Bimekizumab maintenance of efficacy over 4 years in biologic-naïve and biologic-experienced patients with moderate to severe plaque psoriasis

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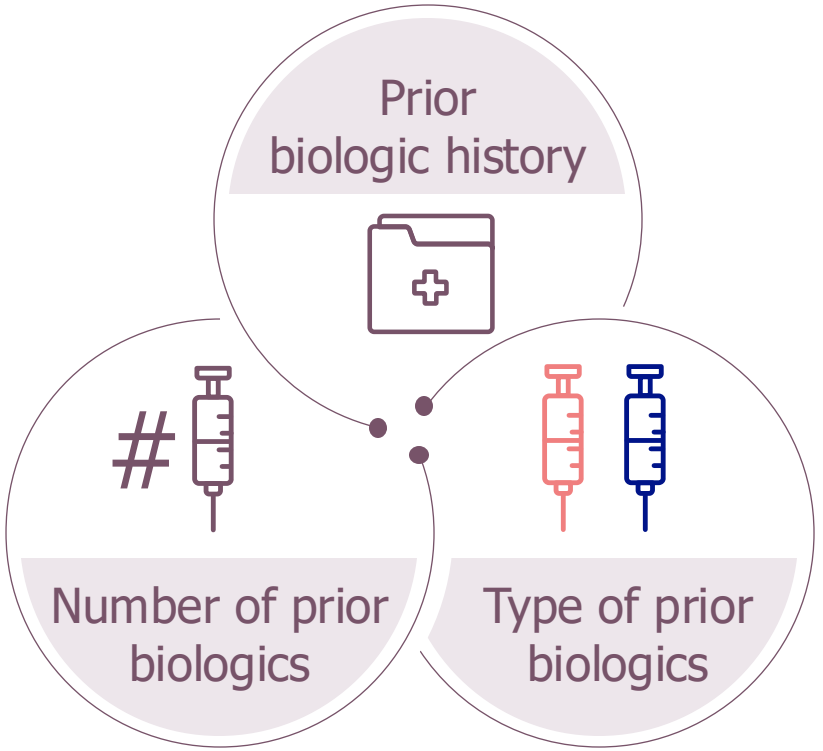
Introduction

- **Prior biologic treatment can impact responses** to subsequent biologics in patients with psoriasis.[1]
- Given the chronic nature of the disease, and the range of different therapies available, **switching or discontinuing** treatments is common.[2,3]
- Bimekizumab (BKZ), a first-in-class monoclonal IgG1 antibody that inhibits interleukin (IL)-17F in addition to IL-17A,[4] has demonstrated **consistently high efficacy** to Week 48 in biologic-naïve and biologic-experienced patients, independent of **prior biologic type** and **number of prior biologics**.[5]

Factors affecting biologic efficacy

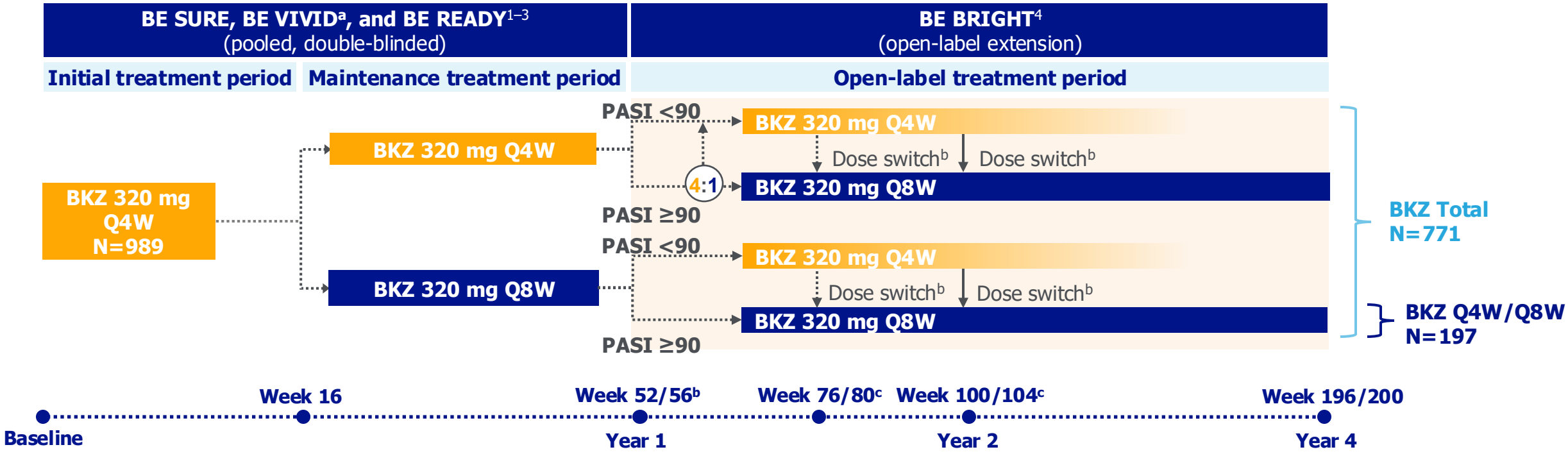


OBJECTIVE: To report 4-year efficacy of BKZ in patients stratified according to the number and type of prior biologics they had received.

1. Wade R et al. Systematic Reviews 2020;9:132; **2.** Schmitt-Egenholf M et al. Dermatol Ther (Heidelb) 2021;11:2107–21; **3.** Doshi JA et al. J Am Acad Dermatol 2016;74:1057–65; **4.** Adams R et al. Front Immunol 2020;11:1894; **5.** Lebwohl M et al. J of Skin 2022;6:s64. BKZ: bimekizumab; Ig: immunoglobulin; IL: interleukin.

Methods

- Data were pooled from the 52-week BE VIVID and 56-week BE SURE and BE READY phase 3 trials, and their open-label extension (OLE) BE BRIGHT.[1–4]



PASI 90 and PASI 100 responses are reported to Year 4 for the following subgroups:

- Biologic-naïve and biologic-experienced patients (split into those with 1 prior biologic and ≥2 prior biologics).
- Patients with prior anti-tumour necrosis factor (TNF), anti-IL-12/23, anti-IL-17A/anti-IL-17R and anti-IL-23 therapy (patients could have received multiple classes of prior biologic therapies).

[a] BE VIVID did not include an option for BKZ Q8W dosing during the maintenance period; **[b]** BE VIVID lasted 52 weeks, BE SURE and BE READY lasted 56 weeks; **[c]** 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. **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); BKZ: bimekizumab; IL: interleukin; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; PASI 90/100: ≥90%/100% improvement from baseline in PASI; Q4W: every 4 weeks; Q8W: every 8 weeks; TNF: tumour necrosis factor.

Baseline characteristics

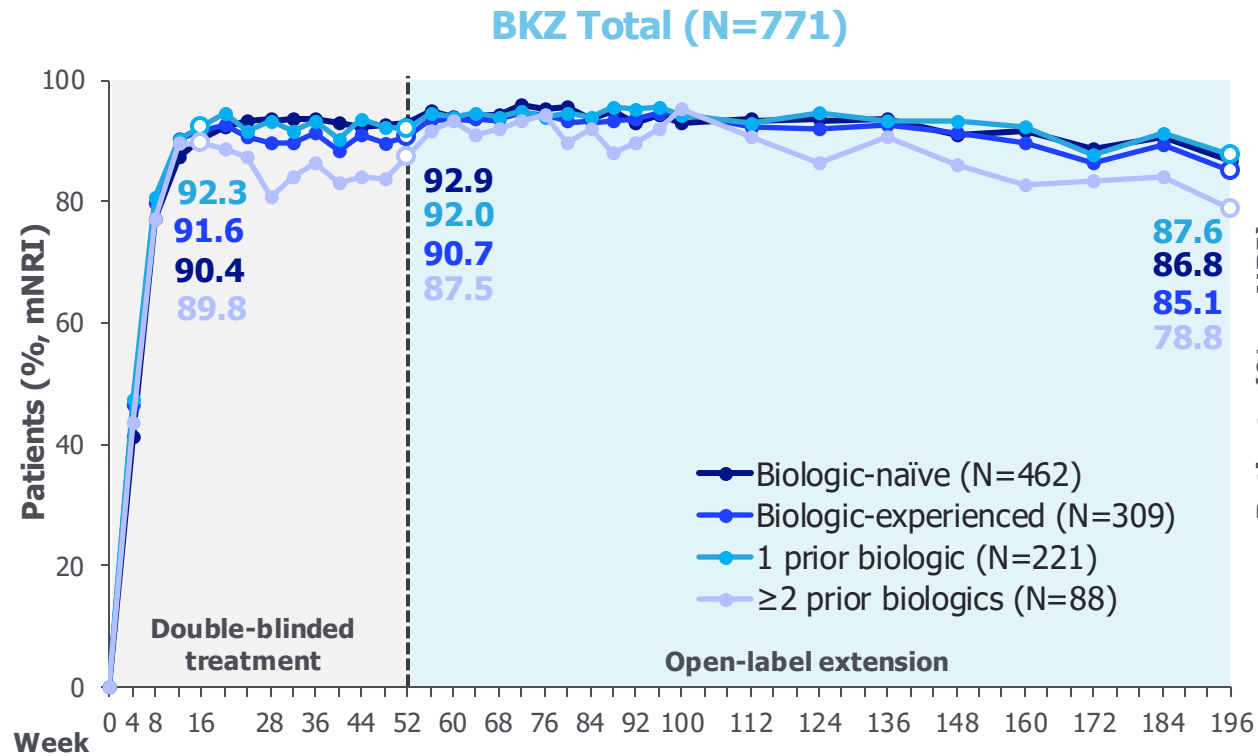
- Of the patients initially randomised to BKZ at baseline, **771** continued to receive BKZ throughout the maintenance period and into the OLE (**BKZ Total**).
- Among these, **197** received BKZ Q4W to Week 16 followed by BKZ Q8W thereafter (the approved dosing regimen for most patients with psoriasis; **BKZ Q4W/Q8W**).[1,2]

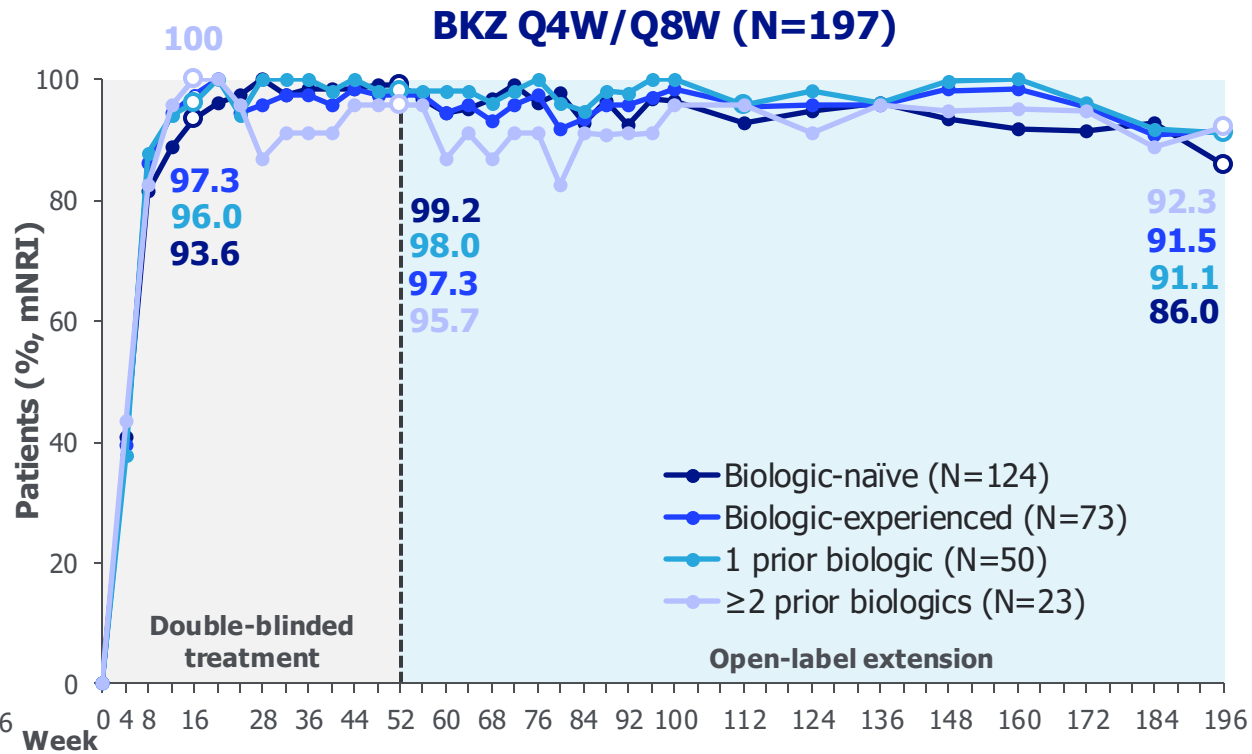
		By biologic history		By number of prior biologics		By type of prior biologic[a]			
	BKZ Total N=771	Biologic-naïve N=462	Biologic-experienced N=309	1 prior biologic N=221	≥2 prior biologics N=88	Prior anti-TNF N=113	Prior anti-IL-12/23 N=43	Prior anti-IL-17 N=193	Prior anti-IL-23 N=37
Age (years), mean (SD)	45.4 (13.5)	44.1 (13.4)	47.5 (13.4)	46.6 (13.8)	49.7 (12.1)	48.5 (12.9)	50.5 (11.4)	47.6 (13.6)	47.1 (14.3)
Sex, male, n (%)	550 (71.3)	329 (71.2)	221 (71.5)	159 (71.9)	62 (70.5)	81 (71.7)	28 (65.1)	140 (72.5)	27 (73.0)
Racial group, white, n (%)	656 (85.1)	377 (81.6)	279 (90.3)	197 (89.1)	82 (93.2)	103 (91.2)	41 (95.3)	177 (91.7)	33 (89.2)
Weight (kg), mean (SD)	89.7 (21.2)	89.8 (21.5)	89.4 (20.9)	87.9 (20.5)	93.5 (21.3)	93.0 (19.8)	95.1 (21.3)	88.5 (21.1)	88.8 (22.5)
Duration of psoriasis (years), mean (SD)	18.6 (12.7)	16.0 (12.1)	22.5 (12.6)	21.6 (12.5)	24.7 (12.8)	23.7 (13.5)	26.6 (12.8)	22.5 (13.0)	22.1 (11.2)
PASI, mean (SD)	21.1 (7.6)	20.9 (7.9)	21.5 (7.2)	21.7 (7.4)	21.1 (6.7)	20.9 (6.8)	21.7 (8.4)	21.8 (7.2)	21.3 (6.8)
BSA (%), mean (SD)	27.0 (15.6)	26.5 (15.6)	27.8 (15.5)	28.5 (16.0)	26.2 (14.3)	26.8 (15.6)	26.9 (17.3)	28.5 (14.9)	26.3 (14.8)
DLQI total score, mean (SD)	10.5 (6.3)	10.2 (5.9)	11.1 (6.9)	11.2 (6.8)	11.1 (7.2)	10.8 (6.6)	12.0 (7.5)	11.3 (7.2)	11.4 (6.8)
mNAPSI >0, n (%)	457 (59.3)	276 (59.7)	181 (58.6)	126 (57.0)	55 (62.5)	75 (66.4)	23 (53.5)	115 (59.6)	17 (45.9)

[a] Patients could have received multiple prior biologic therapy types. **1.** Food and Drug Administration, Bimekizumab Prescribing Information, 2024. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761151s010lbl.pdf [Accessed June 2025]; **2.** European Medicines Agency. Bimekizumab Summary of Product Characteristics, 2025. Available at: https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf [Accessed June 2025]. BKZ: bimekizumab; DLQI: Dermatology Life Quality Index; IGA: Investigator's Global Assessment; IL: interleukin; mNAPSI: modified Nail Psoriasis Severity Index; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; Q4W: every 4 weeks; Q8W: every 8 weeks; SD: standard deviation; TNF: tumour necrosis factor.

PASI 90 response rate through 4 years (mNRI, OC)

By number of prior biologics





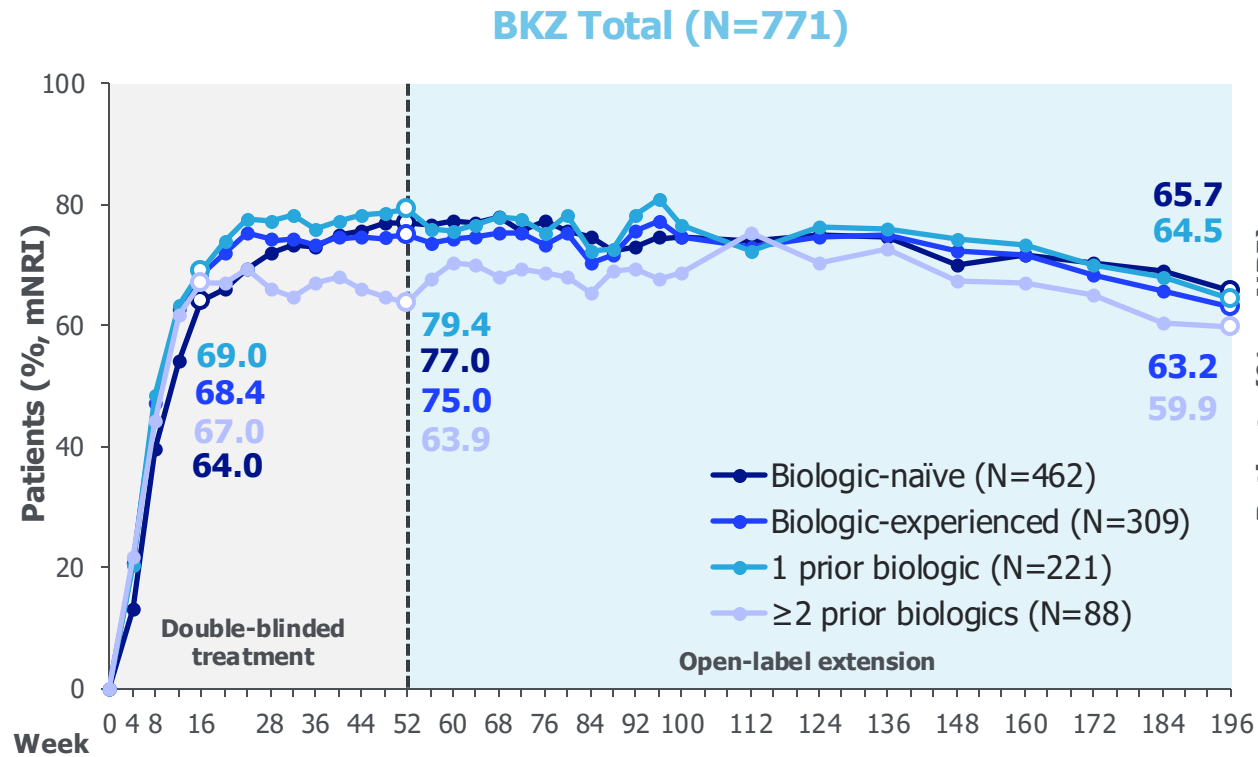
	BKZ Total (N=771)					BKZ Q4W/Q8W (N=197)				
	Week 16	Year 1	Year 2	Year 3	Year 4	Week 16	Year 1	Year 2	Year 3	Year 4
OC, n/N_{obs}[a]	414/457	421/438			347/375	114/121	121/122			87/93
	282/307	278/289			225/248	71/73	71/73			61/64
	203/219	202/209			162/175	48/50	49/50			42/45
	79/88	76/80			63/73	23/23	22/23			19/19

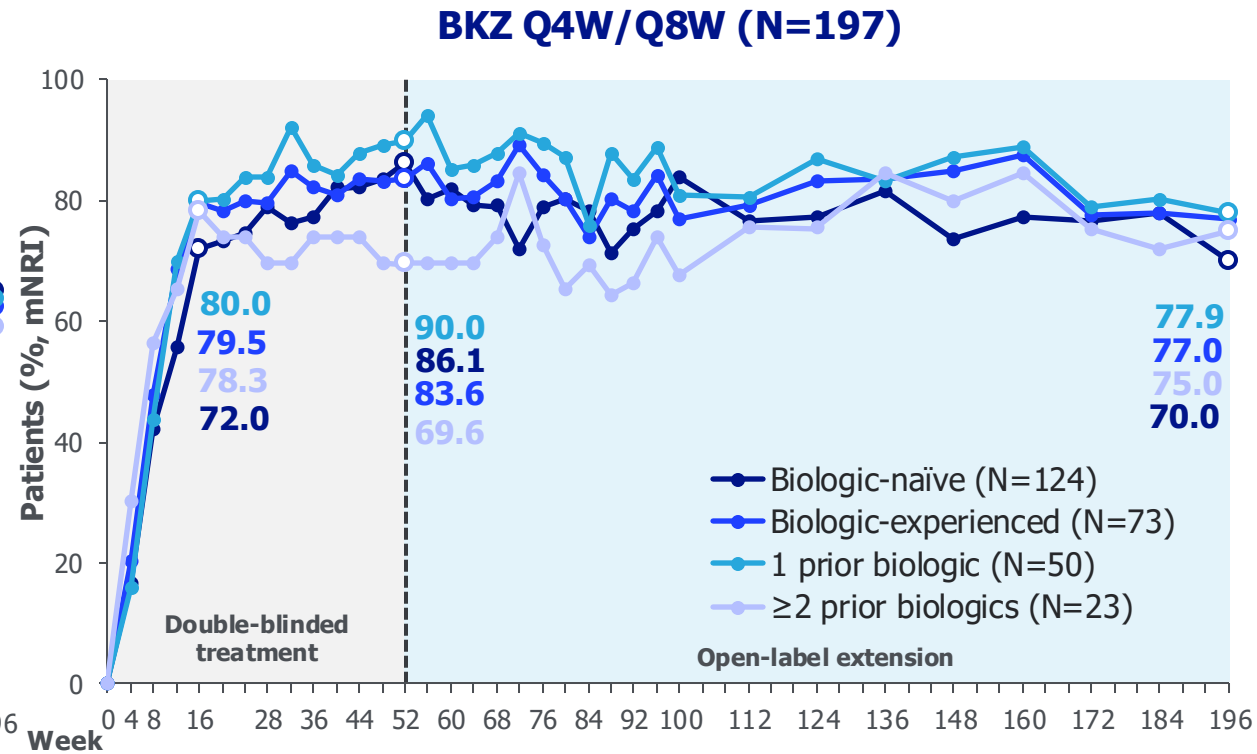
High proportions of BKZ-treated patients achieved PASI 90 from Week 16 through to Year 4, regardless of the **number** of prior biologics they had received.

For 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. **[a]** N_{obs} represents the number of patients with observed data at a given timepoint. BKZ: bimekizumab; mNRI: modified non-responder imputation; OC: observed case; PASI: Psoriasis Area and Severity Index; PASI 90: ≥90% improvement from baseline in PASI; Q4W: every 4 weeks; Q8W: every 8 weeks.

PASI 100 response rate through 4 years (mNRI, OC)

By number of prior biologics





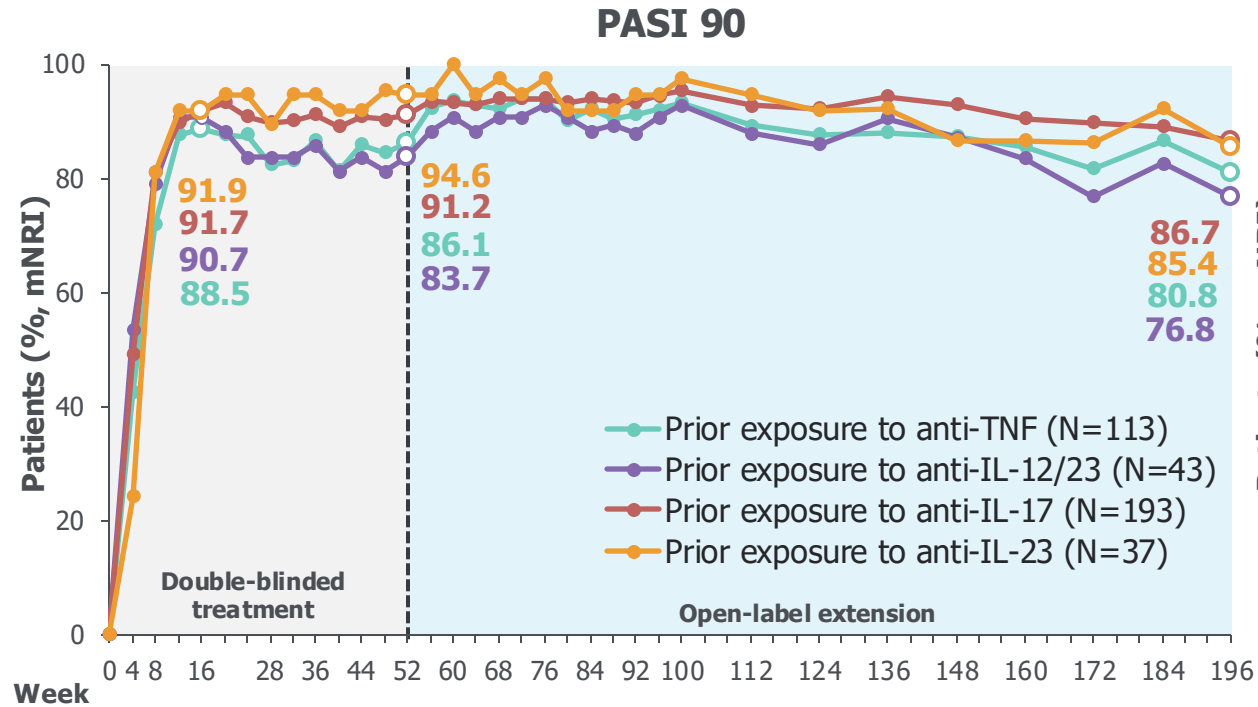
	Week 16	Year 1	Year 2	Year 3	Year 4	Week 16	Year 1	Year 2	Year 3	Year 4
OC, n/N_{obs}[a]	294/457	352/438			275/375	88/121	106/122			74/93
	211/307	231/289			177/248	58/73	61/73			53/64
	152/219	175/209			127/175	40/50	45/50			37/45
	59/88	56/80			50/73	18/23	16/23			16/19

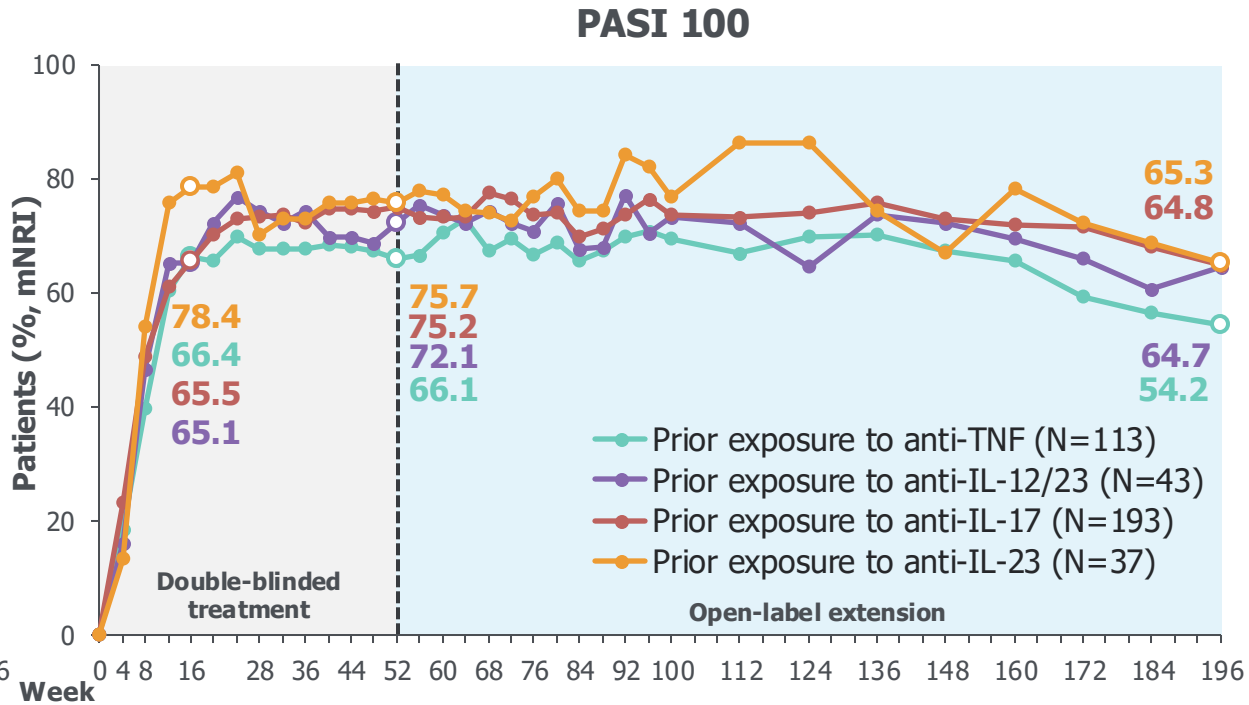
High proportions of BKZ-treated patients achieved PASI 100 from Week 16 through to Year 4, regardless of the **number** of prior biologics they had received.

For 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. **[a]** N_{obs} represents the number of patients with observed data at a given timepoint. BKZ: bimekizumab; mNRI: modified non-responder imputation; OC: observed case; PASI: Psoriasis Area and Severity Index; PASI 100: 100% improvement from baseline in PASI; Q4W: every 4 weeks; Q8W: every 8 weeks.

PASI 90 and PASI 100 response rates through 4 years (mNRI, OC; BKZ Total)

By type of prior biologic[a]





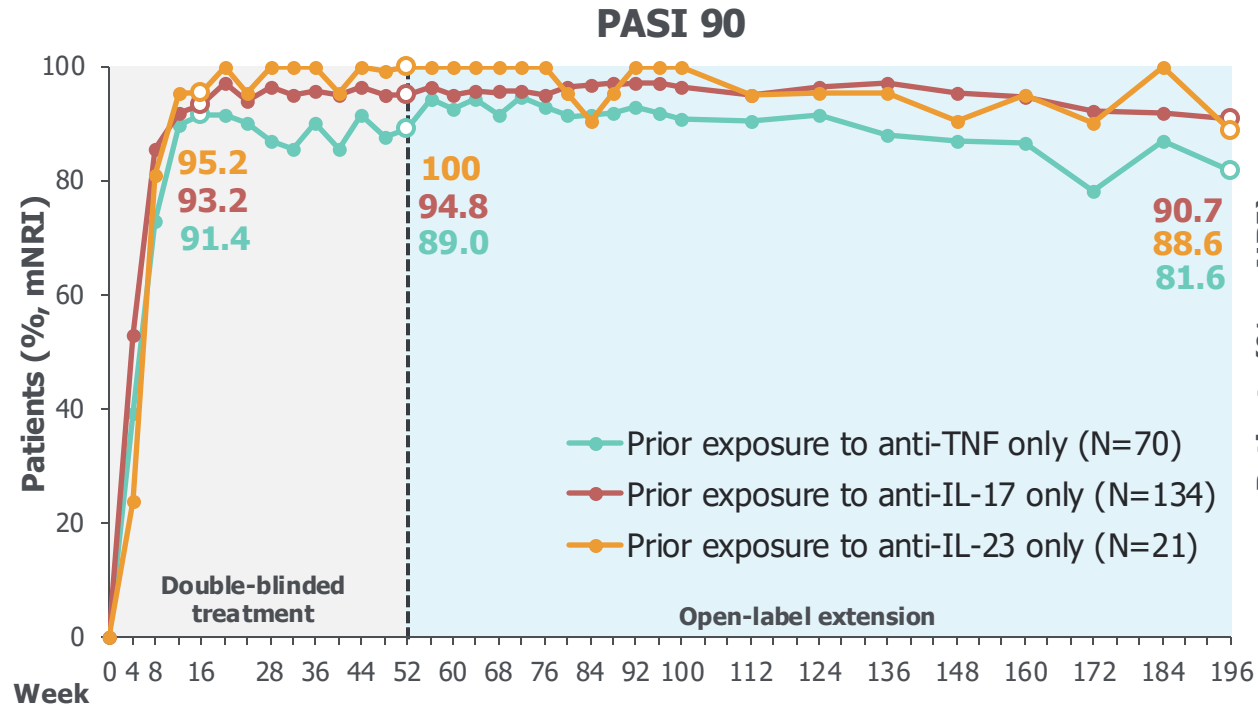
OC, n/N_{obs}[b]	Week 16	Year 1	Year 2	Year 3	Year 4	Week 16	Year 1	Year 2	Year 3	Year 4
	100/112	95/101			76/86	75/112	74/101			54/86
	39/43	36/38			27/33	28/43	31/38			25/33
	176/192	175/181			148/161	126/192	145/181			116/161
	34/37	35/37			27/30	29/37	28/37			22/30

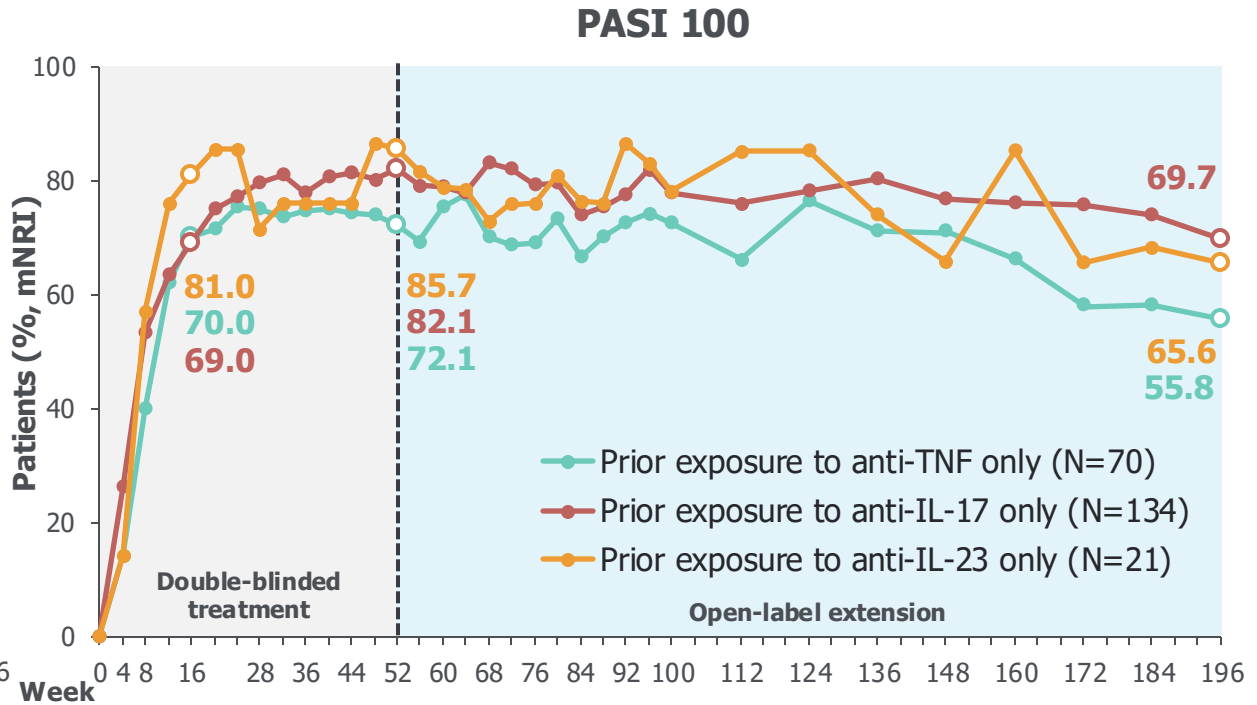
High proportions of BKZ-treated patients achieved PASI 90 and PASI 100 from Week 16 through to Year 4, regardless of the **type** of prior biologic they had received.

For 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. **[a]** Patients could have received multiple prior biologic therapy types; **[b]** N_{obs} represents the number of patients with observed data at a given timepoint. BKZ: bimekizumab; IL: interleukin; mNRI: modified non-responder imputation; OC: observed case; PASI: Psoriasis Area and Severity Index; PASI 90/100: ≥90%/100% improvement from baseline in PASI; Q4W: every 4 weeks; Q8W: every 8 weeks; TNF: tumour necrosis factor.

PASI 90 and PASI 100 response rates through 4 years (mNRI, OC; BKZ Total)

*Patients with prior exposure to **anti-TNF/anti-IL-17/anti-IL-23** only[a]*





OC, n/N_{obs}[b]	Week 16	Year 1	Year 2	Year 3	Year 4	Week 16	Year 1	Year 2	Year 3	Year 4
	124/133	127/129			108/113	92/133	110/129			87/113
	64/69	61/64			45/49	49/69	50/64			33/49
	20/21	21/21			15/17	17/21	18/21			12/17

Results were consistent across patients who had received **anti-TNF/anti-IL-17/anti-IL-23 treatment only**. For those **previously exposed to ixekizumab only** (N=61), Week 16 PASI 90 and PASI 100 responses were 90.2% and 65.6%, and were maintained to Year 4 (91.3% and 73.5%).

For 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. **[a]** Some patients had prior exposure to only one type of prior biologic, but received multiple medications within that biologic type; **[b]** N_{obs} represents the number of patients with observed data at a given timepoint. BKZ: bimekizumab; IL: interleukin; mNRI: modified non-responder imputation; OC: observed case; PASI: Psoriasis Area and Severity Index; PASI 90/100: ≥90%/100% improvement from baseline in PASI; Q4W: every 4 weeks; Q8W: every 8 weeks; TNF: tumour necrosis factor.

Conclusions

Bimekizumab-treated **biologic-naïve** and **biologic-experienced** patients maintained **high skin clearance levels** over 4 years.

Responses were high among biologic-experienced patients **regardless of the number** and **type** of **prior biologics** received.

Outcomes were **consistent** in the **bimekizumab Q4W/Q8W** group.

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Q4W: every 4 weeks; Q8W: every 8 weeks.

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