

# Bimekizumab efficacy through 3 years in patients with moderate to severe plaque psoriasis: Long-term pooled analysis from BE BRIGHT

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## Synopsis

- A key determinant of biologic discontinuation in plaque psoriasis is loss of response over time; considering long-term treatment efficacy is therefore important.<sup>1</sup>
- Bimekizumab (BKZ), a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A,<sup>2</sup> has demonstrated rapid and superior efficacy in the treatment of patients with moderate to severe plaque psoriasis in head-to-head studies versus ustekinumab, adalimumab, and secukinumab, with established long-term durability of response.<sup>3–7</sup>

## Objective

To report efficacy of BKZ from baseline through 3 years of treatment in patients with moderate to severe plaque psoriasis, pooled across three phase 3 clinical trials and their open-label extension (OLE).

## Methods

- Data were pooled from the following trials: BE SURE, BE VIVID, BE READY, and their common OLE, BE BRIGHT (Figure 1).<sup>3–5,7</sup>
- Proportions of patients achieving PASI 75 (≥75% improvement in Psoriasis Area and Severity Index from baseline), PASI 90, PASI ≤2, PASI 100, body surface area (BSA) ≤1%, and Dermatology Life Quality Index (DLQI) 0/1 (no effect of skin disease on a patient's life)<sup>8</sup> are reported over 3 years.
- Data are reported for all patients who were treated continuously with BKZ through the initial and maintenance periods, and then entered the OLE (BKZ Total). Data are also presented for the subgroup that received BKZ Q4W/Q8W/Q8W (initial/maintenance/OLE).
- Data are reported using modified non-responder imputation (mNRI): patients who discontinued treatment due to lack of efficacy or treatment-related adverse events were considered non-responders at subsequent timepoints; multiple imputation was used for all other missing data. Data are also reported using non-responder imputation (NRI) and as observed case (OC) for all outcomes.

## Results

- 771 patients continuously treated with BKZ through to the end of the first year entered the OLE. 197 patients received BKZ Q4W/Q8W/Q8W.
- Baseline characteristics for included patients are presented in Table 1.
- At Week 16, patients in the BKZ Total group achieved high levels of PASI 75, PASI 90, and PASI ≤2 response (Figure 2A–C; Table 2).
  - These responses remained high through to Year 3 (Week 148) (Figure 2A–C; Table 2).
- PASI 100, BSA ≤1%, and DLQI 0/1 responses increased through the first year (Figure 2D–F; Table 2).
  - High levels of PASI 100, BSA ≤1%, and DLQI 0/1 response achieved at Year 1 were sustained through to Year 3 (Figure 2D–F; Table 2).
- Similar trends were observed in patients that received BKZ Q4W/Q8W/Q8W (Figure 2A–F; Table 2).

## Conclusions

High and durable clinical and health-related quality of life responses were observed over 3 years of BKZ treatment across three phase 3 trials and their OLE.

## Summary

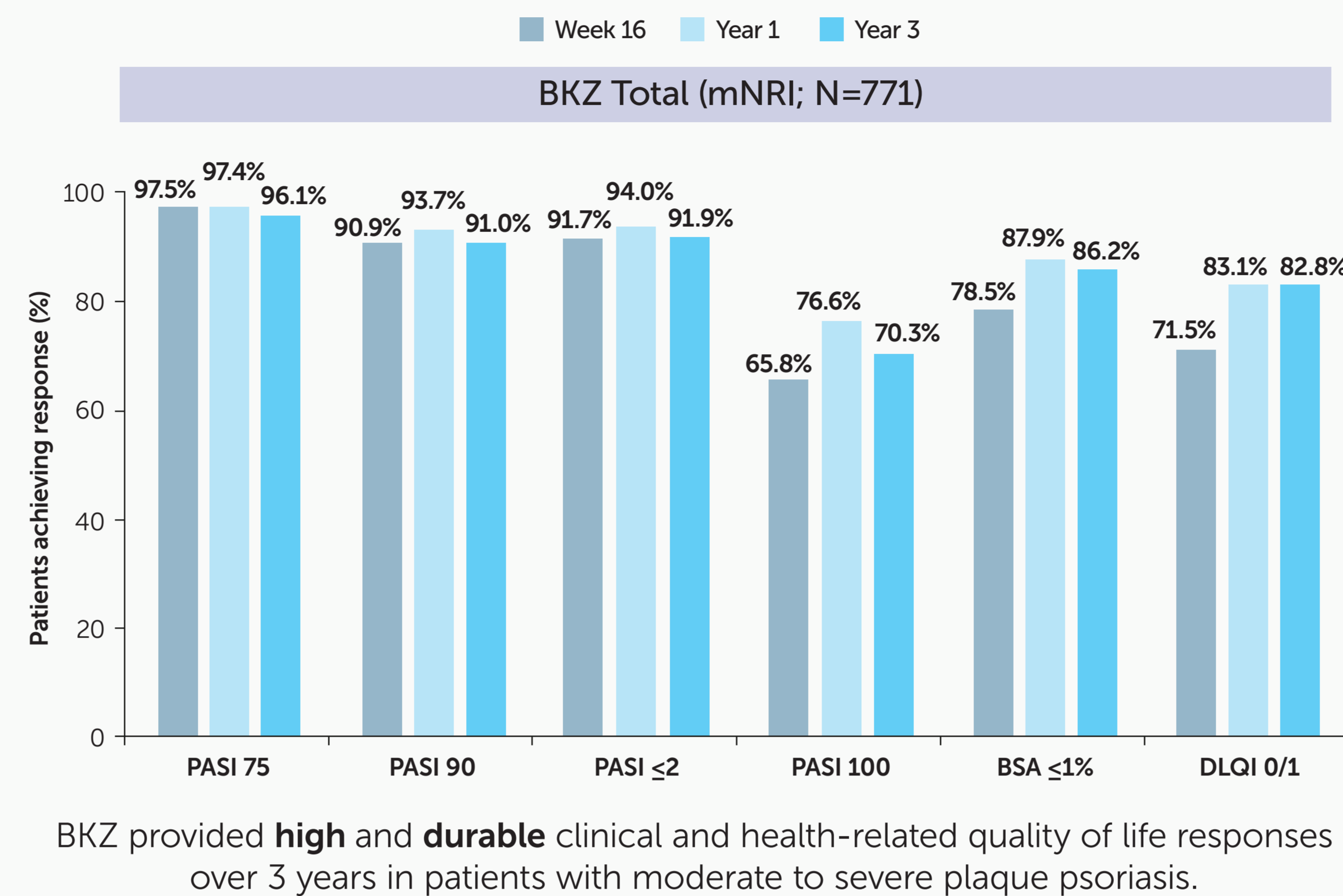


Figure 1 Study design (included patients)

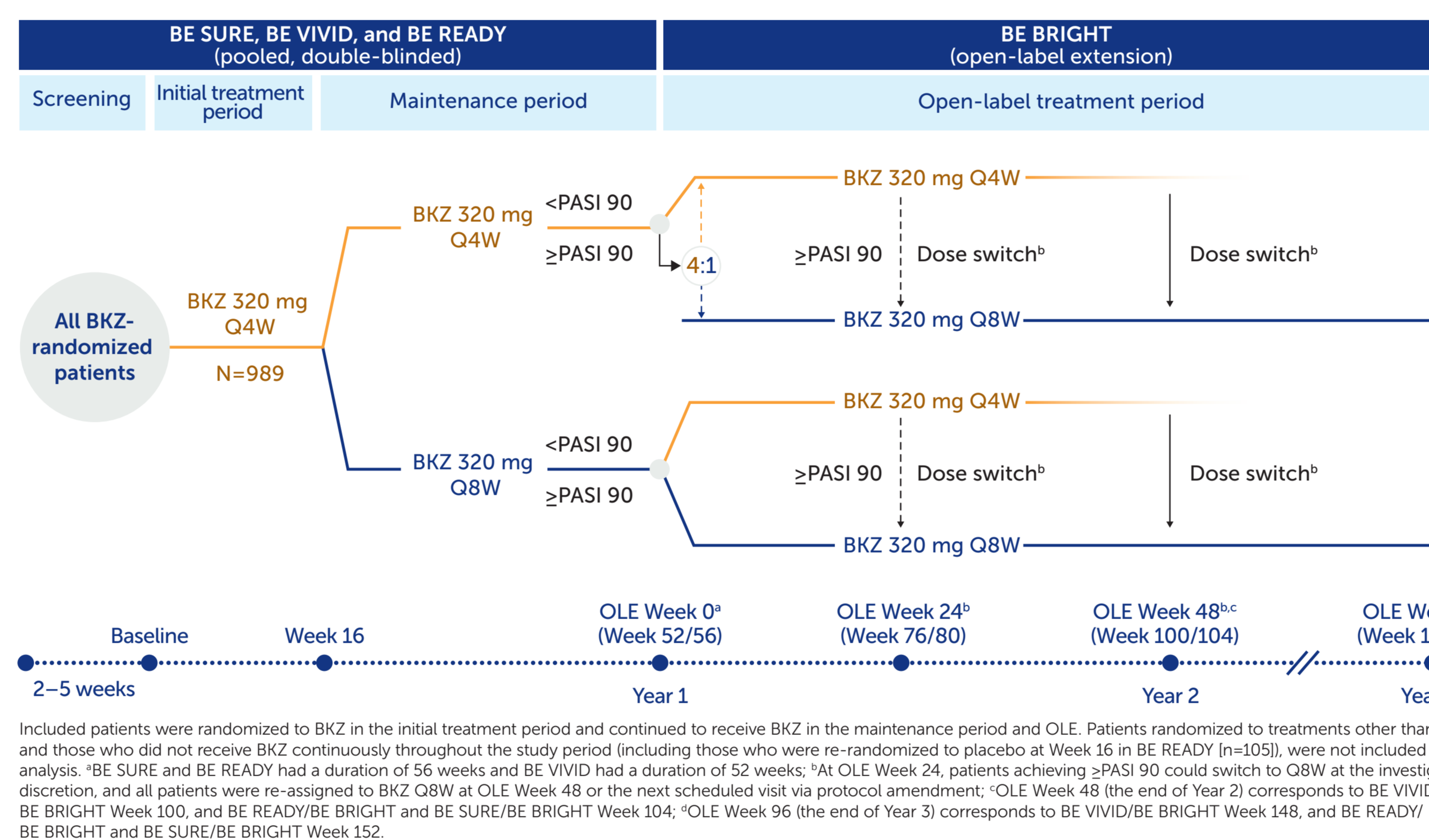


Figure 2 Efficacy responses with BKZ through 3 years (mNRI)

Table 1 Baseline characteristics

	BKZ Total (N=771)	BKZ Q4W/Q8W/Q8W (N=197)
Age (years), mean ± SD	45.4 ± 13.5	45.0 ± 14.1
Male, n (%)	550 (71.3)	141 (71.6)
White, n (%)	656 (85.1)	185 (93.9)
Weight (kg), mean ± SD	89.7 ± 21.2	88.5 ± 20.8
Duration of psoriasis (years), mean ± SD	18.6 ± 12.7	18.9 ± 12.0
PASI, mean ± SD	21.1 ± 7.6	20.4 ± 6.9
BSA (%), mean ± SD	27.0 ± 15.6	24.5 ± 12.2
IGA, n (%)		
3: moderate	508 (65.9)	142 (72.1)
4: severe	262 (34.0)	55 (27.9)
DLQI total score, mean ± SD	10.5 ± 6.3	10.8 ± 6.0
Any prior systemic therapy, n (%)	618 (80.2)	154 (78.2)
Any prior biologic therapy, n (%)	309 (40.1)	73 (37.1)
Anti-TNF	113 (14.7)	19 (9.6)
Anti-IL-17	193 (25.0)	48 (24.4)
Anti-IL-12/23	43 (5.6)	13 (6.6)
Anti-IL-23	37 (4.8)	13 (6.6)

Data are reported for all patients who were treated continuously with BKZ through the initial and maintenance periods, and entered the OLE.

Table 2 Summary of efficacy outcomes (NRI and OC)

	BKZ Total (N=771)		BKZ Q4W/Q8W/Q8W (N=197)	
	NRI, n (%) <sup>a</sup>	OC, n/Nsub (%) <sup>b</sup>	NRI, n (%) <sup>a</sup>	OC, n/Nsub (%) <sup>b</sup>
<b>PASI 75</b>				
Week 16	746 (96.8)	746/764 (97.6)	194 (98.5)	194/194 (100.0)
Year 1	719 (93.3)	719/727 (98.9)	195 (99.0)	195/195 (100.0)
Year 3	668 (86.6)	668/674 (99.1)	170 (86.3)	170/171 (99.4)
<b>PASI 90</b>				
Week 16	696 (90.3)	696/764 (91.1)	185 (93.9)	185/194 (95.4)
Year 1	699 (90.7)	699/727 (96.1)	192 (97.5)	192/195 (98.5)
Year 3	638 (82.7)	638/674 (94.7)	168 (85.3)	168/171 (98.2)
<b>PASI ≤2</b>				
Week 16	702 (91.1)	702/764 (91.9)	188 (95.4)	188/194 (96.9)
Year 1	699 (90.7)	699/727 (96.1)	193 (98.0)	193/195 (99.0)
Year 3	643 (83.4)	643/674 (95.4)	170 (86.3)	170/171 (99.4)
<b>PASI 100</b>				
Week 16	505 (65.5)	505/764 (66.1)	146 (74.1)	146/194 (75.3)
Year 1	583 (75.6)	583/727 (80.2)	167 (84.8)	167/195 (85.6)
Year 3	518 (67.2)	518/674 (76.9)	143 (72.6)	143/171 (83.6)
<b>BSA ≤1%</b>				
Week 16	601 (78.0)	601/763 (78.8)	171 (86.8)	171/194 (88.1)
Year 1	656 (85.1)	656/727 (90.2)	185 (93.9)	185/195 (94.9)
Year 3	610 (79.1)	610/674 (90.5)	164 (83.2)	164/171 (95.9)
<b>DLQI 0/1<sup>a</sup></b>				
Week 16	547 (70.9)	547/765 (71.5)	131 (66.5)	131/194 (67.5)
Year 1	621 (80.5)	621/725 (85.7)	168 (85.3)	168/195 (86.2)
Year 3	581 (75.4)	581/673 (86.3)	157 (79.7)	157/171 (91.8)

Year 1 refers to Week 52 for all outcome measures except DLQI 0/1. Year 3 refers to OLE Week 96. <sup>a</sup>For DLQI 0/1 efficacy responses, Year 1 corresponds to the Week 48 assessment for BE SURE and BE READY, and Week 52 for BE VIVID, due to the lack of common visits at which DLQI 0/1 was assessed in these studies. <sup>b</sup>Patients with missing data at a given week are counted as non-responders. <sup>c</sup>Nsub represents the number of subjects with a non-missing measurement, and percentages are calculated accordingly.

BKZ: bimekizumab; BSA: body surface area; DLQI: Dermatology Life Quality Index; IGA: Investigator's Global Assessment; IL: interleukin; mNRI: modified non-responder imputation; NRI: non-responder imputation; OC: observed case; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; PASI 75/90/100: ≥75/≥90/100% improvement from baseline in PASI; Q4W: every 4 weeks; Q8W: every 8 weeks; SD: standard deviation.

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