Bimekizumab efficacy and safety over 48 weeks in US and Canadian patients with psoriasis who had a treatment interruption after 3 years of treatment: Results from BE RADIANT

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Synopsis

- Patients with psoriasis treated with biologics frequently experience treatment interruptions;[1,2] therefore, it is important to assess recovery of response upon retreatment.

Objective

To report efficacy and safety of bimekizumab (BKZ) in patients from the US and Canada treated for 1 year following a treatment interruption during the BE RADIANT study.

Methods

- After 144 weeks in BE RADIANT (3 years; 48-week double-blinded period plus a 96-week open-label extension period [OLE]),[3] patients from the US and Canada could enter a second OLE (OLE2; 48 weeks); most had a treatment interruption before entering OLE2 (**Figure 1**).
- Patients scoring ≤2 in the Investigator's Global Assessment (IGA) at OLE2 baseline received BKZ every 8 weeks (Q8W), and those scoring IGA ≥3 received BKZ every 4 weeks (Q4W) for 16 weeks then Q8W thereafter.
- The following efficacy outcomes were reported through OLE2 in patients who had a treatment interruption, using non-responder imputation (NRI) and observed cases (OC):
  - ≥90%/100% improvement from baseline in Psoriasis Area and Severity Index (PASI 90/100);
  - IGA 0/1 (clear or almost clear);
  - Dermatology Life Quality Index (DLQI) 0/1 (no effect of skin disease on quality of life).[4]
- Following a treatment interruption, the proportions of patients who had treatment-emergent adverse events (TEAEs) during OLE2 were reported, regardless of dosing regimen (BKZ Total).
  - Rates of TEAEs are also reported as exposure-adjusted incidence rates per 100 patient-years (EAIR/100 PY).

Results

Efficacy

- Baseline characteristics at the start of BE RADIANT are shown in **Table 1**.
- 66 patients had an IGA score of ≤2 at OLE2 entry and received BKZ Q8W after a median (range) treatment interruption of 23 (6–51) weeks.
  - Among these patients, PASI 100 rates were high at Week 144 (74.2%; last visit before treatment interruption), decreased to OLE2 baseline (27.3%; after treatment interruption), regained to OLE2 Week 12 (69.7%; 3 months), and were maintained to OLE2 Week 48 (71.2%; Year 1; **Figure 2A**).
  - PASI 90, IGA 0/1, and DLQI 0/1 rates followed a similar trend (**Figures 2B**–**D**).
- 59 patients had an IGA score ≥3 at OLE2 entry and received BKZ Q4W/Q8W after a median treatment interruption of 28 (7–49) weeks.
  - Among these patients, PASI 100 rates were high at Week 144 (64.4%), decreased to OLE2 baseline (0%), regained after 3 months (64.4%), and were maintained to Year 1 (54.2%; **Figure 2A**).
  - PASI 90, IGA 0/1, and DLQI 0/1 rates followed a similar trend (**Figures 2B**–**D**).

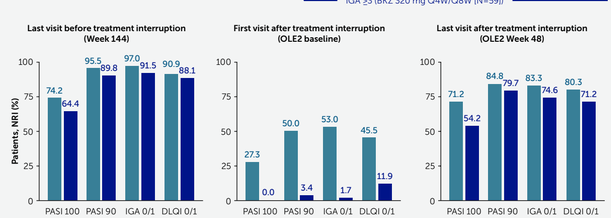
Safety

- The proportions of patients who reported TEAEs and TEAEs of interest are shown in **Table 2**.
- One death occurred in OLE2 (pneumonia on a background of metastatic cancer; patient had underlying risk factors).
- The most common TEAEs were coronavirus infection (OLE2 started during the global COVID-19 pandemic), oral candidiasis, and nasopharyngitis.
- Oral candidiasis events occurred in 9 (7.2%) patients. No cases of oral candidiasis were serious, severe, or led to discontinuation.

Conclusions

After bimekizumab retreatment following a treatment interruption, efficacy responses were regained and maintained through 1 year; bimekizumab was well-tolerated with no unexpected safety findings.

Summary



Efficacy responses (as measured by **PASI**, **IGA**, and **DLQI**) were **regained and maintained** through **1 year of bimekizumab retreatment** following a treatment interruption, with no unexpected safety findings.

[a] Includes patients who received SEC 300 mg for the first 48 weeks.

Figure 1 BE RADIANT study design

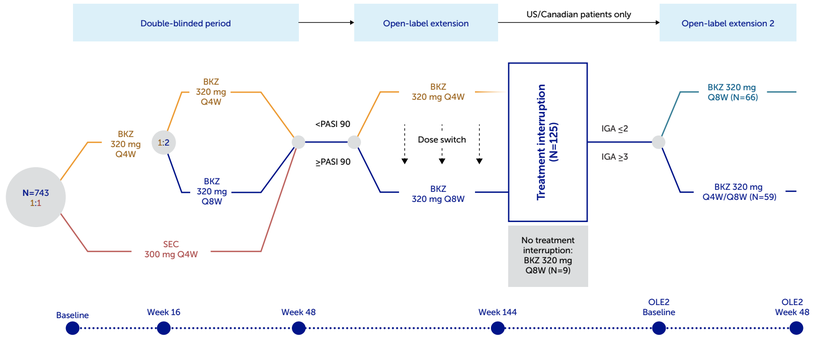


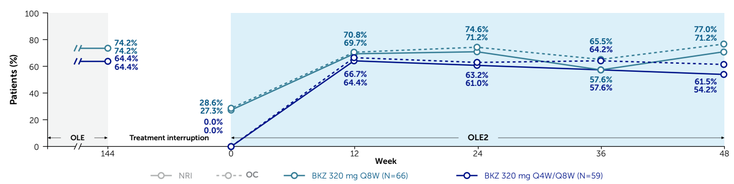
Table 1 Baseline characteristics

Baseline characteristics	BKZ 320 mg Q8W N=66	BKZ 320 mg Q4W/Q8W N=59
Age (years), mean ± SD	49.7 ± 15.0	49.8 ± 14.5
Sex, male, n (%)	41 (62.1)	45 (76.3)
Racial group, white, n (%)	58 (87.9)	51 (86.4)
Weight (kg), mean ± SD	88.2 ± 17.9	102.2 ± 26.7
BMI (kg/m²), mean ± SD	31.1 ± 6.3	33.8 ± 7.3
Duration of psoriasis (years), mean ± SD	16.1 ± 12.3	20.3 ± 15.5
PASI, mean ± SD	20.5 ± 5.8	18.6 ± 6.4
BSA (%), mean ± SD	23.7 ± 14.1	21.6 ± 13.3
IGA, n (%)		
3: moderate	37 (56.1)	36 (61.0)
4: severe	29 (43.9)	23 (39.0)
DLQI total, mean ± SD	10.7 ± 6.9	8.8 ± 6.0
Prior systemic therapy, n (%)	45 (68.2)	36 (61.0)
Prior biologic therapy, n (%)	24 (36.4)	25 (42.4)

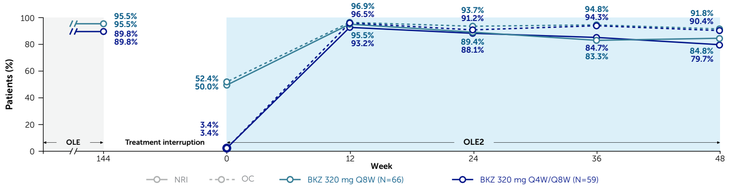
These characteristics were recorded at baseline of the double-blinded period of the BE RADIANT study. Data are presented for patients who scored IGA ≤2 at OLE2 baseline and received BKZ Q8W; and for patients who scored IGA ≥3 at OLE2 baseline and received BKZ Q4W for 16 weeks then Q8W thereafter.

Figure 2 Efficacy responses before and after treatment interruption in OLE2 (NRI, OC)

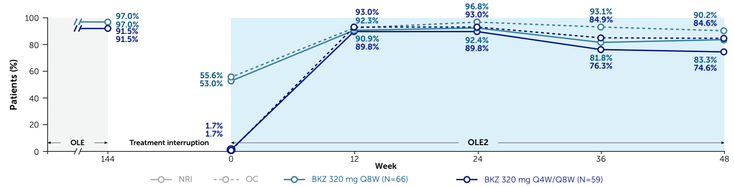
A) PASI 100



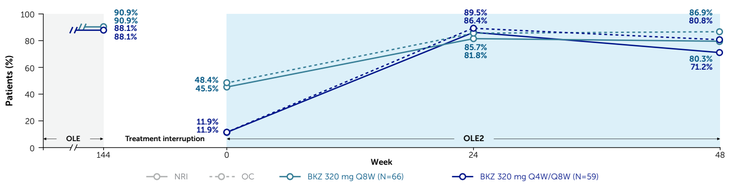
B) PASI 90



C) IGA 0/1



D) DLQI 0/1



Efficacy data are presented for patients who scored IGA ≤2 at OLE2 baseline and received BKZ Q8W, and for patients who scored IGA ≥3 at OLE2 baseline and received BKZ Q4W for 16 weeks then Q8W thereafter. Data were reported using non-responder imputation (NRI) and observed case (OC).

Table 2 Rates of TEAEs in OLE2

Overview of TEAEs	BKZ Total (N=125) n (%)	BKZ Total (N=125) EAIR/100 PY (95% CI)
TEAE summary		
Any TEAE	71 (56.8)	83.2 (65.0, 104.9)
Serious TEAEs	5 (4.0)	3.7 (1.2, 8.6)
Discontinuations due to TEAEs	2 (1.6)	1.5 (0.2, 5.3)
Severe TEAEs	2 (1.6)	1.5 (0.2, 5.3)
TEAEs leading to death	1 (0.8)	0.7 (0.0, 4.1)
Most common TEAEs		
Coronavirus infection	18 (14.4)	14.3 (8.5, 22.6)
Oral candidiasis	9 (7.2)	6.8 (3.1, 13.0)
Nasopharyngitis	4 (3.2)	2.9 (0.8, 7.5)
TEAEs of interest		
Serious infections	2 (1.6)	1.5 (0.2, 5.3)
Active tuberculosis	0	0
Fungal infections	12 (9.6)	9.3 (4.8, 16.3)
Candida infections	9 (7.2)	6.8 (3.1, 13.0)
Oral candidiasis	9 (7.2)	6.8 (3.1, 13.0)
Definite or probable adjudicated IBD	0	0
Adjudicated suicidal ideation and behavior	0	0
Adjudicated major adverse cardiac events	0	0
Malignancies[a]	4 (3.2)	3.0 (0.8, 7.6)
Any malignancies (excluding NMSC)	2 (1.6)	1.5 (0.2, 5.3)
Serious hypersensitivity reactions	0	0
Injection site reactions	0	0
Hepatic events[b]	5 (4.0)	3.7 (1.2, 8.6)
ALT or AST >3x ULN	2 (1.6)	1.5 (0.2, 5.3)
ALT or AST >5x ULN	1 (0.8)	0.7 (0.0, 4.1)

OLE2 safety data were presented for all patients who had a treatment interruption and entered OLE2 (BKZ Total). [a] Of the four malignancy events, two were basal cell carcinomas, one was lentigo maligna, and one was a fatal metastatic neoplasm in the liver (as described in the Results text). [b] The majority of reported hepatic TEAEs were elevated liver enzymes; all were non-serious, mild or moderate in severity, and did not lead to discontinuation.

ALT: alanine aminotransferase; **AST:** aspartate aminotransferase; **BKZ:** bimekizumab; **BMI:** body mass index; **BSA:** body surface area; **CI:** confidence interval; **DLQI:** Dermatology Life Quality Index; **EAIR:** exposure-adjusted incidence rate; **IBD:** inflammatory bowel disease; **IGA:** Investigator's Global Assessment; **NMSC:** non-melanoma skin cancer; **NRI:** non-responder imputation; **OC:** observed case; **OLE:** open-label extension; **PASI:** Psoriasis Area and Severity Index; **PY:** patient-years; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks; **SD:** standard deviation; **SEC:** secukinumab; **TEAE:** treatment-emergent adverse event; **ULN:** upper limit of normal.

References: [1]Heung M et al. J Am Acad Dermatol 2013;68:664–72; [2]Schmitt-Egenolf M et al. Dermatol Ther (Heidelb) 2021;11:2107–21; [3]Reich K et al. N Engl J Med 2021;385:142–52. NCT03536884; [4]Hongbo Y et al. J Invest Dermatol 2005;125:659–64.

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