Bimekizumab efficacy and safety through 96 weeks in patients with moderate to severe plaque psoriasis: Results from the open-label extension period of the BE RADIANT phase 3b trial

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Presentation Number: 34321

OBJECTIVES:

- To assess long-term efficacy of bimekizumab (BKZ) compared to secukinumab (SEC) in patients with psoriasis
- To evaluate safety during the second year of the BE RADIANT phase 3b study
- To compare efficacy of BKZ in patients on continuous BKZ to those who switched from SEC to BKZ

Background:

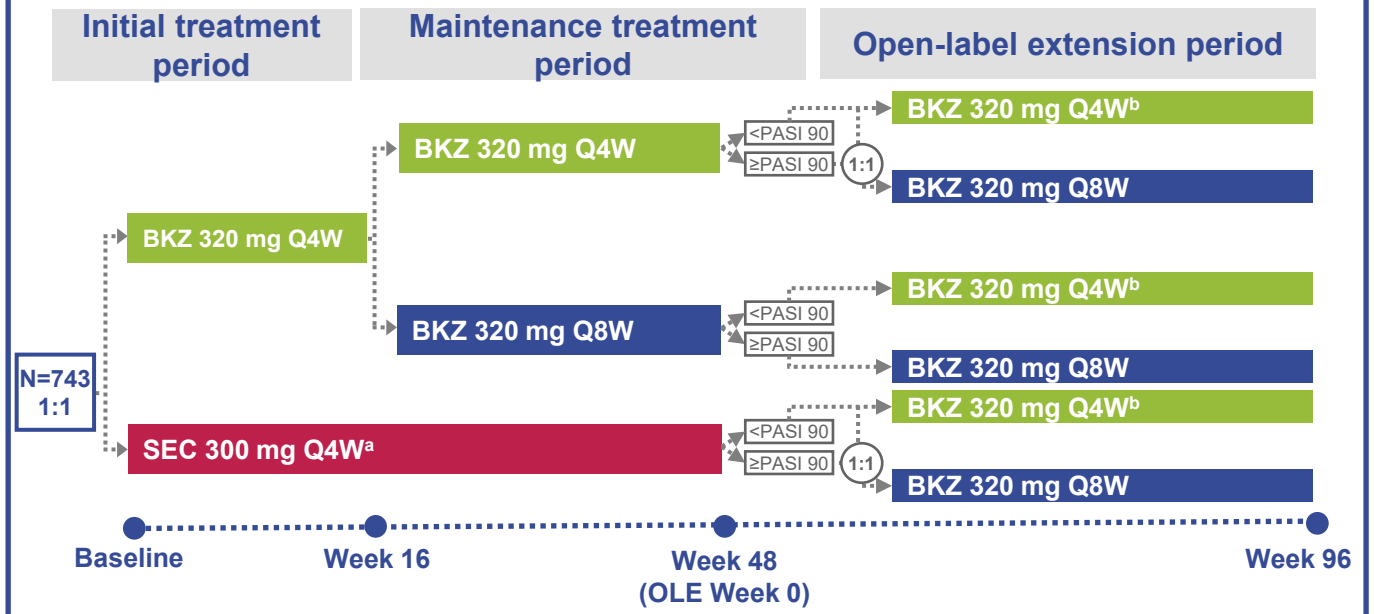
- BKZ is a monoclonal IgG1 antibody which selectively inhibits **interleukin (IL)-17F** in addition to **IL-17A**[1]
- **BE RADIANT** was the first phase 3 study to compare inhibition of IL-17A and IL-17F with inhibition of IL-17A alone[2]
- Patients who completed the 48-week double-blinded study period could enter the **open-label extension (OLE)**

Methods:

- Data are from the ongoing BE RADIANT phase 3b trial, including the OLE period up to Week 96 (OLE Week 48)
- The analyses reported here focus on safety and efficacy in all patients who completed the double-blinded period of the BE RADIANT phase 3b and entered the OLE
- From Week 48, all patients received BKZ 320 mg every 4 weeks (Q4W) or Q8W, based on Week 48 PASI 90 status
- Data are analyzed with BKZ doses pooled
- PASI ≤2 (a key treat to target objective)[3] and PASI 100 (study primary endpoint) responses are reported
- Efficacy data are reported using OC, NRI, and mNRI (patients who discontinued due to lack of efficacy were considered non-responders at subsequent timepoints, multiple imputation was used for other missing data)

1. Adams R et al. Front Immunol 2020;11:1894. **2.** Reich K et al. N Engl J Med 2021;385(2):142–52, NCT03536884. **3.** Mahil SK et al. Br J Dermatol 2020;182(5):1158–66. BKZ: bimekizumab; IL: interleukin; mNRI: modified non-responder imputation; NRI: non-responder imputation; OC: observed case; OLE: open-label extension; PASI 90: ≥90% improvement from baseline in Psoriasis Area and Severity Index; Q4W: every 4 weeks; Q8W: every 8 weeks; SEC: secukinumab.

BE RADIANT Study Design:



Patients included in this analysis:

Randomized to
BKZ Q4W or **SEC**

Entered OLE
BKZ Total[c] → **BKZ Total[c]** (N=336)
SEC → **BKZ Total[c]** (N=318)

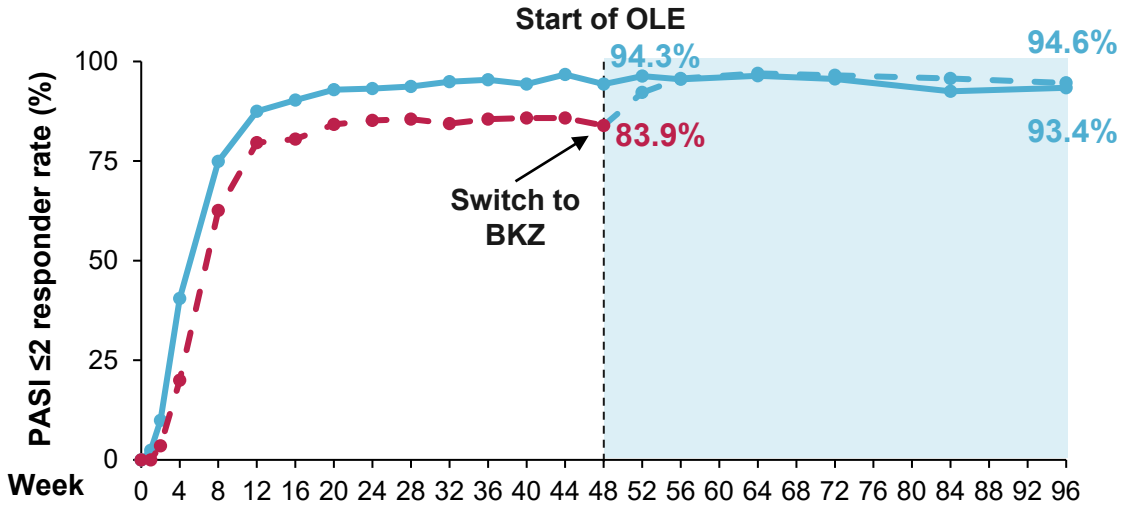
Baseline Characteristics for Patients who Entered the BE RADIANT OLE

	BKZ/BKZ N=336	SEC/BKZ N=318
Age (years), mean ± SD	45.5 ± 14.3	44.5 ± 14.5
Male, n (%)	227 (67.6)	209 (65.7)
Caucasian, n (%)	312 (92.9)	301 (94.7)
Weight (kg), mean ± SD	90.2 ± 21.0	89.1 ± 19.5
Duration of psoriasis (years), mean ± SD	18.4 ± 13.1	17.5 ± 12.1
PASI, mean ± SD	20.3 ± 7.7	19.5 ± 6.1
BSA (%), mean ± SD	25.3 ± 16.0	23.0 ± 13.3
IGA, n (%)		
3: moderate	214 (63.7)	234 (73.6)
4: severe	120 (35.7)	84 (26.4)
DLQI, mean ± SD	10.9 ± 6.7	11.2 ± 7.3
Any prior systemic therapy, n (%)	241 (71.7)	237 (74.5)
Any prior biologic therapy, n (%)	114 (33.9)	105 (33.0)

[a] SEC 300 mg was administered at baseline, Weeks 1, 2, 3 and 4, then Q4W for the remainder of the double-blinded treatment period; [b] Following a protocol amendment, all patients receiving BKZ 320 mg Q4W in the open-label extension period were switched to BKZ 320 mg Q8W at the next scheduled clinic visit on or after the Week 64 visit; [c] BKZ total includes both BKZ Q4W and BKZ Q8W treatment arms. BKZ: bimekizumab; BSA: body surface area; DLQI: Dermatology Life Quality Index; IGA: Investigator's Global Assessment; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; Q4W: every 4 weeks; Q8W: every 8 weeks; SD: standard deviation; SEC: secukinumab.

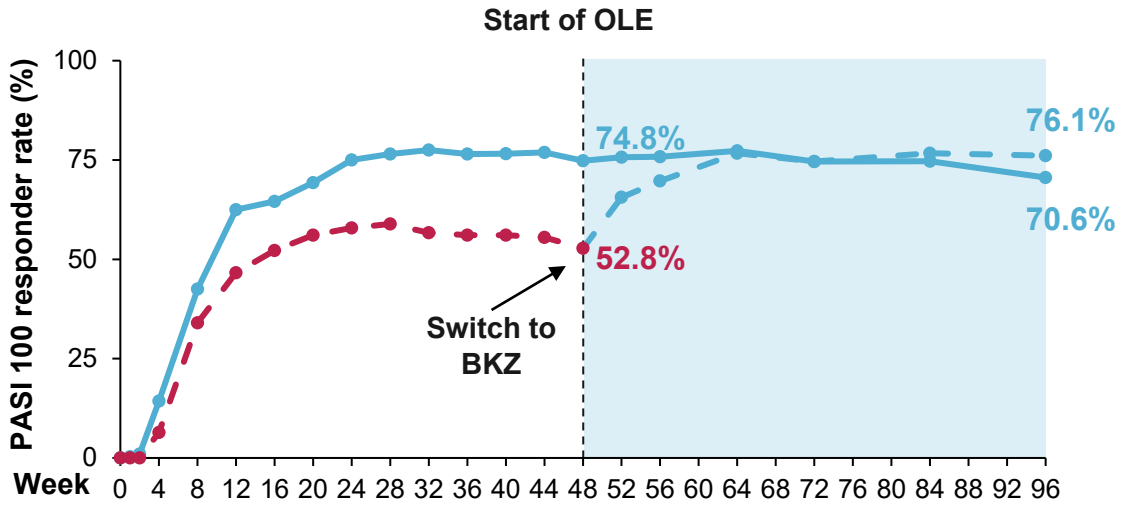
PASI Responses through Week 96 in Patients who Entered the OLE after receiving BKZ or SEC in the Double-Blind Study Period

PASI ≤2 (mNRI[a])



Week		16	48	64	84	96
OC; % (n/N)	BKZ/BKZ	90.4 (300/332)	94.2 (310/329)	96.8 (302/312)	93.9 (295/314)	95.8 (293/306)
	SEC/BKZ	80.4 (254/316)	84.1 (264/314)	97.6 (284/291)	97.9 (279/285)	96.2 (275/286)
mNRI; %	BKZ/BKZ	90.3	94.3	96.4	92.5	93.4
	SEC/BKZ	80.5	83.9	97.0	95.7	94.6
NRI; %	BKZ/BKZ	89.3	92.3	89.3	87.8	87.2
	SEC/BKZ	79.9	83.0	89.9	87.7	86.5

PASI 100 (mNRI[a])



Week		16	48	64	84	96
OC; % (n/N)	BKZ/BKZ	65.1 (216/332)	75.4 (248/329)	80.1 (250/312)	78.3 (246/314)	74.5 (228/306)
	SEC/BKZ	52.2 (165/316)	53.2 (167/314)	80.4 (234/291)	82.1 (234/285)	81.8 (234/286)
mNRI; %	BKZ/BKZ	64.6	74.8	77.3	74.7	70.6
	SEC/BKZ	52.2	52.8	76.7	76.7	76.1
NRI; %	BKZ/BKZ	64.3	73.8	74.4	73.2	67.9
	SEC/BKZ	51.9	52.5	73.6	73.6	73.6

BKZ Total → BKZ Total (N=336)

SEC → BKZ Total (N=318)

[a] mNRI: patients who discontinued due to lack of efficacy were considered non-responders at subsequent timepoints, multiple imputation was used for other missing data. BKZ: bimekizumab; mNRI: modified non-responder imputation; NRI: non-responder imputation; OC: observed case; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; PASI 100: 100% improvement from baseline in PASI; Q4W: every 4 weeks; Q8W: every 8 weeks; SEC: secukinumab.

Incidence of TEAEs through Weeks 48–96 (OLE Weeks 0–48)

	BKZ/BKZ N=336, Total PY=3700 EAIR per 100 PY [95% CI]	SEC/BKZ N=318, Total PY=3470 EAIR per 100 PY [95% CI]
Any TEAE	131.5 [115.5. 149.2]	158.7 [139.4, 180.0]
Serious TEAEs	5.0 [3.0, 7.9]	5.33 [3.2, 8.4]
Discontinuation due to TEAEs	2.2 [0.9, 4.3]	2.9 [1.4, 5.3]
Severe TEAEs	5.6 [3.4, 8.6]	5.0 [2.9, 8.0]
Death	0	0.3 [0.1, 1.6][a]
Most Common TEAEs		
Nasopharyngitis	11.8 [8.5, 16.1]	12.1 [8.6, 16.6]
Oral candidiasis	7.8 [5.1, 11.3]	12.2 [8.6, 16.6]
Urinary tract infection	4.5 [2.6, 7.3]	5.7 [3.4, 8.9]
TEAEs of Interest		
Serious infections	0.81 [0.17, 2.38]	1.45 [0.47, 3.39]
Adjudicated IBD	0	0
Adjudicated SIB	0	0
Malignancies	0.54 [0.07, 1.95]	0
Serious hypersensitivity reactions	0	0.29 [0.01, 1.61]
Adjudicated MACE	0.54 [0.07, 1.96]	0.29 [0.01, 1.61]
Hepatic events	3.58 [1.90, 6.12]	3.21 [1.60, 5.75]
Administration & injection site reactions	1.64 [0.60, 3.56]	2.36 [1.02, 4.64]

- Incidence of serious TEAEs and discontinuation rates were low
- Most oral candidiasis events were mild or moderate; two led to discontinuation in the SEC/BKZ study arm

[a] 1 death occurred due to hepatic pain which was not considered treatment-related. AE: adverse event; BKZ: bimekizumab; CI: confidence interval; EAIR: exposure-adjusted incidence rate; IBD: inflammatory bowel disease; MACE: major adverse cardiac event; OLE: open-label extension; PY: patient years; SEC: secukinumab; SIB: suicidal ideation and behavior; TEAE: treatment-emergent adverse event.

CONCLUSIONS:

- Former SEC-treated patients reached the same level of response as BKZ patients after switch
- Responses in BKZ patients were maintained through Week 96
- Responses improved for patients originally randomized to SEC who switched to BKZ on entering the OLE
- AEs were mostly comparable between patients on continuous BKZ and those who switched from SEC to BKZ during the first 48 weeks of the OLE and were consistent with the 1-year AE rates of BKZ[1]

Disclosures: **BS**: Consultant (honoraria) from AbbVie, Almirall, Amgen, Arcutis, Arena, Aristea, Asana, Boehringer Ingelheim, Immunic Therapeutics, Bristol Myers Squibb, Celgene, Dermavant, Dermira, Eli Lilly, Equillium, GSK, Janssen, LEO Pharma, Meiji Seika Pharma, Mindera, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sanofi Genzyme, Sun Pharma, and UCB Pharma; speaker for AbbVie, Amgen, Eli Lilly, Janssen, and Ortho Dermatologics; Scientific Director (consulting fee) for CorEvitas Psoriasis Registry; investigator for AbbVie, Cara Therapeutics, CorEvitas Psoriasis Registry, Dermavant, Dermira, and Novartis; Editor-in-Chief (honorarium) for Journal of Psoriasis and Psoriatic Arthritis. **CP**: Consulting fees and/or grants from AbbVie, Almirall, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly, GSK, Janssen Cilag, LEO Pharma, Novartis, Pierre Fabre, Pfizer, Sanofi Regeneron, and UCB Pharma. **AB**: Served as a scientific adviser and/or clinical study investigator for AbbVie, Abcentra, Aligos, Almirall, Amgen, Arcutis, Arena, Aslan, Athenex, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, EcoR1, Eli Lilly, Evommune, Forte, Galderma, Incyte, Janssen, Landos, LEO Pharma, Novartis, Pfizer, Rapt, Regeneron, Sanofi Genzyme, Sun Pharma, UCB Pharma, and Vibliome. **DT**: Honoraria for participation on advisory boards, as a speaker and for consultancy from AbbVie, Almirall, Amgen, Biogen-Idec, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, DS Biopharma, Eli Lilly, Galapagos, Janssen, LEO Pharma, Morphosis, Novartis, Pfizer, Regeneron, Samsung, Sandoz-Hexal, Sanofi Genzyme, and UCB Pharma; research grants received from Celgene, LEO Pharma, and Novartis. **BE**: Received research support as funding to Case Western Reserve University from AbbVie, AnaptysBio, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly, Incyte, LEO Pharma, Merck, Menlo, Novartis, Pfizer, Regeneron, Sun Pharma, UCB Pharma, Valeant, and Vanda; Consultant (honoraria) from Arcutis, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly, LEO Pharma, Menlo, Novartis, Pfizer, Sun Pharma, UCB Pharma, and Valeant, and Verrica. **KW**, **VV**, **DD**, **FS**: Employees and shareholders of UCB Pharma. **KE**: Speaker and/or advisor for AbbVie, Almirall, Bristol Myers Squibb, Eli Lilly, Janssen, LEO Pharma, Pfizer, Novartis, Sanofi, and UCB Pharma.

This study was funded by UCB Pharma. We would like to thank the patients and their caregivers in addition to all the investigators and their teams who contributed to this study. The authors acknowledge Susanne Wiegratz, MSc, UCB Pharma, Monheim, Germany, for publication coordination, Natalie Nunez Gomez, MD, UCB Pharma, Brussels, Belgium, for critical review, and Emma Francis-Gregory, BA, Costello Medical, Cambridge, UK for medical writing support and editorial assistance. All costs associated with development of this presentation were funded by UCB Pharma.

1. Reich K et al. N Engl J Med 2021;385(2):142–52, NCT03536884. AE: adverse event; BKZ: bimekizumab; OLE: open-label extension; SEC: secukinumab.