BIMEKIZUMAB EFFICACY & SAFETY VERSUS RISANKIZUMAB IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS: 16-WEEK RESULTS FROM A HEAD-TO-HEAD, MULTICENTRE, RANDOMISED, PHASE 3B STUDY (BE BOLD)

This slide deck has been adapted from its original presentation and is limited to Week 16 data only. Full 24-week results will be provided following data base lock.

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Disclosures

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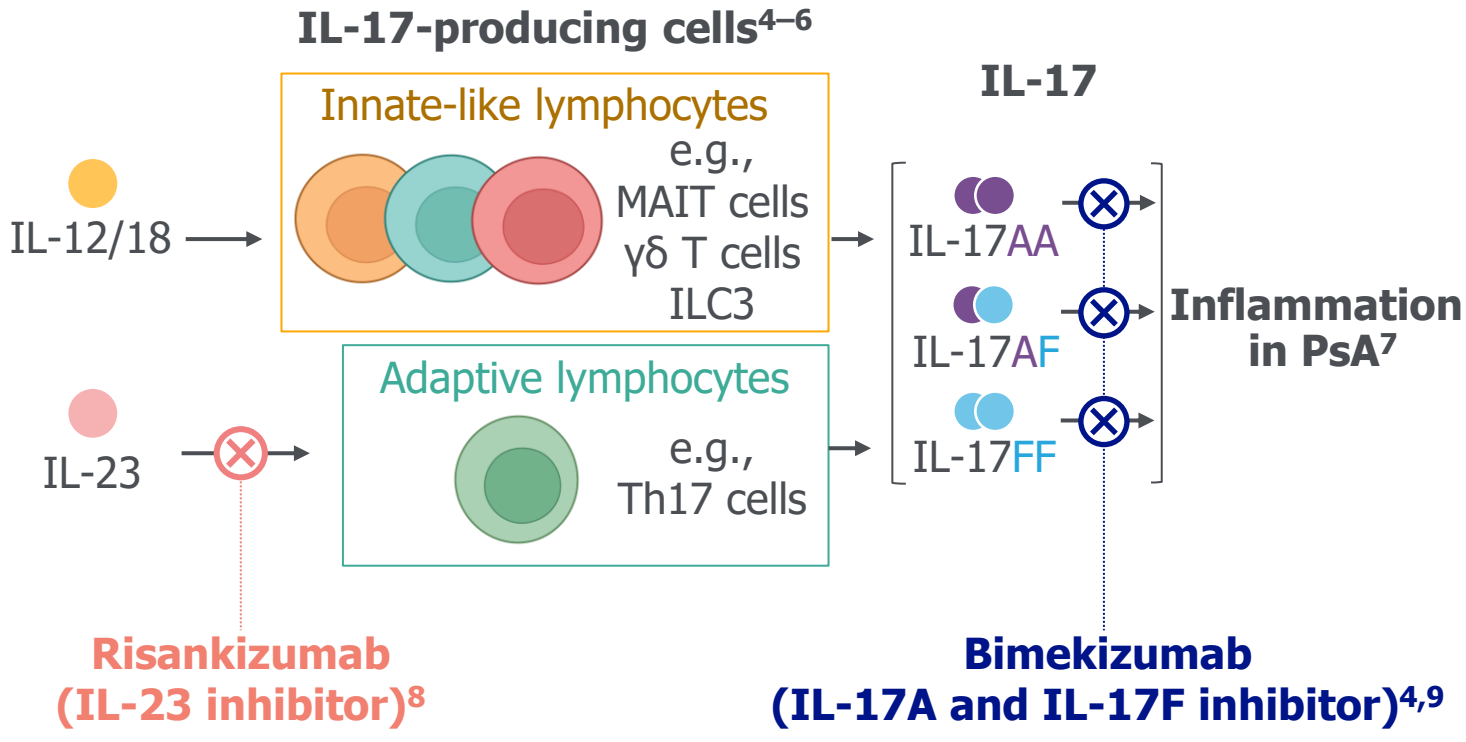
Background

- Bimekizumab (BKZ), a selective inhibitor of interleukin (IL)-17A and IL-17F from IL-23-dependent and -independent sources, and risankizumab (RZB), an IL-23 inhibitor, are both approved treatments that have demonstrated efficacy and tolerability in psoriatic arthritis (PsA).[1–3]
- **BE BOLD is the first head-to-head (H2H) study comparing an IL-17A and IL-17F inhibitor with an IL-23 inhibitor in patients with PsA.**

Bimekizumab and Risankizumab MoA



OBJECTIVE: To directly evaluate the efficacy and safety of BKZ and RZB at approved doses in patients with active PsA to 16 weeks, utilising the joint-focused primary endpoint of ACR50.

1. Gossec L. Rheumatology (Oxford) 2026:keag118 (NCT03895203, NCT03896581, NCT04009499); **2.** Kristensen LE. Rheumatol Ther 2024;11:617–32 (NCT03675308); **3.** Östör A. Rheumatol Ther 2024;11:633–48 (NCT03671148); **4.** Tsukazaki H, Kaito T. Int J Mol Sci 2020;21:6401; **5.** Cole S. Front Immunol 2020;11:585134; **6.** Łukasik Z. Rheumatology (Oxford) 2021;60:iv16–27; **7**. Wang EA. Eur J Rheumatol 2017;4:272–7; **8.** Pang Y. Clin Transl Sci 2024;17:e13706; **9.** Glatt S. Ann Rheum Dis 2018;77:523–32. **Abbreviations: ACR50:** ≥50% improvement from baseline in American College of Rheumatology response criteria; **BKZ:** bimekizumab; **H2H:** head-to-head; **IL:** interleukin; **ILC3:** group 3 innate lymphoid cells; **MAIT:** mucosal-associated invariant T; **MoA:** mechanism of action; **PsA:** psoriatic arthritis; **RZB:** risankizumab; **Th:** T helper.

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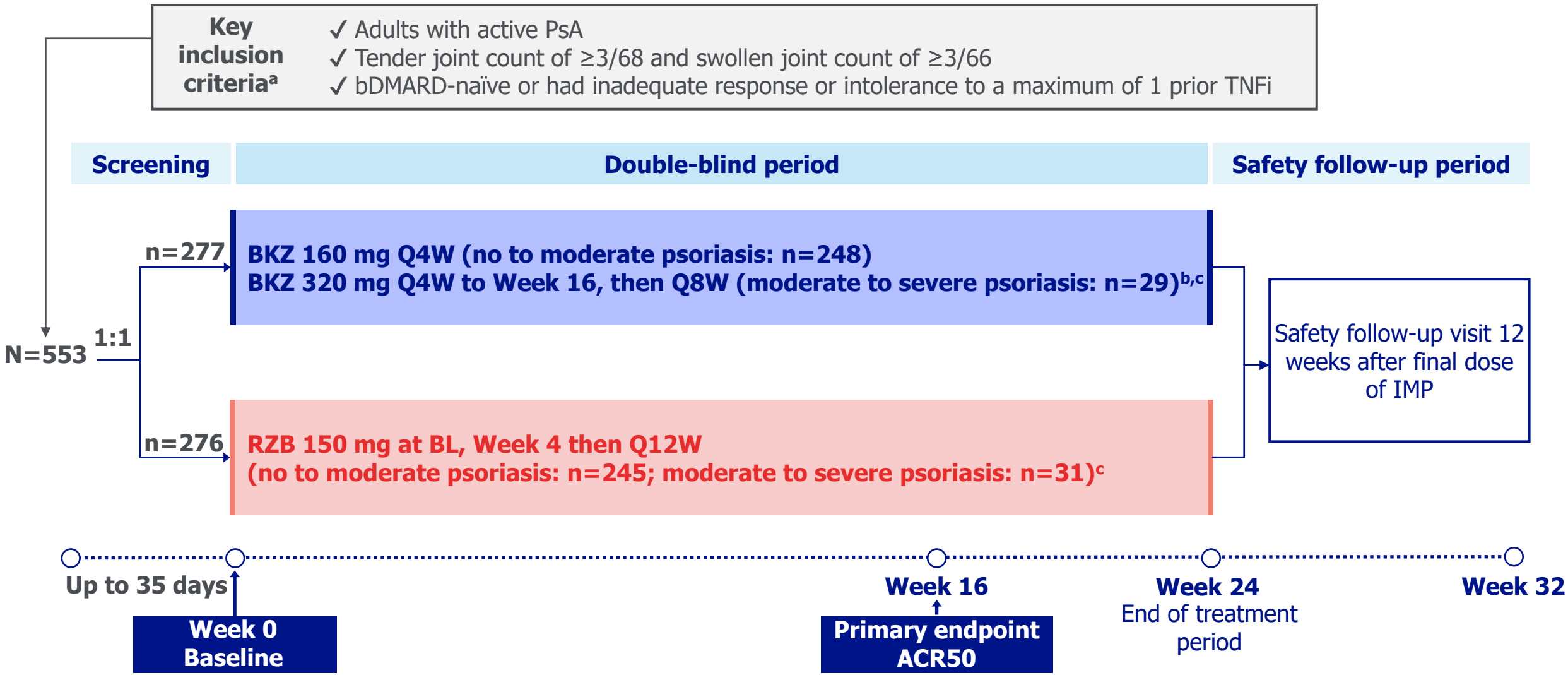
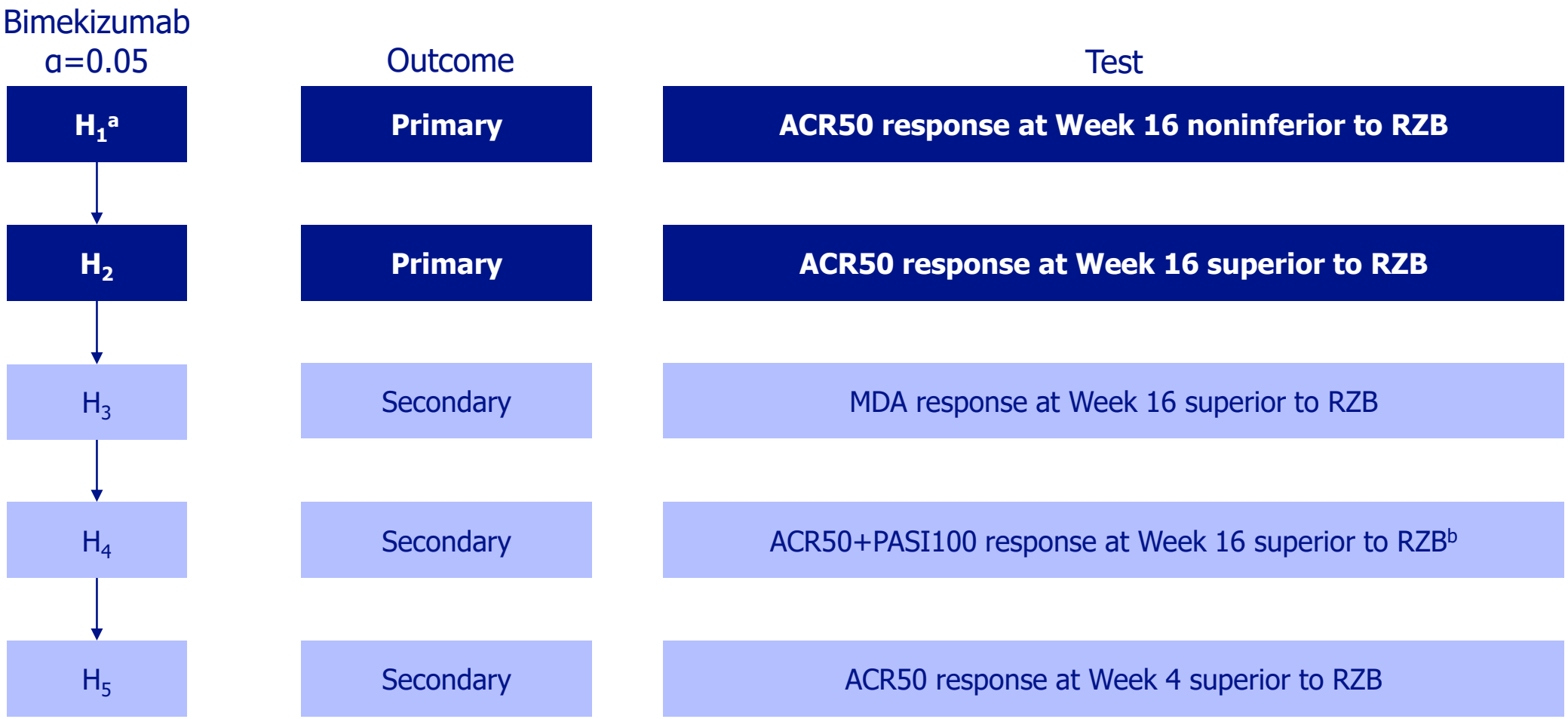
Methods – BE BOLD Study Design



BE BOLD (NCT06624228) study design. **[a]** Eligible patients had active PsA according to the CASPAR criteria, ≥1 active psoriatic lesion and/or history of chronic plaque-type psoriasis; concomitant stable doses of csDMARDs were permitted; **[b]** This is the approved dose for BKZ in patients with moderate to severe psoriasis; **[c]** Moderate to severe psoriasis defined as baseline BSA ≥10%, IGA ≥3 and PASI ≥12. **Abbreviations: bDMARD:** biologic disease-modifying antirheumatic drug; **BKZ:** bimekizumab; **BSA:** body surface area; **CASPAR:** ClASsification criteria for Psoriatic Arthritis; **csDMARD:** conventional synthetic disease-modifying antirheumatic drug; **IGA:** Investigator's Global Assessment; **IMP:** investigational medicinal product; **PASI:** Psoriasis Area and Severity Index; **Q4/8/12W:** every 4/8/12 weeks; **RZB:** risankizumab; **TNFi:** tumour necrosis factor inhibitor.

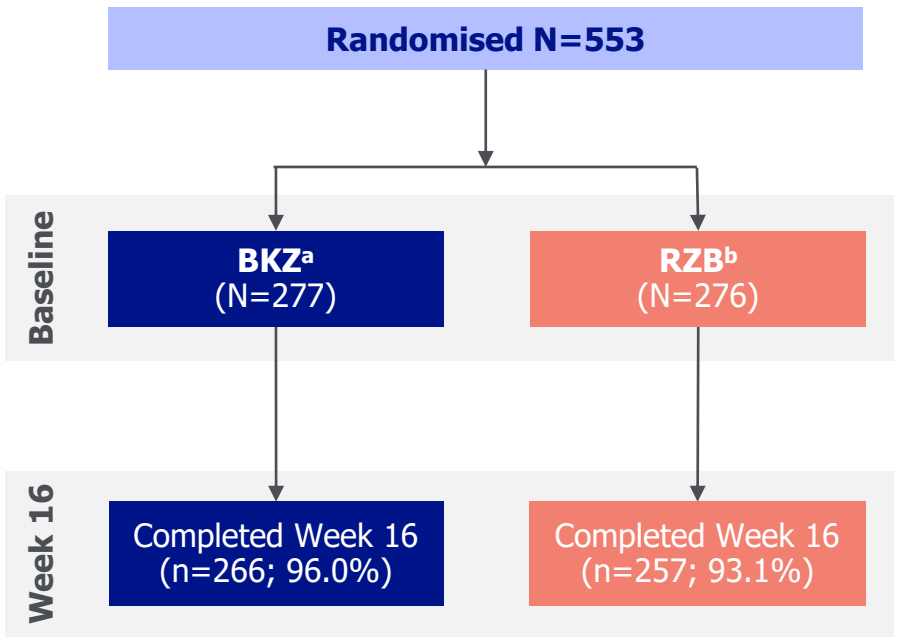
Methods – Statistical Testing Hierarchy

All Study Participants (BKZ 160/320 mg vs RZB 150 mg)



[a] Based on a 10% noninferiority margin; **[b]** In patients with baseline BSA ≥3%.
Abbreviations: ACR50: ≥50% improvement from baseline in American College of Rheumatology response criteria; **BKZ:** bimekizumab; **BSA:** body surface area; **MDA:** minimal disease activity; **PASI100:** 100% improvement from baseline in Psoriasis Area and Severity Index; **RZB:** risankizumab.

Patient Disposition and Baseline 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)
Time since first diagnosis of PsA, years, mean (SD)	6.5 (7.3)	6.0 (6.9)
Prior TNFi, n (%)	55 (19.9)	58 (21.0)
Any csDMARDs at baseline, n (%)[c]	191 (69.0)	195 (70.7)
Concomitant methotrexate, n (%)[d]	166 (59.9)	165 (59.8)
TJC (of 68 joints), mean (SD)	17.3 (12.7)	16.6 (12.2)
SJC (of 66 joints), mean (SD)	10.1 (7.4)	9.5 (6.8)
Moderate to severe psoriasis, n (%)[e]	29 (10.5)	31 (11.2)
Psoriasis BSA, n (%)		
<3%	101 (36.5)	100 (36.2)
≥3 to ≤10%	113 (40.8)	108 (39.1)
>10%	63 (22.7)	68 (24.6)
PASI, mean (SD)[f]	8.9 (7.5)	8.2 (7.1)
Enthesitis, LEI >0, n (%)	130 (46.9)[g]	133 (48.2)[g]
Dactylitis, LDI >0, n (%)	44 (15.9)[g]	41 (14.9)[g]
hs-CRP ≥6 mg/L, n (%)	84 (30.3)	83 (30.1)
PtGA-PsA, mean (SD)	59.8 (21.0)	58.5 (20.3)

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]** Includes methotrexate, sulfasalazine and leflunomide; **[d]** Based on safety set (n=275 for RZB); **[e]** Moderate to severe psoriasis defined as BSA ≥10%, IGA ≥3 and PASI ≥12; **[f]** In patients with baseline psoriasis ≥3% BSA: BKZ Total n=176 (BKZ 160 mg Q4W n=147; BKZ 320 mg Q4W/Q8W n=29); RZB n=176; **[g]** Data missing for 1 patient. **Abbreviations: BKZ:** bimekizumab; **BMI:** body mass index; **BSA:** body surface area; **csDMARD:** conventional synthetic disease-modifying antirheumatic drug; **hs-CRP:** high-sensitivity C-reactive protein; **IGA:** Investigator's Global Assessment; **LDI:** Leeds Dactylitis Index; **LEI:** Leeds Enthesitis Index; **PASI:** Psoriasis Area and Severity Index; **PtGA-PsA:** Patient's Global Assessment for Psoriatic Arthritis; **Q4/8W:** every 4/8 weeks; **RZB:** risankizumab; **SD:** standard deviation; **SJC:** swollen joint count; **TJC:** tender joint count; **TNFi:** tumour necrosis factor inhibitor.

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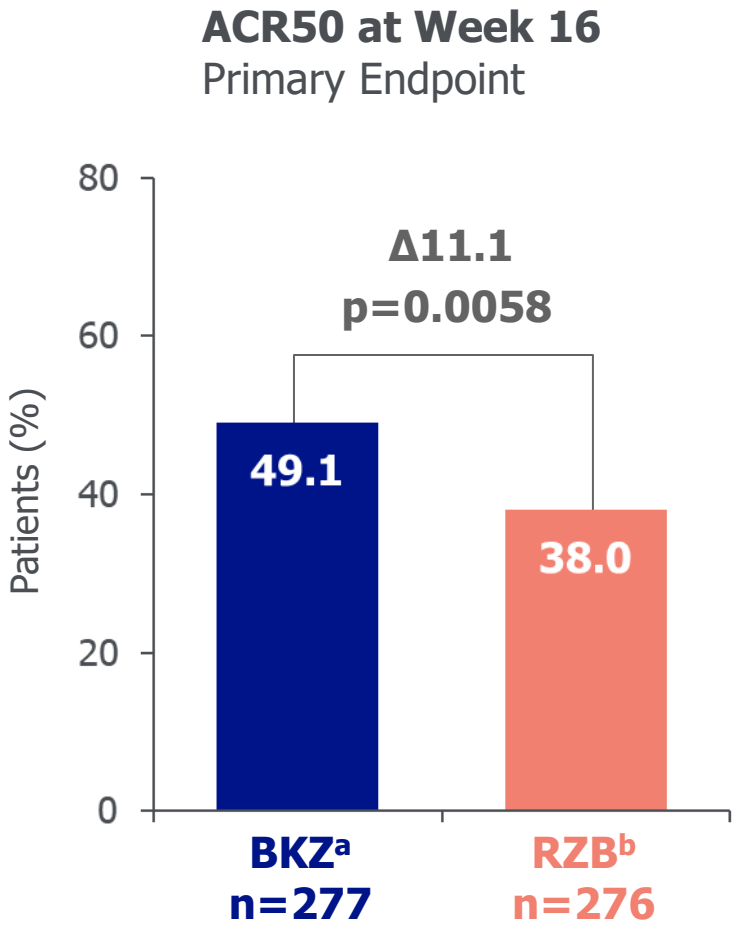
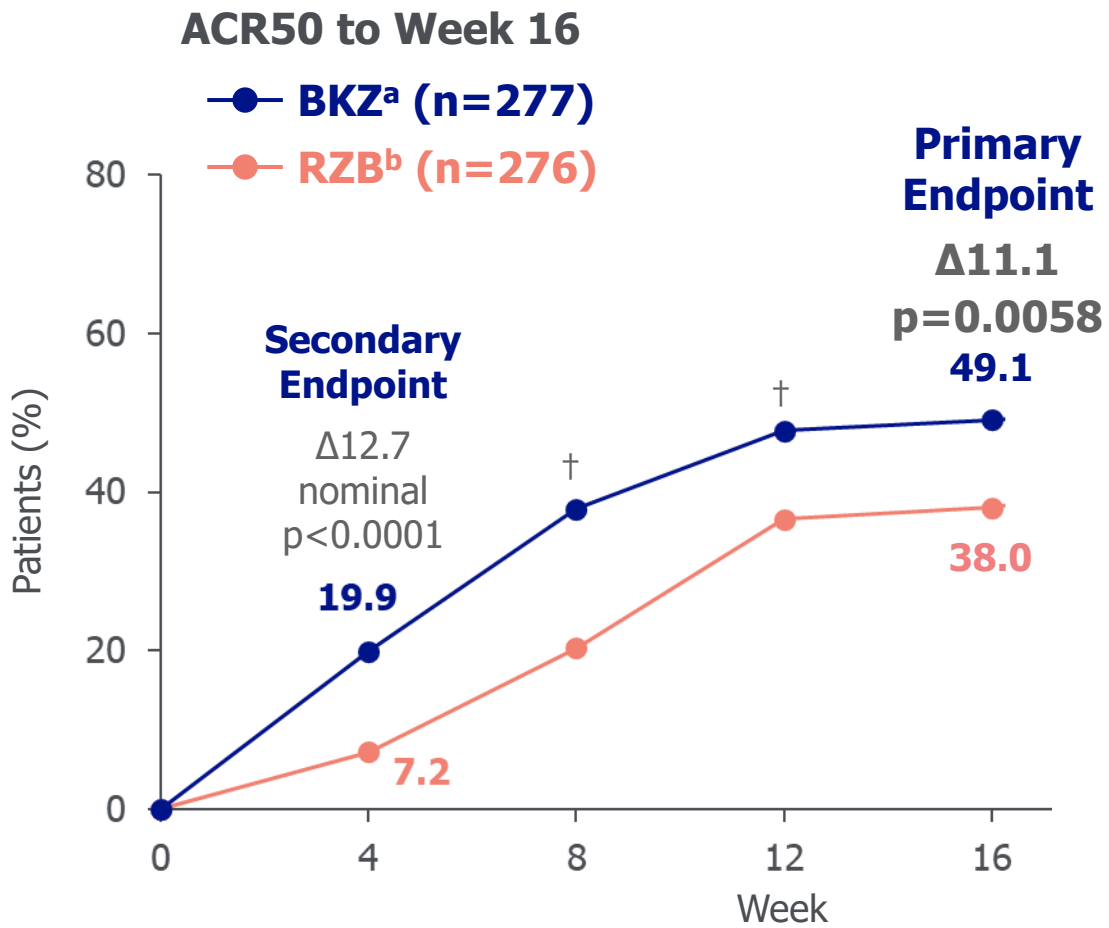
Primary Endpoint: ACR50 at Week 16 and Over Time (NRI)

BKZ demonstrated superior efficacy in joints, with more patients achieving ACR50 than RZB across all timepoints to Week 16

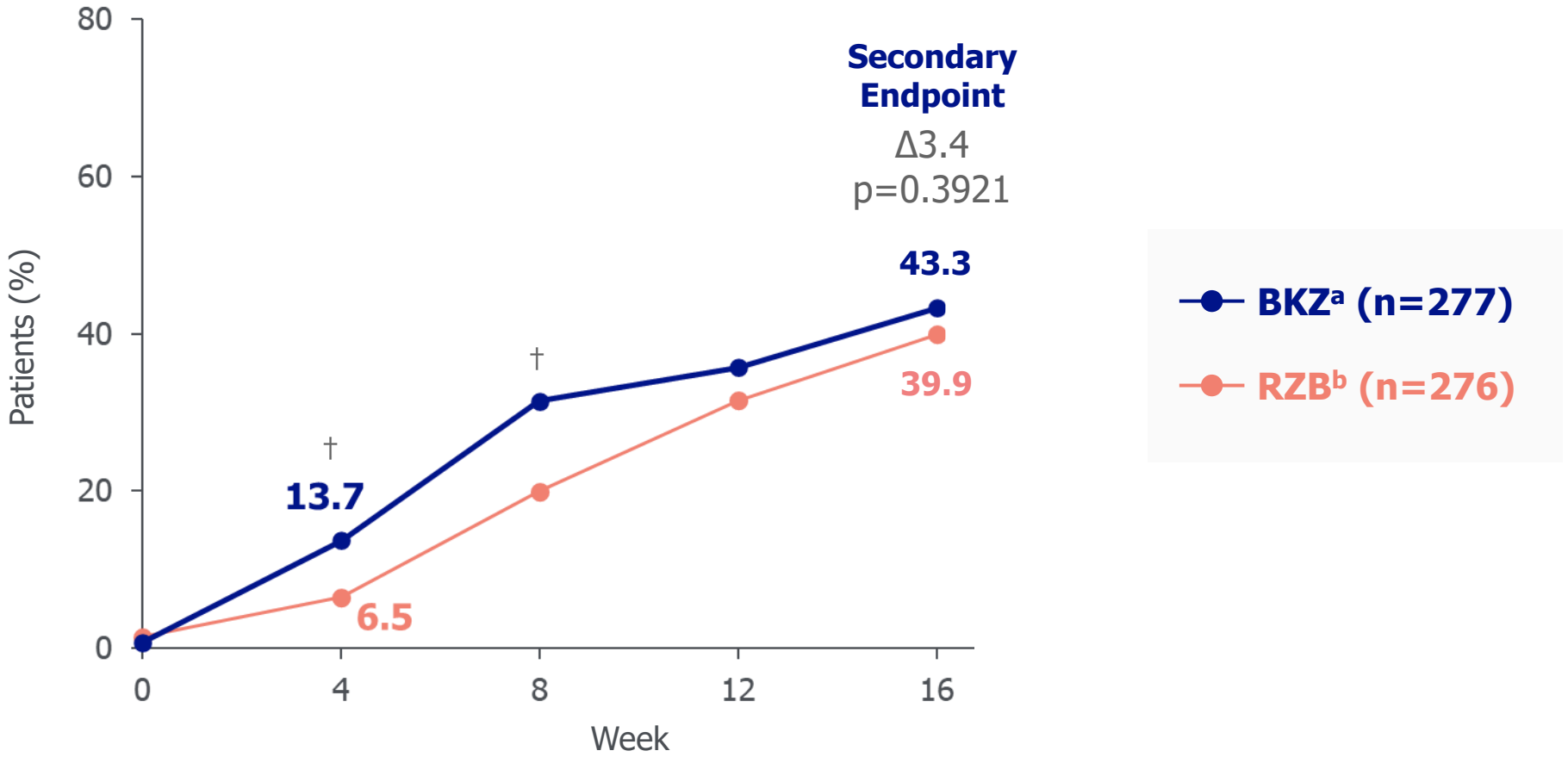




Randomised set. ACR50 at Week 4 was a multiplicity-controlled endpoint. **[a]** BKZ 160 mg Q4W and BKZ 320 mg Q4W/Q8W; **[b]** RZB 150 mg at baseline, Week 4 and Week 16. †Pre-specified p values and differences between BKZ and RZB results are displayed for comparisons in the statistical testing hierarchy only. For endpoints outside the testing hierarchy, nominal p values for BKZ vs RZB were p<0.0001 at Week 8, p=0.0055 at Week 12. **Abbreviations. ACR50:** ≥50% improvement from baseline in American College of Rheumatology response criteria; **BKZ:** bimekizumab; **NRI:** non-responder imputation; **Q4/8W:** every 4/8 weeks; **RZB:** risankizumab.

MDA Over Time to Week 16 (NRI)

Significance for the secondary endpoint of MDA response at Week 16 was not met; MDA was numerically higher for BKZ- vs RZB-treated patients at all timepoints to Week 16

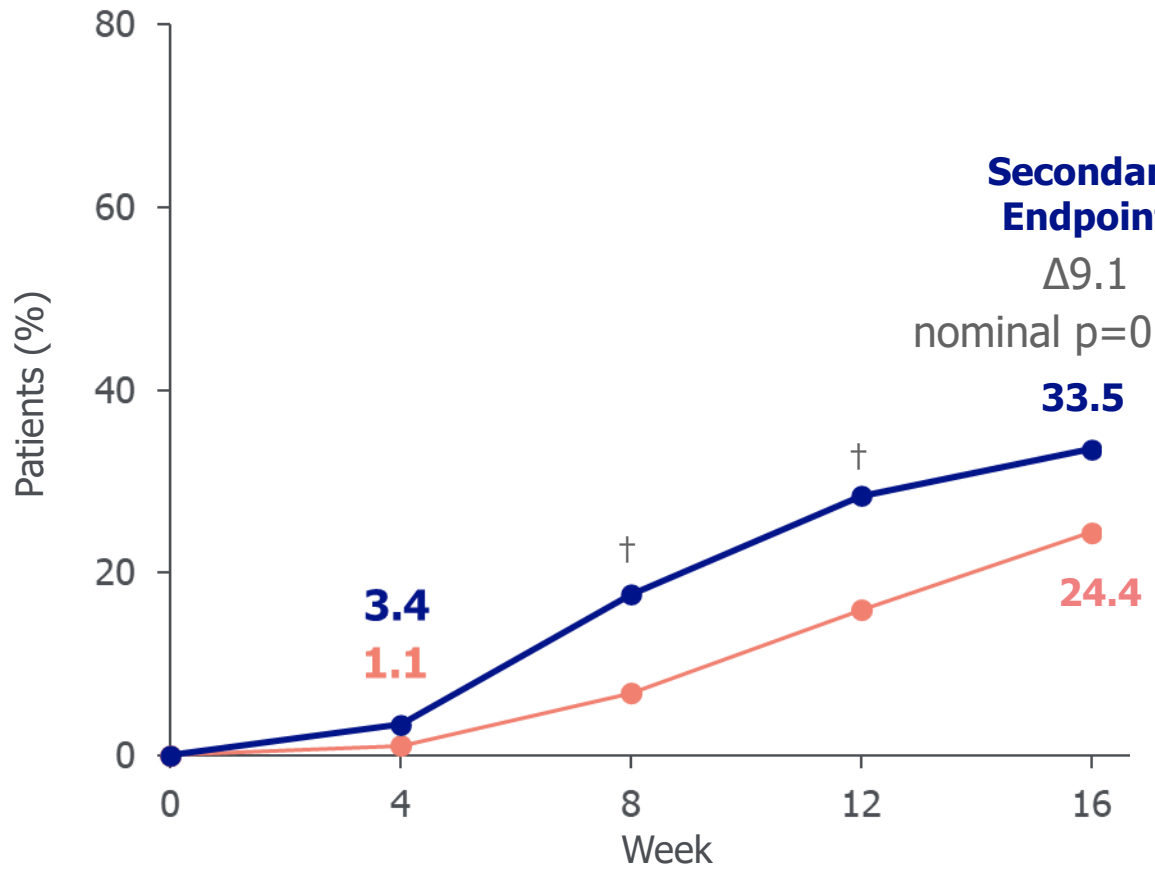


Randomised set. MDA at Week 16 was a secondary endpoint. **[a]** BKZ 160 mg Q4W and BKZ 320 mg Q4W/Q8W; **[b]** RZB 150 mg at baseline, Week 4 and Week 16. †Pre-specified p values and differences between BKZ and RZB results are displayed for comparisons in the statistical testing hierarchy only. For endpoints outside the testing hierarchy, nominal p values for BKZ vs RZB were p=0.0035 at Week 4 and p=0.0015 at Week 8. **Abbreviations. BKZ:** bimekizumab; **MDA:** minimal disease activity; **NRI:** non-responder imputation; **Q4/8W:** every 4/8 weeks; **RZB:** risankizumab.

ACR50+PASI100 Over Time to Week 16 (NRI)

In patients with ≥3% BSA at baseline

ACR50+PASI100 response was numerically higher for BKZ- vs RZB-treated patients at all timepoints to Week 16; most BKZ patients had mild to moderate psoriasis and received BKZ 160mg Q4W



BKZ (n=176)

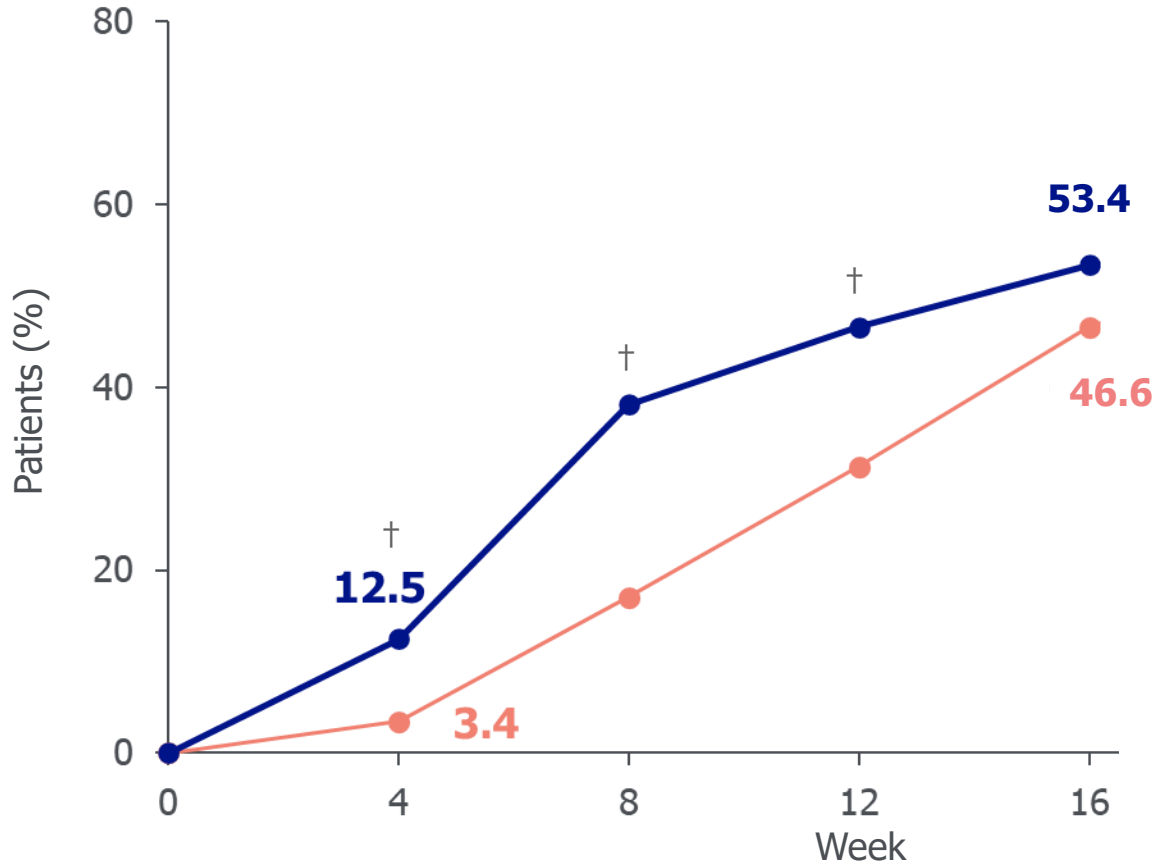
- **Mild to moderate psoriasis**: BKZ 160 mg Q4W, n=147 (**83.5%**)
- **Moderate to severe psoriasis**: BKZ 320 mg Q4W/Q8W, n=29 (16.5%)[a]

RZB[b] (n=176)

Randomised set. ACR50+PASI100 at Week 16 was a secondary endpoint. **[a]** This is the approved dose for BKZ in patients with moderate to severe psoriasis; moderate to severe psoriasis defined as BSA ≥10%, IGA ≥3 and PASI ≥12; **[b]** RZB 150 mg at baseline, Week 4 and Week 16. †Pre-specified p values and differences between BKZ and RZB results are displayed for comparisons in the statistical testing hierarchy only. For endpoints outside the testing hierarchy, nominal p values for BKZ vs RZB were p=0.0022 at Week 8 and p=0.0038 at Week 12. **Abbreviations. ACR50:** ≥50% improvement from baseline in American College of Rheumatology response criteria; **BKZ:** bimekizumab; **BSA:** body surface area; **NRI:** non-responder imputation; **PASI100:** 100% improvement from baseline in Psoriasis Area and Severity Index; **Q4/8W:** every 4/8 weeks; **RZB:** risankizumab.

PASI100 Over Time to Week 16 (NRI)
In patients with ≥3% BSA at baseline

In a PsA population where most patients had mild to moderate psoriasis, BKZ treatment resulted in higher complete skin clearance responses compared to RZB at earlier timepoints through Week 12



BKZ (n=176)

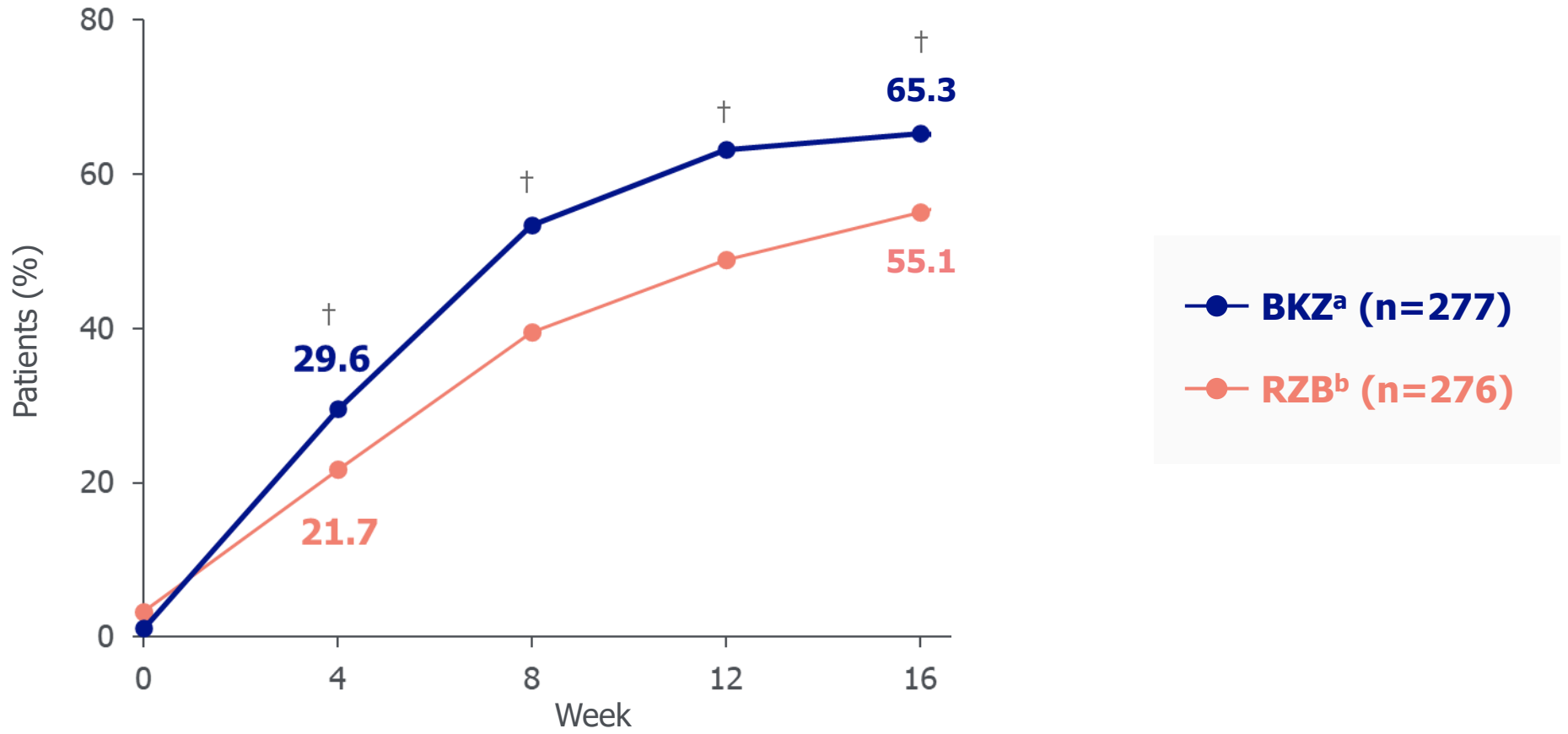
- **Mild to moderate psoriasis**: BKZ 160 mg Q4W, n=147 (**83.5%**)
- **Moderate to severe psoriasis**: BKZ 320 mg Q4W/Q8W, n=29 (16.5%)[a]

RZB[b] (n=176)

Randomised set. **[a]** This is the approved dose for BKZ in patients with moderate to severe psoriasis; moderate to severe psoriasis defined as BSA ≥10%, IGA ≥3 and PASI ≥12; **[b]** RZB 150 mg at baseline, Week 4 and Week 16. †Pre-specified p values and differences between BKZ and RZB results are displayed for comparisons in the statistical testing hierarchy only. For endpoints outside the testing hierarchy, nominal p values for BKZ vs RZB were p=0.0037 at Week 4, p<0.0001 at Week 8 and p=0.0037 at Week 12. **Abbreviations. BKZ:** bimekizumab; **BSA:** body surface area; **NRI:** non-responder imputation; **PASI100:** 100% improvement from baseline in Psoriasis Area and Severity Index; **PsA:** psoriatic arthritis; **Q4/8W:** every 4/8 weeks; **RZB:** risankizumab.

DAPSA LDA+REM Over Time to Week 16 (NRI)

Numerically higher DAPSA LDA+REM response rates were achieved with BKZ vs RZB across all timepoints to Week 16



Randomised set. DAPSA LDA+REM is defined as a DAPSA score of ≤14. DAPSA calculated using PGA-Arthritis. **[a]** BKZ 160 mg Q4W and BKZ 320 mg Q4W/Q8W; **[b]** RZB 150 mg at baseline, Week 4 and Week 16. †Pre-specified p values and differences between BKZ and RZB results are displayed for comparisons in the statistical testing hierarchy only. For endpoints outside the testing hierarchy, nominal p values for BKZ vs RZB were p=0.0286 at Week 4, p=0.0006 at Week 8, p=0.0004 at Week 12, and p=0.0087 at Week 16. **Abbreviations. BKZ:** bimekizumab; **DAPSA:** Disease Activity Index for Psoriatic Arthritis; **LDA:** low disease activity; **NRI:** non-responder imputation; **PGA:** patient global assessment; **Q4/8W:** every 4/8 weeks; **REM:** remission; **RZB:** risankizumab.

Safety to Week 16

Treatment arms not disclosed for all safety topics of interest to preserve blinding of the ongoing study; no new safety signals were identified

Safety Overview

	BKZ N=277	RZB N=275
Total time at-risk, PY	154.2	151.0
Any TEAE, n (%)	158 (57.0)	143 (52.0)
Serious TEAEs, n (%)	5 (1.8)	8 (2.9)
Severe TEAEs, n (%)	5 (1.8)	5 (1.8)

- Discontinuations due to TEAEs were low between treatment arms
- One death occurred, deemed unrelated to treatment by the Investigator, with a reported cause of myocardial infarction in a patient with coronary artery disease, hypertension and hyperlipidaemia[a]

Safety Topics of Interest[a]

- Cases of serious infection, IBD, malignancy, neutropenia, hypersensitivity, hepatic events and cardiovascular events were **low across both treatment arms**
- ***Candida* infections** were more frequent in BKZ-treated patients
  - **All were mild or moderate**
  - None were serious, systemic or led to study discontinuation

Safety set. Safety is reported for all data available up to the cut-off date of 23 February 2026; including collected data after Week 16. TEAEs were classified using the Medical Dictionary for Regulatory Activities v27.0.
[a] Treatment arm has not been disclosed to preserve blinding of the ongoing study. **Abbreviations. BKZ**: bimekizumab; **IBD:** inflammatory bowel disease; **PY:** patient-years; **RZB:** risankizumab; **TEAE**: treatment-emergent adverse event.

Conclusions

- Dual inhibition of IL-17A and IL-17F with BKZ was **superior for the primary endpoint of ACR50 at Week 16** vs IL-23 inhibition with RZB, in patients with active PsA.
- **A numerically higher proportion of BKZ-treated patients achieved secondary outcomes** encompassing **joint, skin** and **overall disease activity vs RZB-treated patients** over **16 weeks**.

- **No new safety signals were identified through Week 16.**
- Full safety data will be presented following the database lock.

- This is the first H2H study in PsA to demonstrate superiority for a joint-focused primary endpoint.
- These findings may help **guide treatment decisions** and **inform clinical recommendations** for the **management of PsA**.

Abbreviations: ACR50: ≥50% improvement from baseline in American College of Rheumatology response criteria; **BKZ:** bimekizumab; **H2H:** head-to-head; **IL:** interleukin; **PsA:** psoriatic arthritis; **RZB:** risankizumab.