Bimekizumab efficacy across subgroups of patients with moderate to severe plaque psoriasis: Pooled analysis from up to 3 years of treatment in 5 phase 3/3b clinical trials

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OBJECTIVES:

- To evaluate efficacy outcomes in patients with moderate to severe plaque psoriasis treated with bimekizumab (BKZ), using the largest pool of phase 3/3b data over 3 years.
- To assess **efficacy outcomes** across **subgroups** of age, weight, and baseline disease characteristics in patients with psoriasis.

Background:

- Patient characteristics can impact psoriasis treatment response.[1]
- BKZ is a monoclonal IgG1 antibody which selectively inhibits IL-17F in addition to IL-17A.[2]
- Here, we report efficacy outcomes across patients receiving BKZ through 3 years.

Methods:

- Data were pooled from BE SURE, BE VIVID, 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).[3–7]

Subgroups analyzed


Age and weight


Disease duration


Disease severity


Prior biologic treatment

- Achievement of **PASI 90** and **PASI 100** at **Year 3** are reported using modified non-responder imputation (mNRI).[a]

[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.[5] **1.** Edson-Heredia E et al. J Invest Dermatol 2014;134:18–23; **2.** Adams R et al. Front Immunol 2020;11:1894. **3.** Warren B et al. N Engl J Med 2021;385:130–41, NCT03412747; **4.** Reich K et al. Lancet 2021;397:487–98, NCT03370133; **5.** Gordon KB et al. Lancet 2021;397:475–86, NCT03410992; **6.** Strober B et al. Br J Dermatol 2023;188:749–59, NCT03598790; **7.** Reich K et al. N Engl J Med 2021;385:142–52, NCT03536884. BKZ: bimekizumab; IL interleukin; mNRI: modified non-responder imputation; OLE: open-label extension; PASI 90/100: ≥90/100% improvement from baseline in Psoriasis Area and Severity Index.

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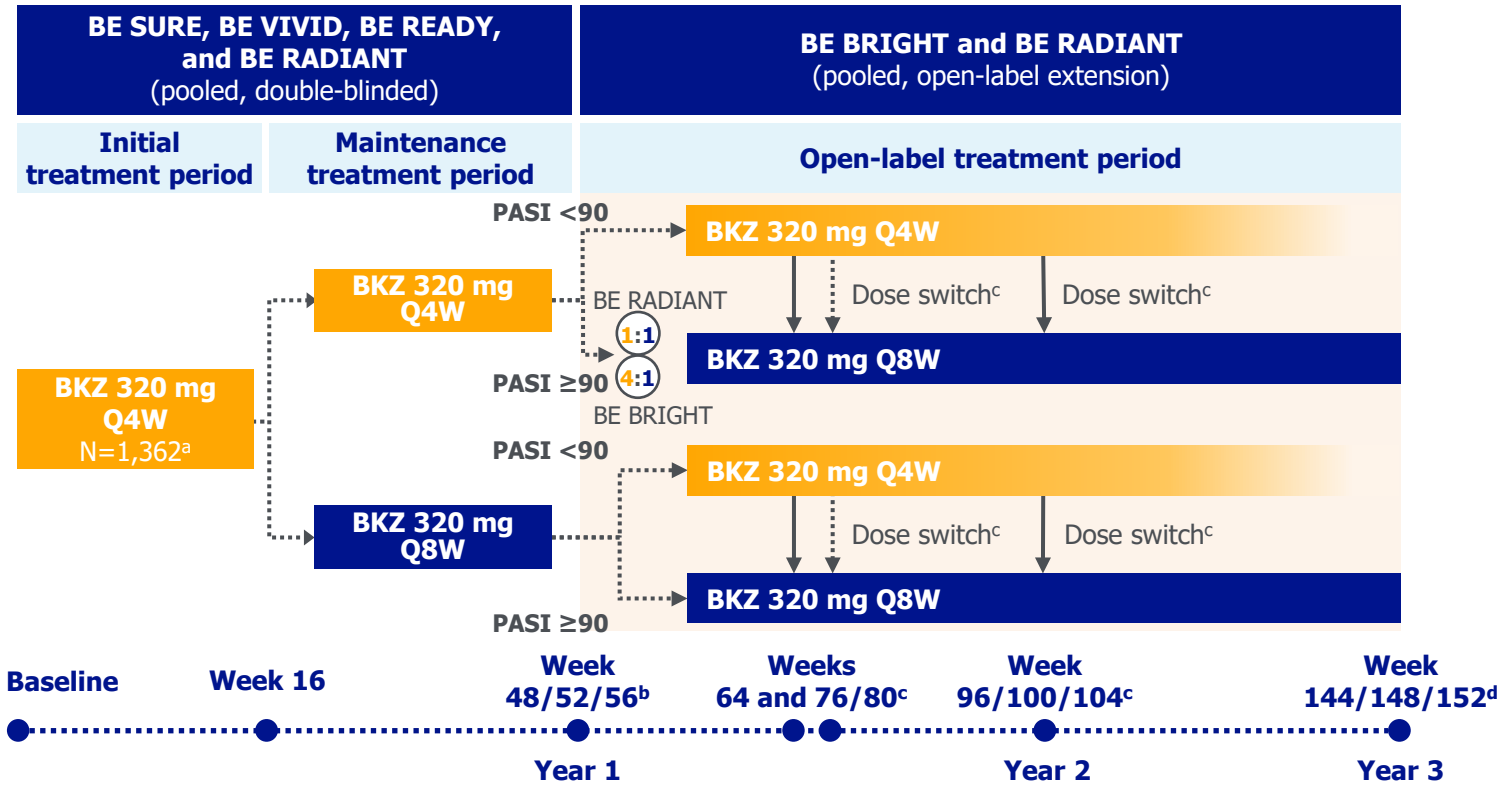
Study Design



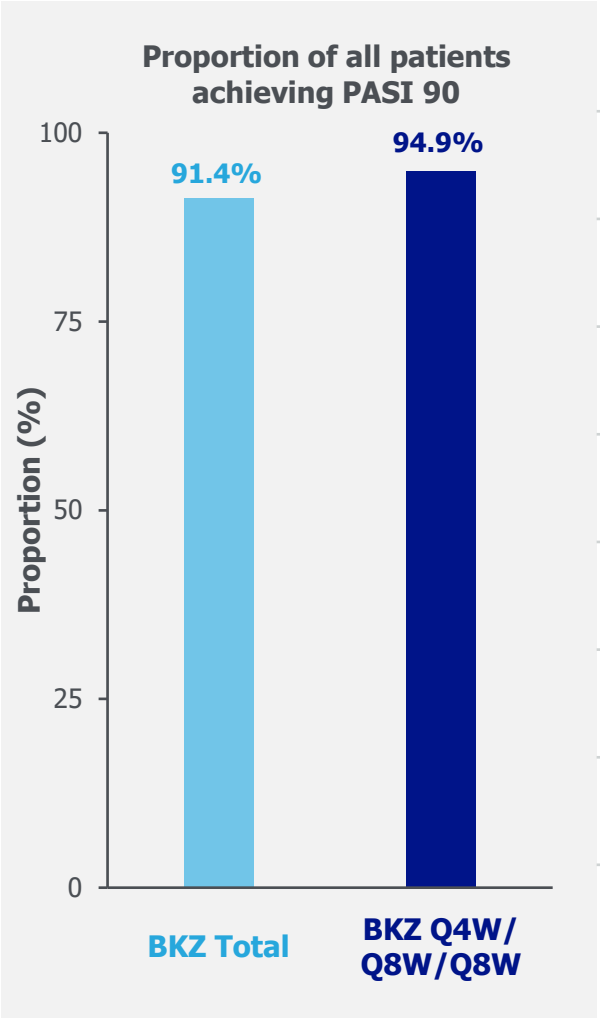
- Of the patients randomized to BKZ Q4W at baseline, 1,107 continued to receive BKZ throughout the maintenance treatment period and into the OLE, regardless of dosing regimen (**BKZ Total**).
- The subset of patients who received **BKZ Q4W/Q8W/Q8W** (initial/maintenance/OLE) were also analyzed (N=374).

Baseline Characteristics

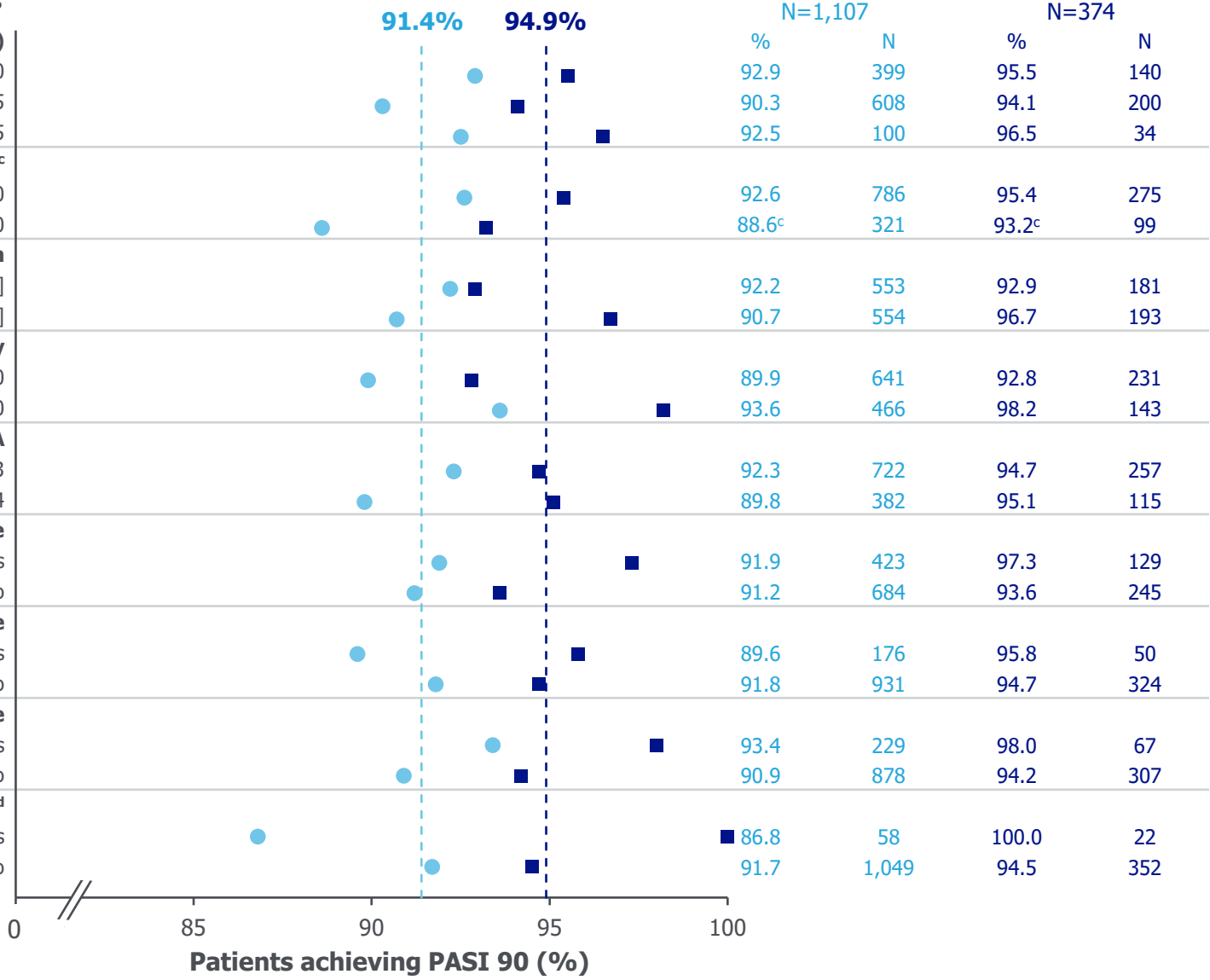
	BKZ Total N=1,107	**BKZ Q4W/Q8W/Q8W** N=374
Age (years), mean ± SD	45.5 ± 13.7	45.0 ± 14.1
Male, n (%)	777 (70.2)	266 (71.1)
White, n (%)	968 (87.4)	354 (94.7)
Weight (kg), mean ± SD	89.8 ± 21.2	89.2 ± 20.8
Duration of psoriasis (years), mean ± SD	18.5 ± 12.8	18.7 ± 12.4
PASI, mean ± SD	20.9 ± 7.6	20.4 ± 7.4
BSA (%), mean ± SD	26.5 ± 15.7	24.5 ± 13.5
IGA, n (%)		
3: moderate	722 (65.2)	257 (68.7)
4: severe	382 (34.5)	115 (30.7)
DLQI total score, mean ± SD	10.6 ± 6.4	10.7 ± 6.3
Any prior systemic therapy, n (%)	859 (77.6)	285 (76.2)
Any prior biologic therapy, n (%)	423 (38.2)	129 (34.5)

[a] 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) are not included in these analyses. **[b]** 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. Patients receiving BKZ 320 mg Q4W who achieved PASI 90 at the end of the feeder studies were randomized 1:1 in BE RADIANT and 4:1 in BE BRIGHT to BKZ 320 mg Q4W or Q8W; patients receiving BKZ 320 mg Q8W who achieved PASI 90 at the end of the feeder studies remained on Q8W dosing; **[c]** In BE RADIANT, at Week 64 or the next scheduled clinic visit, all patients switched to BKZ Q8W via protocol amendment; in BE BRIGHT at Week 76/80, 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; **[d]** For the Week 144/148/152 timepoint: Week 144 corresponds to BE RADIANT OLE Week 96; Week 148 corresponds to BE VIVID/BE BRIGHT OLE Week 96; and Week 152 corresponds to BE SURE/BE BRIGHT and BE READY/BE BRIGHT OLE Week 96. BKZ: bimekizumab; BSA: body surface area; DLQI: Dermatology Life Quality Index; IGA: Investigator's Global Assessment; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; Q4W: every 4 weeks; Q8W: every 8 weeks; SD: standard deviation.

Achievement of PASI 90 at Year 3 by Subgroups (mNRI)

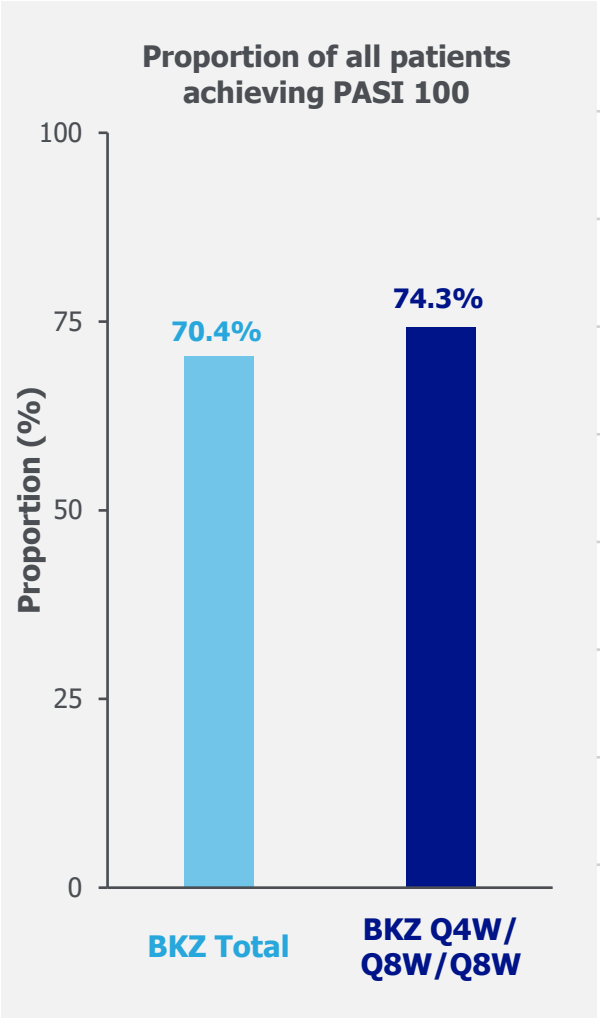


Subgroups	BKZ Total[a,b] N=1,107 %	BKZ Total[a,b] N=1,107 N	BKZ Q4W/Q8W/Q8W N=374 %	BKZ Q4W/Q8W/Q8W N=374 N
Age (years)				
<40	92.9	399	95.5	140
40–<65	90.3	608	94.1	200
≥65	92.5	100	96.5	34
Baseline weight (kg)[c]				
≤100	92.6	786	95.4	275
>100	88.6[c]	321	93.2[c]	99
Psoriasis disease duration				
<median [16.21 years]	92.2	553	92.9	181
≥median [16.21 years]	90.7	554	96.7	193
Baseline disease severity				
PASI <20	89.9	641	92.8	231
PASI ≥20	93.6	466	98.2	143
Baseline IGA				
3	92.3	722	94.7	257
4	89.8	382	95.1	115
Prior biologic exposure				
Yes	91.9	423	97.3	129
No	91.2	684	93.6	245
Prior anti-TNF exposure				
Yes	89.6	176	95.8	50
No	91.8	931	94.7	324
Prior anti-IL-17 exposure				
Yes	93.4	229	98.0	67
No	90.9	878	94.2	307
Prior anti-IL-23 exposure[d]				
Yes	86.8	58	100.0	22
No	91.7	1,049	94.5	352



Results differ slightly from the accepted abstract due to updated mNRI methodology. **[a]** BKZ Total includes all patients randomized to BKZ who received BKZ throughout the maintenance period and into the OLE, regardless of the dosing regimen they received; **[b]** All patients were re-assigned to BKZ Q8W by Year 2/next scheduled visit via protocol amendment; **[c]** For some patients with a body weight ≥120 kg (who did not achieve complete skin clearance at Week 16), BKZ 320 mg Q4W after Week 16 may further improve treatment response;[1] **[d]** Anti-IL-23 category does not include anti-IL-12/23 therapies. **1.** Food and Drug Administration, Bimekizumab Prescribing Information, 2023. BKZ: bimekizumab; IGA: Investigator's Global Assessment; IL: interleukin; mNRI: modified non-responder imputation; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; PASI 90: ≥90% improvement from baseline in PASI; Q4W: every 4 weeks; Q8W: every 8 weeks; TNF: tumor necrosis factor.

Achievement of PASI 100 at Year 3 by Subgroups (mNRI)



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Age (years)				
<40	71.4	399	75.9	140
40–<65	69.1	608	72.3	200
≥65	73.8	100	79.4	34
Baseline weight (kg)[c]				
≤100	72.9	786	78.9	275
>100	64.1[c]	321	61.4[c]	99
Psoriasis disease duration				
<median [16.21 years]	69.1	553	70.8	181
≥median [16.21 years]	71.7	554	77.5	193
Baseline disease severity				
PASI <20	69.6	641	74.4	231
PASI ≥20	71.4	466	74.0	143
Baseline IGA				
3	71.7	722	76.1	257
4	67.7	382	69.8	115
Prior biologic exposure				
Yes	72.0	423	79.6	129
No	69.4	684	71.5	245
Prior anti-TNF exposure				
Yes	68.0	176	73.2	50
No	70.8	931	74.4	324
Prior anti-IL-17 exposure				
Yes	73.5	229	81.4	67
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Prior anti-IL-23 exposure[d]				
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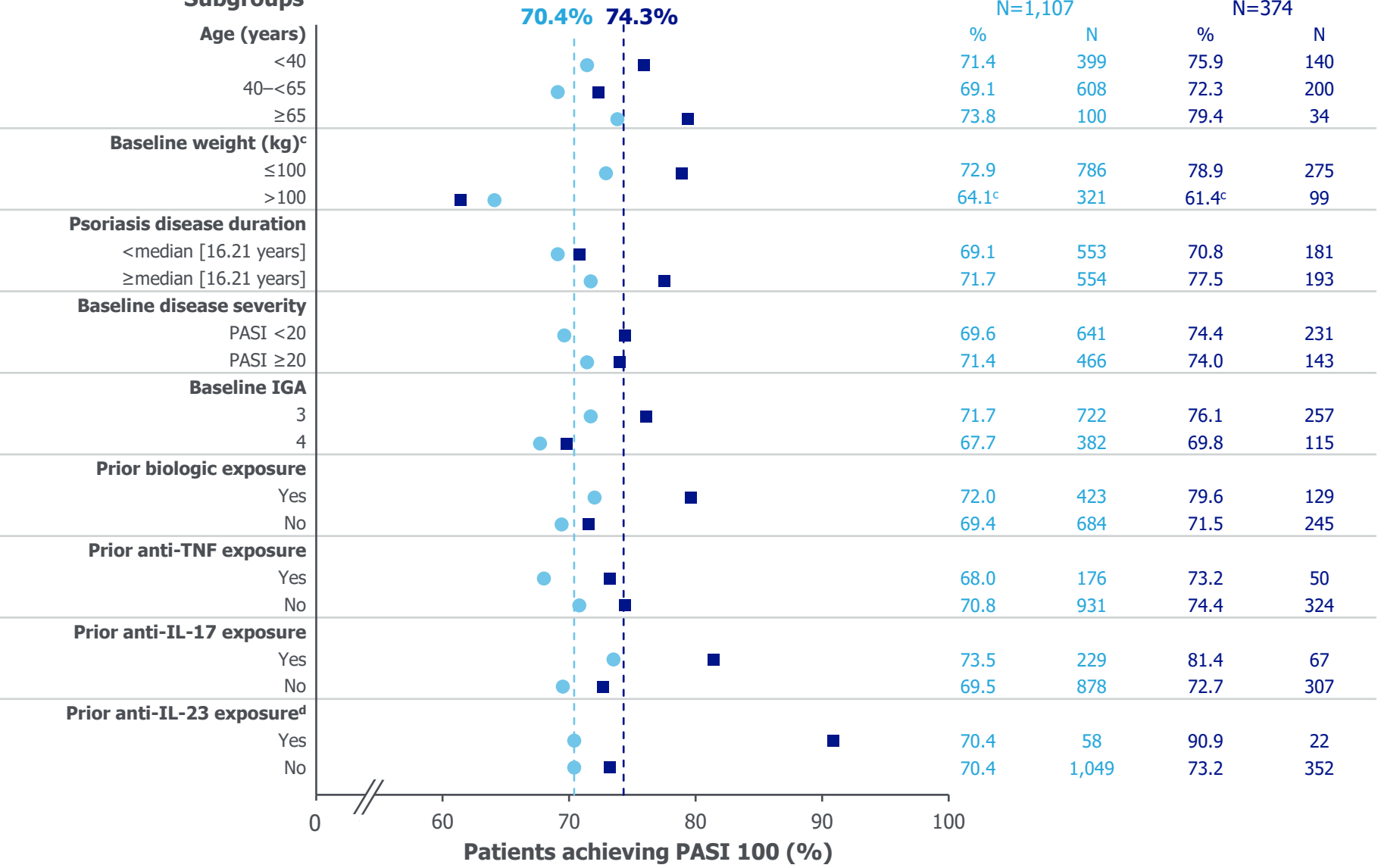

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CONCLUSIONS:

- High and durable levels of complete and near-complete skin clearance were achieved through 3 years of bimekizumab treatment, regardless of baseline demographics, disease characteristics, or prior exposure to biologic therapies.
- These results support bimekizumab as a treatment suitable for a wide variety of patients with psoriasis.
- Weight was the subgroup most associated with skin clearance rate, with patients ≤100 kg more likely to achieve PASI 90 and PASI 100 than patients >100 kg.[a]

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