Bimekizumab durability of response through 4 years in patients with plaque psoriasis who stopped and re-started treatment

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Objective

- To report the long-term durability of treatment responses over an extended follow-up period (up to 4 years) in patients with moderate to severe plaque psoriasis who stopped and then restarted bimekizumab (BKZ).

Background

- Real-world psoriasis treatment may be **interrupted** due to factors including, but not limited to, surgery, hospitalization, financial considerations, and travel.
- While BKZ has demonstrated durable responses through 2 years' retreatment following interruption,[1] it is important to continue assessing how well responses are **recaptured or maintained** over longer periods upon retreatment.

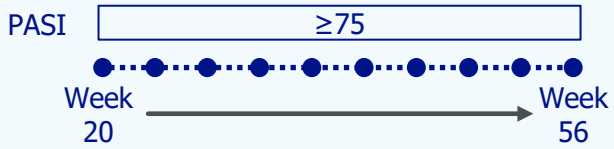
Methods

- **PASI 90**, **PASI 100**, and **DLQI 0/1** responses are reported as observed cases (OC) from the **BE READY** phase 3 trial and its open-label extension (OLE) **BE BRIGHT**,[2,3] among the following patient subgroups who stopped and restarted BKZ:

Patients randomized to BKZ for 16 weeks, then withdrawn on placebo (PBO) before entering the OLE

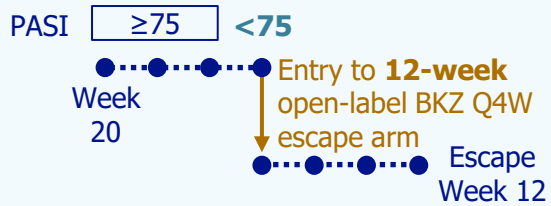
Week 16–56 PBO Group

Maintained ≥PASI 75 at every visit[a] from Week 16–56 with PBO



Escape Group

Relapsed (lost PASI 75) at any visit[a] from Week 20–56 with PBO



[a] Blue dots represent clinical trials visits every 4 weeks. **1.** Costanzo A et al. Presented at EADV 2023; Poster P2511; **2.** Gordon KB et al. Lancet 2021;397:475–86 (NCT03410992); **3.** Blauvelt A et al. J Am Acad Dermatol 2025;93:644–53 (NCT03598790). BKZ: bimekizumab; DLQI: Dermatology Life Quality Index; OC: observed case; OLE: open-label extension; PASI 75/90/100: ≥75%/≥90%/100% improvement from baseline in Psoriasis Area and Severity Index; PBO: placebo; Q4W: every 4 weeks.

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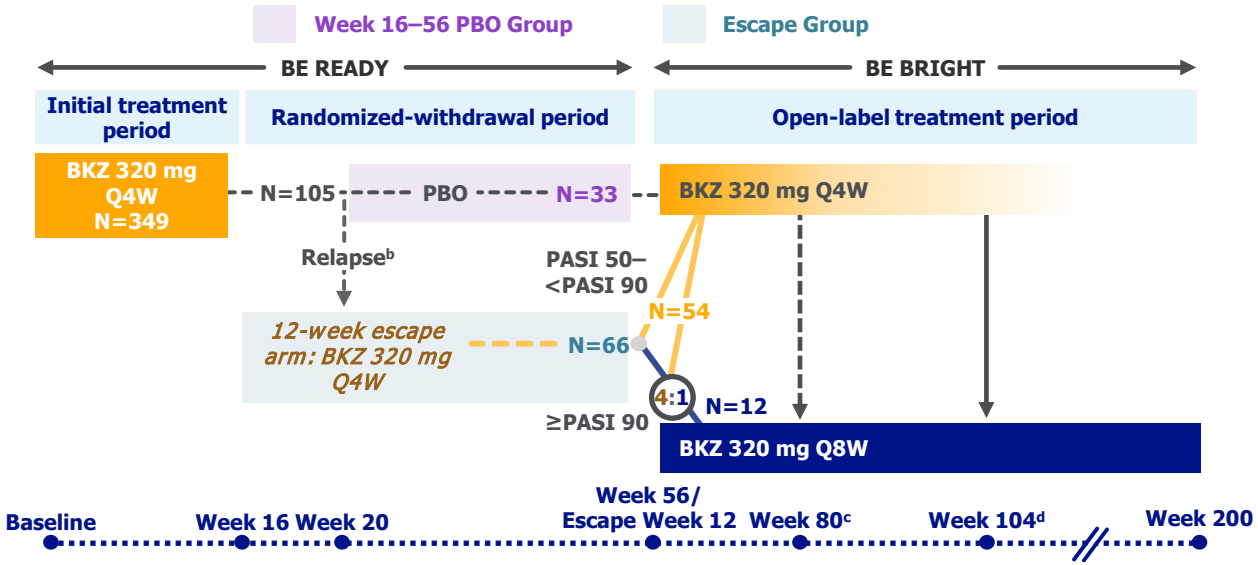
BE READY/BE BRIGHT Study Design[a]



- **105** patients initially randomized to BKZ Q4W who achieved PASI 90 were rerandomized to **PBO** at Week 16;[e] **31.4% (33/105)** maintained ≥PASI 75 to Week 56 and entered the OLE (**Week 16–56 PBO Group**).

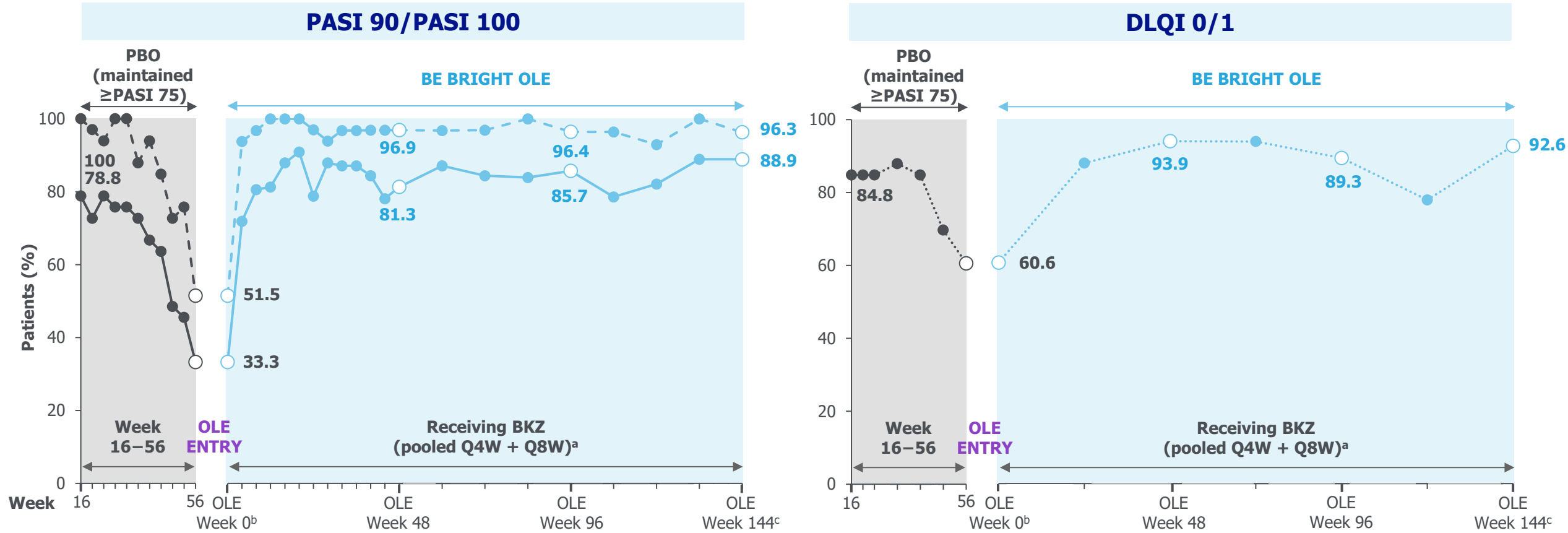
- Of the patients rerandomized to PBO, **62.9% (66/105)** relapsed during the randomized-withdrawal period and entered the escape arm to receive BKZ Q4W before entering the OLE (**Escape Group**).

Baseline Characteristics

	All patients rerandomized to PBO N=105	Week 16–56 PBO Group N=33	Escape Group N=66
Age (years), mean (SD)	42.3 (11.6)	41.2 (10.7)	43.2 (11.8)
Sex, male, n (%)	77 (73.3)	22 (66.7)	50 (75.8)
Racial group, white, n (%)	95 (90.5)	32 (97.0)	59 (89.4)
Weight (kg), mean (SD)	87.6 (19.2)	81.8 (20.9)	90.8 (18.3)
Duration of psoriasis (years), mean (SD)	18.9 (12.5)	14.6 (8.3)	20.6 (13.0)
PASI, mean (SD)	19.4 (6.8)	18.2 (4.8)	19.7 (7.5)
BSA (%), mean (SD)	22.9 (14.5)	18.9 (10.4)	24.6 (16.0)
IGA, n (%)			
3: moderate	73 (69.5)	24 (72.7)	45 (68.2)
4: severe	32 (30.5)	9 (27.3)	21 (31.8)
DLQI total score, mean (SD)	9.4 (5.7)	9.4 (6.2)	9.6 (5.7)
Any prior systemic therapy, n (%)	77 (73.3)	19 (57.6)	54 (81.8)
Any prior biologic therapy, n (%)	40 (38.1)	6 (18.2)	33 (50.0)
Medical history of PsA,[f] n (%)	18 (17.1)	6 (18.2)	12 (18.2)

[a] Full study designs have been reported previously;[1–3] **[b]** 'Relapse' was defined as <PASI 75 response at any visit between Week 20–56; median time to relapse from last BKZ dose (Week 12) in Week 16 PASI 90 responders was 32 weeks;[2] median time to loss of PASI 90 was 28 weeks;[4] **[c]** Patients receiving BKZ 320 mg Q4W who had achieved PASI 90 could be switched to receive BKZ 320 mg Q8W at the investigator's discretion (7 patients in the **Week 16-56 PBO Group**; 9 patients in the **Escape Group**); **[d]** At Week 104 (OLE Week 48), or the next scheduled visit, all patients who had remained on BKZ 320 mg Q4W were re-assigned to BKZ 320 mg Q8W; **[e]** Excludes patients who escaped PBO treatment without meeting the criteria to do so; of the remaining 105 patients who achieved PASI 90 at Week 16 and were rerandomized to PBO, 99 entered the OLE (5 patients discontinued from BE READY [3 due to adverse events, 2 lost to follow-up] and 1 was not treated in the OLE);[1,2] **[f]** Based on patients' reported medical history of PsA. **1.** Costanzo A et al. Presented at EADV 2023; Poster P2511; **2.** Gordon KB et al. Lancet 2021;397:475–86 (NCT03410992); **3.** Blauvelt A et al. J Am Acad Dermatol 2025;93:644–53 (NCT03598790); **4.** Blauvelt A et al. Presented at AAD 2021; Poster 27380. BKZ: bimekizumab; BSA: body surface area; DLQI: Dermatology Life Quality Index; IGA: Investigator's Global Assessment; OLE: open-label extension; PASI 50/75/90: ≥50%/≥75%/≥90% improvement from baseline in Psoriasis Area and Severity Index; PBO: placebo; PsA: psoriatic arthritis; Q4W: every 4 weeks; Q8W: every 8 weeks; SD: standard deviation.

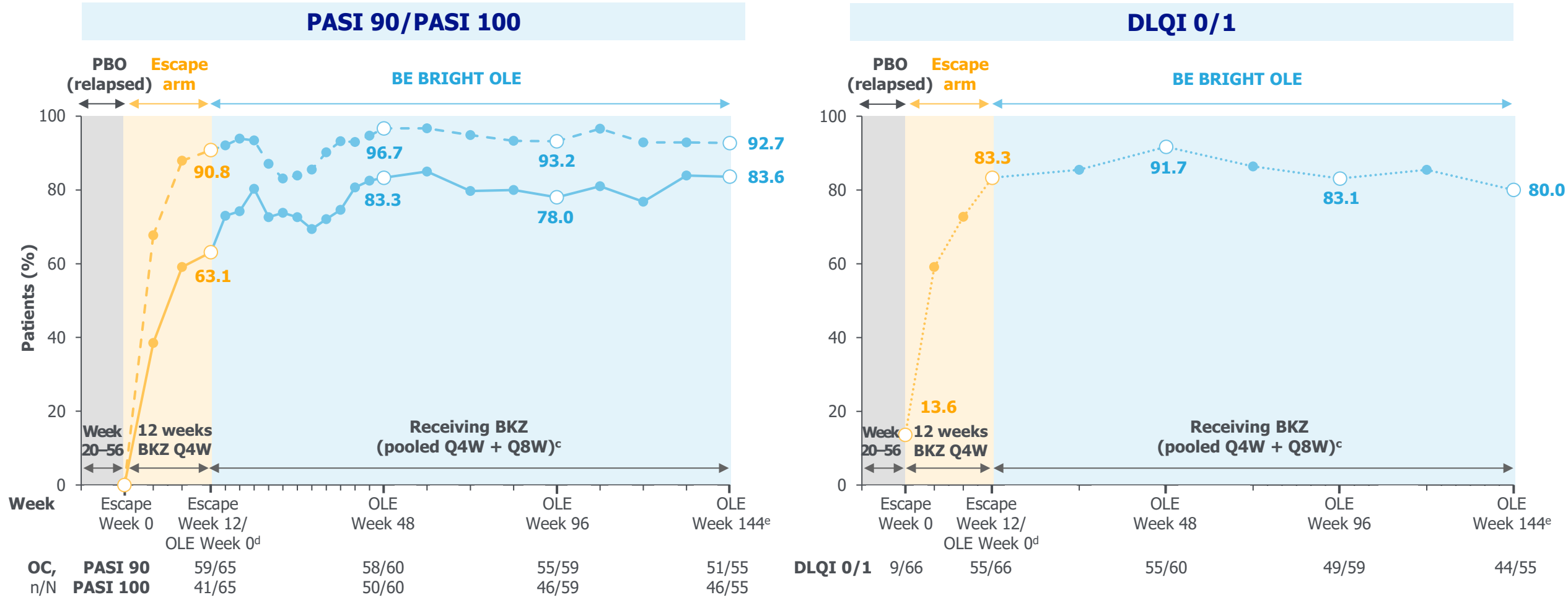
Week 16–56 PBO Group (Maintained ≥PASI 75 from Week 16–56); PASI 90, PASI 100, and DLQI 0/1 Response Rates Through 4 Years (OC)



OC, n/N					
PASI 90	17/33	31/32	27/28	26/27	
PASI 100	11/33	26/32	24/28	24/27	
DLQI 0/1	20/33	31/33	25/28	25/27	

[a] Data reported from the BE BRIGHT OLE are pooled for patients who received BKZ 320 mg Q4W and Q8W; **[b]** Patients in the **Week 16–56 PBO Group** had their OLE Week 0 study assessments at the end of the 40-week randomized-withdrawal period (Week 56), having maintained ≥PASI 75 at every visit prior to that point; **[c]** At Year 4, 6 patients were missing from the **Week 16–56 PBO Group** having discontinued during the OLE (2 due to adverse events, 1 due to lack of efficacy, 1 due to protocol violation, 1 lost to follow-up, 1 due to consent being withdrawn). BKZ: bimekizumab; DLQI: Dermatology Life Quality Index; OC: observed case; OLE: open-label extension; PASI 75/90/100: ≥75%/≥90%/100% improvement from baseline in Psoriasis Area and Severity Index; PBO: placebo; Q4W: every 4 weeks; Q8W: every 8 weeks.

Escape Group (Relapsed During BKZ Withdrawal);[a,b]
PASI 90, PASI 100, and DLQI 0/1 Response Rates Through 4 Years (OC)



OC, n/N		Escape Week 12/ OLE Week 0[d]	OLE Week 48	OLE Week 96	OLE Week 144[e]
PASI 90		59/65	58/60	55/59	51/55
PASI 100		41/65	50/60	46/59	46/55
DLQI 0/1	9/66	55/66	55/60	49/59	44/55

Mean time to relapse (SD) in the **Escape Group** was 158.8 (47.7) days/22.7 (6.8) weeks.

[a] 'Relapse' was defined as <PASI 75 response at any visit between Week 20–56; **[b]** Generally, patients with higher weight (>100 kg [n=25] vs ≤100 kg [n=74]; OR: 2.22 [95% CI: 0.78, 6.30]; nominal p=0.1249), longer disease duration (≥median disease duration [17.17 years; n=50] vs <median disease duration [17.17 years; n=49]; OR: 4.55 [95% CI: 1.78, 11.65]; nominal p=0.0013), and with prior biologic exposure (prior biologic exposure [n=39] vs no prior biologic exposure [n=60]; OR: 7.27 [95% CI: 2.38, 22.15]; nominal p<0.001) had higher relapse rates in the BE READY randomized-withdrawal period. ORs (95% CIs) and p-values are from a stratified CMH test with region as the stratification variable; p-values are nominal and intended for exploratory insight, with an OR >1 indicating a higher relapse rate; **[c]** Data reported from the BE BRIGHT OLE are pooled for patients who received BKZ 320 mg Q4W and Q8W; **[d]** Patients in the **Escape Group** had their OLE Week 0 study assessments at the end of the 12-week escape arm, having achieved PASI 50 at the end of the 12 weeks; 65/66 patients had a PASI measurement recorded at Escape Week 12/OLE Week 0, as 1 patient missed this visit; **[e]** At Year 4, 11 patients were missing from the **Escape Group** having discontinued during the OLE (6 due to adverse events, 1 due to lack of efficacy, 1 lost to follow-up, 3 due to consent being withdrawn). BKZ: bimekizumab; CI: confidence interval; CMH: Cochran-Mantel-Haenszel; DLQI: Dermatology Life Quality Index; OC: observed case; OLE: open-label extension; OR: odds ratio; PASI 50/75/90/100: ≥50%/≥75%/≥90%/100% improvement from baseline in Psoriasis Area and Severity Index; PBO: placebo; Q4W: every 4 weeks; Q8W: every 8 weeks; SD: standard deviation.

Conclusions

Among patients who maintained ≥PASI 75 during bimekizumab withdrawal, 100% achieved PASI 90 following 12 weeks of bimekizumab retreatment.

Among patients who relapsed after bimekizumab withdrawal, high proportions achieved complete/near-complete skin clearance and DLQI 0/1 after 12 weeks' retreatment.

In both groups, high response levels were durable through ≥3 years' bimekizumab retreatment, suggesting that pausing bimekizumab treatment did not meaningfully impact long-term disease control.

Author Contributions: Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **CEMG, AC, KAP, DR, LP, AB, KW, JMLP, JL, RW, GH**; Drafting of the publication, or reviewing it critically for important intellectual content: **CEMG, AC, KAP, DR, LP, AB, KW, JMLP, JL, RW, GH**; Final approval of the publication: **CEMG, AC, KAP, DR, LP, AB, KW, JMLP, JL, RW, GH**.

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DLQI: Dermatology Life Quality Index; PASI 75/90: ≥75%/≥90% improvement from baseline in Psoriasis Area and Severity Index.