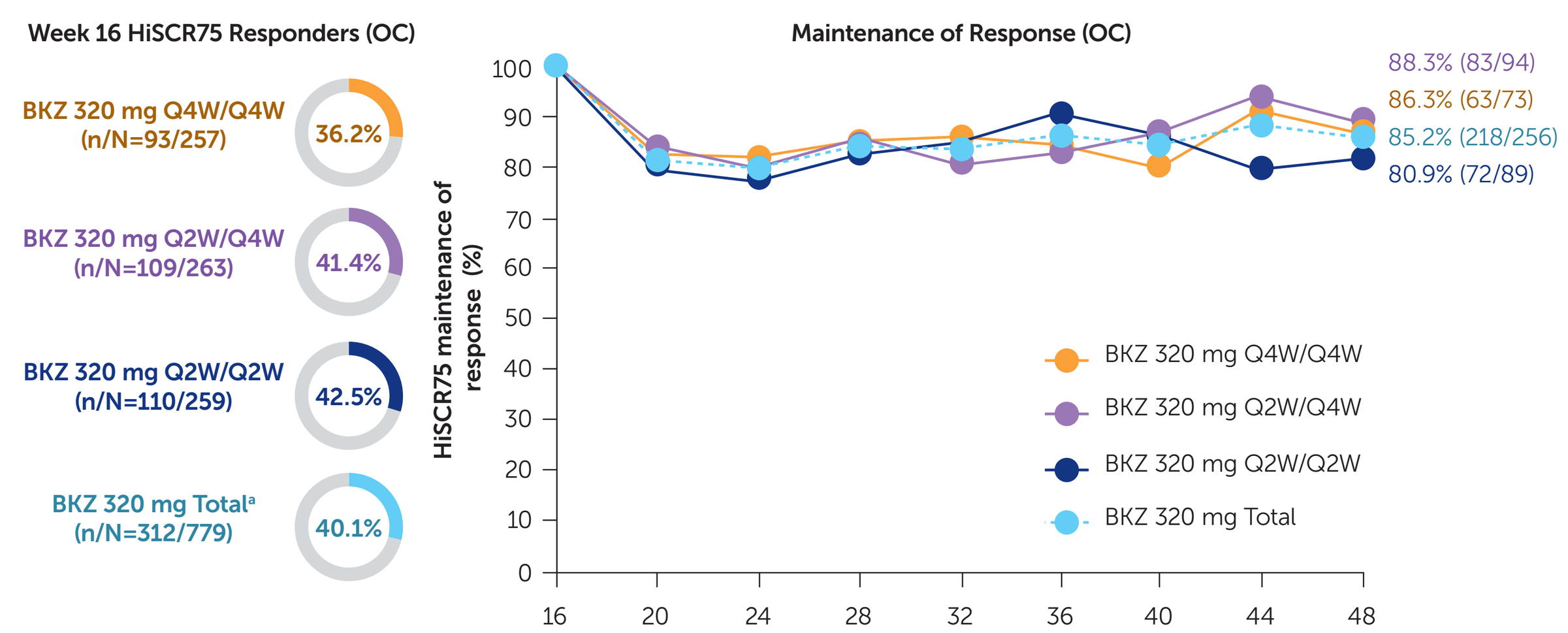
Figure 2 HiSCR50 maintenance of response (OC, LOCF)



LOCF: n (%)	16	20	24	28	32	36	40	44	48
BKZ 320 mg Q4W/Q4W	152 (100)	131 (86.2)	128 (84.2)	128 (84.2)	134 (88.2)	137 (90.1)	133 (87.5)	137 (90.1)	131 (86.2)
BKZ 320 mg Q2W/Q4W	155 (100)	140 (90.3)	126 (81.3)	131 (84.5)	129 (83.2)	136 (87.7)	132 (85.2)	137 (88.4)	133 (85.8)
BKZ 320 mg Q2W/Q2W	160 (100)	145 (90.6)	147 (91.9)	143 (89.4)	143 (89.4)	144 (90.0)	142 (88.8)	142 (88.8)	142 (88.8)
BKZ 320 mg Total	467 (100)	416 (89.1)	401 (85.9)	402 (86.1)	406 (86.9)	417 (89.3)	407 (87.2)	416 (89.1)	406 (86.9)

Randomized 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 LOCF value is used when a patient has missing data at the visit or discontinues the study prior to the visit; [a]BKZ Q2W and Q4W treatment arms are pooled for the BKZ Total group.

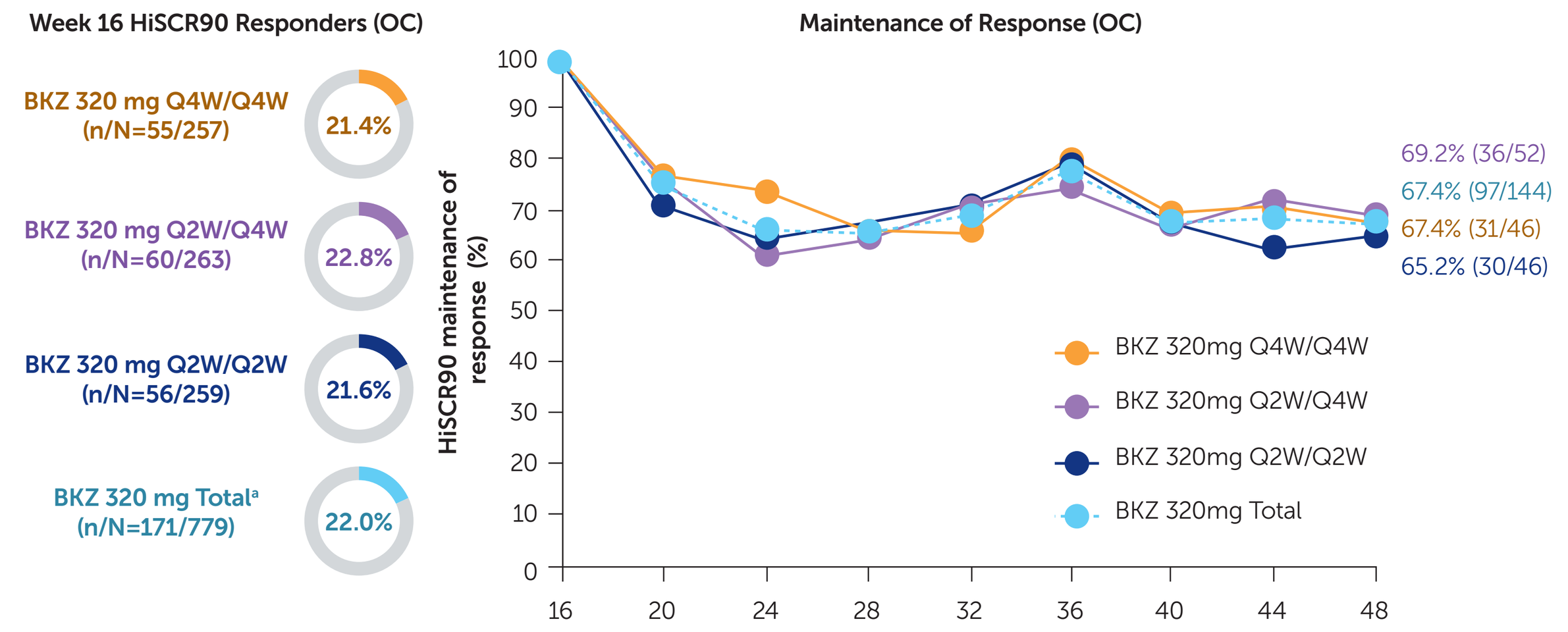
Figure 3 HiSCR75 maintenance of response (OC, LOCF)



LOCF: n (%)	16	20	24	28	32	36	40	44	48
BKZ 320 mg Q4W/Q4W	93 (100)	77 (82.8)	77 (82.8)	79 (84.9)	79 (84.9)	75 (80.6)	72 (77.4)	79 (84.9)	75 (80.6)
BKZ 320 mg Q2W/Q4W	109 (100)	91 (83.5)	86 (78.9)	90 (82.6)	85 (78.0)	87 (79.8)	88 (80.7)	97 (89.0)	92 (84.4)
BKZ 320 mg Q2W/Q2W	110 (100)	88 (80.0)	83 (75.5)	89 (80.9)	91 (82.7)	97 (88.2)	94 (85.5)	86 (78.2)	88 (80.0)
BKZ 320 mg Total	312 (100)	256 (82.1)	246 (78.8)	258 (82.7)	255 (81.7)	259 (83.0)	254 (81.4)	262 (84.0)	255 (81.7)

Randomized 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 LOCF value is used when a patient has missing data at the visit or discontinues the study prior to the visit; [a]BKZ Q2W and Q4W treatment arms are pooled for the BKZ Total group.

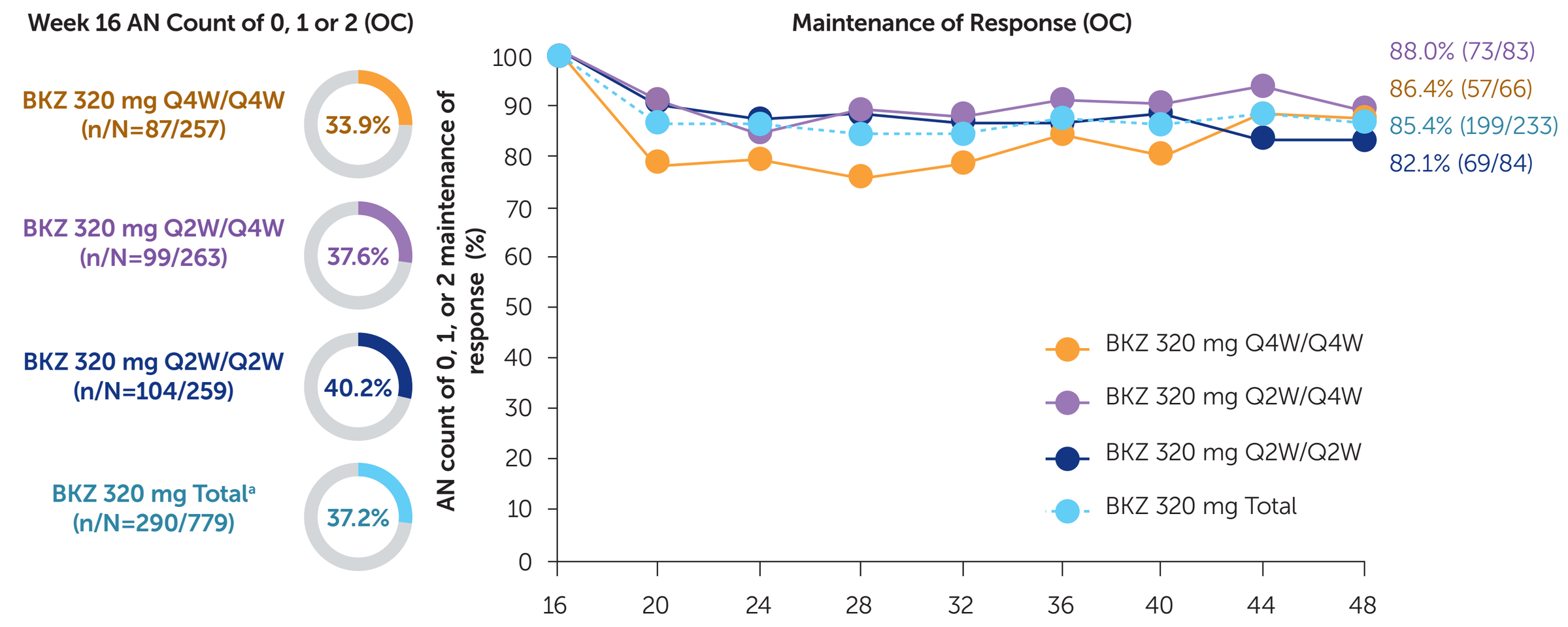
Figure 4 HiSCR90 maintenance of response (OC, LOCF)



LOCF: n (%)	16	20	24	28	32	36	40	44	48
BKZ 320 mg Q4W/Q4W	55 (100)	43 (78.2)	42 (76.4)	37 (67.3)	37 (67.3)	42 (76.4)	38 (69.1)	38 (69.1)	36 (65.5)
BKZ 320 mg Q2W/Q4W	60 (100)	45 (75.0)	36 (60.0)	38 (63.3)	41 (68.3)	42 (70.0)	38 (63.3)	41 (68.3)	39 (65.0)
BKZ 320 mg Q2W/Q2W	56 (100)	40 (71.4)	36 (64.3)	37 (66.1)	39 (69.6)	42 (75.0)	38 (67.9)	35 (62.5)	37 (66.1)
BKZ 320 mg Total	171 (100)	128 (74.9)	114 (66.7)	112 (65.5)	117 (68.4)	126 (73.7)	114 (66.7)	114 (66.7)	112 (65.5)

Randomized 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 LOCF value is used when a patient has missing data at the visit or discontinues the study prior to the visit; [a]BKZ Q2W and Q4W treatment arms are pooled for the BKZ Total group.

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



LOCF: n (%)	16	20	24	28	32	36	40	44	48
BKZ 320 mg Q4W/Q4W	87 (100)	68 (78.2)	68 (78.2)	66 (75.9)	68 (78.2)	70 (80.5)	68 (78.2)	74 (85.1)	72 (82.8)
BKZ 320 mg Q2W/Q4W	99 (100)	88 (88.9)	81 (81.8)	84 (84.8)	82 (82.8)	84 (84.8)	83 (83.8)	86 (86.9)	82 (82.8)
BKZ 320 mg Q2W/Q2W	104 (100)	93 (89.4)	90 (86.5)	90 (86.5)	89 (85.6)	87 (83.7)	89 (85.6)	84 (80.8)	85 (81.7)
BKZ 320 mg Total	290 (100)	249 (85.9)	239 (82.4)	240 (82.8)	239 (82.4)	241 (83.1)	240 (82.8)	244 (84.1)	239 (82.4)

Randomized 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 LOCF value is used when a patient has missing data at the visit or discontinues the study prior to the visit; [a]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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