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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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.

Introduction

• Patients with psoriasis treated with biologics frequently experience treatment interruptions;^{1,2} therefore, it is important to assess recovery of response upon retreatment.

Methods

- After 144 weeks of 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 Q4W for 16 weeks then Q8W thereafter (Q4W/Q8W).
- 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
- 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

- 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
- 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).

- The proportions of patients who reported TEAEs and TEAEs of interest are
- One death occurred in OLE2 (pneumonia on a background of metastatic
- 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.

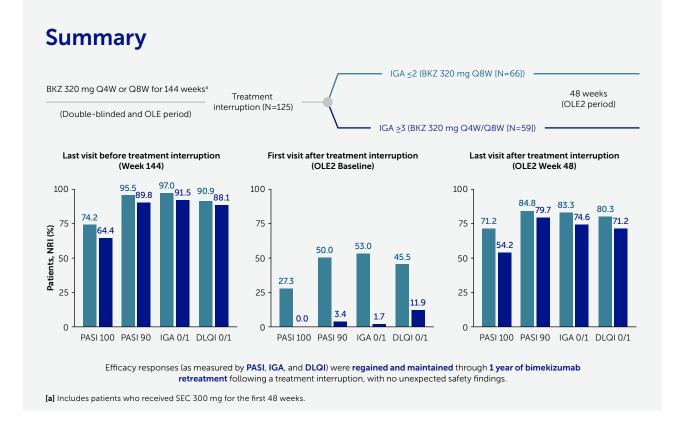


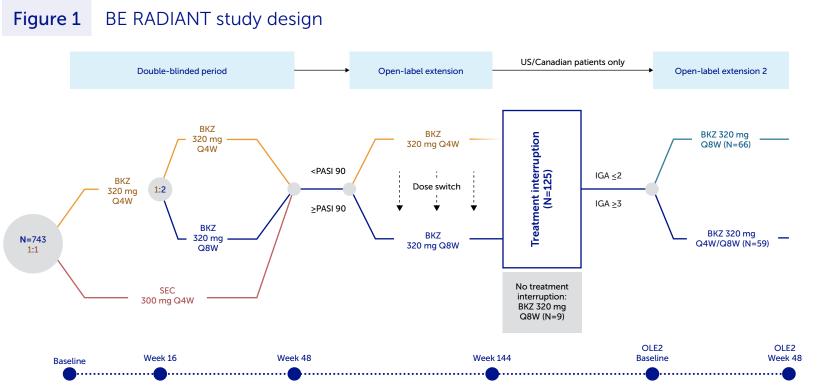
Figure 2 Efficacy responses before and after treatment interruption in OLE2 (NRI, OC)

─○ BKZ 320 mg Q8W (N=66)

—O— BKZ 320 mg Q8W (N=66)

─ BKZ 320 mg Q4W/Q8W (N=59)

—O— BKZ 320 mg Q4W/Q8W (N=59)



─○ BKZ 320 mg Q8W (N=66

--O-- OC BKZ 320 mg Q8W (N=66

── BKZ 320 mg Q4W/Q8W (N=59)

—O— BKZ 320 mg Q4W/Q8W (N=59)

Table 1 Baseline characteristics

| Baseline characteristics | BKZ 320 mg Q8W N=66 | BKZ 320 mg Q4W/Q8W N=59 |
|--|------------------------|----------------------------|
| Age (years) , mean \pm SD | 49.7 <u>±</u> 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 \pm 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 \pm 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) |

for patients who scored IGA ≤2 at OLE2 baseline and received BKZ Q8W; and for patients who scored IGA ≥3 at OLE2

Table 2 Rates of TEAEs in OLE2

| | BKZ Total (N=125) | |
|--|-------------------|----------------------|
| Overview of TEAEs | n (%) | 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 | | į |
| 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 neo in the liver (as described in the Results text); **[b]** The majority of reported hepatic TEAEs were elevated liver enzymes; a

B) PASI 90

D) DLQI 0/1

References: 'Yeung H et al. J Am Acad Dermatol 2013;68:64—72; 'Schmitt-Egenolf M et al. Dermatol Ther (Heidelb) 2021;11:2107—21; 'Reich K et al. N Engl J Med 2021;385:142—52, NCT03536884; 'Hongbo Y et al. J Invest Dermatol 2005;125:659—64. Author Contributions: Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: MLe, KP, BE, MLo, PR, BS, AA, JMLP, MK, DD, MW, RV; Darfting of the publication, or reviewing it critically for important intellectual content: MLe, KP, BE, MLo, PR, BS, AA, JMLP, MK, DD, MW, RV; Darfting of the publication, or reviewing it critically for important intellectual content: MLe, KP, BE, MLo, PR, BS, AA, JMLP, MK, DD, MW, RV; Darfting of the publication, or reviewing it critically for important intellectual content: MLe, KP, BE, MLo, PR, BS, AA, JMLP, MK, DD, MW, RV; Darfting of the publication, or reviewing it critically for important intellectual content: MLe, KP, BE, MLo, PR, BS, AA, JMLP, MK, DD, MW, RV; Darfting of the publication, or reviewing it critically for important intellectual content: MLe, KP, BE, MLo, PR, BS, AA, JMLP, MK, DD, MW, RV; Darfting of the publication, or reviewing it critically for important intellectual content: MLe, KP, BE, MLo, PR, BS, AA, JMLP, MK, DD, MW, RV; Darfting of the publication, or reviewing it critically for important intellectual content: MLe, KP, BE, MLo, PR, BS, AA, JMLP, MK, DD, MW, RV; Darfting of the publication, or reviewing it critically for important intellectual content. All the publication of the publication, or reviewing it critically for important intellectual content. All the publication of the publication, or reviewing it critically for important intellectual content. All the publication, or reviewing it critically for important intellectual content. All the publication of the publication, or reviewing it critically for indication in the publication. All the publication is publica Pfizer, Regeneron, Takeda, and UCB; speakers bureau/honoraria from AbbVie, Actelion, Amgen, Bausch Health, Celgene, Cipher, Eli Lilly and Company, Galderma, GSK, Janssen, LEO Pharma, Merck, Novartis, Palladin, Pfizer, and UCB. Acknowledgments: This study was funded by UCB. We thank the patients and their caregivers in addition to the investigators and their teams who contributed to this study. The authors acknowledge Inés Dueñas Pousa, PhD, ÜCB, Madrid, Spain for publication coordination, Calum Suggett, MSc, Costello Medical Creative team for graphic design assistance. All costs associated with development of this poster were funded by UCB.



A) PASI 100

C) IGA 0/1