Bimekizumab response in the nail matrix and nail bed through 3 years in patients with moderate to severe plaque psoriasis

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P2530

Objective

To evaluate bimekizumab (BKZ) efficacy in resolving nail psoriasis in both the nail matrix and nail bed over 3 years in patients with moderate to severe plaque psoriasis.

Introduction

- Nail psoriasis, in particular in the **matrix**, is a key risk factor for progression to psoriatic arthritis (PsA) due to its anatomical connection to the musculoskeletal system.[1]
- Early, targeted treatment of nail psoriasis is therefore important to help prevent PsA progression by reducing inflammation of the entheseal complex.[1,2]
- Clinical responses to treatment in the **nail matrix** may also be slower than in the **nail bed**, as resolution requires nail outgrowth.[2]
- BKZ, an interleukin (IL)-17A and IL-17F inhibitor,[3] has previously shown a beneficial effect on key risk factors associated with increased risk of progression to PsA. In addition to achieving complete scalp and nail clearance over 2 years of treatment, BKZ has demonstrated sustained skin clearance in patients with risk factors for progression to PsA at baseline.[4,5]
  - Additionally, BKZ achieved higher rates of concurrent skin and nail clearance over comparator-controlled periods versus adalimumab, ustekinumab, and secukinumab.[6]
- However, BKZ efficacy specifically within the **nail matrix** or **nail bed** has not been reported.

Methods

- Data were pooled from the 52-week BE VIVID and 56-week BE SURE and BE READY phase 3 trials, 96 weeks of their open-label extension (OLE), BE BRIGHT, and the BE RADIANT phase 3b trial (48-week double-blinded period, 96-week OLE).[7–11]
  - Included patients were randomised to BKZ 320 mg every 4 weeks (Q4W) to Week 16, then received BKZ Q4W or every 8 weeks (Q8W) into the OLE.
  - All patients received BKZ Q8W from Week 64 in BE RADIANT (OLE Week 16) or Week 100/104 in BE BRIGHT (OLE Week 48), or the next scheduled clinic visit.
- Nail psoriasis severity was assessed using the modified Nail Psoriasis Severity Index (mNAPSI; total score: 0–130), with sub-scores for the **matrix** and **bed** (**Figure 1**).[1]
  - Proportions of patients achieving complete nail clearance (mNAPSI 0 response) and ≥90% improvement from baseline in mNAPSI (mNAPSI 90 response; indicating near-complete clearance) are reported for **matrix**/**bed** sub-scores, up to Week 144/148/152 (Year 3; OLE Week 96).
- Analyses were conducted post hoc for patients with baseline nail involvement (mNAPSI >0) using observed cases (OC).
  - Data are also reported for the subgroup of patients without PsA at baseline (no medical history of PsA and Psoriatic Arthritis Screening and Evaluation [PASE] questionnaire score <47).
- Data are reported regardless of dosing regimen (BKZ Total), and for the subset who received BKZ Q4W to Week 16 then Q8W into the OLE (Q4W/Q8W; approved dosing regimen for most patients with psoriasis).[12]

Results

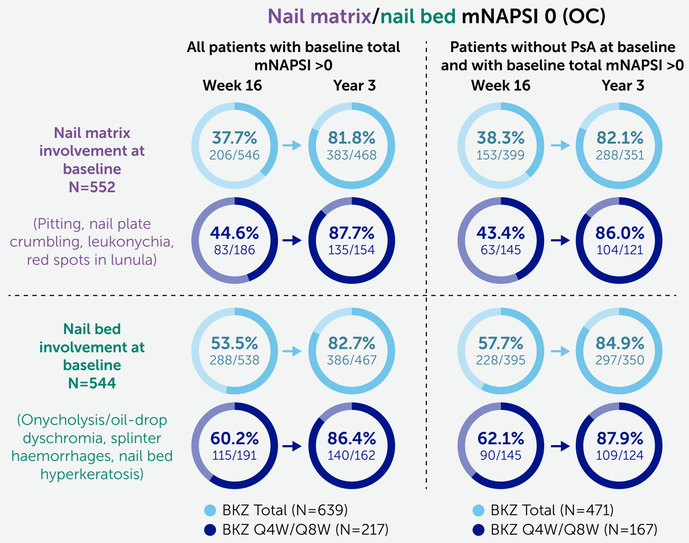
- Among 639 BKZ Total patients with baseline mNAPSI >0 who entered the OLEs (BKZ Q4W/Q8W: N=217), 552 had **nail matrix** involvement (BKZ Q4W/Q8W: N=188) and 544 had **nail bed** involvement (BKZ Q4W/Q8W: N=193).
  - Baseline characteristics are presented in **Table 1**.
- Of BKZ Total patients with **nail matrix** involvement, 37.7%/81.8% achieved **nail matrix** mNAPSI 0 and 40.7%/84.4% achieved **nail matrix** mNAPSI 90 at Week 16/Year 3 (**Figure 2A**, **Figure 3A**).
- Of those with **nail bed** involvement, 53.5%/82.7% achieved **nail bed** mNAPSI 0 and 58.0%/86.7% achieved **nail bed** mNAPSI 90 at Week 16/Year 3 (**Figure 2B**, **Figure 3B**).
- In the BKZ Q4W/Q8W subgroup, **nail matrix** and **nail bed** responses were consistent with the BKZ Total group (**Figures 2–3**).
- Similar results were seen in the subgroup without PsA at baseline (**Figure 4**).

Conclusions

High long-term clearance levels (>80%) were reached in the nail matrix and nail bed after 3 years of bimekizumab treatment, with nail matrix resolution occurring more slowly than nail bed resolution as expected due to its dependency on nail growth.

Early and effective resolution of nail psoriasis in both the matrix and bed with bimekizumab may contribute to altering disease course, potentially mitigating the risk of progression to PsA in patients who are predisposed.

Summary



BKZ achieved sustained responses in both **nail matrix** and **nail bed** over 3 years, which **may help to minimise the risk of progression to PsA** in patients with moderate to severe plaque psoriasis.

Figure 1 mNAPSI overall scoring system with **nail matrix** and **nail bed** sub-scores

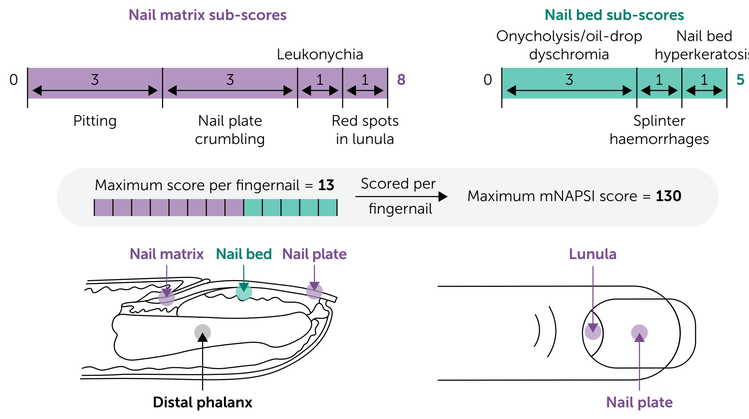


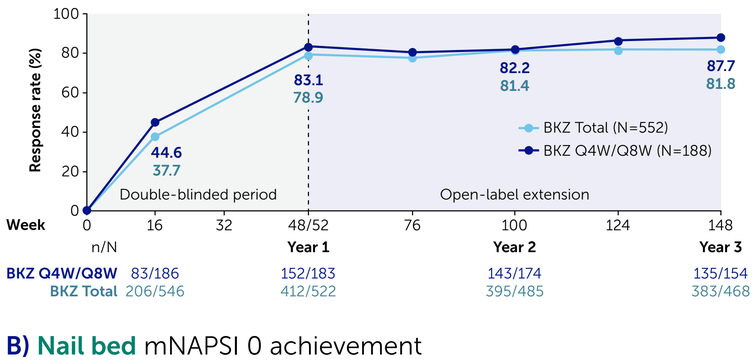
Table 1 Baseline characteristics

	All patients with baseline total mNAPSI >0		Patients without PsA at baseline[a] and with baseline total mNAPSI >0	
	BKZ Total (N=639)	BKZ Q4W/Q8W (N=217)	BKZ Total (N=471)	BKZ Q4W/Q8W (N=167)
Age (years), mean (SD)	45.9 (13.4)	45.7 (13.6)	45.1 (12.9)	44.2 (12.8)
Sex, **male**, n (%)	502 (78.6)	163 (75.1)	379 (80.5)	126 (75.4)
Racial group, **white**, n (%)	551 (86.2)	204 (94.0)	404 (85.8)	157 (94.0)
Weight (kg), mean (SD)	91.5 (21.1)	90.9 (21.7)	91.2 (21.1)	90.2 (21.8)
Duration of disease (years), mean (SD)	19.1 (12.6)	19.4 (12.2)	18.3 (12.2)	18.3 (11.3)
PASI, mean (SD)	21.8 (8.2)	21.1 (8.2)	21.5 (8.0)	20.9 (8.4)
mNAPSI total score, mean (SD)	20.4 (20.3)	19.0 (17.2)	20.4 (21.0)	19.2 (18.0)
BSA (%), mean (SD)	28.2 (17.1)	25.7 (14.1)	27.9 (17.0)	25.3 (13.8)
IGA, n (%)				
3: moderate	388 (60.7)	134 (61.8)	289 (61.4)	99 (59.3)
4: severe	249 (39.0)	82 (37.8)	180 (38.2)	67 (40.1)
DLQI total score, mean (SD)	10.7 (6.5)	11.1 (6.4)	10.0 (6.1)	10.4 (6.0)
Any prior systemic therapy, n (%)	501 (78.4)	166 (76.5)	355 (75.4)	126 (75.4)
Any prior biologic therapy, n (%)	247 (38.7)	72 (33.2)	164 (34.8)	51 (30.5)
Anti-TNF	112 (17.5)	28 (12.9)	71 (15.1)	17 (10.2)
Anti-IL-17	138 (21.6)	38 (17.5)	93 (19.7)	30 (18.0)
Anti-IL-12/23	34 (5.3)	11 (5.1)	25 (5.3)	10 (6.0)
Anti-IL-23	25 (3.9)	10 (4.6)	18 (3.8)	8 (4.8)

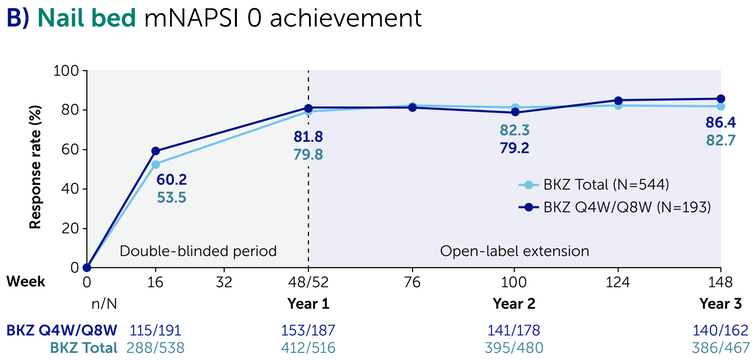
[a] Patients with no medical history of PsA and PASE <47.

Figure 2 **Nail matrix** and **nail bed** mNAPSI 0 response rate through 3 years (OC)

A) **Nail matrix** mNAPSI 0 achievement



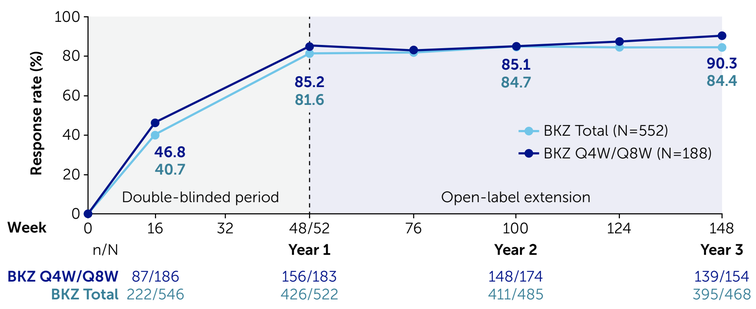
B) **Nail bed** mNAPSI 0 achievement



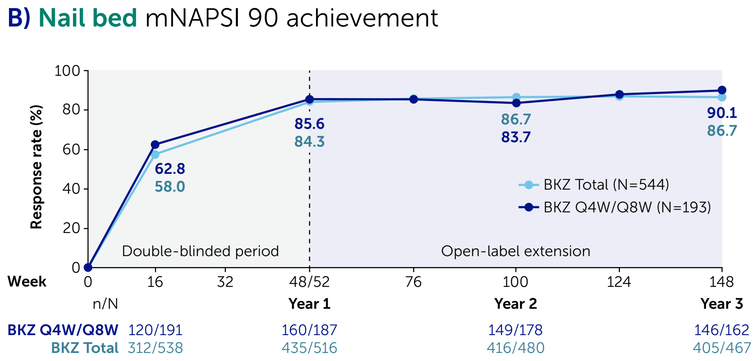
Data are reported in **A)** patients with baseline mNAPSI >0 in the nail matrix; **B)** patients with baseline mNAPSI >0 in the nail bed. mNAPSI 0 indicates complete clearance specific to matrix or bed. To pool data across studies, Week 56 data from BE SURE and BE READY were not included. Week 48/52 represents a combined timepoint for the last mNAPSI assessment before entering the OLEs.

Figure 3 **Nail matrix** and **nail bed** mNAPSI 90 response rate through 3 years (OC)

A) **Nail matrix** mNAPSI 90 achievement



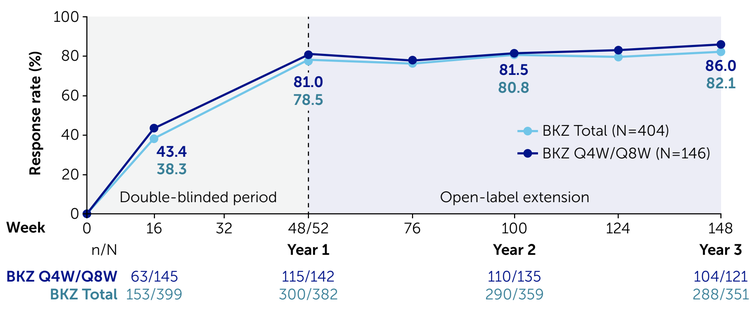
B) **Nail bed** mNAPSI 90 achievement



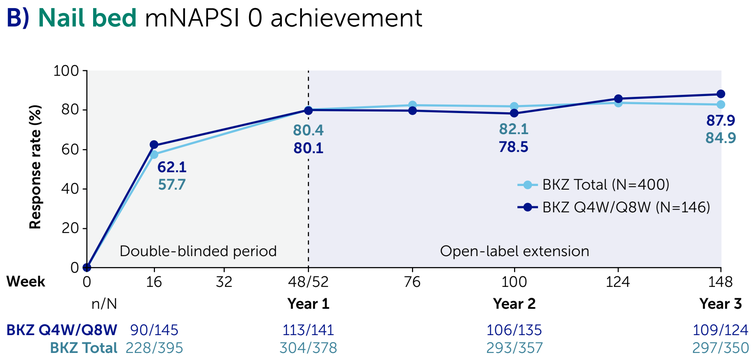
Data are reported in **A)** patients with baseline mNAPSI >0 in the nail matrix; **B)** patients with baseline mNAPSI >0 in the nail bed. mNAPSI 90 indicates near-complete clearance specific to matrix or bed. To pool data across studies, Week 56 data from BE SURE and BE READY were not included. Week 48/52 represents a combined timepoint for the last mNAPSI assessment before entering the OLEs.

Figure 4 **Nail matrix** and **nail bed** mNAPSI 0 response rate through 3 years in patients without PsA at baseline (OC)

A) **Nail matrix** mNAPSI 0 achievement



B) **Nail bed** mNAPSI 0 achievement



Data are reported in patients without PsA at baseline (no medical history of PsA and PASE <47) and **A)** baseline mNAPSI >0 in the nail matrix; **B)** baseline mNAPSI >0 in the nail bed. mNAPSI 0 indicates complete clearance specific to matrix or bed. To pool data across studies, Week 56 data from BE SURE and BE READY were not included. Week 48/52 represents a combined timepoint for the last mNAPSI assessment before entering the OLEs.

BKZ: bimekizumab; **BSA:** body surface area; **DLQI:** Dermatology Life Quality Index; **IGA:** Investigator's Global Assessment; **IL:** interleukin; **mNAPSI:** modified Nail Psoriasis Severity Index; **mNAPSI 90:** ≥90% improvement from baseline in mNAPSI; **OC:** observed case; **OLE:** open-label extension; **PASE:** Psoriatic Arthritis Screening and Evaluation; **PASI:** Psoriasis Area and Severity Index; **PsA:** psoriatic arthritis; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks; **SD:** standard deviation; **TNF:** tumour necrosis factor.

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