



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

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 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 are reported through OLE2, in patients who had a treatment interruption, using non-responder imputation (NRI) and observed cases (OC):
 - $\geq 90\%/100\%$ 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 are reported, regardless of dosing regimen (BKZ Total).
 - Rates of TEAEs are also reported as exposure-adjusted incidence rates per 100 patient-years.

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 nine (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

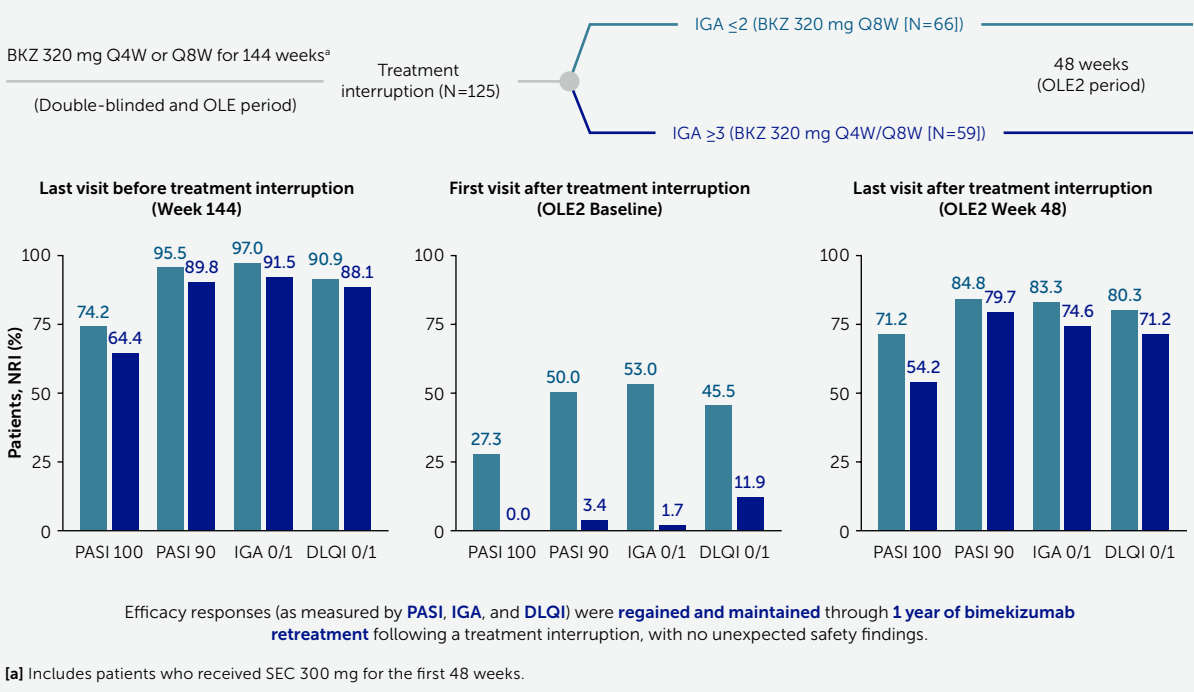
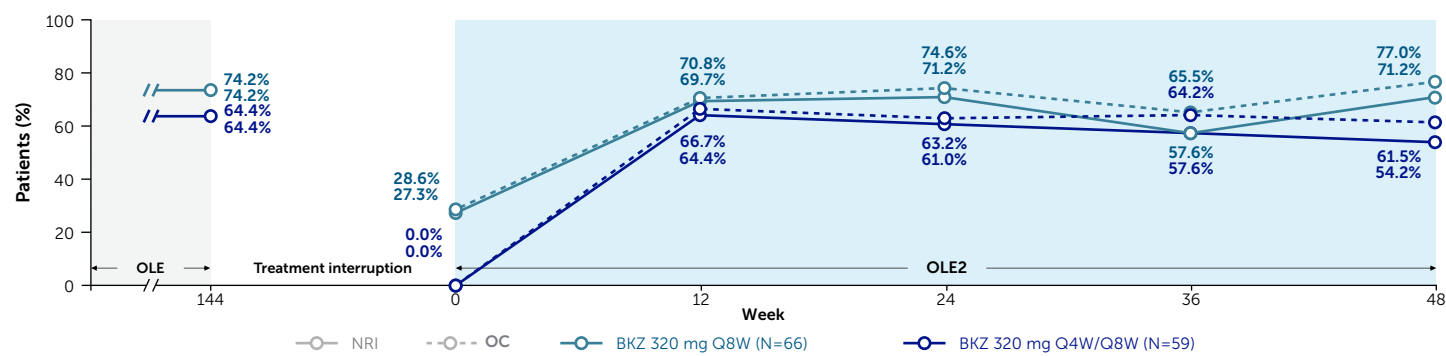


Figure 2 Efficacy responses before and after treatment interruption in OLE2 (NRI, OC)

A) PASI 100



C) IGA 0/1

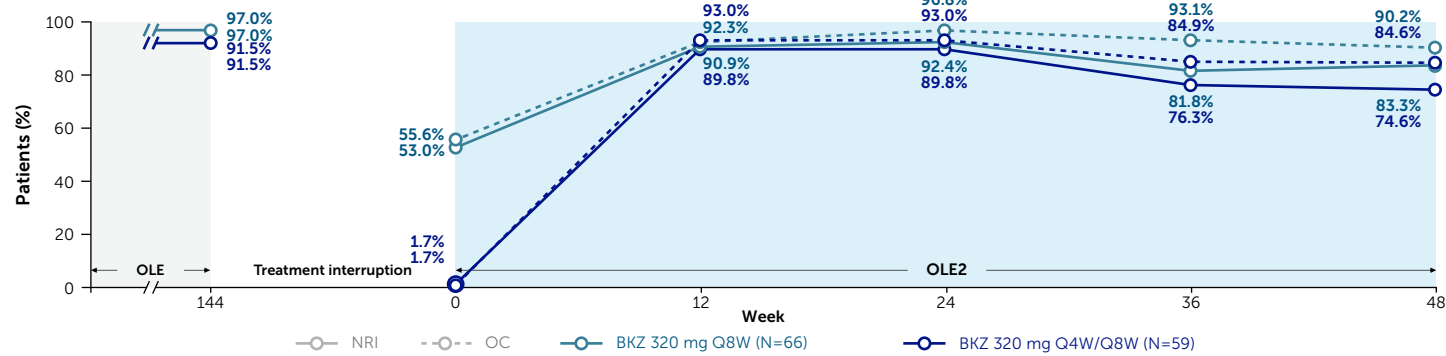
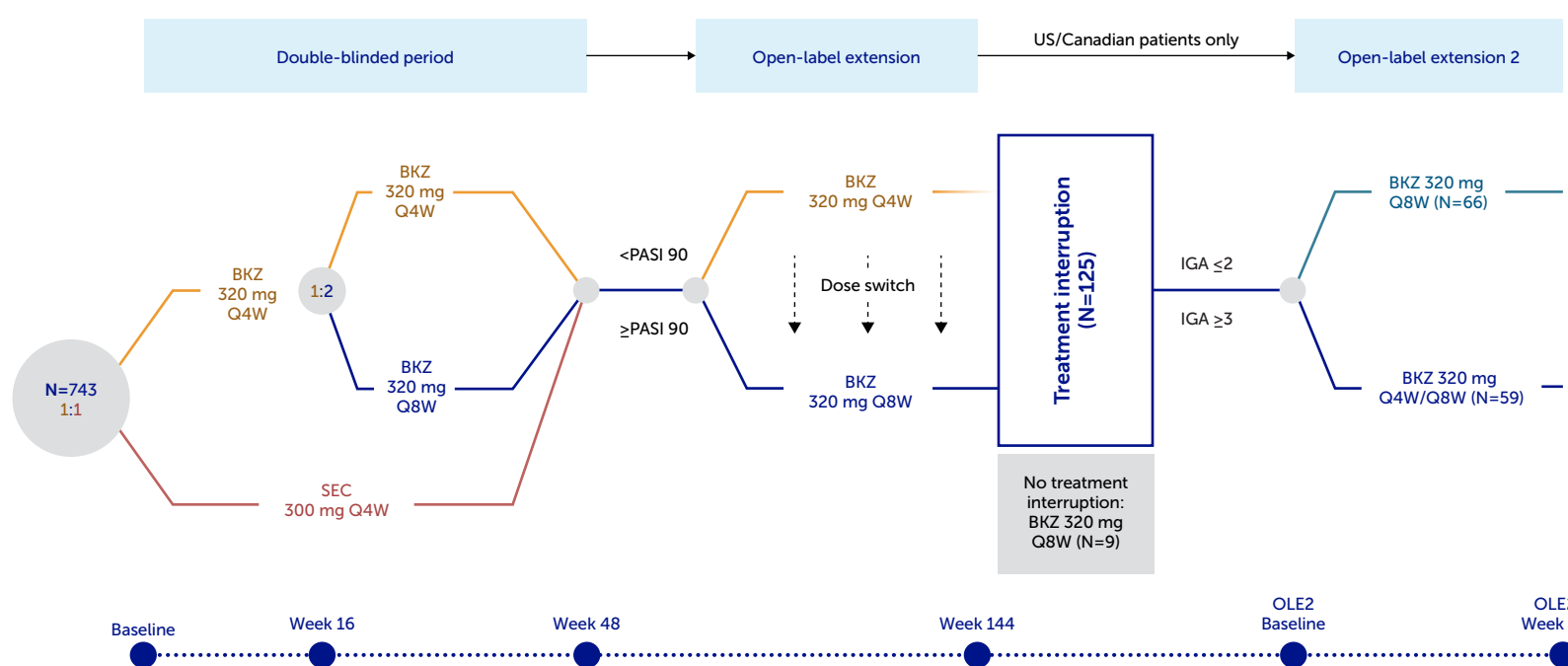
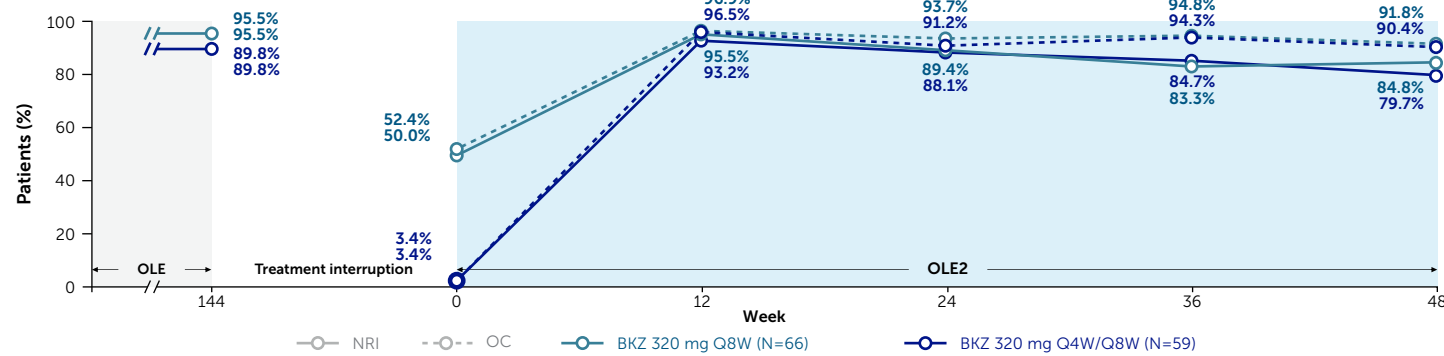


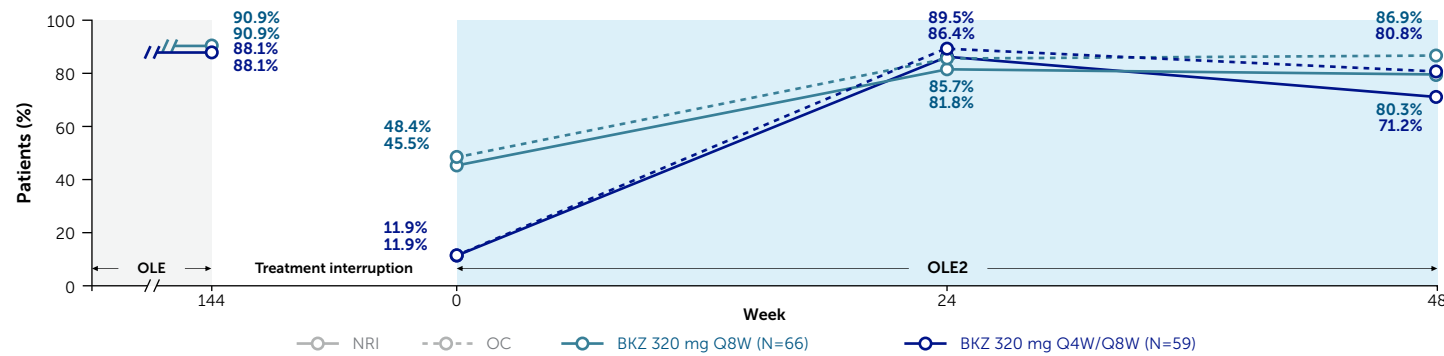
Figure 1 BE RADIANT study design



B) PASI 90



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 are reported using non-responder imputation (NRI) and observed case (OC).

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; kg: kilogram; 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.

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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: **ML, KP, BE, ML, PR, BS, AA, JMLP, MK, DD, MW, RV.** Drafting of the publication, or reviewing it critically for important intellectual content: **ML, KP, BE, ML, PR, BS, AA, JMLP, MK, DD, MW, RV.** Final approval of the publication: **ML, KP, BE, ML, PR, BS, AA, JMLP, MK, DD, MW, RV.** **Author Disclosures:** **ML:** Employee of Mount Sinai and receives research funds from AbbVie, Amgen, Arcutis, Avotres, Boehringer Ingelheim, Cara Therapeutics, Dermavant, Eli Lilly and Company, Incyte, Inozyme, Janssen, Ortho Dermatologics, Pfizer, Sanofi-Regeneron, and UCB; consultant for Almirall, AltruBio, AnaptysBio, Apogee, Arcutis, AstraZeneca, Atommise, Avotres, Brickell Biotech, Boehringer Ingelheim, Bristol Myers Squibb, Castle Biosciences, Celltrion, CorEvitas, Dermavant, EPI, Evmmune, Facilitation of International Dermatology Education, Forte Biosciences, Foundation for Research and Education in Dermatology, Galderma, Genentech, Incyte, LEO Pharma, Meiji Seika Pharma, Mindera, Pfizer, Sanofi-Regeneron, Searegry, Strata, Takeda, Trevi, and Verrica. **KP:** Received honoraria and/or grants from AbbVie, Acelyrin, Akros, Alumis, Amgen, Arcutis, Bausch Health/ Valeant, Boehringer Ingelheim, Bristol Myers Squibb, Can-Fite Biopharma, Celltrion, Concert Pharmaceuticals, Dermavant, Dermira, DICE Pharmaceuticals, DICE Therapeutics, Eli Lilly and Company, Evelo Biosciences, Forbion, Galderma, Horizon Therapeutics, Incyte, Janssen, Kymab, Kyowa Hakko Kirin, LEO Pharma, Meiji Seika Pharma, Mitsubishi Pharma, Nimbus Therapeutics, Novartis, Pfizer, Stone, Sanofi-Aventis/Genzyme, Sandoz, Sun Pharma, Takeda, Tarsus Pharmaceuticals, UCB, and Zai Lab. **BE:** Speaker, consultant and/or receives honoraria/grants from AbbVie, Acelyrin, Actavis, Alkermes, Almirall, Alumis, Amgen, AnaptysBio, Arcutis, Athenex, Boehringer Ingelheim, Bristol Myers Squibb, Concert Pharma, Dermavant Sciences, Eli Lilly and Company, Evelo Biosciences, Evmmune, Incyte, Janssen, Kymab, LEO Pharma, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sanofi Genzyme, Sun Pharma, Takeda, UCB, and Ventyx. **PR:** Principal investigator/clinical trials for AbbVie, Amgen, Arcutis, Bristol Myers Squibb, Dermavant, Eli Lilly and Company, Janssen, Sun Pharma, and UCB. **BS:** Consultant honoraria for AbbVie, Acelyrin, Alkermes, Almirall, Alumis, Amgen, Arcutis, Arena, Aristea, Asana, Boehringer Ingelheim, Bristol Myers Squibb, Capital One, Celltrion, CorEvitas, Dermavant, Eli Lilly and Company, Imagenebio, Janssen, Kangru Pharmaceuticals, LEO Pharma, Maruho, Meiji Seika Pharma, Protagonist, Monte Carlo, Novartis, Pfizer, Rapt, Regeneron, Sanofi-Genzyme, SG Cowen, Sun Pharma, Takeda, UCB, Union Therapeutics, Ventyxio, and VIV Therapeutics; stock options from Connect Biopharma, Mindera Health, speaker for AbbVie, Arcutis, Dermavant, Eli Lilly and Company, Incyte, Janssen, Regeneron, and Sanofi-Genzyme; Scientific Co-Director (consulting fee) for CorEvitas; investigator for CorEvitas; editor-in-chief (honorarium) for Journal of Psoriasis and Psoriatic Arthritis. **AA:** Research investigator and/or scientific advisor for AbbVie, Almirall, Arcutis, ASLAN, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Dermira, Eli Lilly and Company, EPI, Incyte, Janssen, LEO Pharma, Nimbus, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sun Pharma, Sanofi, and UCB. **JMLP, MK, DD, MW:** Employees and shareholders of UCB. **RV:** Grants/research support from AbbVie, Amgen, Centocor, Dermira, Dermavant, Eli Lilly and Company, Galderma, GSK, LEO Pharma, Novartis, Merck, Pfizer, Regeneron, Takeda, and UCB; speakers bureau/honoraria from AbbVie, Actelion, Amgen, Bausch Health, Celgene, Ciphor, Eli Lilly and Company, Galderma, GSK, Janssen, LEO Pharma, Merck, Novartis, Pfizer, and UCB. **Acknowledgements:** 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, UCB, Madrid, Spain for publication coordination, Calum Suggett, MSc, Costello Medical, London, UK, for medical writing and editorial assistance and the Costello Medical Creative team for graphic design assistance. All costs associated with development of this poster were funded by UCB.

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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 $\pm$ 15.0	49.8 $\pm$ 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 $\pm$ 17.9	102.2 $\pm$ 26.7
BMI (kg/m ²), mean $\pm$ SD	31.1 $\pm$ 6.3	33.8 $\pm$ 7.3
Duration of psoriasis (years), mean $\pm$ SD	16.1 $\pm$ 12.3	20.3 $\pm$ 15.5
PASI, mean $\pm$ SD	20.5 $\pm$ 5.8	18.6 $\pm$ 6.4
BSA (%), mean $\pm$ SD	23.7 $\pm$ 14.1	21.6 $\pm$ 13.3
IGA, n (%)		
3: moderate	37 (56.1)	36 (61.0)
4: severe	29 (43.9)	23 (39.0)
DLQI total, mean $\pm$ SD	10.7 $\pm$ 6.9	8.8 $\pm$ 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.

Table 2 Rates of TEAEs in OLE2

	BKZ Total (N=125)	
	n (%)	EAIR/100 PY (95% CI)
Overview of TEAEs		
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*	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*	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 are 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.



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