Bimekizumab efficacy through 96 weeks in patients with moderate to severe plaque psoriasis: Patient-reported outcomes from the BE RADIANT phase 3b trial

Georgios Kokolakis,[1] Richard G. Langley,[2] Alice B. Gottlieb,[3] Matthias Augustin,[4] Nina Magnolo,[5] Boni Elewski,[6] Ronald Vender,[7] Anna López Ferrer,[8] Rhys Warham,[9,10] Susanne Wiegratz,[11] Valerie Ciaravino,[12] Steven R. Feldman[13]

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Objectives

Evaluate the proportion of patients with a score of 0 for the itching, skin pain, and scaling items of the Psoriasis Symptoms and Impacts Measure (P-SIM), or a score of 0/1 in the Dermatology Life Quality Index (DLQI) in patients with moderate to severe plaque psoriasis treated with bimekizumab (BKZ) for up to two years.

Introduction

- Psoriasis can greatly reduce patients' quality of life, however patient experiences may not be fully captured by objective psoriasis severity measures.[1]
- It is therefore important to measure patient-reported outcomes (PROs) alongside clinical parameters.[2]
- Two-year outcomes from the BE RADIANT (NCT03536884) phase 3b trial of BKZ showed high levels of skin clearance in patients with moderate to severe plaque psoriasis.[3]
- The P-SIM is a reliable and well-defined PRO measure developed to capture key symptoms and impacts of psoriasis.[2]
- Here, PROs over 96 weeks of BE RADIANT are reported.

Materials and Methods

- BE RADIANT comprises a 48-week double-blinded period, with patients randomised to BKZ or secukinumab (SEC), followed by an ongoing open-label extension (OLE) in which all patients receive BKZ (**Figure 1**).[4]
- We report proportions of patients with scores of 0 (no symptom, scored 0–10) on P-SIM itching, skin pain, and scaling items, and 0 or 1 on the DLQI (no effect of skin disease on a patient's life, scored 0–30).
- Missing data were imputed via modified non-responder imputation (mNRI): patients who discontinued study treatment due to lack of efficacy were considered non-responders at subsequent timepoints; multiple imputation was used for other missing data. Non-responder imputation (NRI) and observed case (OC) data are reported in **Table 2**.

Results

- Of the 743 patients who entered BE RADIANT, 336 BKZ- and 318 SEC-randomised patients entered the OLE.
- Mean baseline P-SIM and DLQI scores were similar for patients randomised to BKZ and SEC (**Table 1**).
- Baseline P-SIM=0 rates were higher for the skin pain P-SIM item than for itching or scaling for both BKZ- and SEC-randomised patients (**Table 1**).
- Baseline P-SIM=0 and DLQI 0/1 rates were consistent across BKZ-and SEC-randomised patients, although baseline skin pain P-SIM=0 rates were slightly higher in patients randomised to BKZ (**Figure 2**; **Table 2**).
- At Week 48, BKZ-randomised patients had increased P-SIM=0 and DLQI 0/1 rates versus SEC-randomised patients (**Figure 2**; **Table 2**).
- High P-SIM=0 rates were maintained through to Week 96 for continuous BKZ-treated patients; SEC-randomised patients had higher or maintained rates after switching to BKZ (**Figure 2A–C**; **Table 2**).
- High DLQI 0/1 rates were maintained to Week 96 for BKZ-randomised patients; Week 96 rates in those who switched from SEC to BKZ were consistent with Week 48 (**Figure 2D**; **Table 2**).

Summary

The Psoriasis Symptoms and Impacts Measure (P-SIM) is a **reliable, well-defined patient-reported outcome measure** developed to **capture key signs, symptoms and impacts of psoriasis**.[2]

Three **P-SIM items and the DLQI were scored** by patients at baseline and at specific timepoints.

A **P-SIM score of 0 indicates no symptom**, and a **DLQI score of 0/1 indicates no effect of a skin disease on a patient's life**.

At Week 48, BKZ-treated patients reported higher rates of no itching, no skin pain, and no scaling, and DLQI 0/1 versus SEC-treated patients; high rates were sustained through to Week 96.

Patients who switched from SEC to BKZ had improved or maintained P-SIM=0 and DLQI 0/1 rates, consistent with patients who received continuous BKZ.

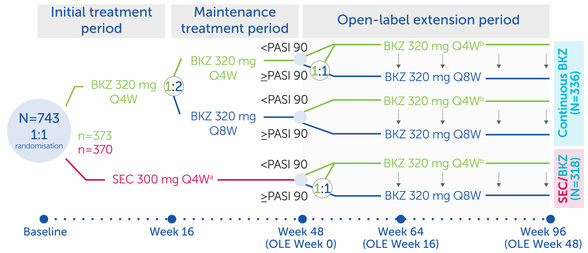
Table 1 Baseline characteristics

	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
BMI (kg/m²), n (%)		
<25	77 (22.9)	73 (23.0)
25–< 30	110 (32.7)	108 (34.0)
≥30	149 (44.3)	137 (43.1)
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)
P-SIM score, mean ± SD		
Itching	6.6 ± 2.8	6.6 ± 2.7
Skin pain	4.5 ± 3.3	4.6 ± 3.1
Scaling	6.7 ± 2.5	6.7 ± 2.4
DLQI, mean ± SD	10.9 ± 6.7	11.2 ± 7.3
History of psoriatic arthritis, n (%)	54 (16.1)	59 (18.6)
Any prior systemic therapy, n (%)	241 (71.7)	237 (74.5)
Any prior biologic therapy, n (%)	114 (33.9)	105 (33.0)
Prior anti-IL-17 therapy	36 (10.7)	47 (14.8)
Prior anti-IL-12/23 therapy	23 (6.8)	15 (4.7)
Prior anti-IL-23 therapy	21 (6.3)	20 (6.3)

Data presented are for patients who entered the OLE only.

BKZ: bimekizumab; **BMI:** body mass index; **BSA:** body surface area; **DLQI:** Dermatology Life Quality Index; **IGA:** Investigator's Global Assessment; **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; **PRO:** patient-reported outcome; **P-SIM:** Psoriasis Symptoms and Impacts Measure; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks; **SD:** standard deviation; **SEC:** secukinumab.

Figure 1 BE RADIANT study design



[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 OLE period switched to BKZ 320 mg Q8W at the next scheduled clinic visit on or after the Week 64 visit. In this analysis, BKZ Q4W and Q8W treatment arms are pooled.

Figure 2 Percentages of patients with no symptoms in the itching, skin pain, and scaling items of the P-SIM, and no effect of skin disease on a patient's life in the DLQI (mNRI)

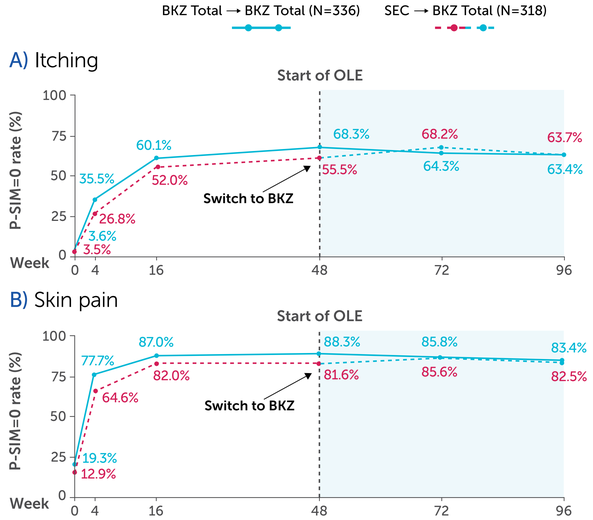
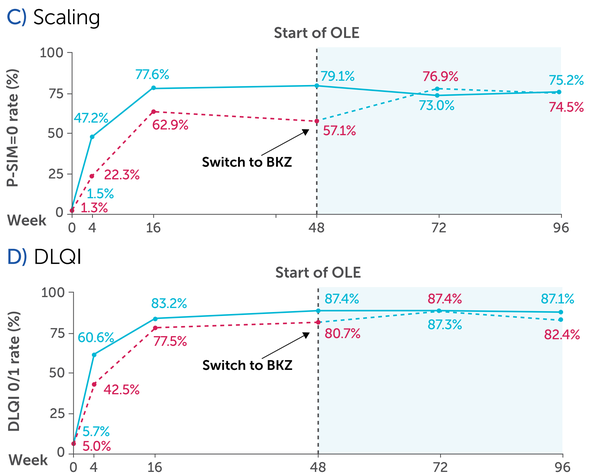


Table 2 P-SIM=0 and DLQI 0/1 rates through Weeks 0–96 of BE RADIANT (NRI, OC)

	BKZ/BKZ (N=336)		SEC/BKZ (N=318)	
	NRI n (%)	OC n/N (%)	NRI n (%)	OC n/N (%)
Itching P-SIM=0				
Baseline	12 (3.6)	12/336 (3.6)	11 (3.5)	11/318 (3.5)
Week 48	225 (67.0)	225/327 (68.8)	175 (55.0)	175/313 (55.9)
Week 72	209 (62.2)	209/318 (65.7)	209 (65.7)	209/297 (70.4)
Week 96	201 (59.8)	201/307 (65.5)	193 (60.7)	193/287 (67.2)
Skin pain P-SIM=0				
Baseline	65 (19.3)	65/336 (19.3)	41 (12.9)	41/318 (12.9)
Week 48	290 (86.3)	290/327 (88.7)	257 (80.8)	257/313 (82.1)
Week 72	279 (83.0)	279/318 (87.7)	261 (82.1)	261/297 (87.9)
Week 96	265 (78.9)	265/307 (86.3)	246 (77.4)	246/287 (85.7)
Scaling P-SIM=0				
Baseline	5 (1.5)	5/336 (1.5)	4 (1.3)	4/318 (1.3)
Week 48	260 (77.4)	260/327 (79.5)	180 (56.6)	180/313 (57.5)
Week 72	237 (70.5)	237/318 (74.5)	234 (73.6)	234/297 (78.8)
Week 96	239 (71.1)	239/307 (77.9)	225 (70.8)	225/287 (78.4)
DLQI 0/1				
Baseline	19 (5.7)	19/336 (5.7)	16 (5.0)	16/318 (5.0)
Week 48	287 (85.4)	287/327 (87.8)	255 (80.2)	255/313 (81.5)
Week 72	281 (83.6)	281/317 (88.6)	263 (82.7)	263/293 (89.8)
Week 96	274 (81.5)	274/306 (89.5)	247 (77.7)	247/287 (86.1)



Data presented are for patients who entered the OLE only.

Institutions: [1]Psoriasis Research and Treatment Center, Department of Dermatology, Venereology and Allergology, Charité–Universitätsmedizin Berlin, Corporate member of Freie Universität Berlin and Humboldt-Universität zu Berlin, Berlin, Germany; [2]Dalhousie University, Halifax, Nova Scotia, Canada; [3]Department of Dermatology, The Icahn School of Medicine, Mount Sinai, New York, New York, USA; [4]Institute for Health Services Research in Dermatology and Nursing (IVDP), University Medical Center Hamburg-Eppendorf (UKE), Hamburg, Germany; [5]Department of Dermatology, University Hospital Münster, Münster, Germany; [6]Department of Dermatology, University Hospitals of Cleveland, Case Western Reserve University, Cleveland, Ohio, USA; [7]Dermatrials Research Inc., Hamilton, Ontario, Canada; [8]Department of Dermatology, Hospital de la Santa Creu i Sant Pau, Barcelona, Spain; [9]Veramed, London, UK; [10]UCB Pharma, Monheim, Germany; [11]UCB Pharma, Slough, UK; [12]UCB Pharma, Colombes, France; [13]Wake Forest School of Medicine, Winston-Salem, North Carolina, USA.

References: [1]Augustin M et al. Expert Rev Pharmacoecon Outcomes Res 2014;14:559–65; [2]Warren RB et al. Dermatol Ther (Heidelb) 2021;11:1551–69; [3]Strober B et al. Presented at AAD 2022, poster 34321 [4]Reich K et al. N Engl J Med 2021;385:142–52.

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Conclusions

High levels of PRO responses to BKZ were maintained to Week 96.

SEC-treated patients who switched to BKZ at Week 48 maintained high DLQI 0/1 rates to Week 96; P-SIM=0 rates were maintained or improved, reaching similar levels to BKZ-randomised patients at Week 96.