Bimekizumab response through 3 years in patients with plaque psoriasis who stopped and re-started treatment

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Objective

To understand how well clinical responses can be maintained after withdrawal of bimekizumab (BKZ) treatment and to identify whether clinical responses can be re-captured and maintained for up to 2 years with BKZ re-treatment.

Introduction

- Patients with moderate to severe plaque psoriasis may report interruptions in biologic treatment.
- Therefore, it is important to understand how long responses can be maintained after treatment withdrawal, and whether responses can be re-captured and maintained upon re-treatment.
- In the BE READY phase 3 trial, the median time to relapse (loss of PASI 75 [≥75% improvement from baseline Psoriasis Area and Severity Index]) from last BKZ dose (Week 12) in Week 16 PASI 90 responders was 32 weeks;[1] median time to loss of PASI 90 was 28 weeks.[2]
- Here, we report responses to BKZ through 3 years in two BE READY patient groups who stopped and re-started treatment.

Methods

- Data are reported from the BE READY randomised-withdrawal trial and its ongoing open-label extension (OLE), BE BRIGHT.[1,3]
- Included patients were initially randomised to BKZ 320 mg every 4 weeks (Q4W), achieved PASI 90 at Week 16, and were re-randomised to placebo (PBO) for the 40-week randomised-withdrawal period, before entering the OLE (**Figure 1**).
  - Patients who maintained PASI 75 throughout the randomised-withdrawal period continued to receive PBO to Week 56, then entered the OLE (**Week 16–56 PBO Group**); these patients underwent a mandatory switch to BKZ Q4W on OLE entry.
  - Patients who relapsed while receiving PBO (<PASI 75 response at any visit between Week 20–56) entered a 12-week escape arm and were re-treated with open-label BKZ Q4W. Those who achieved PASI 50 after 12 weeks of escape treatment entered the OLE (**Escape Group**), and received either BKZ Q4W or Q8W depending on Escape Week 12 PASI 90 response.
- Proportions of patients achieving near-complete/complete skin clearance (PASI 90/PASI 100) are reported through OLE Week 96, as observed case (patients with non-missing measurements at the respective timepoint).

Results

- At Week 16, 317/349 (90.8%) BKZ Q4W-randomised patients achieved PASI 90;[1] 105 of these patients were re-randomised to PBO. Their baseline characteristics are presented in **Table 1**.[2]
- Of these, 31.4% (33/105) continued on PBO for 40 weeks and maintained PASI 75 at every visit until OLE entry at Week 56 (**Week 16–56 PBO Group**).
  - 51.5% (17/33) maintained PASI 90 and 33.3% (11/33) achieved PASI 100 at Week 56 (OLE Week 0).
  - Responses greatly improved following BKZ re-treatment up to OLE Week 96 (**Figure 2**).
- Of the patients re-randomised to PBO, 62.9% (66/105) relapsed during the randomised-withdrawal period (**Escape Group**) and entered the escape arm before entering the OLE.
  - Of these, 90.8% (59/65) re-gained PASI 90 and 63.1% (41/65) achieved PASI 100 after 12 weeks of BKZ Q4W re-treatment (OLE Week 0).
  - PASI 90 responses were sustained to OLE Week 96, while PASI 100 responses increased (**Figure 3**).

Conclusions

Almost one third of patients treated with BKZ Q4W who achieved PASI 90 at Week 16 maintained at least PASI 75 at every visit for 40 weeks upon withdrawal of BKZ; after re-starting BKZ treatment, rates of near-complete/complete skin clearance greatly improved.

The vast majority of patients who relapsed while receiving PBO achieved near-complete/complete skin clearance after 12 weeks of BKZ re-treatment.

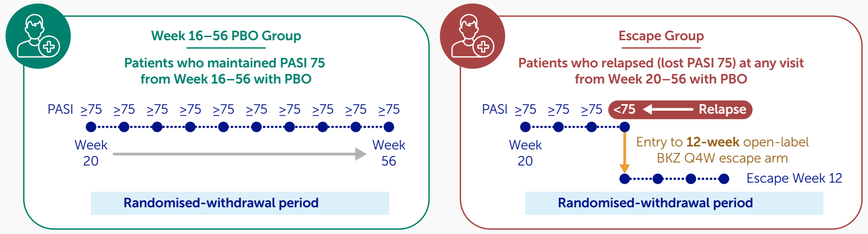
In both groups, high responses were durable through 2 years of BKZ re-treatment, indicating that stopping BKZ for up to 40 weeks and re-starting did not meaningfully impact long-term disease control.

Summary

Analysed patient groups

Two BE READY patient groups who stopped and re-started treatment were analysed

Both groups were randomised to BKZ 320 mg Q4W, achieved PASI 90 at Week 16, and were re-randomised to PBO



Almost one third of patients did not relapse after withdrawal of BKZ
Levels of skin clearance greatly improved after re-starting BKZ treatment

The vast majority of patients who relapsed regained high levels of skin clearance after re-starting BKZ treatment

High responses were durable through 2 years of BKZ re-treatment

Figure 2 Achievement of PASI 90 and PASI 100 over 3 years in patients in the **Week 16–56 PBO Group** (OC)

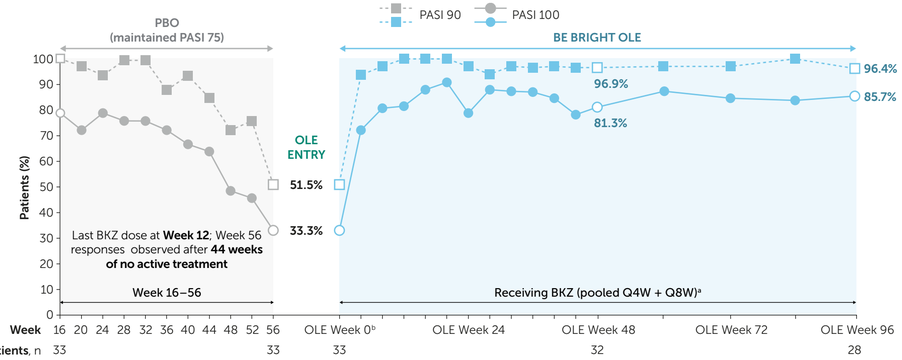
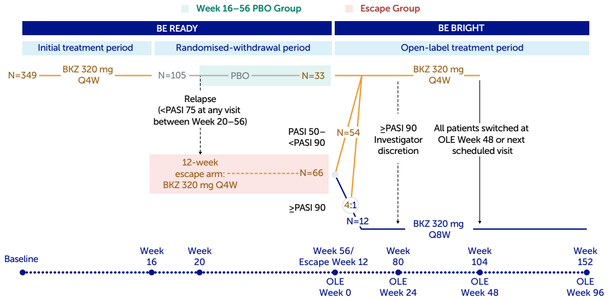


Figure 1 BE READY/BE BRIGHT study design



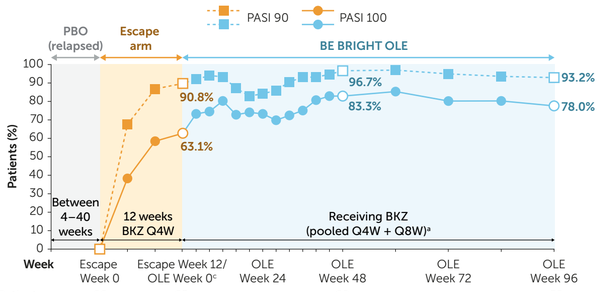
Full study designs have been reported previously.[1,3] BE READY treatment arms not included in these analyses are not shown. Out of 105 patients who achieved PASI 90 at Week 16 and were re-randomised to PBO, 99 entered the OLE (5 patients discontinued from BE READY [3 due to adverse events, 2 lost to follow-up] and 1 was not treated in the OLE). Patients in the Week 16–56 PBO Group maintained PASI 75 at every visit until OLE entry at Week 56, at which point they received BKZ 320 mg Q4W (N=33). All Escape Group patients achieved PASI 50 at Escape Week 12 and entered the OLE (PASI measurements recorded for 65 patients at Escape Week 12/OLE Week 0; 1 patient missed a visit). Escape patients entered the OLE straight after their 12 weeks of open-label BKZ treatment, so could have entered before or after Week 56. 54 Escape Group patients started the OLE on BKZ Q4W and 12 patients started on BKZ Q8W, before dose switching occurred. By OLE Week 96, all ongoing Week 16–56 PBO Group (N=28) and Escape Group (N=59) patients had switched to BKZ Q8W.

Table 1 Baseline characteristics

	All patients re-randomised 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
Male, n (%)	77 (73.3)	22 (66.7)	50 (75.8)
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)
Prior biologic therapy, n (%)	40 (38.1)	6 (18.2)	33 (50.0)

Data are reported for patients who achieved PASI 90 after 16 weeks of BKZ treatment and were re-randomised to PBO.

Figure 3 Achievement of PASI 90 and PASI 100 over 3 years in patients in the **Escape Group** (OC)



[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 randomised-withdrawal period (Week 56), having maintained PASI 75 at every visit throughout; [c]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 one patient missed this visit.

BKZ: bimekizumab; **BSA**: body surface area; **DLQI**: Dermatology Life Quality Index; **IGA**: Investigator's Global Assessment; **OC**: observed case; **OLE**: open-label extension; **PASI**: Psoriasis Area and Severity Index; **PASI 50/75/90/100**: ≥50%/≥75%/≥90%/100% improvement from baseline in PASI; **PBO**: placebo; **Q4W**: every 4 weeks; **Q8W**: every 8 weeks; **SD**: standard deviation.

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