Bimekizumab 3-year efficacy in patients with psoriasis and risk factors for progression to psoriatic arthritis or screening positive for psoriatic arthritis: Long-term results from BE BRIGHT and BE RADIANT

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OBJECTIVES

- To evaluate bimekizumab (BKZ) response rates in patients with psoriasis and concurrent risk factors for progression to psoriatic arthritis (PsA), or screening PsA-positive, and compare them with the overall BKZ-treated population.
- To further explore these response rates in patients without PsA at baseline, who have risk factors for progression to PsA.

Background

- PsA affects up to one-third of patients with psoriasis;[1] early identification and intervention for patients at risk may help reduce progression.
- Severe psoriasis, nail involvement, scalp involvement, and obesity are recognized long-term predictors of progression of psoriasis to PsA.[1–3]
- Understanding the impact of BKZ, which selectively inhibits interleukin (IL)-17F and IL-17A,[4] on patients with these risk factors, or those screening PsA-positive, is important to potentially prevent progression.[1]

Methods

- Data were pooled from BE VIVID, BE SURE, BE READY, the first 96 weeks of their open-label extension (OLE) BE BRIGHT, and BE RADIANT (48-week double-blinded period, plus 96-week OLE).[5–9]
- Achievement of **complete skin clearance** (PASI 100) was evaluated through **Year 3** using modified non-responder imputation (mNRI).

Subgroups analyzed

Patients screening PsA-positive (PASE ≥47)[a]

Patients with nail involvement (mNAPSI >10)

Patients with ≥3 PsA risk factors (out of mNAPSI >10, scalp IGA ≥3, absolute PASI ≥20, BMI >30 kg/m^2)[1–3]

[a] The PASE questionnaire is a validated self-administered PsA screening tool designed to help dermatologists identify patients with psoriasis who would benefit from a prompt referral to a rheumatologist; a score of ≥47 indicates a high likelihood of PsA.[10,11]

1. Zabotti A et al. Ann Rheum Dis 2023;82:1162–70; **2.** Yan D et al. Dermatol Ther (Heidelb) 2018;8:593–604; **3.** Wilson FC et al. Arthritis Rheum 2009;61:233–39; **4.** Adams R et al. Front Immunol 2020;11:1894; **5.** Reich K et al. Lancet 2021;397:487–98 (NCT03370133); **6.** Warren RB et al. N Engl J Med 2021;385:130–41 (NCT03412747); **7.** Gordon KB et al. Lancet 2021;397:475–86 (NCT03410992); **8.** Strober B et al. Br J Dermatol 2023;188:749–59 (NCT03598790); **9.** Strober B et al. J Am Acad Dermatol 2023;89:486–95 (NCT03536884); **10.** Iragorri N et al. Rheumatology (Oxford) 2019;58:692–707; **11.** Husni ME et al. J Am Acad Dermatol 2007;57:581–7.

BKZ: bimekizumab; BMI: body mass index; IGA: Investigator's Global Assessment; IL: interleukin; mNAPSI: modified Nail Psoriasis Severity Index; mNRI: modified non-responder imputation; OLE: open-label extension; PASE: Psoriatic Arthritis Screening and Evaluation; PASI: Psoriasis Area and Severity Index; PsA: psoriatic arthritis.

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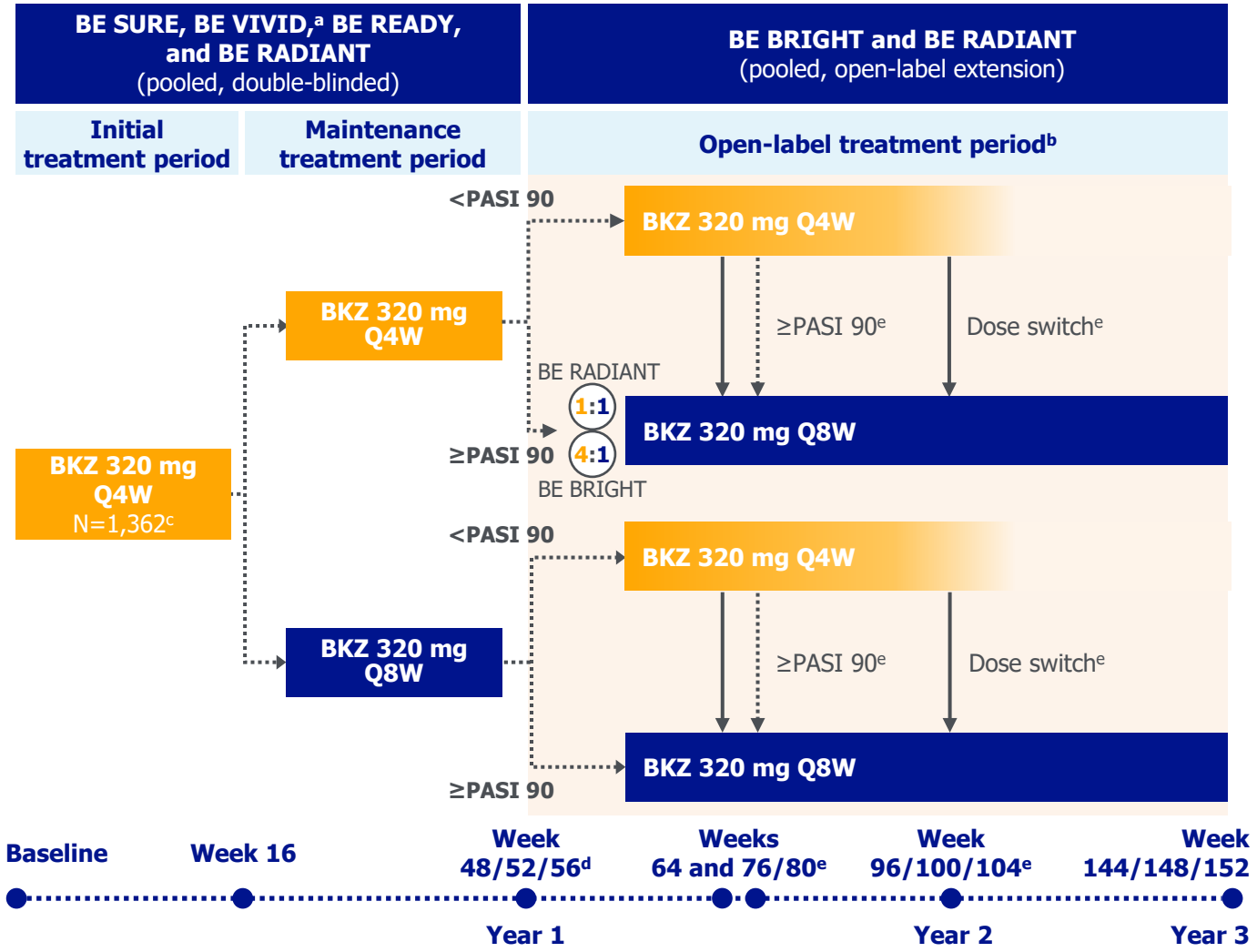
Study Design



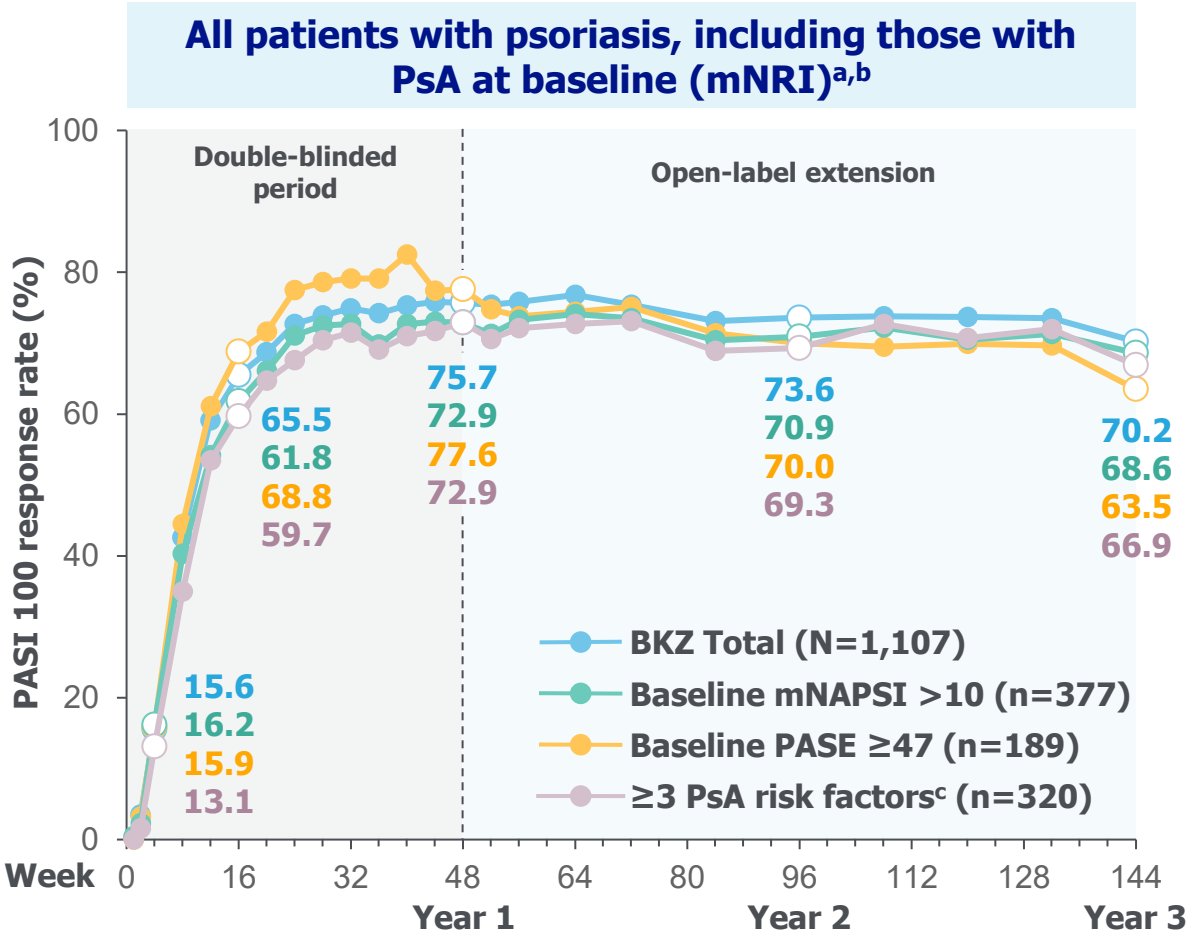
Baseline Characteristics

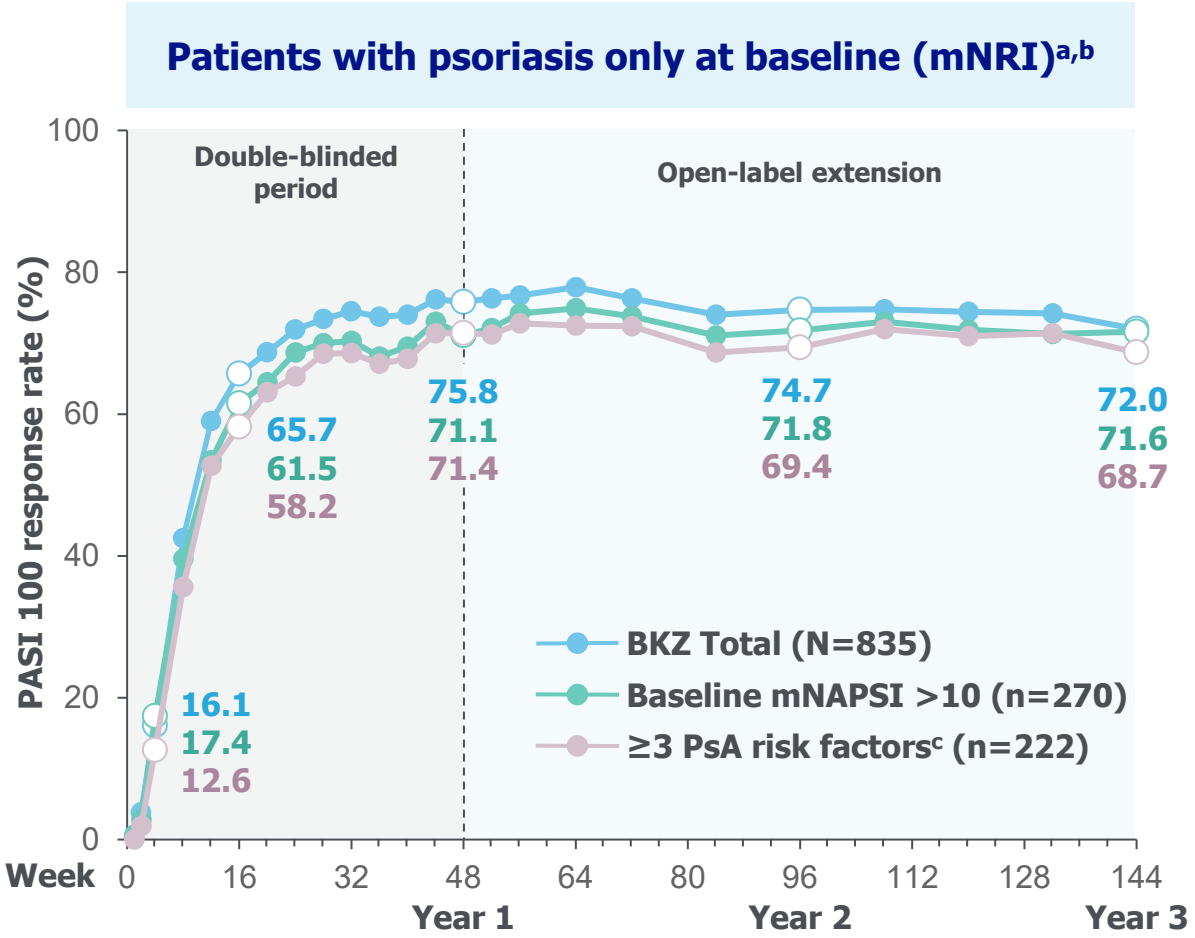
	BKZ Total N=1,107	BKZ Q4W/Q8W N=374	BKZ Total with psoriasis only[f] N=835	BKZ Q4W/Q8W with psoriasis only[f] N=297
Presence of PsA at baseline, n (%)[f]	272 (24.6)	77 (20.6)	0 (0)	0 (0)
PASE ≥47, n (%)	189 (17.1)	53 (14.2)	0 (0)	0 (0)
mNAPSI >10, n (%)	377 (34.1)	129 (34.5)	270 (32.3)	98 (33.0)
Scalp IGA ≥3, n (%)	821 (74.2)	277 (74.1)	627 (75.1)	224 (75.4)
PASI ≥20, n (%)	466 (42.1)	143 (38.2)	344 (41.2)	108 (36.4)
BMI >30 kg/m^2, n (%)	493 (44.5)	151 (40.4)	355 (42.5)	117 (39.4)

- Of the patients initially randomized to BKZ at baseline, **1,107** continued BKZ throughout the maintenance period and into the OLE (**BKZ Total**; Q4W and Q8W doses pooled).
- Among these, **374** received BKZ Q4W to Week 16 followed by BKZ Q8W thereafter (the approved dosing regimen for most patients with psoriasis; **BKZ Q4W/Q8W**).[1]
- The **BKZ Total** group contained **835** patients with psoriasis only at baseline; among these, **297** received **BKZ Q4W/Q8W**.

[a] BE VIVID did not include an option for Q8W dosing of BKZ during the maintenance period; **[b]** In BE RADIANT and BE BRIGHT, patients receiving BKZ 320 mg Q4W who achieved PASI 90 at the end of the maintenance treatment period were re-randomized 1:1 and 4:1, respectively, to BKZ 320 mg Q4W and BKZ 320 mg Q8W upon entering the open-label treatment period; **[c]** Only BKZ-randomized patients are included in this study design; BKZ-randomized patients who were re-randomized to placebo at Week 16 in BE READY (n=105) were not included in these analyses; **[d]** Different week numbers are presented due to different feeder study lengths; Week 48/52/56 refers to OLE Week 0 and corresponds to BE RADIANT/BE VIVID/BE SURE and BE READY, respectively; **[e]** In BE RADIANT, all patients switched to BKZ Q8W at Week 64 or the next scheduled clinic visit via protocol amendment; in BE BRIGHT, at Week 76/80 (OLE Week 24), patients achieving ≥PASI 90 could switch to Q8W at the investigator's discretion; all patients were re-assigned to BKZ Q8W at Week 100/104 (OLE Week 48) or the next scheduled visit via protocol amendment; **[f]** Baseline PsA was defined as PASE ≥47 or a reported medical history of PsA. **1.** Food and Drug Administration, Bimekizumab Prescribing Information, 2023. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761151s000lbl.pdf [Accessed January 2025]. BKZ: bimekizumab; BMI: body mass index; IGA: Investigator's Global Assessment; mNAPSI: modified Nail Psoriasis Severity Index; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; PASI 90: ≥90% improvement from baseline in PASI; PsA: psoriatic arthritis; Q4W: every 4 weeks; Q8W: every 8 weeks.

Achievement of Complete Skin Clearance Over 3 Years in BKZ Total Patients with Risk Factors for Progression to PsA or Screening PsA-Positive at Baseline





[a] Patients discontinuing treatment due to lack of efficacy or treatment-related adverse events were considered non-responders at subsequent timepoints; multiple imputation was used for all other missing data. Patients who entered the BE READY escape arm were considered as non-responders from the date of escape until the end of BE READY, after which they were considered in the same way as all other non-escape patients during the BE BRIGHT OLE;[1] **[b]** Baseline PsA was defined as PASE ≥47, or a reported medical history of PsA; **[c]** The sub-population of patients with ≥3 risk factors could have any combination of mNAPSI >10, scalp IGA ≥3, PASI ≥20, and BMI >30 kg/m^2 at baseline. **1.** Gordon KB et al. Lancet 2021;397:475–86 (NCT03410992).
BKZ: bimekizumab; BMI: body mass index; IGA: Investigator's Global Assessment; mNAPSI: modified Nail Psoriasis Severity Index; mNRI: modified non-responder imputation; OLE: open-label extension; PASE: Psoriatic Arthritis Screening and Evaluation; PASI: Psoriasis Area and Severity Index; PASI 100: 100% improvement from baseline in PASI; PsA: psoriatic arthritis.

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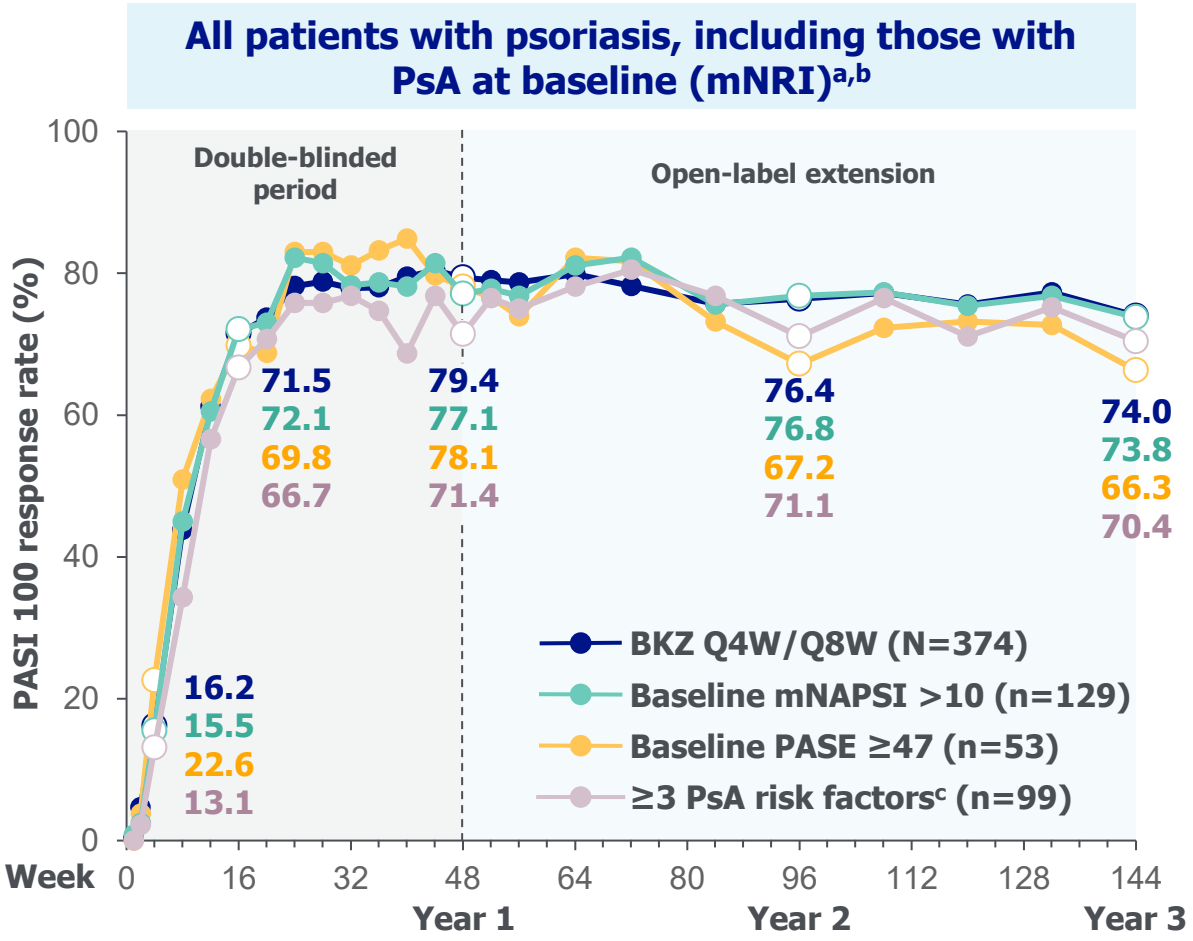
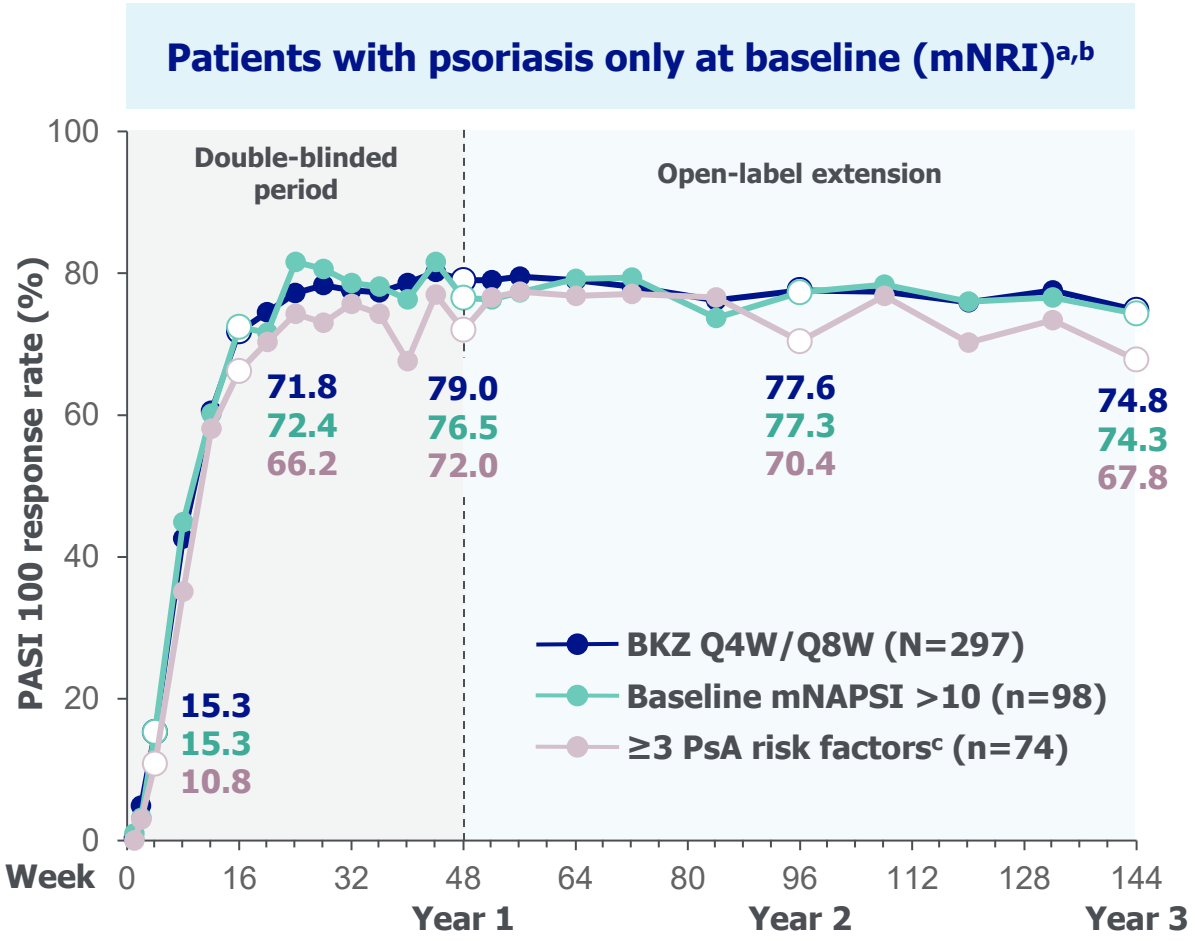
Achievement of Complete Skin Clearance Over 3 Years in BKZ Q4W/Q8W Patients with Risk Factors for Progression to PsA or Screening PsA-Positive at Baseline





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CONCLUSIONS

Complete skin clearance rates were high through Year 3 in bimekizumab-treated patients with psoriasis and risk factors for progression to psoriatic arthritis, or who screened positive for psoriatic arthritis, consistent with the overall bimekizumab-treated group.

Outcomes were similar when the analysis was restricted to patients with only psoriasis at baseline, and in the group who received bimekizumab Q4W/Q8W, the approved dosing regimen for the majority of patients with psoriasis.[1]

Highly effective treatment of psoriasis with bimekizumab in patients at higher risk of psoriatic arthritis may help to prevent progression in the long term.

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