

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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Disclosures & acknowledgements

Disclosures

PG: Consultant for AbbVie, Abiogen, Almirall, Celgene, Eli Lilly and Company, Janssen, LEO Pharma, Merck, MSD, Novartis, Otsuka, Pfizer, Pierre Fabre, Sanofi, and UCB. **JFM:** Consultant and/or investigator for AbbVie, Amgen, AstraZeneca, Biogen, Bristol Myers Squibb, Boehringer Ingelheim, Dermavant, Eli Lilly and Company, Incyte, Janssen, LEO Pharma, MoonLake Immunotherapeutics, Novartis, Pfizer, Sanofi-Regeneron, Sun Pharma, and UCB. **DT:** Investigator and/or consultant/advisor for AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celltrion, Eli Lilly and Company, Galderma, Johnson and Johnson Kyowa Kirin, LEO Pharma, L'Oréal, New Bridge, Novartis, Pfizer, Regeneron, Samsung, Sanofi, Target-RWE, UCB, and Vichy; received grants from AbbVie, LEO Pharma. **EN:** Consultant for AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Daiichi Sankyo, Eli Lilly and Company, Janssen, Kyowa Kirin, LEO Pharma, Maruho, Novartis, Pfizer, Regeneron, Sanofi, Sun Pharma, Taiho, Torii, and UCB. **RBW:** Consulting fees from AbbVie, Almirall, Amgen, Arena, Astellas, Avillion, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, DICE Therapeutics, Eli Lilly and Company, GSK, Janssen, LEO Pharma, Meiji Pharma, Novartis, Pfizer, RAPT Therapeutics, Sanofi, Sun Pharma, UCB, and Union Therapeutics; research grants to his institution from AbbVie, Almirall, Amgen, Celgene, Eli Lilly and Company, Janssen, LEO Pharma, Novartis, Pfizer, and UCB; honoraria from AbbVie, Almirall, Bristol Myers Squibb, Eli Lilly and Company, Galderma, Janssen, and Novartis. **JMLP:** Employee and shareholder of UCB. **SK:** Consultant for Aclipse Therapeutics, Aliada Therapeutics, Allay Therapeutics, Cognition Therapeutics, Colorado Prevention Center, Karuna Therapeutics, Kisbee Therapeutics, LB Pharma, Nesos, Novartis, Onward, PharPoint Research, Summit Analytical, Therini Bio, Tonix Pharmaceuticals, Tornado Therapeutics, UCB, Whitsell Innovations, Worldwide Clinical Trials, and Zosano Pharma. **RGL:** Principal investigator for AbbVie, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly and Company, LEO Pharma, Merck, Novartis, Pfizer, and UCB; served on scientific advisory boards for AbbVie, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly and Company, LEO Pharma, Merck, Novartis, Pfizer, and UCB; provided lectures for AbbVie, Amgen, Celgene, Eli Lilly and Company, LEO Pharma, Merck, Novartis, and Pfizer.

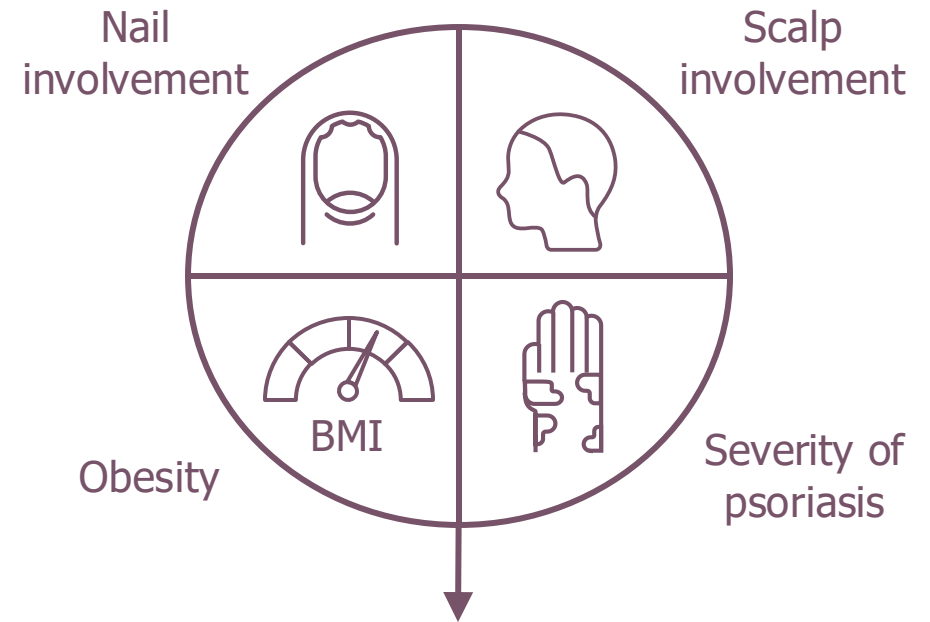
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Introduction

- **Psoriatic arthritis** (PsA) affects up to **one-third** of patients with psoriasis;¹ early identification and intervention for patients who are at risk may help reduce progression
- **Severe psoriasis, nail involvement, scalp involvement, and obesity** are recognised medium- to long-term risk factors for PsA development¹⁻³
- Bimekizumab (BKZ) is a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A⁴
- IL-17A and IL-17F play an important role in the **development of psoriatic disease** at the **skin and joint** level⁵
- Understanding the **impact of BKZ** on patients with these risk factors, or those screening PsA-positive, is important to potentially **prevent progression**¹

Risk factors for progression to PsA analysed here¹⁻³

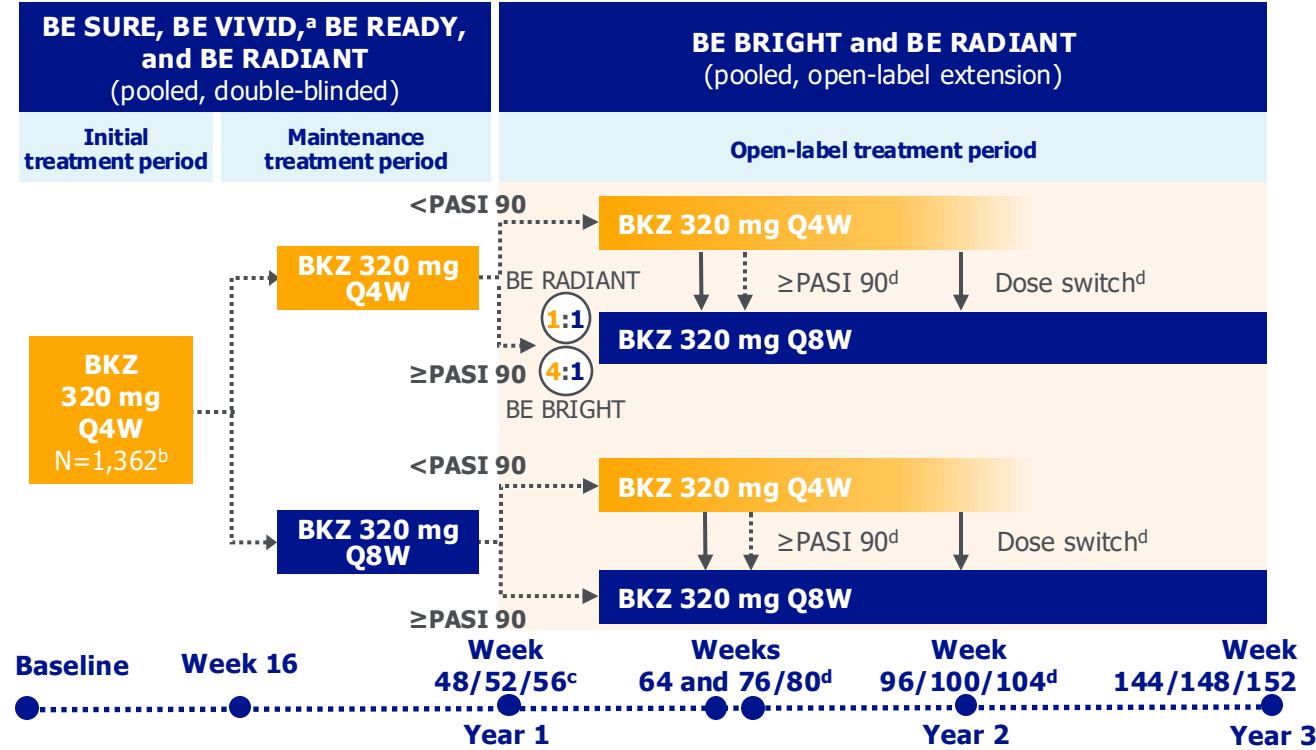


One-third of patients with psoriasis develop PsA¹





OBJECTIVE: To evaluate BKZ response rates in patients with psoriasis with risk factors for progression to PsA or screening PsA-positive, and compare them with the overall BKZ-treated population

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)¹⁻⁵
- Achievement of complete skin clearance (PASI 100; 100% improvement from baseline in Psoriasis Area and Severity Index) was evaluated through Year 3 using modified non-responder imputation (mNRI)



Subgroups analysed

-  **Patients with self-reported signs/symptoms of PsA (PASE ≥47)^e**
-  **Patients with significant nail involvement (mNAPSI >10)**
-  **Patients with moderate/severe scalp involvement (scalp IGA ≥3)**
-  **Patients with ≥3 PsA risk factors (out of mNAPSI >10, scalp IGA ≥3, absolute PASI ≥20, BMI >30 kg/m²)⁶⁻⁸**

[a] BE VIVID did not include an option for Q8W dosing of BKZ during the maintenance period; [b] Only BKZ-randomised patients are included in this study design; BKZ-randomised patients who were re-randomized to placebo at Week 16 in BE READY (n=105) were not included in these analyses; [c] 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; [d] 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; [e] 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.^{9,10} 1. Reich K et al. Lancet 2021;397:487-98 (NCT03370133); 2. Warren RB et al. N Engl J Med 2021;385:130-41 (NCT03412747); 3. Gordon KB et al. Lancet 2021;397:475-86 (NCT03410992); 4. Strober B et al. Br J Dermatol 2023;188:749-59 (NCT03598790); 5. Strober B et al. J Am Acad Dermatol 2023;89:486-95 (NCT03536884); 6. Zabotti A et al. Ann Rheum Dis 2023;82:1162-70; 7. Yan D et al. Dermatol Ther (Heidelb) 2018;8:593-604; 8. Wilson FC et al. Arthritis Rheum 2009;61:233-39; 9. Iragorri N et al. Rheumatology (Oxford) 2019;58:692-707; 10. Husni ME et al. J Am Acad Dermatol 2007;57:581-7. 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 90/100: ≥90%/100% improvement from baseline in PASI; PsA: psoriatic arthritis; Q4W: every 4 weeks; Q8W: every 8 weeks.

Baseline characteristics

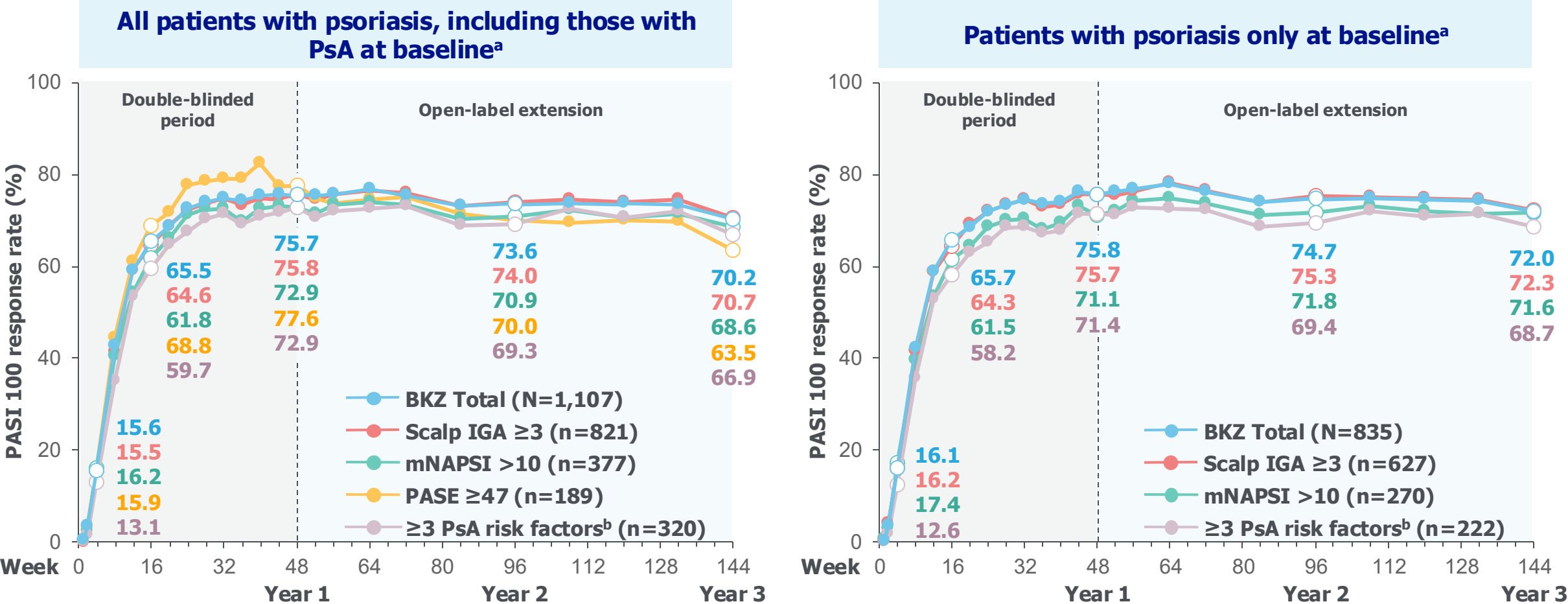
Of the patients initially randomised to BKZ at baseline:

- **1,107** continued BKZ throughout the maintenance period and into the OLE (**BKZ Total**; Q4W and Q8W doses pooled). **835** of these patients had psoriasis only at baseline^a
- **374** of these received BKZ Q4W to Week 16 followed by BKZ Q8W thereafter (approved dosing for most patients with psoriasis; **BKZ Q4W/Q8W**).¹ **297** of these patients had psoriasis only at baseline^a

	Patients with psoriasis only ^a			
	BKZ Total N=1,107	BKZ Q4W/Q8W N=374	BKZ Total N=835	BKZ Q4W/Q8W N=297
Age, years, mean (SD)	45.5 (13.7)	45.0 (14.1)	44.4 (13.4)	43.0 (13.5)
Sex, male, n (%)	777 (70.2)	266 (71.1)	603 (72.2)	212 (71.4)
Racial group, white, n (%)	968 (87.4)	354 (94.7)	730 (87.4)	281 (94.6)
BMI >30 kg/m ² , n (%)	493 (44.5)	151 (40.4)	355 (42.5)	117 (39.4)
Duration of psoriasis, years, mean (SD)	18.5 (12.8)	18.7 (12.4)	18.0 (12.6)	17.7 (11.7)
PASI ≥20, n (%)	466 (42.1)	143 (38.2)	344 (41.2)	108 (36.4)
BSA (%), mean (SD)	26.5 (15.7)	24.5 (13.5)	26.3 (15.3)	24.4 (13.2)
IGA, n (%)				
3: moderate	722 (65.2)	257 (68.7)	552 (66.1)	203 (68.4)
4: severe	382 (34.5)	115 (30.7)	280 (33.5)	92 (31.0)
DLQI total score, mean (SD)	10.6 (6.4)	10.7 (6.3)	10.1 (6.1)	10.1 (5.9)
Scalp IGA ≥3, n (%)	821 (74.2)	277 (74.1)	627 (75.1)	224 (75.4)
mNAPSI >10, n (%)	377 (34.1)	129 (34.5)	270 (32.3)	98 (33.0)
Any prior systemic therapy, n (%)	859 (77.6)	285 (76.2)	627 (75.1)	220 (74.1)
Any prior biologic therapy, n (%)	423 (38.2)	129 (34.5)	289 (34.6)	92 (31.0)
PsA at baseline, ^a n (%)	272 (24.6)	77 (20.6)	0 (0)	0 (0)
PASE ≥47, n (%)	189 (17.1)	53 (14.2)	0 (0)	0 (0)

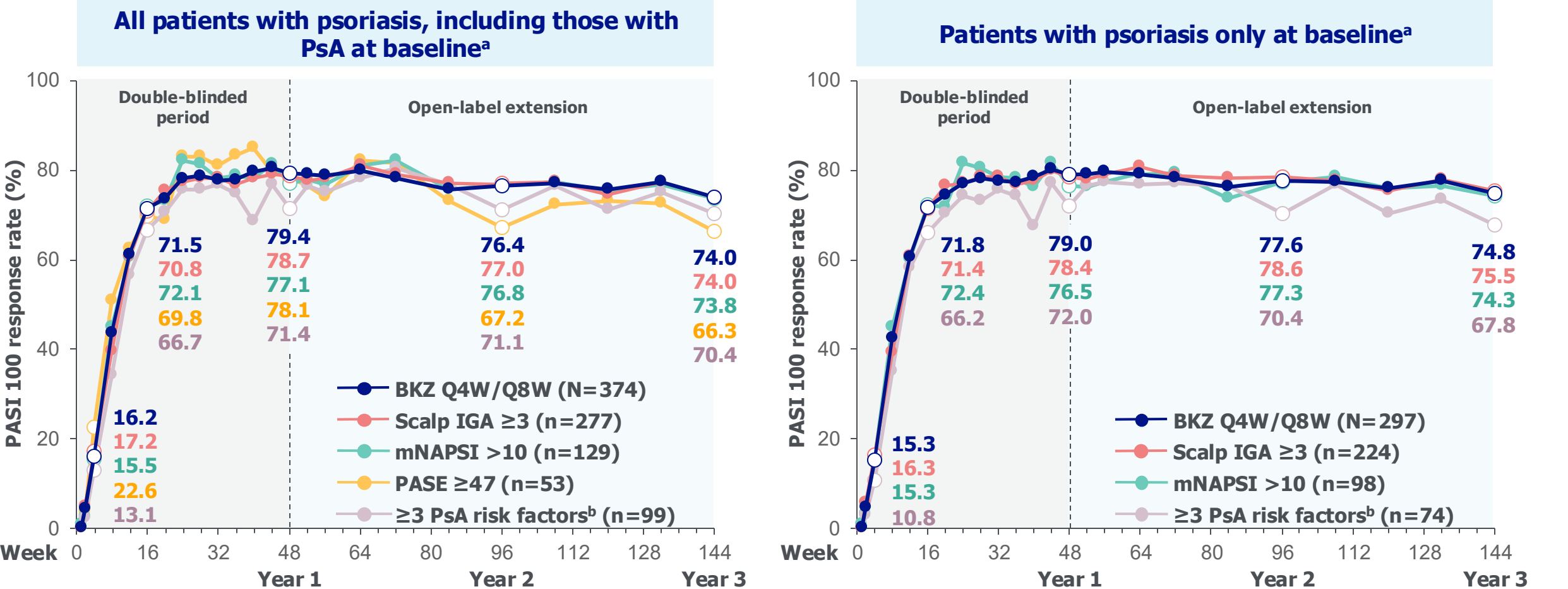
[a] Baseline PsA was defined as PASE ≥47 or a reported medical history of PsA. 1. European Medicines Agency. Bimekizumab Summary of Product Characteristics. 2023. Available at: <https://www.ema.europa.eu/en/medicines/human/EPAR/bimzelx> [Accessed May 2025]. BKZ: bimekizumab; BMI: body mass index; BSA: body surface area; DLQI: Dermatology Life Quality Index; IGA: Investigator's Global Assessment; mNAPSI: modified Nail Psoriasis Severity Index; 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.

Achievement of complete skin clearance over 3 years in BKZ Total patients (mNRI)



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 [a] Baseline PsA was defined as PASE ≥47, or a reported medical history of PsA; [b] 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/m² 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.

Achievement of complete skin clearance over 3 years in BKZ Q4W/Q8W patients (mNRI)



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 [a] Baseline PsA was defined as PASE ≥47, or a reported medical history of PsA; [b] 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/m² 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; Q4W: every 4 weeks; Q8W: every 8 weeks.

Conclusions



Complete skin clearance rates were **high through Year 3** in bimekizumab-treated patients with **psoriasis**, including the significant proportions who had **risk factors for disease progression to psoriatic arthritis**.



Outcomes were similar between the **overall** group of **bimekizumab-treated** patients, and in the group with **psoriasis only** at baseline. This result was consistent in the subset who received the **approved Q4W/Q8W dosing regimen**.¹



Bimekizumab's high efficacy in patients with psoriasis and **risk factors for progression** to psoriatic arthritis may suggest a **preventative effect**. The effect of **bimekizumab** on **disease progression** should be investigated further.

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¹. European Medicines Agency. Bimekizumab Summary of Product Characteristics. 2023. Available at: <https://www.ema.europa.eu/en/medicines/human/EPAR/bimzelyx> [Accessed May 2025].
Q4W: every 4 weeks; Q8W: every 8 weeks.