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

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OBJECTIVES:

- Evaluate efficacy of bimekizumab (BKZ) in secukinumab (SEC) responders and non-responders who switched to BKZ after 1 year of SEC treatment
- Assess safety of switching from SEC to BKZ without a washout period

Background:

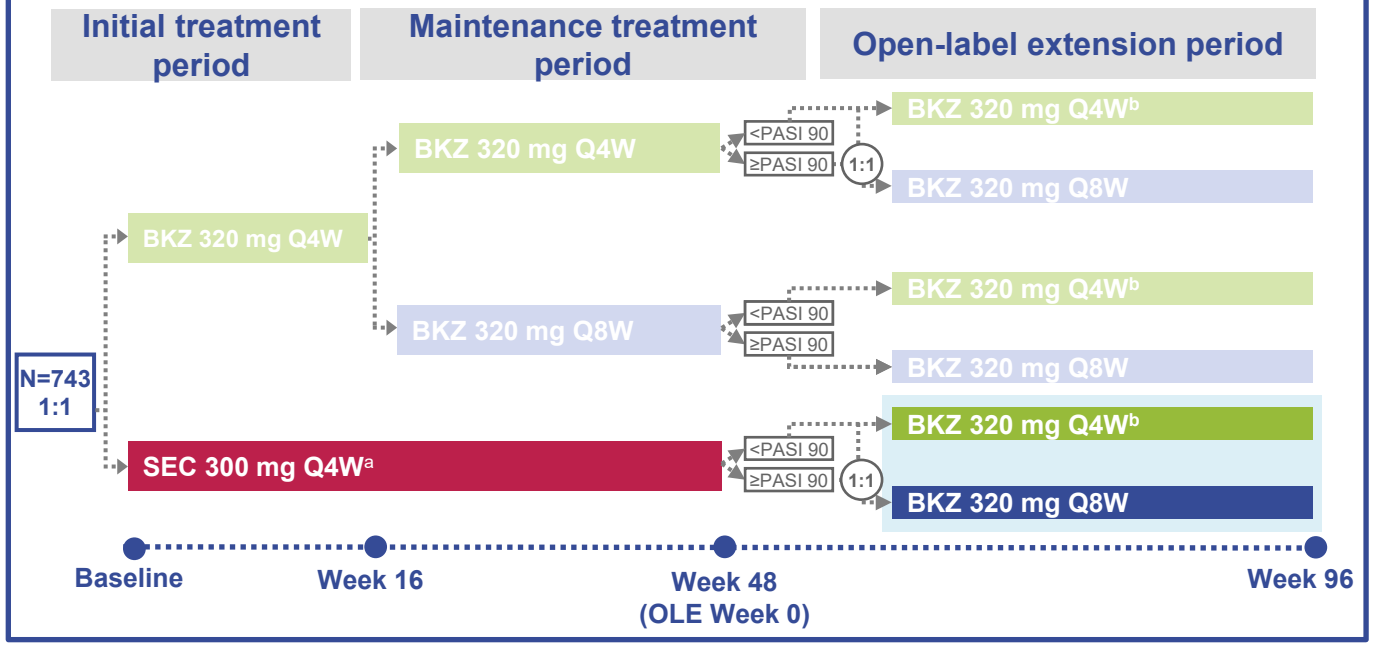
- BKZ is a monoclonal immunoglobulin G1 (IgG1) antibody which selectively inhibits **IL-17F** in addition to **IL-17A**[1]
- The phase 3b **BE RADIANT** study was the first phase 3 study to compare inhibition of IL-17A and IL-17F with inhibition of IL-17A alone[2]
- Patients who completed the 48-week double-blinded study period could enter the **open-label extension (OLE)**

Methods:

- We report data from the ongoing BE RADIANT phase 3b trial including the OLE using cut-off to summarize ≥ Week 96 data
- The analyses reported here focus on SEC-randomized patients who entered the OLE and switched to BKZ every 4 weeks (Q4W) or Q8W dose based on Week 48 PASI 90 response
- Efficacy data are reported using OC, NRI and mNRI[a]

[a] 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. 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 **SEC** in blinded study period **(N=370)**

- Week 48 PASI 90 Non-Responders (N=53)[c] → **BKZ 320mg Q4W**
- Week 48 PASI 90 Responders (N=256)[c] → Randomized 1:1 to **BKZ 320mg Q4W (N=140)** & **BKZ 320mg Q8W (N=116)**

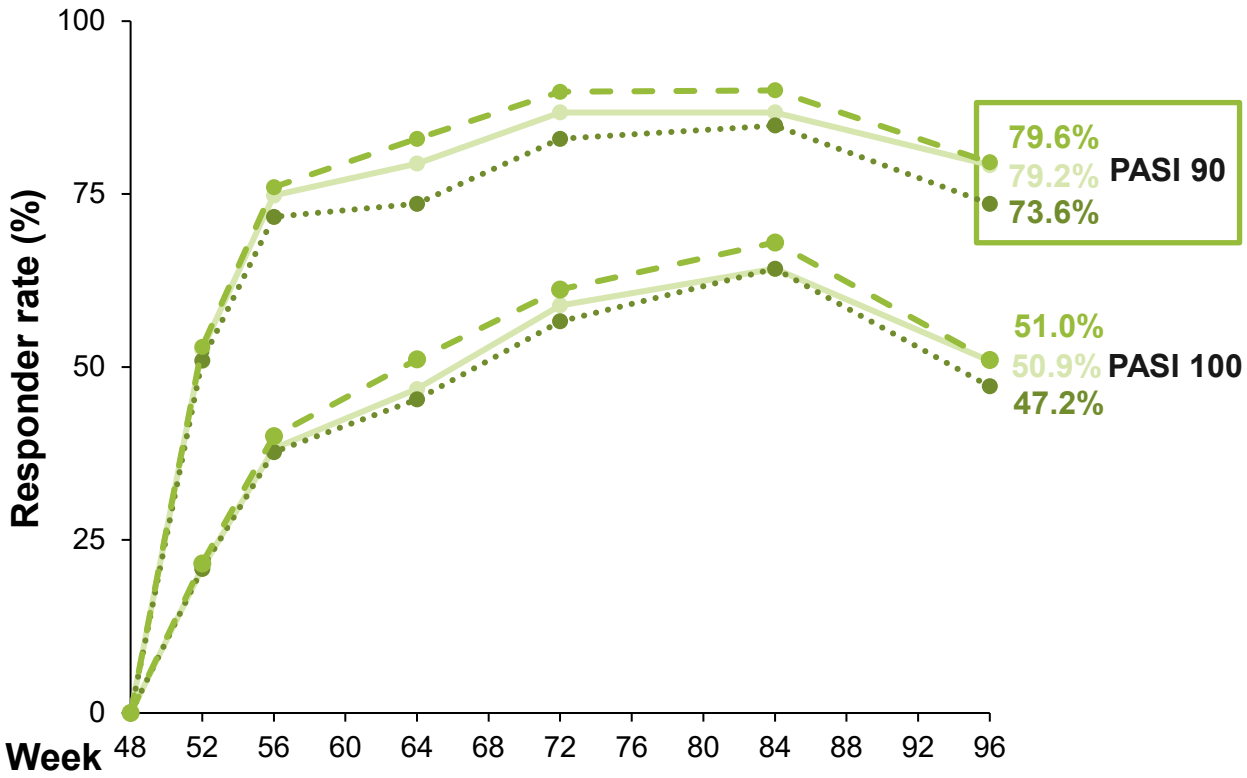
Baseline Characteristics: SEC-Randomized Patients who Entered the OLE

	SEC/BKZ N=318		
	BKZ Q4W N=196	BKZ Q8W N=122	Total N=318
Age (years), mean ± SD	44.7 ± 14.4	44.2 ± 14.6	44.5 ± 14.5
Male, n (%)	134 (68.4)	75 (61.5)	209 (65.7)
Caucasian, n (%)	185 (94.4)	116 (95.1)	301 (94.7)
Weight (kg), mean ± SD	89.9 ± 19.3	87.8 ± 19.8	89.1 ± 19.5
Duration of psoriasis (years), mean ± SD	17.2 ± 12.4	18.0 ± 11.7	17.5 ± 12.1
PASI, mean ± SD	19.5 ± 5.8	19.5 ± 6.7	19.5 ± 6.1
BSA (%), mean ± SD	23.3 ± 13.0	22.6 ± 13.8	23.0 ± 13.3
IGA, n (%)			
3: moderate	145 (74.0)	89 (73.0)	234 (73.6)
4: severe	51 (26.0)	33 (27.0)	84 (26.4)
DLQI total, mean ± SD	11.0 ± 7.2	11.5 ± 7.4	11.2 ± 7.3
Any prior systemic therapy, n (%)	148 (75.5)	89 (73.0)	237 (74.5)
Any prior biologic therapy, n (%)	70 (35.7)	35 (28.7)	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] Patients who were re-randomized incorrectly are not included in this analysis.
BKZ: bimekizumab; BSA: body surface area; DLQI: Dermatology Life Quality Index; IGA: Investigator's Global Assessment; OLE: open-label extension; PASI 90: ≥90% improvement from baseline in Psoriasis Area and Severity Index; Q4W: every 4 weeks; Q8W: every 8 weeks; SD: standard deviation; SEC: secukinumab.

PASI 90 Responses through Weeks 48–96 in Patients Switching from SEC to BKZ upon Entering the OLE at Week 48 (NRI, mNRI, OC)

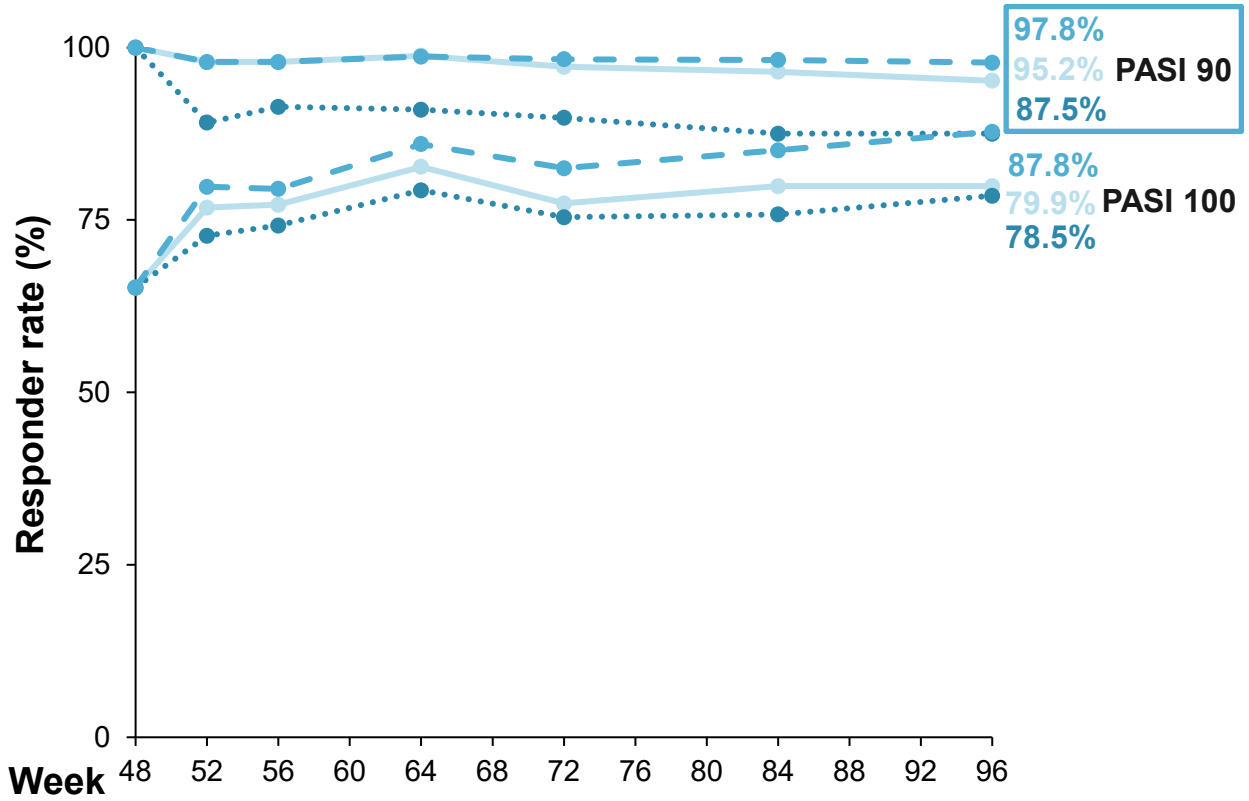
PASI 90/100 in SEC PASI 90 Non-Responders at Week 48



SEC 300 mg → BKZ 320 mg Q4W (N=53)[a]

NRI mNRI OC

PASI 90/100 in SEC PASI 90 Responders at Week 48



SEC 300 mg → BKZ 320 mg Q4W or Q8W (N=256)[a]

NRI mNRI OC

[a] 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. BKZ: bimekizumab; mNRI: modified non-responder imputation; NRI: non-responder imputation; OC: observed case; OLE: open-label extension; PASI 90/100: ≥90/100% improvement from baseline in Psoriasis Area and Severity Index; Q4W: every 4 weeks; Q8W: every 8 weeks; SEC: secukinumab.

Incidence of TEAEs in SEC to BKZ Switchers through Weeks 48–96 (OLE Weeks 0–48)

	Exposure-adjusted incidence rate per 100 PY (95% CI)		
	≤20 weeks[a] from last SEC dose (N=318)	>20 weeks from last SEC dose (N=316)	Total (N=318)
Any TEAE	220.42 (186.56, 258.65)	139.13 (120.60, 159.69)	158.70 (139.37, 179.96)
Serious TEAEs	4.22 (1.15, 10.80)	6.49 (3.71, 10.54)	5.33 (3.16, 8.42)
Discontinuation due to TEAEs	2.10 (0.25, 7.59)	3.20 (1.38, 6.31)	2.90 (1.39, 5.34)
Severe TEAEs	1.05 (0.03, 5.86)	6.49 (3.71, 10.53)	4.99 (2.91, 7.99)
Death	0	0.40 (0.01, 2.22)	0.29 (0.01, 1.61)
Most Common TEAEs			
Nasopharyngitis	28.77 (18.80, 42.16)	6.14 (3.44, 10.13)	12.11 (8.57, 16.63)
Oral candidiasis	13.88 (7.39, 23.73)	12.76 (8.61, 18.21)	12.15 (8.64, 16.61)
Urinary tract infection	8.52 (3.68, 16.80)	5.71 (3.12, 9.57)	5.68 (3.42, 8.87)
TEAEs of Interest			
Serious infections	0	2.01 (0.65, 4.69)	1.45 (0.47, 3.39)
Adjudicated IBD	0	0	0
Adjudicated SIB	0	0	0
Malignancies	1.05 (0.03, 5.85)	0	0.29 (0.01, 1.61)
Serious hypersensitivity reactions	0	0.40 (0.01, 2.22)	0.29 (0.1, 1.61)
Adjudicated MACE	1.05 (0.03, 5.86)	0	0.29 (0.01, 1.61)
Hepatic events	2.11 (0.26, 7.61)	3.62 (1.66, 6.88)	3.22 (1.61, 5.75)

- EAIRs of any TEAEs were slightly higher ≤20 weeks from last SEC dose compared to >20 weeks from last SEC dose, mainly due to AEs related to upper respiratory tract infections; these were non-serious and considered non-clinically relevant
- Incidence of nasopharyngitis during the ≤20 weeks from last SEC dose period was comparable with that previously reported for BKZ trials (EAIR of 23.8 across phase 2 and 3 trials for all BKZ doses)[1]
- Weeks 48–96 of this study aligned with the global pandemic which introduced confounding factors, such as social distancing, mask-wearing, and self-isolation, according with local guidelines, which may have resulted in the reduced rates of nasopharyngitis observed in the later period of this study, although it is difficult to draw definitive conclusions

[a] 20 weeks is equivalent to 5 SEC half-lives[2]. **1.** Reich K et al. AAD 2021; Poster Presentation: Abstract 27468; **2.** Frieder J et al. Ther Adv Chronic Dis 2018;9(1):5–21. AE adverse event; BKZ: bimekizumab; CI: confidence interval; IBD: inflammatory bowel disease; MACE: major adverse cardiac event; OLE: open-label extension; PY: patient years; SEC: secukinumab; SIB: suicidal ideation and behaviour; TEAE: treatment-emergent adverse event.

CONCLUSIONS:

- SEC Week 48 PASI 90 non-responders demonstrated rapid, substantial and sustained improvements in PASI 90/PASI 100 response after switching to BKZ
- Among SEC Week 48 PASI 90 responders, PASI 90 response was sustained, and PASI 100 response increased after switching
- There were no unexpected safety findings in patients who switched from SEC to BKZ without washout

Disclosures: **ML**: Employee of Mount Sinai and receives research funds from Abbvie, Amgen, Arcutis, Avotres, Boehringer Ingelheim, Dermavant Sciences, Eli Lilly, Incyte, Janssen Research & Development, LLC, Ortho Dermatologics, Regeneron, and UCB Pharma, and is a consultant for Aditum Bio, Almirall, AltruBio Inc., AnaptysBio, Arcutis, Inc., Aristea Therapeutics, Arrive Technologies, Avotres Therapeutics, BiomX, Boehringer Ingelheim, Bristol Myers Squibb, Cara Therapeutics, Castle Biosciences, Corrona, Dermavant Sciences, Dr. Reddy's Laboratories, Evelo Biosciences, Evommune, Inc., Facilitatation of International Dermatology Education, Forte Biosciences, Foundation for Research and Education in Dermatology, Helsinn Therapeutics, Hexima Ltd., LEO Pharma, Meiji Seika Pharma, Mindera, Pfizer, Seanergy, and Verrica. **KG**: Received grants, consulting fees, and/or speaker's fees from AbbVie, Almirall, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly, Janssen-Cilag, LEO Pharma, Medac, Novartis, Pfizer, Roche, and UCB Pharma. **BS**: Consultant (honoraria): AbbVie, Almirall, Amgen, Arcutis, Arena, Aristea, Asana, Boehringer Ingelheim, Immunic Therapeutics, Bristol Myers Squibb, Connect Biopharma, Dermavant, EPI Health, Equillium, Evelo Biosciences, Janssen, LEO Pharma, Eli Lilly, Maruho, Meiji Seika Pharma, Mindera Health, Novartis, Pfizer, UCB Pharma, Sun Pharma, Regeneron, Sanofi-Genzyme, Ventyxbio, vTv Therapeutics; Stock Options: Connect Biopharma, Mindera Health; Speaker: AbbVie, Eli Lilly, Janssen, Regeneron, Sanofi-Genzyme; Scientific Co-Director (consulting fee): CorEvitas (formerly Corrona) Psoriasis Registry; Investigator: Dermavant, AbbVie, CorEvitas Psoriasis Registry, Dermira, Cara, Novartis; Editor-in-Chief (honorarium): Journal of Psoriasis and Psoriatic Arthritis. **KE**: Speaker and/or advisor for AbbVie, Almirall, Bristol Myers Squibb, Eli Lilly, Janssen, LEO Pharma, Pfizer, Novartis, Sanofi, and UCB Pharma. **JC**: Advisor for AbbVie, Amgen, Bristol Myers Squibb, Eli Lilly, and Sanofi Genzyme; speaker for AbbVie, Amgen, and Eli Lilly; clinical trials performed for AbbVie, Amgen, Bristol Myers Squibb, Celgene, ChemoCentryx, Eli Lilly, Galderma, Janssen, LEO Pharma, Menlo Therapeutics, Sun Pharma, and UCB Pharma; consultant for Dermavant. **MW**, **CC**, **DD**: Employees and shareholders of UCB Pharma. **FS**, **NNG**: Employees of UCB Pharma. **LP**: Received consultancy/speaker's honoraria from and/or participated in trials sponsored by AbbVie, Almirall, Amgen, Baxalta, Biogen, Boehringer Ingelheim, Celgene, Eli Lilly, Gebro, Janssen, JS BIOCAD, LEO Pharma, Merck-Serono, MSD, Mylan, Novartis, Pfizer, Regeneron, Roche, Samsung-Bioepis, Sandoz, Sanofi Genzyme, and UCB Pharma.

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