Bimekizumab versus secukinumab for the treatment of nail psoriasis in patients with moderate to severe plaque psoriasis: Results from the BE RADIANT phase 3b trial

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OBJECTIVES:

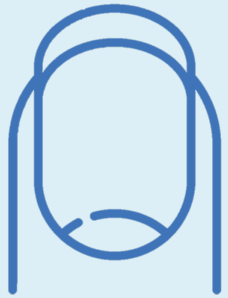
- Compare the efficacy of bimekizumab (BKZ) versus secukinumab (SEC) through 48 weeks for the treatment of nail psoriasis, including complete nail clearance, in patients with moderate to severe plaque psoriasis who had moderate to severe nail involvement at baseline
- Compare modified Nail Psoriasis Severity Index (mNAPSI) sub-score complete clearance rates at Week 16 and Week 48 in patients treated with BKZ versus SEC

Background:

- Psoriatic lesions in highly visible areas, including the nails, disproportionately affect patients' health-related quality of life[1]
- Here, we assessed **mNAPSI** total scores and **mNAPSI sub-scores** among patients with **baseline mNAPSI >10** in the BE RADIANT phase 3b trial[2]

mNAPSI[a]

Each nail is scored as follows:



0–3 for:
- Onycholysis/oil drop dyschromia
- Nail plate crumbling
- Pitting

0 (no) or 1 (yes) for:
- Leukonychia
- Nail bed hyperkeratosis
- Splinter hemorrhages
- Reds spots in lunula

mNAPSI is the sum of the scores for all nails (range: 0–130, 0 indicates clear nails)

[a] The mNAPSI has demonstrated superior interrater variability and correlations with patient and physician global assessments versus the NAPSI.[3]

1. Augustin M et al. Br J Dermatol 2019;181(2):358–65; **2.** Reich K et al. N Engl J Med 2021;385(2):142–52, NCT03536884. **3.** Kaeley G et al. J Rheum 2021;48(8):1208–20. BKZ: bimekizumab; mNAPSI: modified Nail Psoriasis Severity Index; NAPSI: Nail Psoriasis Severity Index; SEC: secukinumab.

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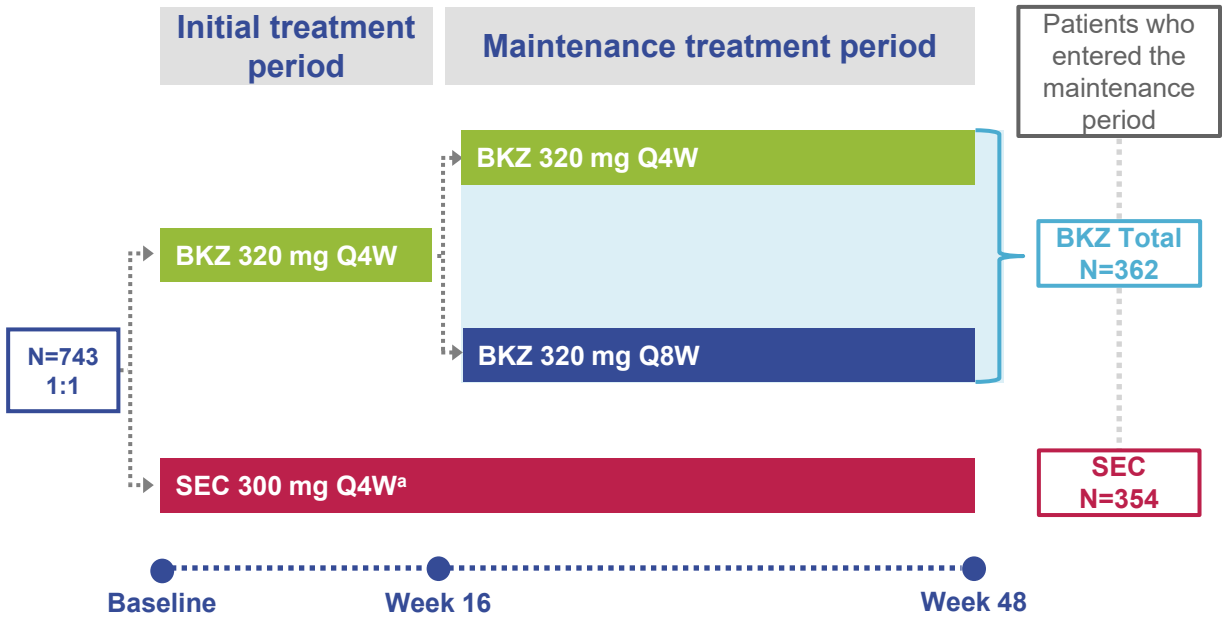
BE RADIANT Study Design[1]



Methods:

- mNAPSI scores (total and sub-scores) are reported for BKZ- and SEC-randomized patients who had baseline **mNAPSI >10 and entered the maintenance period (N=116 BKZ Total; N=99 SEC)**
- Results for BKZ-treated patients are reported as **BKZ Total**, comprising all patients who received ≥1 BKZ dose in the maintenance period (combined **Q4W/Q4W** and **Q4W/Q8W** groups)
- Missing data were handled using non-responder imputation (NRI). Modified non-responder imputation (mNRI) and observed cases (OCs) are also reported

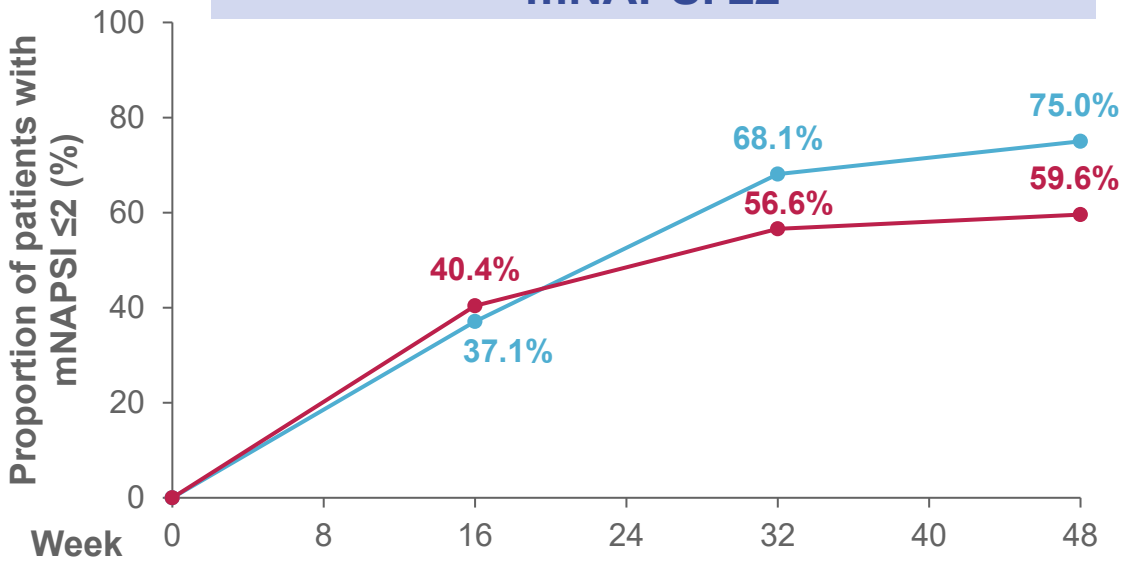
Baseline Characteristics: Included Patients

	BKZ Total[b] N=116	SEC N=99
Age (years), mean ± SD	45.7 ± 14.0	43.9 ± 12.8
Male, n (%)	94 (81.0)	81 (81.8)
White, n (%)	109 (94.0)	97 (98.0)
Weight (kg), mean ± SD	93.0 ± 21.0	90.5 ± 17.9
Duration of psoriasis (years), mean ± SD	20.1 ± 14.3	17.3 ± 10.6
PASI, mean ± SD	21.8 ± 8.9	20.4 ± 6.3
BSA (%), mean ± SD	27.4 ± 18.3	23.4 ± 12.7
IGA, n (%)		
3: moderate	60 (51.7)	71 (71.7)
4: severe	55 (47.4)	28 (28.3)
DLQI, mean ± SD	10.6 ± 6.7	12.3 ± 7.5
mNAPSI, mean ± SD	28.5 ± 17.9	29.6 ± 20.6
Onycholysis/oil drop dyschromia	9.0 ± 7.5	9.1 ± 7.3
Nail plate crumbling	4.4 ± 6.4	4.1 ± 6.0
Pitting	8.4 ± 7.0	8.4 ± 7.3
Leukonychia	2.0 ± 2.9	2.9 ± 3.6
Nail bed hyperkeratosis	2.4 ± 3.2	2.8 ± 3.8
Splinter hemorrhages	1.6 ± 2.5	1.5 ± 2.5
Red spots in lunula	0.6 ± 1.7	0.7 ± 2.2
Any prior systemic therapy, n (%)	87 (75.0)	79 (79.8)
Any prior biologic therapy, n (%)	45 (38.8)	42 (42.4)

[a] SEC was dosed 300 mg weekly until Week 4, then Q4W for the remainder of the double-blinded treatment period; [b] Data were pooled for all patients who received ≥1 BKZ dose at Week 16 or later (BKZ Total). BKZ Total included all patients treated with BKZ Q4W/Q4W (n=42) and patients treated with BKZ Q4W/Q8W (n=74) combined. **1.** Reich K et al. N Engl J Med 2021;385(2):142–52. BKZ: bimekizumab; BSA: body surface area; DLQI: Dermatology Life Quality Index; IGA: Investigator's Global Assessment; mNAPSI: modified Nail Psoriasis Severity Index; NRI: non-responder imputation; OC: observed case; PASI: Psoriasis Area and Severity Index; Q4W: every 4 weeks; Q8W: every 8 weeks; SD: standard deviation; SEC: secukinumab.

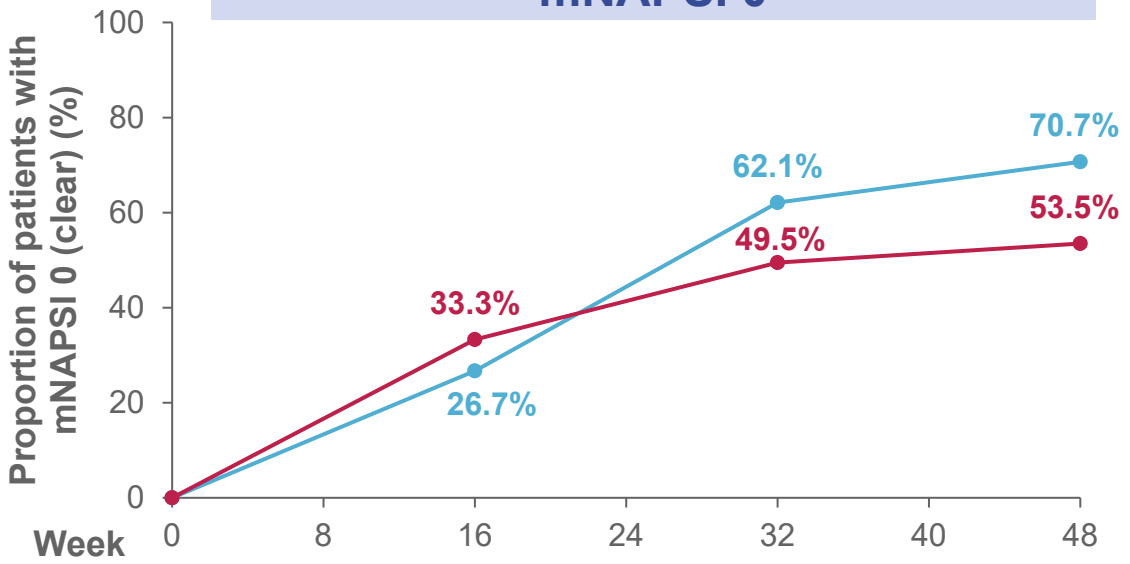
mNAPSI ≤2 and mNAPSI 0 Through Week 48 in Patients with Baseline mNAPSI >10 (NRI)

mNAPSI ≤2



Week		16	32	48
OC; % (n/N)	BKZ Total	37.7 (43/114)	70.5 (79/112)	81.3 (87/107)
	SEC	40.4 (40/99)	60.9 (56/92)	67.8 (59/87)
mNRI;[a] %	BKZ Total	37.6	70.3	78.6
	SEC	40.4	59.3	66.2
NRI; %	BKZ Total	37.1	68.1	75.0
	SEC	40.4	56.6	59.6

mNAPSI 0

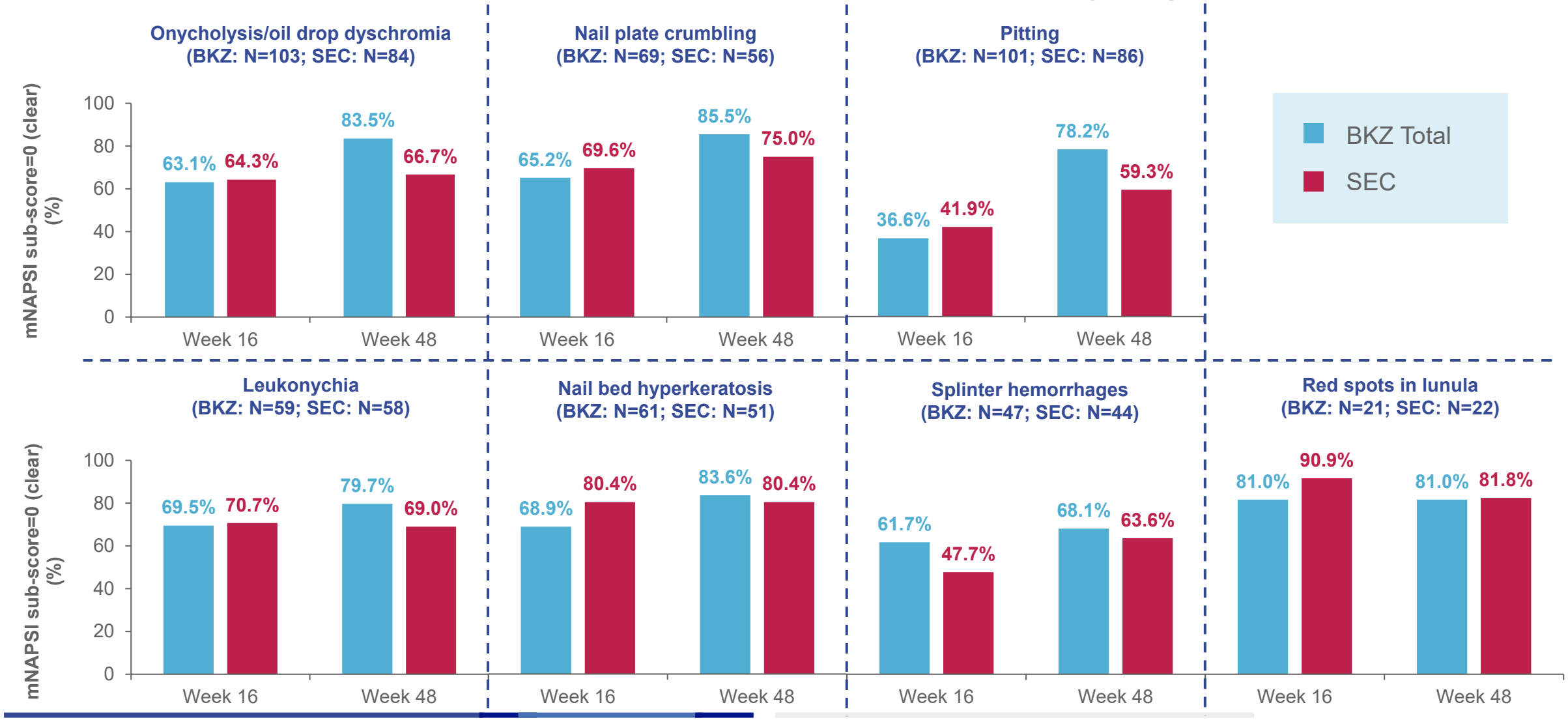


Week		16	32	48
OC; % (n/N)	BKZ Total	27.2 (31/114)	64.3 (72/112)	76.6 (82/107)
	SEC	33.3 (33/99)	53.3 (49/92)	60.9 (53/87)
mNRI;[a] %	BKZ Total	27.1	63.5	73.5
	SEC	33.3	51.5	58.1
NRI; %	BKZ Total	26.7	62.1	70.7
	SEC	33.3	49.5	53.5

BKZ Total (N=116) SEC (N=99)

Only patients with mNAPSI >10 at baseline and who entered the maintenance period of BE RADIANT were included in this analysis. A score of 0 indicates clear nails. [a] For mNRI, patients who discontinued study treatment due to lack of efficacy or adverse events deemed treatment-related by investigators were considered non-responders at subsequent timepoints; multiple imputation was used for all other missing data; BKZ: bimekizumab; mNAPSI: modified Nail Psoriasis Severity Index; mNRI: modified non-responder imputation; NRI: non-responder imputation; OC: observed case; SEC: secukinumab.

Complete Clearance of mNAPSI Sub-Scores at Week 16 and Week 48 in Patients With Baseline mNAPSI >10 and Sub-Score >0 (NRI)



Only patients with mNAPSI >10 at baseline and who entered the maintenance period of BE RADIANT were included in this analysis. A score of 0 indicates clear nails. BKZ: bimekizumab; mNAPSI: modified Nail Psoriasis Severity Index; NRI: non-responder imputation; SEC: secukinumab.

CONCLUSIONS:

- Complete nail clearance (mNAPSI=0) was achieved in numerically higher proportions of BKZ-treated patients than SEC-treated patients by Week 48
- At Week 48, BKZ-treated patients showed numerically higher rates of complete clearance for all mNAPSI sub-scores compared with SEC-treated patients, with the exception of red spots in lunula

Author Contributions: Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **KE, ABG, SP, SB, MG, BK, NT, CM, SW, DdC, BE**; Drafting of the publication or revising it critically for important intellectual content: **KE, ABG, SP, SB, MG, BK, NT, CM, SW, DdC, BE**; Final approval of the publication: **KE, ABG, SP, SB, MG, BK, NT, CM, SW, DdC, BE**.
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