

Bimekizumab efficacy & safety versus risankizumab in patients with active psoriatic arthritis: 24-week results from a head-to-head, multicentre, randomised, phase 3b study (BE BOLD)

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Objective

To report head-to-head (H2H) efficacy and safety of bimekizumab (BKZ) and risankizumab (RZB) at approved doses in patients with active psoriatic arthritis (PsA) to 16 weeks (primary endpoint) and up to 24 weeks.

Background

- BKZ, a selective inhibitor of interleukin (IL)-17A and IL-17F, and risankizumab (RZB), an IL-23 inhibitor, are both approved treatments that have demonstrated efficacy and tolerability in PsA.¹⁻³
 - BKZ inhibits IL-17A and IL-17F from both IL-23-dependent and IL-23-independent sources.
- BE BOLD is the first H2H study comparing an IL-17A and IL-17F inhibitor with an IL-23 inhibitor in patients with PsA.
- To date, no biologic therapies have shown superiority over other biologics in PsA based on joint-focused outcomes.⁴⁻⁷

Methods

- BE BOLD (NCT06624228) was a multicentre, phase 3b, randomised, double-blinded, active comparator-controlled, parallel group, 24-week study in patients aged ≥18 with active PsA who were biologic disease-modifying antirheumatic drug (bDMARD)-naïve or had prior inadequate response or intolerance to a maximum of one tumour necrosis factor inhibitor (TNFi-IR).
- Patients were randomised 1:1 to receive subcutaneous BKZ or RZB to 24 weeks at approved doses; BKZ dosing was based on baseline (BL) psoriasis severity, per the European Medicines Agency (EMA)/United States Food and Drug Administration (FDA) labels:⁸⁻¹¹
 - Most BKZ-randomised patients received BKZ 160 mg every 4 weeks (Q4W; final dose at Week 20);
 - BKZ-randomised patients with PsA and concomitant moderate-to-severe psoriasis (body surface area [BSA] ≥10% and Investigator's Global Assessment ≥3 and Psoriasis Area and Severity Index [PASI]) ≥12 received BKZ 320 mg Q4W up to Week 16, then every 8 weeks (Q8W; final dose at Week 16);
 - RZB 150 mg was administered at BL, Week 4 then every 12 weeks (Q12W; final dose at Week 16), regardless of psoriasis severity.
- The primary endpoint was ≥50% improvement from BL in American College of Rheumatology response criteria (ACR50) at Week 16 (noninferiority and superiority; sequentially tested).
- Secondary endpoints (in sequential testing order) reported here to Week 24, were as follows:
 - Minimal disease activity (MDA) at Week 16;
 - ACR50+PASI100 (100% improvement from BL in PASI: complete skin clearance)¹² at Week 16 in patients with BL BSA ≥3%;
 - ACR50 at Week 4.
- Additional exploratory outcomes to Week 24 included PASI100 in patients with BL BSA ≥3%, and Disease Activity Index for Psoriatic Arthritis (DAPSA) low disease activity or remission (LDA+REM; DAPSA score ≤14).
- Missing data were imputed using non-responder imputation (NRI).
- Safety data reported to end of trial (Week 24 plus safety follow-up). Treatment emergent adverse events (TEAEs) were classified using the Medical Dictionary for Regulatory Activities v27.0.

Results

Patient Characteristics

- Of 553 patients with PsA randomised at baseline, 277 received BKZ and 276 received RZB.
 - 248/277 (89.5%) received BKZ 160 mg Q4W (no-to-mild psoriasis); 29/277 (10.5%) received BKZ 320 mg Q4W/Q8W (moderate-to-severe psoriasis);
 - All 276 patients received RZB 150 mg at BL, Week 4 and Week 16 (245/276 [88.8%] had no-to-mild psoriasis and 31/276 [11.2%] had moderate-to-severe psoriasis).
- Overall, 259/277 (93.5%) BKZ-treated and 248/276 (89.9%) RZB-treated patients completed Week 24. BL characteristics were comparable between treatment groups (Table 1).
- Mean PASI (SD) at BL was 8.9 (7.5) for BKZ-treated patients and 8.2 (7.1) for RZB-treated patients with BL BSA ≥3%.

Efficacy

- BKZ was superior to RZB in achievement of ACR50 at Week 16 (49.1% vs 38.0%; p=0.0059), sustained to Week 24 (nominal p=0.0037), with a greater response as early as Week 4 (nominal p<0.0001; Figure 1A).
- The proportion of BKZ-treated patients achieving MDA was numerically higher than RZB-treated patients across all timepoints to Week 24 (Figure 1B); MDA did not reach statistical significance at Week 16 (43.3% vs 39.9%; p=0.3908).
- Sequential testing stopped at this point and subsequent ranked endpoints are descriptive only.
- Across all timepoints to Week 24, numerically higher proportions of BKZ-treated patients achieved key joint and composite outcome measures compared with RZB-treated patients (Figure 1).
- Across additional exploratory endpoints, higher proportions of BKZ-treated patients achieved PASI100 to Week 16, and DAPSA LDA+REM to Week 24, compared with RZB-treated patients (Figure 2).

Safety

- Safety was comparable between treatment arms and no new safety signals were identified for BKZ (Table 2).
- Discontinuations due to TEAEs were low;
- Cases of serious infection, inflammatory bowel disease, malignancy, neutropenia, hypersensitivity, hepatic, and cardiovascular events were mild across groups;
- Candida infections were more frequent with BKZ; all mild/moderate, none were serious, systemic or led to discontinuation;
- There were no cases of suicidal ideation and behaviour, anaphylaxis or active tuberculosis;
- One death occurred in a patient randomised to RZB; deemed unrelated to treatment (see Table 2 for more details).

Conclusions

Dual inhibition of IL-17A and IL-17F with bimekizumab was superior to IL-23 inhibition with risankizumab for the primary endpoint (ACR50) measuring improvement in joint disease at Week 16 in patients with PsA. A numerically higher proportion of bimekizumab-treated patients achieved key secondary endpoints involving joint, skin and overall disease activity outcomes versus risankizumab-treated patients as early as Week 4, which was sustained up to 24 weeks.

Overall safety profiles were comparable between treatment arms, except for *Candida* infections which were more frequent for bimekizumab, as anticipated by the mechanism of action.

These findings demonstrate the clinical value of targeting IL-17A/F-mediated inflammation to optimise the management of psoriatic arthritis.

Summary

BE BOLD is the first head-to-head study comparing a dual IL-17A and IL-17F inhibitor (bimekizumab) with an IL-23 inhibitor (risankizumab) in patients with psoriatic arthritis

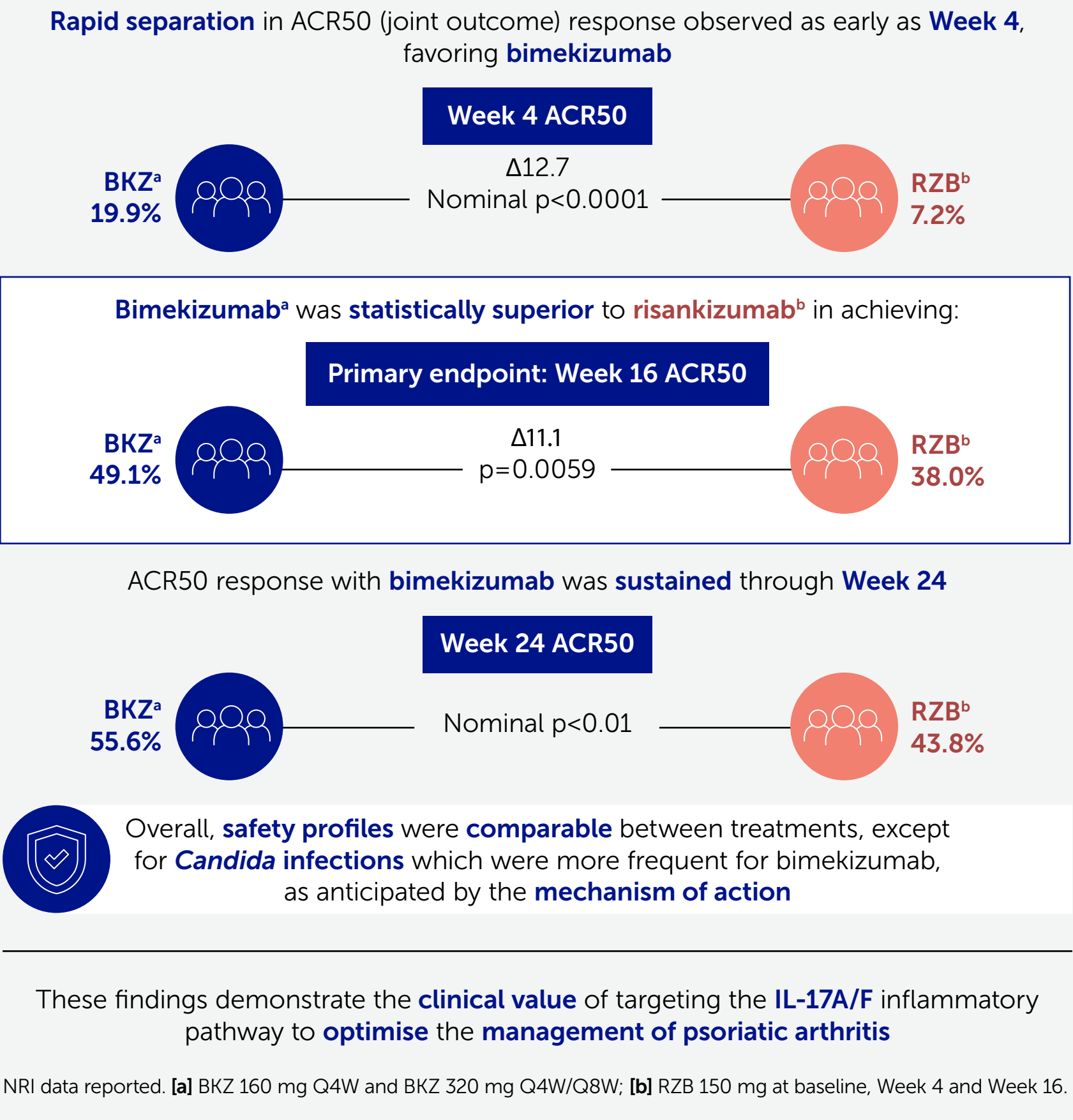
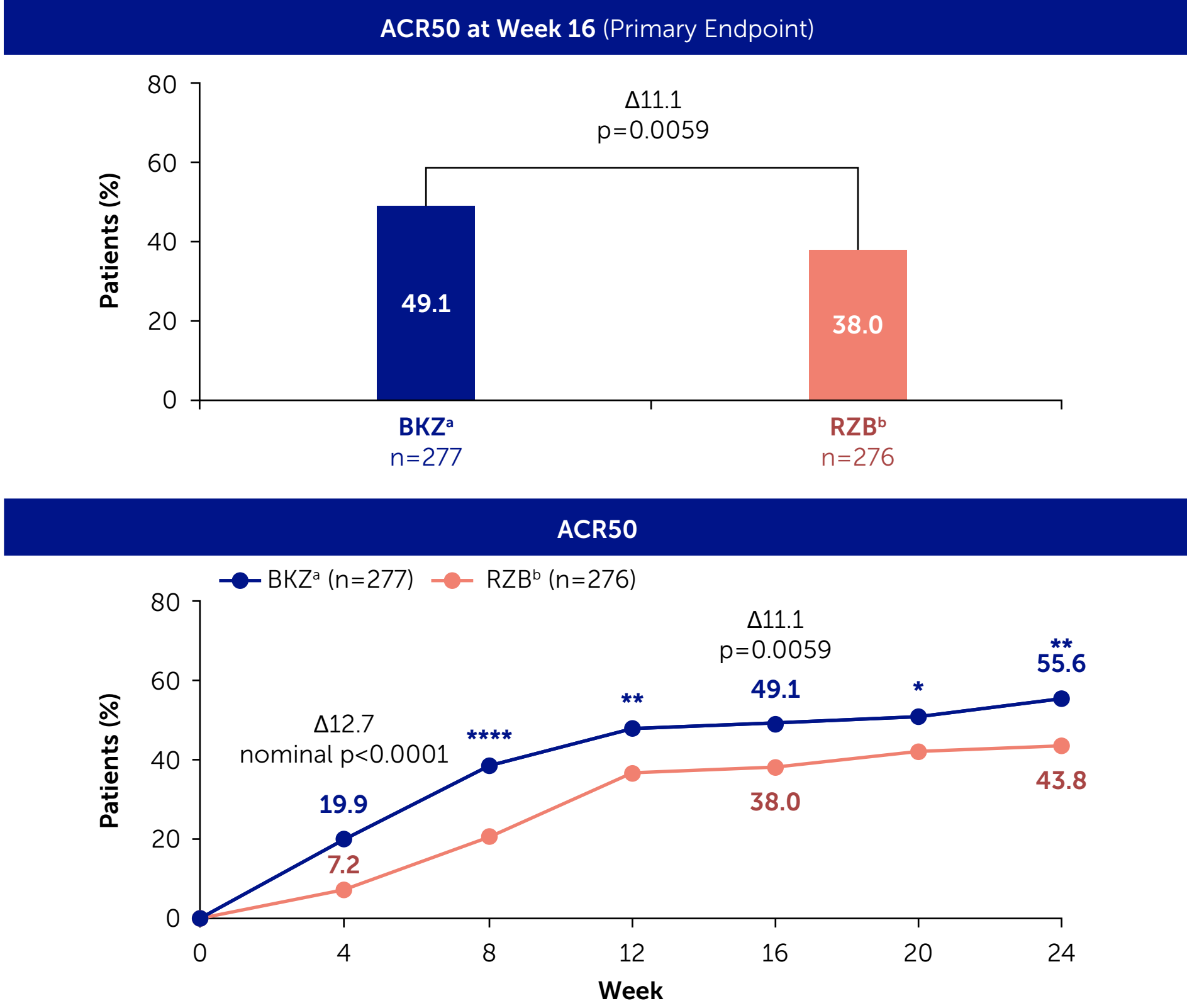


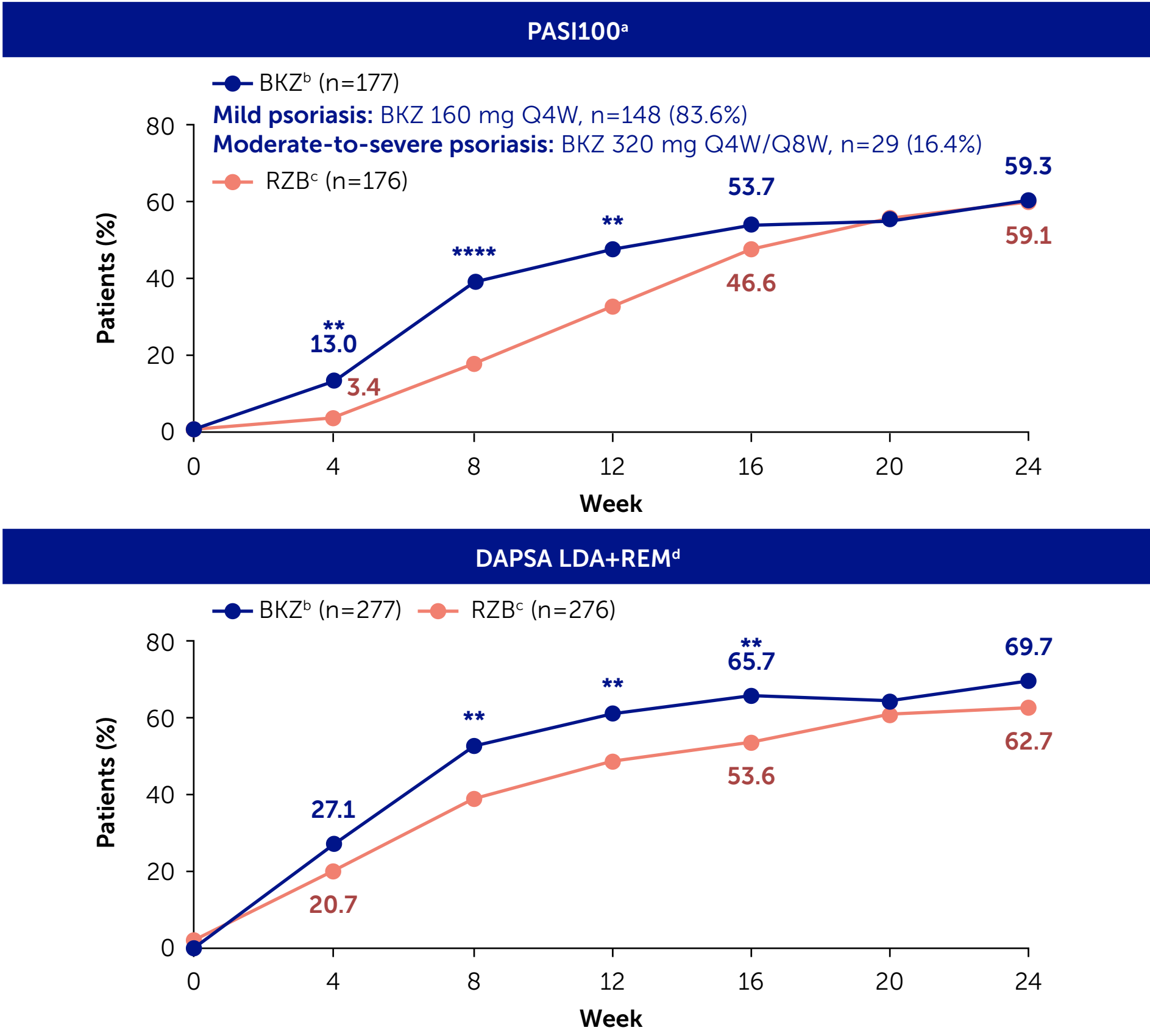
Figure 1 Primary and secondary efficacy outcomes to Week 24 (NRI)

A) Primary Outcome



Randomised set. Pre-specified p values and differences between BKZ and RZB results are displayed for comparisons in the statistical testing hierarchy only. Other nominal p values for BKZ vs RZB: *p<0.05; **p<0.01; ***p<0.001; ****p<0.0001. **[a]** BKZ 160 mg Q4W and BKZ 320 mg Q4W/Q8W; **[b]** RZB 150 mg at baseline, Week 4 and Week 16; **[c]** In patients with baseline psoriasis ≥3% BSA.

Figure 2 Additional exploratory outcomes to Week 24 (NRI)



Randomised set. Nominal p values for BKZ vs RZB: *p<0.01; **p<0.001; ***p<0.0001. **[a]** In patients with baseline psoriasis ≥3% BSA; **[b]** BKZ 160 mg Q4W and BKZ 320 mg Q4W/Q8W; **[c]** RZB 150 mg at baseline, Week 4 and Week 16; **[d]** DAPSA LDA+REM is defined as a DAPSA score of ≤14.

Table 1

Baseline demographics and disease characteristics

	BKZ ^a N=277	RZB ^b N=276
Age, years, mean (SD)	51.1 (13.6)	50.7 (12.7)
Sex, male, n (%)	141 (50.9)	142 (51.4)
BMI, kg/m ² , mean (SD)	29.1 (6.1)	29.2 (6.4)
TJC, mean (SD)	17.3 (12.7)	16.6 (12.2)
SJC, mean (SD)	10.2 (7.4)	9.5 (6.8)
PtGA-PsA, mean (SD)	59.8 (21.0)	58.5 (20.3)
Moderate-to-severe psoriasis, n (%) ^c	29 (10.5)	31 (11.2)
Psoriasis BSA, n (%)		
<3%	100 (36.1)	100 (36.2)
≥3 to ≤10%	114 (41.2)	108 (39.1)
>10%	63 (22.7)	68 (24.6)
PASI, mean (SD) ^d	8.9 (7.5)	8.2 (7.1)
hs-CRP ≥6 mg/L, n (%)	84 (30.3)	83 (30.1)
Prior TNFi, n (%)	55 (19.9)	58 (21.0)
Any csDMARDs at baseline, n (%) ^e	191 (69.0)	195 (70.7)
Enthesitis, LEI >0, n (%)	131 (47.3)	133 (48.2) ^f
Dactylitis, LDI >0, n (%)	45 (16.2)	41 (14.9) ^f

Randomised set. **[a]** BKZ 160 mg Q4W and BKZ 320 mg Q4W/Q8W; **[b]** RZB 150 mg at baseline, Week 4 and Week 16; **[c]** Moderate-to-severe psoriasis defined as BSA ≥10% and IGA ≥3 and PASI ≥12; **[d]** In patients with baseline psoriasis ≥3% BSA; BKZ Total n=177 (BKZ 160 mg Q4W n=148; BKZ 320 mg Q4W/Q8W n=29); RZB n=176; **[e]** Includes methotrexate, sulfasalazine and leflunomide; **[f]** Data missing for 1 patient.

B) Secondary Outcomes

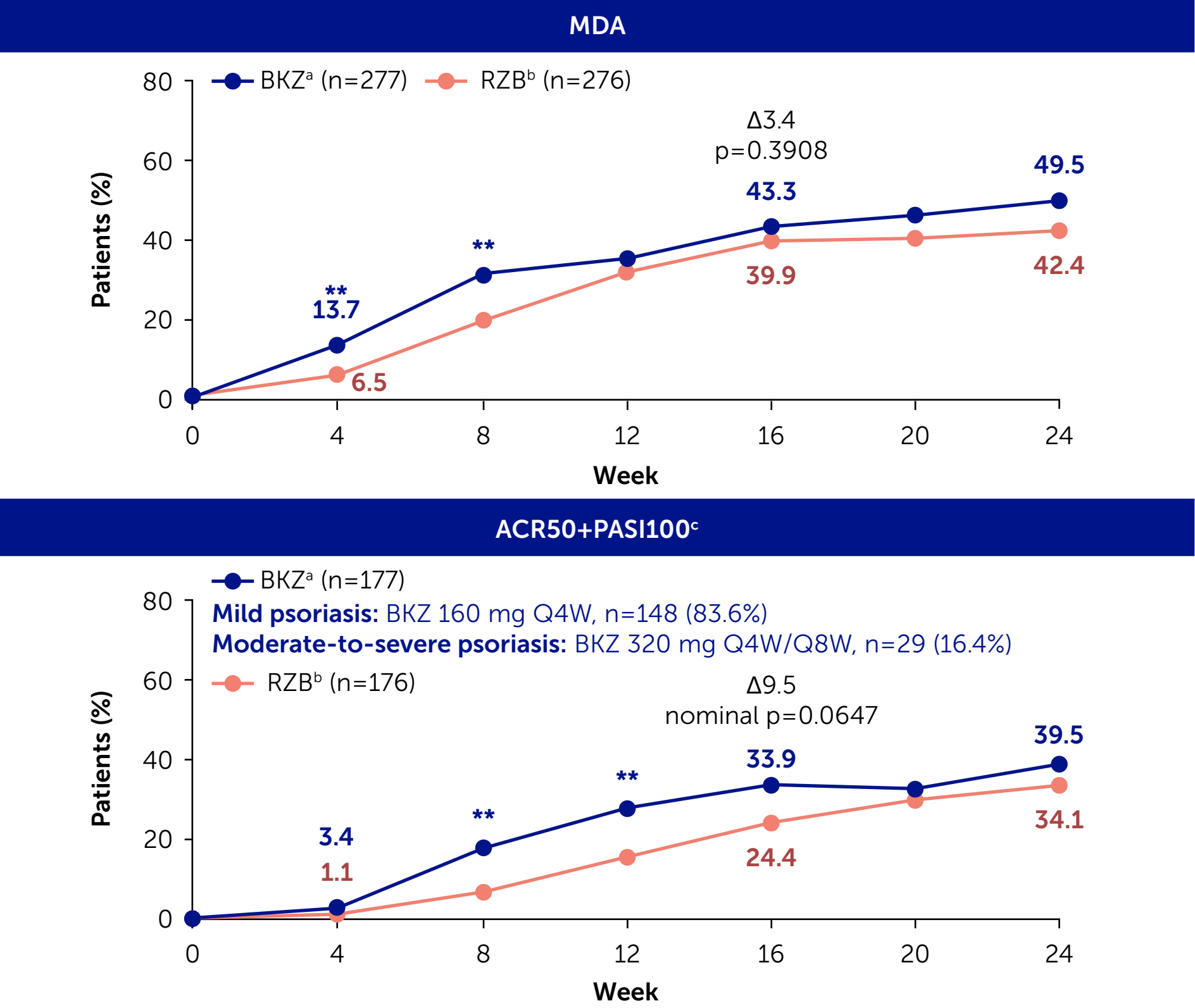


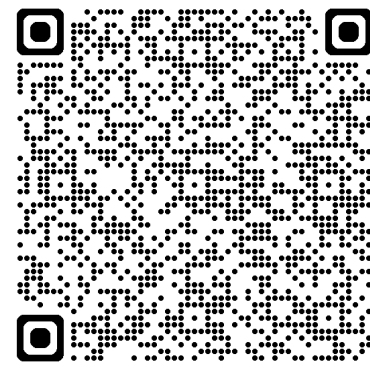
Table 2

Safety to end of trial

n (%)	BKZ ^a N=277; 164.9 PY	RZB ^b N=275; 162.1 PY
Any TEAE	161 (58.1)	153 (55.6)
Serious TEAEs	5 (1.8)	9 (3.3)
Study discontinuations due to TEAEs	4 (1.4)	3 (1.1)
Severe TEAEs	5 (1.8)	5 (1.8)
Drug-related TEAEs	42 (15.2)	31 (11.3)
Deaths	0	1 (0.4) ^c
Most common TEAEs^d		
Nasopharyngitis	33 (11.9)	26 (9.5)
Upper respiratory tract infection	15 (5.4)	7 (2.5)
Safety topics of interest		
Serious infections	2 (0.7)	1 (0.4)
Opportunistic infections	0	1 (0.4)
Fungal infections	16 (5.8)	4 (1.5)
Candida infections	8 (2.9)	2 (0.7)
Oral candidiasis	7 (2.5)	2 (0.7)
Malignancies	1 (0.4)	2 (0.7)
Neutropenia	3 (1.1)	0
Anaphylactic reaction	0	0
Hypersensitivity ^e	8 (2.9)	2 (0.7)
Injection site reaction	4 (1.4)	2 (0.7)
Inflammatory bowel disease	1 (0.4) ^f	0
Suicidal ideation and behaviour	0	0
Cardiovascular events	1 (0.4)	3 (1.1)
Hepatic events	12 (4.3)	9 (3.3)
Elevated liver enzymes ^g	9 (3.2)	9 (3.3)

Safety set. Safety is reported until end of trial, including the 12-week safety follow-up period; as participants were permitted to use any other medications once 28 days had passed from their final study dose, participants may have continued or discontinued the same treatment or switched to another treatment within the safety follow-up period. TEAEs were classified using the Medical Dictionary for Regulatory Activities v27.0. **[a]** BKZ 160 mg Q4W and BKZ 320 mg Q4W/Q8W; **[b]** RZB 150 mg at baseline, Week 4 and Week 16; **[c]** Patient without moderate/severe psoriasis. Deemed unrelated to treatment by the Investigator, with a reported cause of myocardial infarction in a patient with coronary artery disease, hypertension and hyperlipidaemia; **[d]** TEAEs occurring in >5% of either treatment arm; **[e]** No serious or severe hypersensitivity events. Events were mainly dermatitis, rash and urticaria, two were deemed related to treatment, and none led to permanent treatment or study discontinuation; **[f]** A flare of Crohn's disease occurred in a patient with a history of Crohn's disease; **[g]** Elevated liver enzymes include the following preferred terms reported as adverse events: increased/abnormal levels of alanine aminotransferase, aspartate aminotransferase, blood bilirubin, gamma-glutamyltransferase, hepatic enzyme, liver function test, total bile acids or transaminases.

References: ¹Gossec L et al. *Rheumatology* (Oxford) 2026;65(S1):eag118; ²Kristensen LE et al. *Rheumatol Ther* 2024;11:617–32 (NCT03675308); ³Östör A et al. *Rheumatol Ther* 2024;11:633–48; ⁴Mease PJ et al. *Ann Rheum Dis* 2020;79:123–31; ⁵McInnes IB et al. *N Engl J Med* 2021;384(13):1227–39; ⁶Harrison SR et al. *Polish Archives of Internal Medicine* 2024;134(1):16539; ⁷FDA Prescribing Information: BIMZELX[®]. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761151s000lbl.pdf [Accessed September 2026]; ⁸FDA Prescribing Information: SKYRIZI[®]. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761262s000lbl.pdf [Accessed September 2026]; ⁹EMA Summary of Product Characteristics, Bimzelx. Available from: https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf [Accessed September 2026]; ¹⁰EMA Summary of Product Characteristics, Skyrizi. Available from: https://www.ema.europa.eu/en/documents/product-information/skyrizi-epar-product-information_en.pdf [Accessed September 2026]; ¹¹Augustin M. *Dermatol Ther* (Heidelberg) 2024;14:2841–2857. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **IBM, LG, ABG, PJM, AM, YT, DT, BI, AM, JC, ARP, NG, MM, JFM**; Drafting of the publication, or reviewing it critically for important intellectual content: **IBM, LG, ABG, PJM, AM, YT, DT, BI, AM, JC, ARP, NG, MM, JFM**; Final approval of the publication: **IBM, LG, ABG, PJM, AM, YT, DT, BI, AM, JC, ARP, NG, MM, JFM**. **Author Disclosures:** **IBM:** Consulting fees and honoraria from AbbVie, AstraZeneca, BMS, Boehringer Ingelheim, Cabaletta, Novartis Therapeutics, Celgene, Eli Lilly and Company, Janssen, MoonLake Immunotherapeutics, Montal, Novartis, Pioneer Therapeutics and UCB; **LG:** Research grants from AbbVie, AlfaSigma, Amgen, BMS, Celltrion, 360, Eli Lilly and Company, Novartis and UCB; consulting fees from AbbVie, AlfaSigma, Amgen, BMS, Celltrion, 360, Eli Lilly and Company, Novartis and UCB; **ABG:** Research/educational grants from BMS, Johnson & Johnson, MoonLake, and UCB (all paid to Mount Sinai School of Medicine until May 1, 2025); sub 1 at UTWS on studies from BMS and Johnson & Johnson; PI on a BMS study; honoraria as an advisory board member and consultant for Amgen, AbbVie (terminated July 2026), AstraZeneca, Biogen, BMS, Eli Lilly and Company, Johnson & Johnson, Novartis, Orluka, Sanofi, SunPharma, Takeda, Teva, and UCB; **PJM:** Research grants from AbbVie, Acelyrin, Amgen, BMS, Eli Lilly and Company, Johnson & Johnson Innovative Medicine, Novartis, Pfizer, Inc., Sana and UCB; consulting fees from AbbVie, Acelyrin, Amgen, BMS, Century, Cullinan, Eli Lilly and Company, Immagine, Johnson & Johnson Innovative Medicine, MoonLake Immunotherapeutics, Novartis, Pfizer, Spyre, Takeda and UCB; speakers bureau fees from AbbVie, Amgen, Eli Lilly and Company, Johnson & Johnson Innovative Medicine, Novartis, Pfizer and UCB; **AM:** Research grants, consulting fees, and/or speaker's fees from AbbVie, BMS, Boehringer Ingelheim, Celgene, Eisai, Eli Lilly and Company, Janssen, Kyowa Hakko Kirin, LEO Pharma, Maruho, Mitsubishi Tanabe Pharma, Nichi-ko, Nippon Kayaku, Novartis, Pfizer, Sun Pharma, Taiho Pharmaceutical, Torii Pharmaceutical, UCB and Ushio; **YT:** Speaking fees and/or honoraria from AbbVie, AstraZeneca, Biogen, BMS, Boehringer-Ingelheim, Chugai, Eisai, Eli Lilly and Company, Gilead, GSK, Novartis, Otsuka, Sandoz, Sanofi, Taido, Tanabe and UCB; Research grants from Asahi-kasei; **DT:** Investigator and/or consultant/advisor for AbbVie, Almirall, Amgen, BMS, Boehringer Ingelheim, Celltrion, Eli Lilly and Company, Galderma, Incyte, Johnson and Johnson, Kyowa Kirin, LEO Pharma, L'Oréal, New Bridge, Novartis, Pfizer, Regeneron, Samsung, Sanofi, Stada, Sun Pharma, Takeda, Target-RWE, UCB, Viatrix and Vichy; received grants from AbbVie, Almirall, LEO Pharma and Novartis; **BI:** Shareholder of AbbVie, GSK and UCB; employee of UCB; **AMa, JC, ARP, NG, MM:** Shareholder and employee of UCB; **JFM:** Consultant and/or investigator for AbbVie, Amgen, AstraZeneca, Biogen, BMS, Boehringer Ingelheim, Eli Lilly and Company, Galderma, Janssen, MoonLake Immunotherapeutics, Novartis, Orluka, Pfizer, Regeneron, Sanofi, Sun Pharma and UCB. **Acknowledgements:** This study was funded by UCB. We thank the patients and their caregivers in addition to the investigators and their teams who contributed to this study. The authors also thank Lyes Derouiche, PhD, CMPP, of UCB for editorial review and publication coordination, Lilit Ghazaryan, MBIol, of Costello Medical, UK, for editorial assistance, and the Costello Medical Creative team for design support. All costs associated with development of this poster were funded by UCB.



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