Bimekizumab Durability of High-Level Clinical and Quality of Life Responses in Early Responders with Moderate to Severe Plaque Psoriasis: 4-Year Results from Four Phase 3 Studies

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Objective

To examine the maintenance of clinical and quality of life outcomes over 4 years in patients achieving early skin responses with bimekizumab (BKZ).

Synopsis

- BKZ, a monoclonal antibody that inhibits both interleukin (IL)-17A and IL-17F,[1] has demonstrated rapid and sustained efficacy in the treatment of moderate to severe plaque psoriasis, with many patients achieving skin responses at Week 4, after one dose.[2]
- Early clinical response is important to patients, as demonstrated using a cross-sectional survey by Gorelick et al.;[3,4] indeed, it has been shown to correlate with more durable quality of life improvements in the long term.[4,5]
- While early clinical response is important, the chronic nature of plaque psoriasis makes evaluation of the long-term durability of efficacy crucial for both patients and clinicians.[3–6]

Methods

- Data were pooled from the 56-week BE SURE, 52-week BE VIVID, and 56-week BE READY phase 3 clinical trials, and their 144-week open-label extension (OLE), BE BRIGHT (**Figure 1**).[2,7–10]
- Included patients received BKZ 320 mg every 4 weeks (Q4W) to Week 16, then BKZ Q4W or every 8 weeks (Q8W) into the OLE; all patients received BKZ Q8W from OLE Week 48 (Week 100/104) or the next scheduled visit.[2,7–10]
- Data are reported for:
  - All patients who received continuous BKZ treatment from baseline and entered the OLE, regardless of dosing regimen (BKZ Total);
  - The subgroup of patients who received BKZ Q4W to Week 16, then Q8W continuously (BKZ Q4W/Q8W; the approved dosing regimen for the majority of patients with moderate to severe plaque psoriasis).[11]
- The maintenance of ≥75%/≥90%/100% improvement from baseline in Psoriasis Area and Severity Index (PASI 75/90/100) and Dermatology Life Quality Index (DLQI) 0/1 (indicating no impact of skin disease on a patient's life)[12] are reported through Week 196/200 (Year 4) in Week 4 PASI 75, PASI 90, and PASI 100 responders.
- Patients discontinuing due to lack of efficacy or adverse events that were deemed treatment-related by the investigator were considered non-responders at subsequent timepoints; multiple imputation was used for other missing data (modified non-responder imputation [mNRI]).

Results

- Overall, 771 patients received BKZ continuously and entered the OLE (BKZ Total); 592 (76.8%), 331 (42.9%), and 123 (16.0%) were Week 4 PASI 75, PASI 90, and PASI 100 responders, respectively.
  - Of the 197 BKZ Q4W/Q8W patients, 158 (80.2%), 79 (40.1%), and 35 (17.8%) were Week 4 PASI 75, PASI 90, and PASI 100 responders, respectively.
- Baseline characteristics were similar between Week 4 PASI 75 and PASI 90 responders, and the overall population (**Table 1**).
- Among Week 4 PASI 75 responders in the BKZ Total group, 95.3% maintained PASI 75 responses at Year 4 (figure not shown). PASI 90, PASI 100, and DLQI 0/1 response rates increased from Week 4 to Week 16, and were maintained to Year 4 (**Figure 2**).
- Among Week 4 PASI 90 responders in the BKZ Total group, 95.6% maintained PASI 75 responses at Year 4 (figure not shown); 89.2% maintained PASI 90 responses at Year 4 (**Figure 3**). PASI 100 and DLQI 0/1 response rates increased from Week 4 to Week 16, and were maintained to Year 4 (**Figure 3**).
- Among Week 4 PASI 100 responders in the BKZ Total group, PASI 75, PASI 90, PASI 100, and DLQI 0/1 response rates were 94.0%, 89.1%, 77.3%, and 81.8% at Year 4, respectively (figure not shown).
- Similar trends were observed in the BKZ Q4W/Q8W subgroup (**Figure 2, Figure 3**).

Conclusions

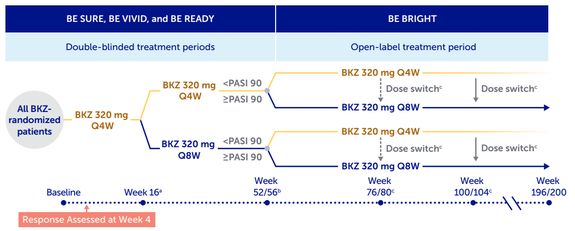
Patients with skin improvement after one dose of bimekizumab (Week 4) maintained or improved high-level clinical skin responses and quality of life improvements through 4 years of treatment.

These findings suggest that dual inhibition of IL-17A and IL-17F with bimekizumab may provide both rapid and durable disease control for patients living with moderate to severe plaque psoriasis, indicating that the early responses achieved with bimekizumab could lead to substantial improvement of patient outcomes in the long and short term.

Summary

592 BKZ Total patients achieved **PASI 75 at Week 4** (mNRI)

Figure 1 Study design



BKZ-randomized patients who were re-randomized to placebo at Week 16 in BE READY were not included in these analyses. **[a]** Patients in BE VIVID did not have the option to switch to Q8W dosing at Week 16 and continued with BKZ Q4W, therefore, they are not included in the BKZ Q4W/Q8W analysis; **[b]** BE VIVID had a duration of 52 weeks, and BE SURE and BE READY had a duration of 56 weeks; **[c]** At Week 76/80, patients achieving PASI 90 could switch to BKZ Q8W at the investigator's discretion; all patients were re-assigned to BKZ Q8W at Week 100/104 or the next scheduled visit.

Table 1 Baseline characteristics

	Overall		Week 4 PASI 75 responders		Week 4 PASI 90 responders	
	BKZ Total N=771	BKZ Q4W/Q8W N=197	BKZ Total N=592	BKZ Q4W/Q8W N=158	BKZ Total N=331	BKZ Q4W/Q8W N=79
Age (years), mean (SD)	45.4 (13.5)	45.0 (14.1)	44.6 (13.5)	44.1 (14.5)	43.5 (13.8)	42.5 (15.3)
Sex, **male**, n (%)	550 (71.3)	141 (71.6)	416 (70.3)	107 (67.7)	231 (69.8)	52 (65.8)
Racial group, **white**, n (%)	656 (85.1)	185 (93.9)	497 (84.0)	147 (93.0)	276 (83.4)	71 (89.9)
BMI ≥30 (kg/m²), n (%)	345 (44.7)	77 (39.1)	254 (42.9)	57 (36.1)	122 (36.9)	24 (30.4)
Duration of psoriasis (years), mean (SD)	18.6 (12.7)	18.9 (12.0)	18.3 (12.8)	18.8 (12.2)	17.9 (13.0)	18.2 (13.0)
PASI, mean (SD)	21.1 (7.6)	20.4 (6.9)	20.9 (7.5)	19.8 (6.3)	20.8 (7.2)	20.4 (6.5)
BSA (%), mean (SD)	27.0 (15.6)	24.5 (12.2)	26.8 (15.6)	23.9 (11.9)	26.4 (15.0)	24.3 (12.7)
IGA, n (%)[a]						
3: moderate	508 (65.9)	142 (72.1)	409 (69.1)	119 (75.3)	227 (68.6)	57 (72.2)
4: severe	262 (34.0)	55 (27.9)	182 (30.7)	39 (24.7)	103 (31.1)	22 (27.8)
DLQI total score, mean (SD)	10.5 (6.3)	10.8 (6.0)	10.4 (6.4)	11.1 (6.1)	10.6 (6.7)	10.9 (6.4)
Any prior systemic therapy, n (%)	618 (80.2)	154 (78.2)	474 (80.1)	123 (77.8)	265 (80.1)	60 (75.9)
Any prior biologic therapy, n (%)	309 (40.1)	73 (37.1)	237 (40.0)	58 (36.7)	143 (43.2)	29 (36.7)
Anti-TNF	113 (14.7)	19 (9.6)	84 (14.2)	16 (10.1)	48 (14.5)	8 (10.1)
Anti-IL-17	193 (25.0)	48 (24.4)	151 (25.5)	38 (24.1)	95 (28.7)	19 (24.1)

[a] One patient in the BKZ Total group had IGA 2 at baseline.

Figure 2 Response rates of clinical and quality of life outcomes in **Week 4 PASI 75 responders** through 4 years (mNRI)

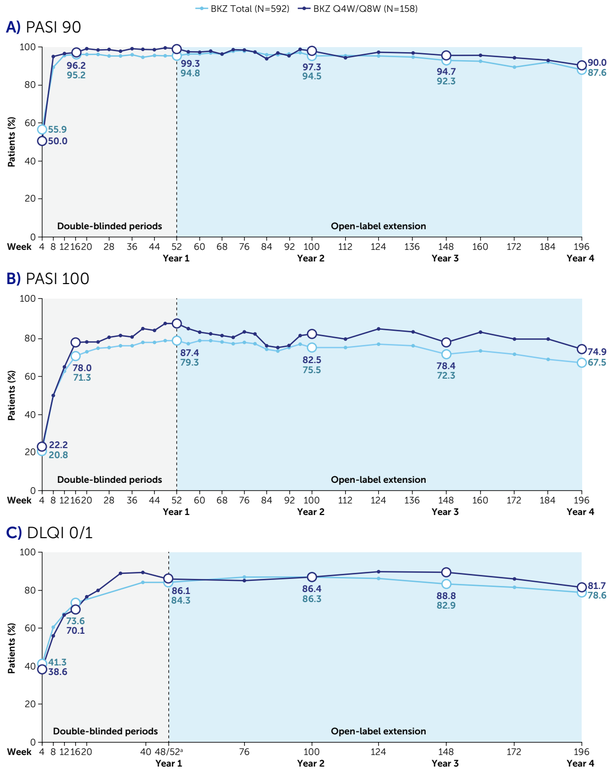
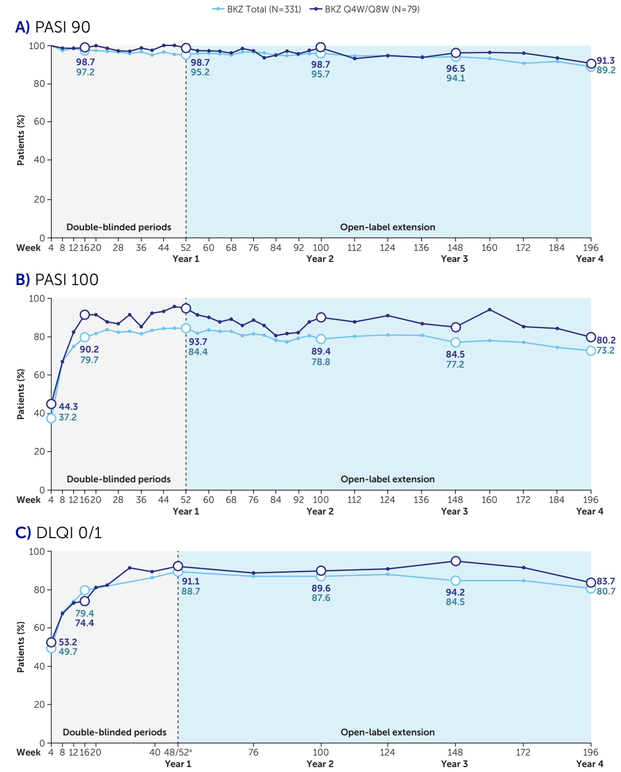


Figure 3 Response rates of clinical and quality of life outcomes in **Week 4 PASI 90 responders** through 4 years (mNRI)



BE VIVID lasted 52 weeks and BE SURE and BE READY lasted 56 weeks; to pool data across studies, Week 56 data were not included. The period after Week 52 corresponds to the BE BRIGHT OLE. Patients who entered the BE READY escape arm were considered as non-responders from the date of escape until the end of BE READY, after which they were considered in the same way as all other non-escape patients during the BE BRIGHT OLE. **[a]** Week 48/52 corresponds to the Week 48 DLQI assessment for BE SURE and BE READY and the Week 52 DLQI assessment for BE VIVID.

BKZ: bimekizumab; **BSA:** body surface area; **DLQI:** Dermatology Life Quality Index; **IGA:** Investigator's Global Assessment; **IL:** interleukin; **mNRI:** modified non-responder imputation; **OLE:** open-label extension; **PASI:** Psoriasis Area 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; **TNF:** tumor necrosis factor.

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