UCB VIRTUAL BRIEFING:

Bimekizumab Phase 3 Studies in Axial Spondyloarthritis (axSpA) and Psoriatic Arthritis (PsA)

Inspired by **patients.**
Driven by **science.**

Bimekizumab is not approved for use in nr-axSpA, AS or PsA by any regulatory authority worldwide. The safety and efficacy of bimekizumab in nr-axSpA, AS and PsA have not been established.

Date of preparation: May 2022. GL-N-BK-AS-2200005

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Lianne S. Gensler, M.D. Professor of Medicine, Director, Spondyloarthritis Research Program & Clinic, University of California, San Francisco, U.S

05 **Bimekizumab Phase 3 Study Results in Psoriatic Arthritis**
Dr. Joseph Merola, Brigham and Women's Hospital, Harvard Medical School, Boston, U.S.

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Welcome

Emmanuel Caeymaex

Executive Vice President Immunology Solutions and Head of US, UCB

BIMZELX® ▼ (bimekizumab) is the first IL-17A and IL-17F inhibitor approved for the treatment of moderate to severe plaque psoriasis

European Union
August 2021[1]

Great Britain
August 2021[2]

Japan
January 2022[3]

Canada
February 2022[4]

Australia
March 2022[5]

Pre-filled Syringe
EU Product and Packaging Only

Pre-filled Pen
EU Product and Packaging Only

Bimekizumab is approved for moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy in the European Union and Great Britain.The label information may differ in other countries. Please check local prescribing information.
▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions

References:
1. BIMZELX (bimekizumab) EU Summary of Product Characteristics https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf . Last accessed: May 2022;
2. BIMZELX (bimekizumab) GB Summary of Product Characteristics https://www.medicines.org.uk/emc/product/12834 ; https://www.medicines.org.uk/emc/product/12833. Last accessed: May 2022.
3. Pharmaceuticals and Medical Devices Agency https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html . Last accessed: May 2022.
4. BIMZELX (bimekizumab) Canada Product Monograph. Available at: https://pdf.hres.ca/dpd_pm/00064702.PDF 00064702.PDF (hres.ca) Last accessed: May 2022.
5. BIMZELX (bimekizumab) Australia. Available at: https://www.tga.gov.au/apm-summary/bimzelx. Last accessed May 2022.

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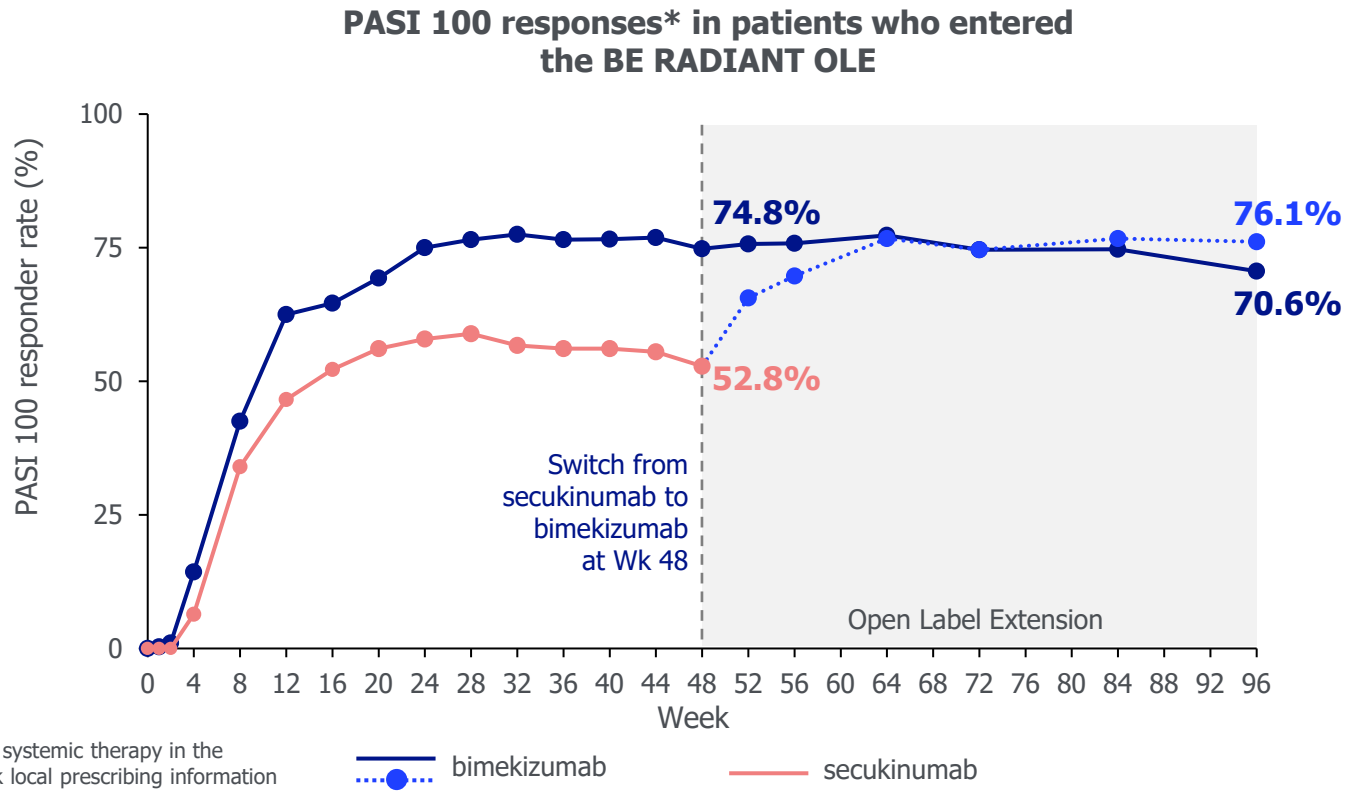
In psoriasis, the Phase 3 BE RADIANT study showed that inhibition of IL-17A and IL-17F with bimekizumab was superior to inhibition of IL-17A with secukinumab with respect to complete skin clearance[1]

In the open-label extension study, complete skin clearance was maintained through 96 weeks and improved for patients switching from secukinumab to bimekizumab



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*mNRI: patients who discontinued due to lack of efficacy were considered non-responders at subsequent timepoints, multiple imputation was used for other missing data

References
1. Reich K, Warren R, Lebwohl M et al. Bimekizumab versus Secukinumab in Plaque Psoriasis *N Engl J Med*. 2021;385(2):142-152. 2. Strober B., Paul C, Blauvelt A et al. Bimekizumab efficacy and safety through 96 weeks in patients with moderate to severe plaque psoriasis: Results from the open-label extension period of the BE RADIANT phase 3b trial. Presented at the 2022 AAD Annual Meeting.

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Bimekizumab has delivered 8 consecutive positive Phase 3 studies to-date in IL-17 mediated diseases

Psoriasis

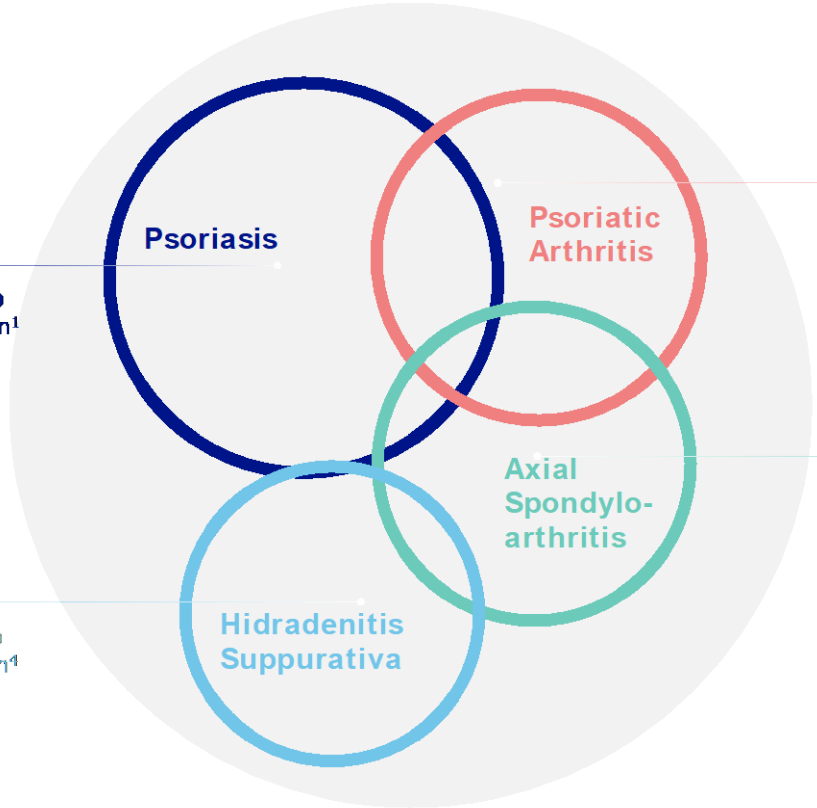
- **BE VIVID** (PS0009) NCT03370133 (vs ustekinumab*)
- **BE READY** (PS0013) NCT03410992 (vs placebo)
- **BE SURE** (PS0008) NCT03412747 (vs adalimumab)
- **BE RADIANT** (PS0015) NCT03536884 (vs secukinumab)

Hidradenitis Suppurativa

Top-line results expected H2 2022

BE HEARD I (HS0003) NCT04242446 (vs placebo)

BE HEARD II (HS0004) NCT04242498 (vs placebo)



Psoriatic Arthritis

- **BE OPTIMAL** (PA0010) NCT03895203 (vs placebo)
- **BE COMPLETE** (PA0011) NCT03896581 (vs placebo)

Axial Spondyloarthritis

- **BE MOBILE1** (AS0010) NCT03928704 (vs placebo in nr-axSpA)
- **BE MOBILE2** (AS0011) NCT03928743 (vs. placebo in AS/r-axSpA)

* Ranked secondary endpoint
† U.S. prevalence

References:

1. National Psoriasis Foundation. Statistics. Available at: https://www.psoriasis.org/content/statistics Last accessed: April 2022
2. Gladman D et al. Ann Rheum Dis. 2005.(Suppl 2);ii14-17.
3. Reveille JD. AM J Med Sci. 2013; 345(6); 431-436.
4. Calao M et al. PLoS ONE. 2018;13(7);e0200683.

Bimekizumab is not approved for use in nr-axSpA, AS, PsA or hidradenitis suppurativa by any regulatory authority worldwide. The safety and efficacy of bimekizumab in nr-axSpA, AS and PsA have not been established.

Introduction to Bimekizumab Phase 3 Studies in axSpA and PsA

Dr. John Ioannou

BMedSci, MB BS, PhD, FRCP

Head of Medical Affairs, Rheumatology, UCB

Content aligned to information publicly available in abstracts

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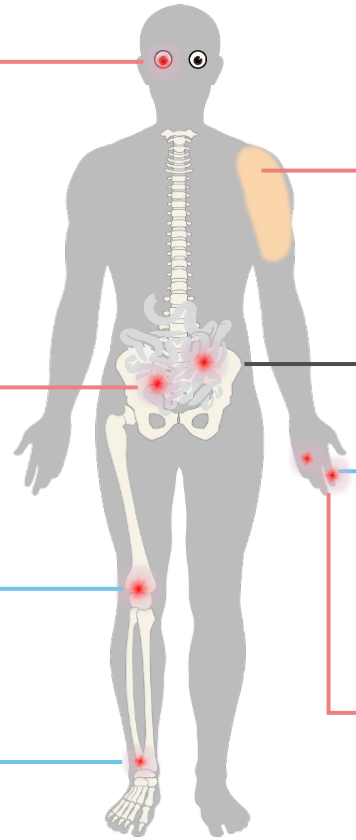
axSpA and PsA have many overlapping clinical features[1,2]



Uveitis

axSpA[3,4]	PsA[5]
16–40%	7–18%

IBD

axSpA[6]	PsA[7]
5%	4%

Peripheral Arthritis

axSpA[4]	PsA[8–12¥]
12–58%	Up to 100%

Enthesitis

axSpA[4]	PsA[13,14]
7–80%	35–57%

Psoriasis

axSpA[6]	PsA[15]
13%	94%

Sacroiliitis

axSpA[6†]	PsA[16]
86%	78%

Dactylitis

axSpA[4]	PsA[17]
4–11%	16–48%

Nail Disease

axSpA	PsA[18]
NA	Up to 80%

Treatment goals and reality

Guidelines recommend treatment should be aimed at reaching the **target of remission,** or **low disease activity**[19,20]

One third of patients achieve these goals within the first six months of taking a biologic*[21,22]

*Based on clinical trial and real-world evidence. Goals measured by minimal disease activity in PsA and clinical remission as defined by ASDAS-Inactive Disease in axSpA; ¥Based on symmetrical polyarthritis, asymmetrical mono-/oligo-arthritis, distal interphalangeal joint involvement, arthritis mutilans and peripheral joints; †Sacroiliitis on MRI

References: Garg N et al. Best Pract Res Clin Rheumatol. 2014;28(5):663–672.; 2. Collantes E et al. Rheumatology. 2007;46(8):1309–1315.; 3. Rosenbaum J et al. Clin Exp Rheum. 2002;20:S143–S145.; 4. de Winter JJ et al. Arthritis Res Ther. 2016;18:196; 5. Chen H and Chou C. Curr Rheumatol Rev. 2008;4:111–14.; 6. Van den Berg et al. Rheumatology. 2013; 52:1492–1499.; 7. Williamson L et al. J Rheumatol. 2004;31:1469–70.; 8. Moll J and Wright V. Semin Arthritis Rheum. 1973;3:55–78.; 9. Torre Alonso J et al. Br J Rheumatol. 1991;30:245–50; 10. Helliwell PS and Taylor WJ. Ann Rheum Dis. 2005;64(Suppl II):ii3–Ii8.; 11. Gladman D. Ann Rheum Dis. 2006;65 Suppl 3, iii22-iii24; 12. Acosta Felquer ML and FitzGerald O. Clin Exp Rheumatol. 2015;33(Suppl 93):S26–S30.; 13. Kaeley GS et al. Semin Arthritis Rheum. 2018;48(1):35–43; 14. D'Agostino MA et al. Arthritis Rheum. 2003;48(2):523–533; 15. Kane D et al. Rheumatology (Oxford) 2003; 42(12): 1460-1468.; 16. Battistone MJ et al. Skeletal Radiol. 1999; 28(4):196–201; 17. Helliwell P et al. J Rheumatol. 2005; 32: 1745–1750.; 18. Sobolewski P et al. Reumatologia. 2017;55(3):131–135; 19. Gossec L, et al. Ann Rheum Dis. 2020;79:700–712; 20. van der Heijde D, et al. Ann Rheum Dis. 2017;76:978–991; 21. Zardin-Moraes M, et al. J Rheumatol. 2020;47(6):839–46; 22. Ørnbjerg LM, et al. Ann Rheum Dis. 2019;78:1536–44.

The Phase 3 clinical development program in axSpA and PsA is aimed at elevating standards of care

Phase 3 studies	**BE MOBILE 1**[1] Phase 3 double-blind study in patients with active **non-radiographic axSpA (nr-axSpA)**	**BE MOBILE 2**[2] Phase 3 double-blind study in patients with active **ankylosing spondylitis (radiographic axSpA)**
Primary end point	**ASAS40** response at week 16	**ASAS40** response at week 16
Focus of today	**Week 24** interim analysis	**Week 24** interim analysis

Phase 3 studies	**BE OPTIMAL**[3] Phase 3 double-blind study in patients with active **PsA who were biologic naive**	**BE COMPLETE**[4] Phase 3 double-blind study in patients with active **PsA with inadequate response to TNFi**
Primary end point	**ACR50** response at week 16	**ACR50** response at week 16
Focus of today	**Week 24** interim analysis	**Week 16** analysis

References:
1. Deodhar A et al. Bimekizumab in patients with active non-radiographic axial spondyloarthritis: 24-week efficacy and safety from BE MOBILE 1, a phase 3, multicentre, randomised, placebo-controlled study. Abstract presented at EULAR 2022.
2. van der Heijde D et al. Bimekizumab in patients with active ankylosing spondylitis: 24-week efficacy and safety from BE MOBILE 2, a phase 3, multicentre, randomised, placebo-controlled study. Abstract presented at EULAR 2022.
3. McInnes I. et al. Bimekizumab in bDMARD-Naïve Patients with Psoriatic Arthritis: 24-Week Efficacy & Safety from BE OPTIMAL, a Phase 3, Multicentre, Randomised, Placebo-Controlled, Active Reference Study. Abstract presented at EULAR 2022.
4. Merola JF et al. Bimekizumab in Patients with Active Psoriatic Arthritis and an Inadequate Response to Tumour Necrosis Factor Inhibitors: 16-Week Efficacy & Safety from BE COMPLETE, a Phase 3, Multicentre, Randomised Placebo-Controlled Study. Abstract presented at EULAR 2022

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Bimekizumab in Patients with Active Ankylosing Spondylitis: 24-Week Efficacy & Safety from BE MOBILE 2, a Phase 3, Multicentre, Randomised, Placebo-Controlled Study

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Bimekizumab is currently in clinical development and is not authorised for use by any regulatory authority worldwide for axSpA or PsA; therefore, this document discusses unlicensed indications and contains off-label information

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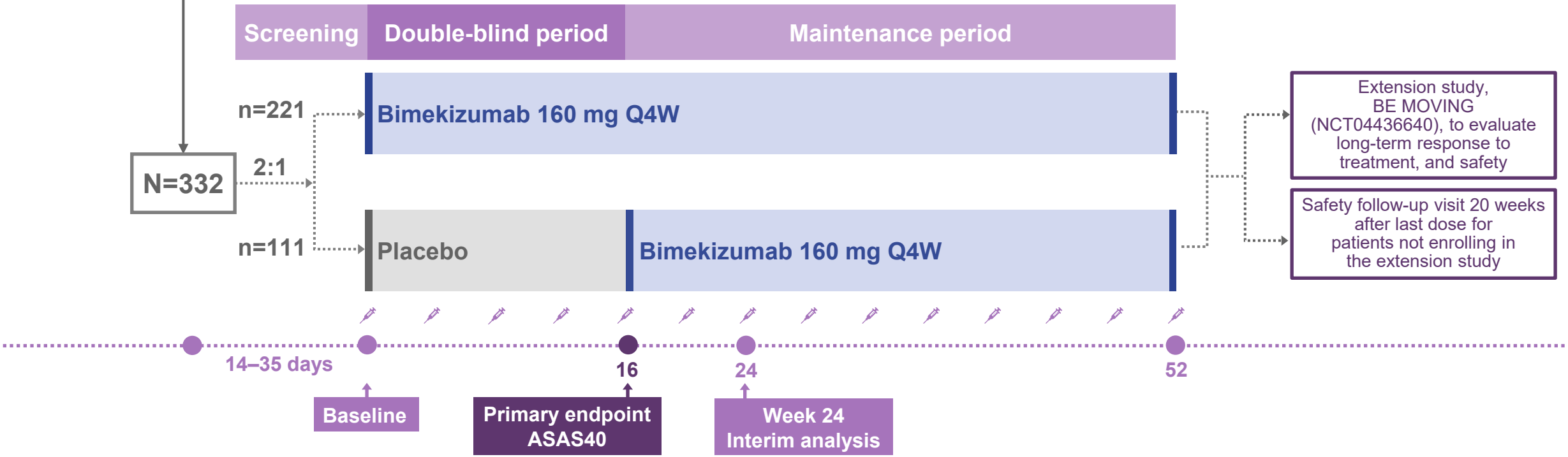
Study Design

Key inclusion criteria

- ✔ ≥18 years of age with AS meeting mNY criteria
- ✔ Active disease at screening and baseline (BASDAI ≥4 and spinal pain ≥4)
- ✔ Failure to respond to two different NSAIDs, or history of intolerance or contraindication to NSAIDs

Key exclusion criteria

- ✘ Failure of >1 TNFi and any previous use of IL-17 biologics
- ✘ Active, symptomatic IBD at baseline or screening (prior history was not an exclusion criteria)
- ✘ Acute anterior uveitis within 6 weeks of baseline visit



Patients eligible to receive non-biologic rescue therapy from Week 20 at the discretion of the investigator while continuing to receive BKZ. AS: ankylosing spondylitis; ASAS40: Assessment of Spondyloarthritis international Society 40% response; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BKZ: bimekizumab; IBD: inflammatory bowel disease; IL-17i: interleukin 17 inhibitor; mNY: modified New York; NSAID: non-steroidal anti-inflammatory drug; Q4W: every 4 weeks; TNFi: tumour necrosis factor inhibitor.

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Patient Demographics and Baseline Disease Characteristics

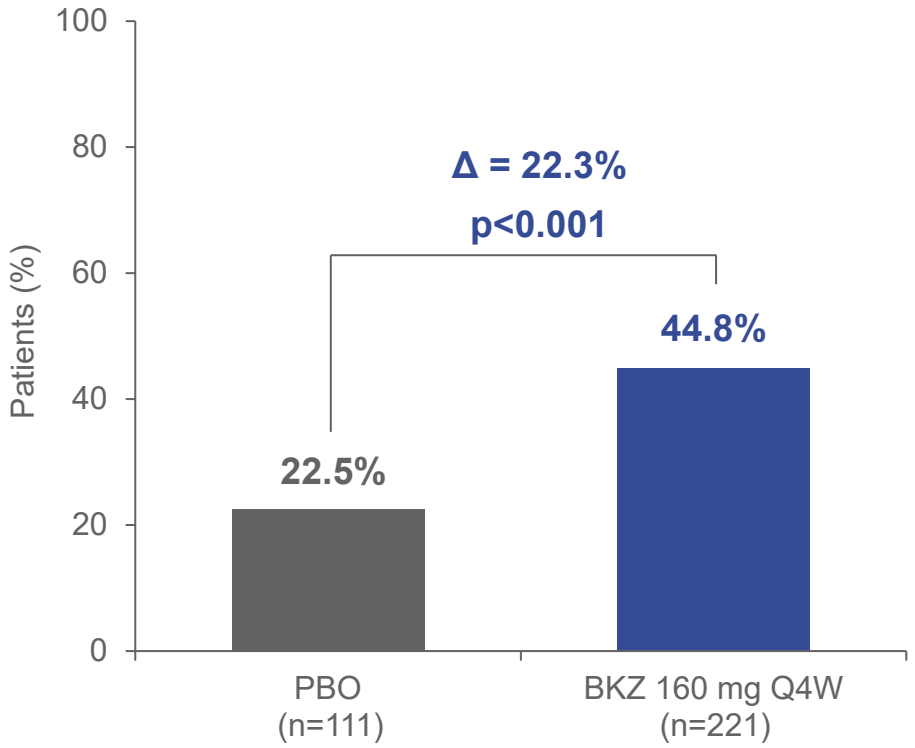
	PBO n=111	BKZ 160 mg Q4W n=221
Age, years, mean (SD)	39.2 (12.6)	41.0 (12.1)
Sex, male, n (%)	80 (72.1%)	160 (72.4%)
HLA-B27 positive, n (%)	93 (83.8%)	191 (86.4%)
Symptom duration, years, mean (SD)	11.9 (8.6)	14.2 (11.0)
ASDAS-CRP, mean (SD)	3.7 (0.8)	3.7 (0.8)
BASDAI, mean (SD)	6.5 (1.3)	6.5 (1.3)
hs-CRP, mg/L, median (min, max)	6.3 (0.3, 104.3)	8.2 (0.1, 105.4)
hs-CRP >ULN,[a] n (%)	67 (60.4%)	137 (62.0%)
Total spinal pain, mean (SD)	7.2 (1.2)	7.1 (1.6)
Current enthesitis (MASES >0), n (%)	67 (60.4%)	132 (59.7%)
MRI spine Berlin score, mean (SD) [Nsub][b]	3.3 (4.9) [45]	3.8 (5.3) [82]
SPARCC MRI SIJ score, mean (SD) [Nsub][b]	5.8 (7.7) [45]	7.4 (10.7) [83]
Prior TNFi exposure, n (%)	17 (15.3%)	37 (16.7%)

Randomised set. [a] ULN value for hs-CRP is 5 mg/L; [b] Only patients enrolled in the SIJ and spine MRI sub-study are included in this analysis. ASDAS: Ankylosing Spondylitis Disease Activity Score; BKZ: bimekizumab; BMI: body mass index; CRP: C-reactive protein; csDMARD: conventional synthetic disease-modifying antirheumatic drug; HLA-B27: human leukocyte antigen-B27; hs-CRP: high-sensitivity C-reactive protein; MASES: Maastricht Ankylosing Spondylitis Enthesitis Score; MRI: magnetic resonance imaging; NSAID: non-steroidal anti-inflammatory drug; Nsub: number of patients in subgroup; PBO: placebo; Q4W: every 4 weeks; SD: standard deviation; SIJ: sacroiliac joint; SPARCC: Spondyloarthritis Research Consortium of Canada; TNFi: tumour necrosis factor inhibitor; ULN: upper limit of normal.

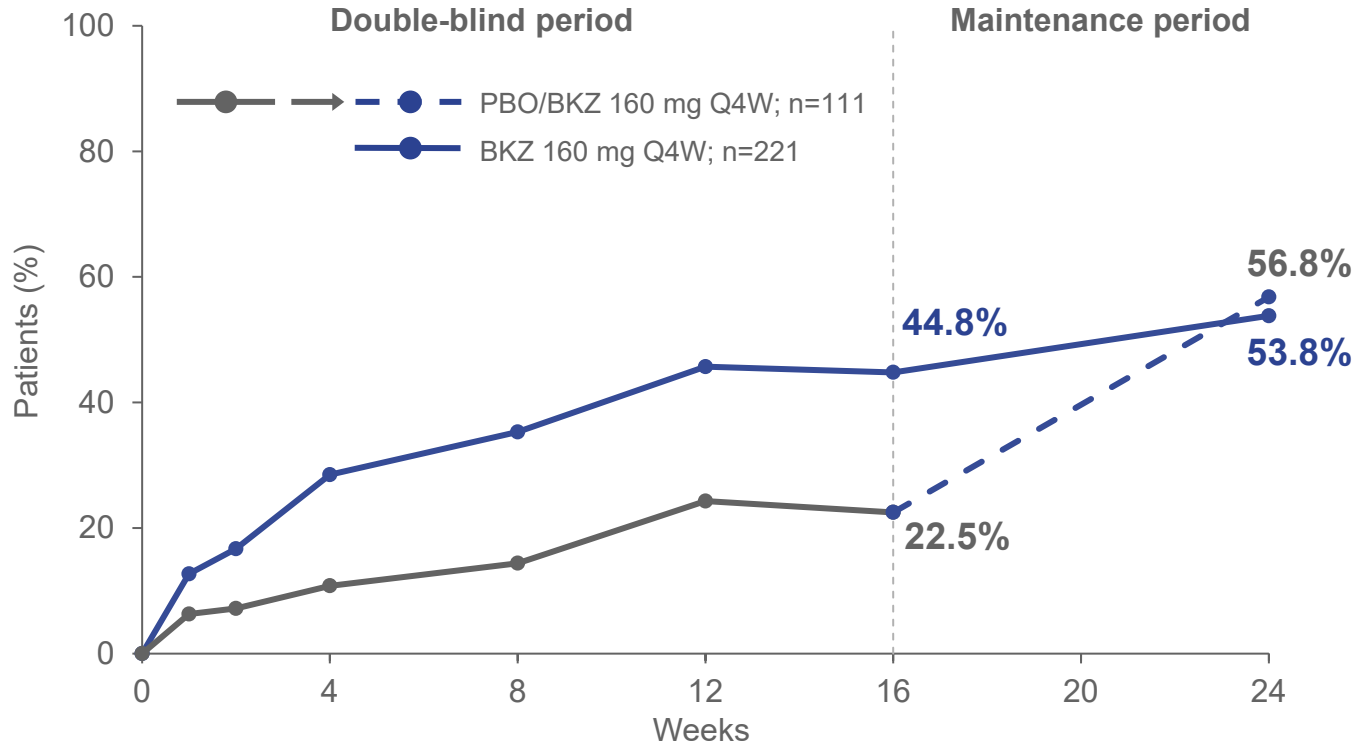
Significantly Greater ASAS40 Response Rate with BKZ vs PBO

Primary endpoint: ASAS40 response with BKZ compared to PBO at Week 16

ASAS40 response at Week 16 (NRI)



ASAS40 kinetics of response to Week 24 (NRI)



Study completion to Week 16/24, n (%)

PBO	111 (100%)	109 (98.2%)	108 (97.3%)
BKZ	221 (100%)	213 (96.4%)	205 (92.8%)

Randomised set. p value was calculated using logistic regression with treatment, prior TNFi exposure and region as factors. ASAS40: Assessment of Spondyloarthritis international Society 40% response; BKZ: bimekizumab; NRI: non-responder imputation; PBO: placebo; Q4W: every 4 weeks; TNFi: tumour necrosis factor inhibitor.

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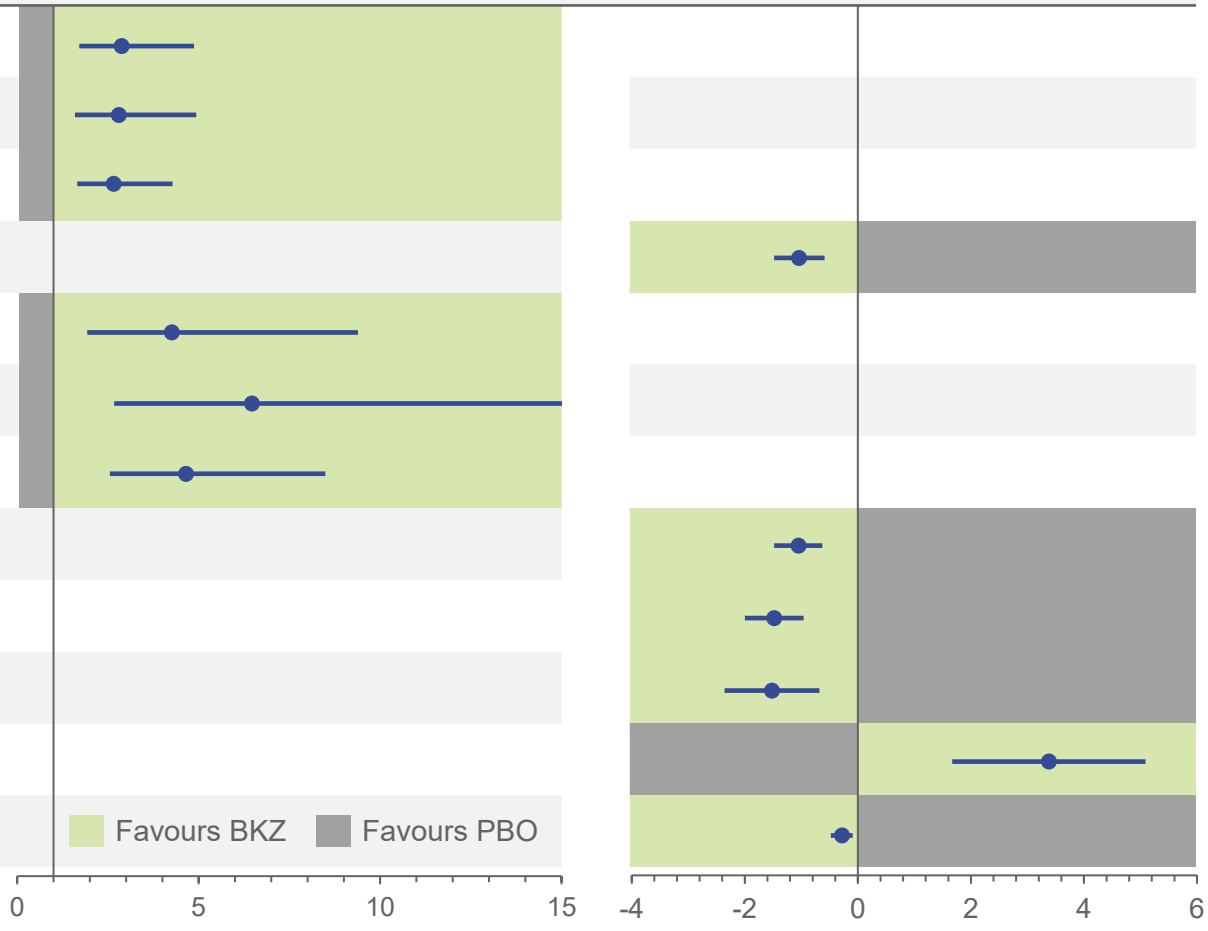
Primary and All Ranked Secondary Endpoints Were Met at Week 16

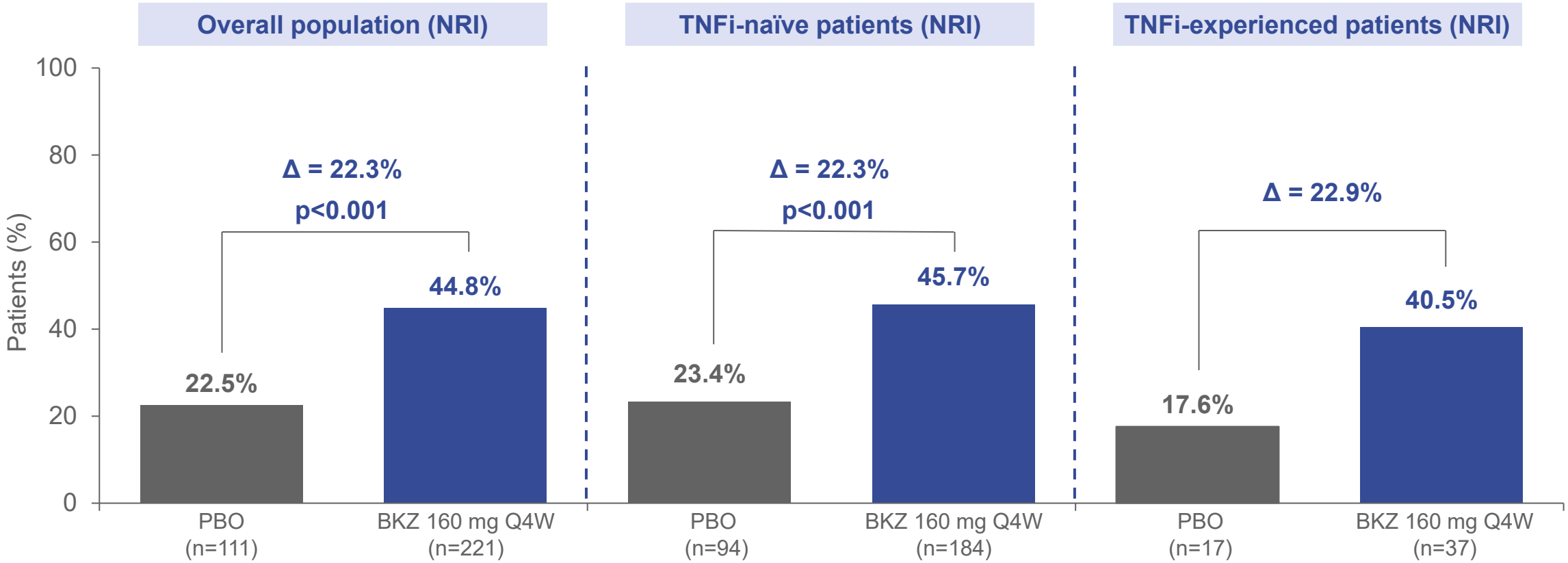
	Efficacy endpoint	PBO n=111	BKZ 160 mg Q4W n=221	p value[a]
1	**ASAS40**,* n (%)	25 (22.5)	99 (44.8)	<0.001
2	**ASAS40 (TNFi-naïve patients)**,† n (%)	22 (23.4)[b]	84 (45.7)[c]	<0.001
3	**ASAS20**,† n (%)	48 (43.2)	146 (66.1)	<0.001
4	**BASDAI** CfB,† mean (SE)	–1.9 (0.2)	–2.9 (0.1)	<0.001
5	**ASAS partial remission**,† n (%)	8 (7.2)	53 (24.0)	<0.001
6	**ASDAS-MI**,† n (%)	6 (5.4)	57 (25.8)	<0.001
7	**ASAS 5/6**,† n (%)	16 (14.4)	94 (42.5)	<0.001
8	**BASFI** CfB,† mean (SE)	–1.1 (0.2)	–2.2 (0.1)	<0.001
9	**Nocturnal spinal pain** CfB,† mean (SE)	–1.9 (0.2)	–3.3 (0.2)	<0.001
10	**ASQoL** CfB,† mean (SE)	–3.2 (0.3)	–4.9 (0.3)	<0.001
11	**SF-36 PCS** CfB,† mean (SE)	5.9 (0.8)	9.3 (0.6)	<0.001
12	**BASMI** CfB,† mean (SE)	–0.2 (0.1)	–0.5 (0.1)	0.005



Randomised set. *Primary endpoint; †Secondary endpoint. [a] All tests performed at a 2-sided alpha level of 0.05. For binary variables, p values were calculated by logistic regression with treatment, prior TNFi exposure and region as factors. For continuous variables, p values were obtained by ANCOVA with treatment, prior TNFi exposure and region as fixed effects, and baseline values as covariates; [b] n=94; [c] n=184. Missing data were imputed using non-responder imputation for binary endpoints and reference-based multiple imputation for continuous endpoints (based on data from the placebo group). ANCOVA: analysis of covariance; ASAS20/40: Assessment of Spondyloarthritis international Society 20%/40% response; ASDAS: Ankylosing Spondylitis Disease Activity Score; ASQoL: Ankylosing Spondylitis Quality of Life; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BASFI: Bath Ankylosing Spondylitis Functional Index; BASMI: Bath Ankylosing Spondylitis Metrology Index; BKZ: bimekizumab; CfB: change from baseline; CI: confidence interval; MI: major improvement; PBO: placebo; PCS: Physical Component Summary; Q4W: every 4 weeks; SE: standard error; SF-36: Short-Form 36-item Health Survey; TNFi: tumour necrosis factor inhibitor.

Consistent ASAS40 Response Rate with BKZ in TNFi-Naïve and TNFi-Experienced Patients

Ranked secondary endpoint: ASAS40 response at Week 16 in TNFi-naïve patients
Exploratory endpoint: ASAS40 response at Week 16 in TNFi-experienced patients



Randomised set. p values were calculated using logistic regression with treatment, prior TNFi exposure and region as factors (overall population) or treatment and region as factors (TNFi-naïve patients). ASAS40: Assessment of Spondyloarthritis international Society 40% response; BKZ: bimekizumab; CRP: C-reactive protein; NRI: non-responder imputation; PBO: placebo; Q4W: every 4 weeks; TNFi: tumour necrosis factor inhibitor.

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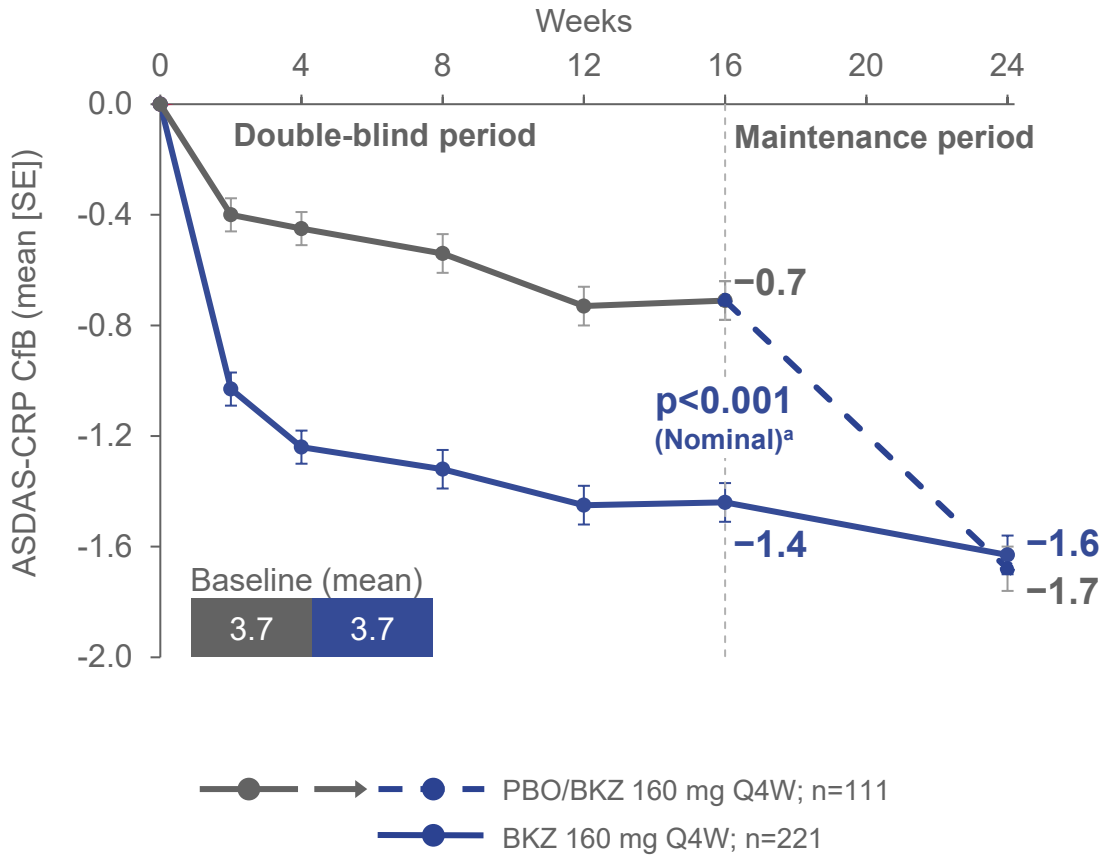
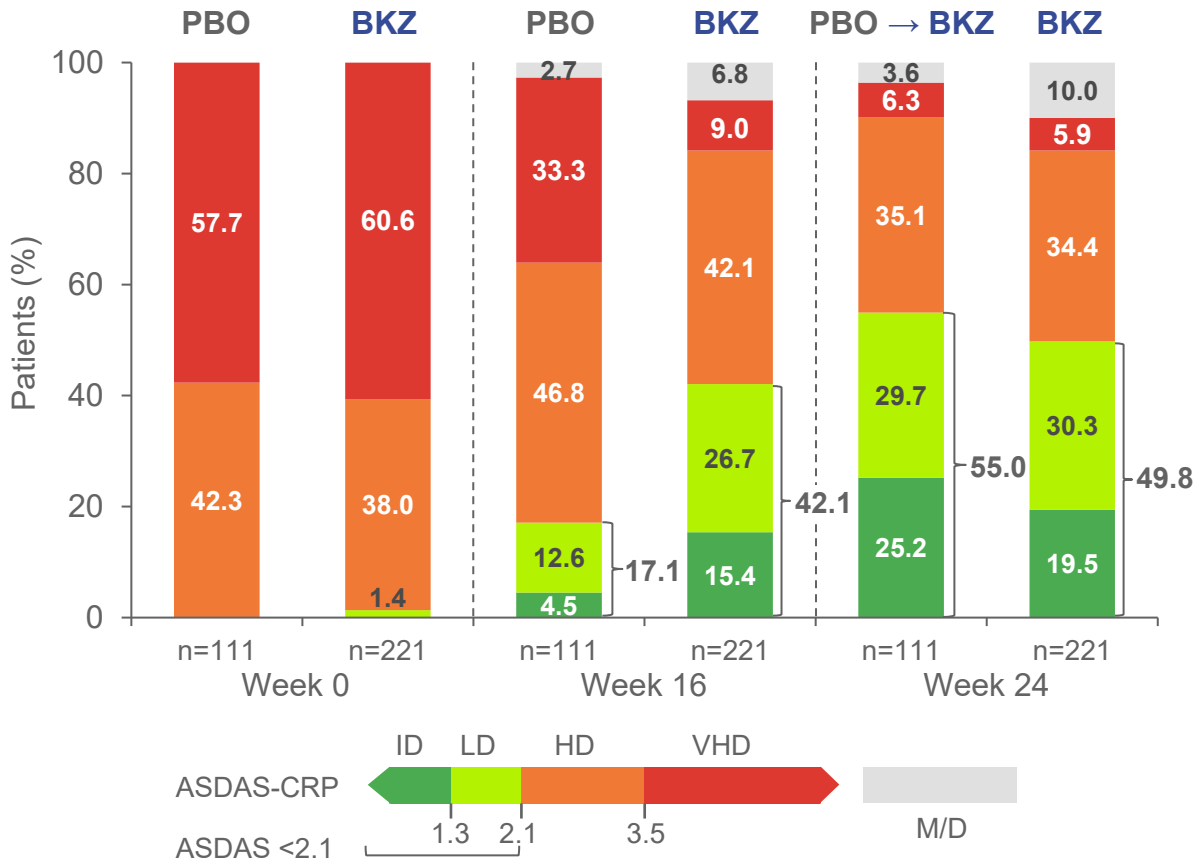
Improvement in ASDAS with BKZ

Exploratory endpoints: ASDAS disease states and change from baseline in ASDAS-CRP with BKZ compared to PBO

ASDAS-CRP CfB (MI)



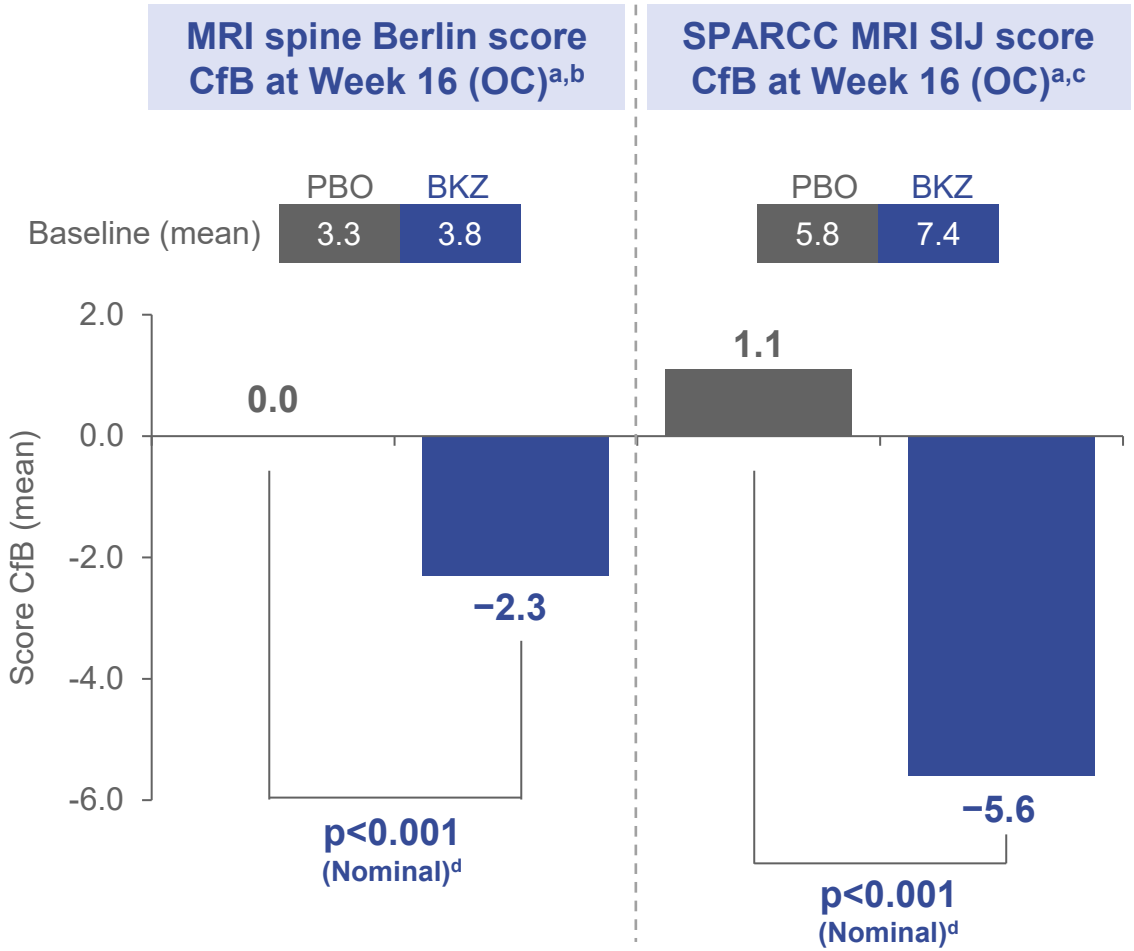
ASDAS Disease States (OC)

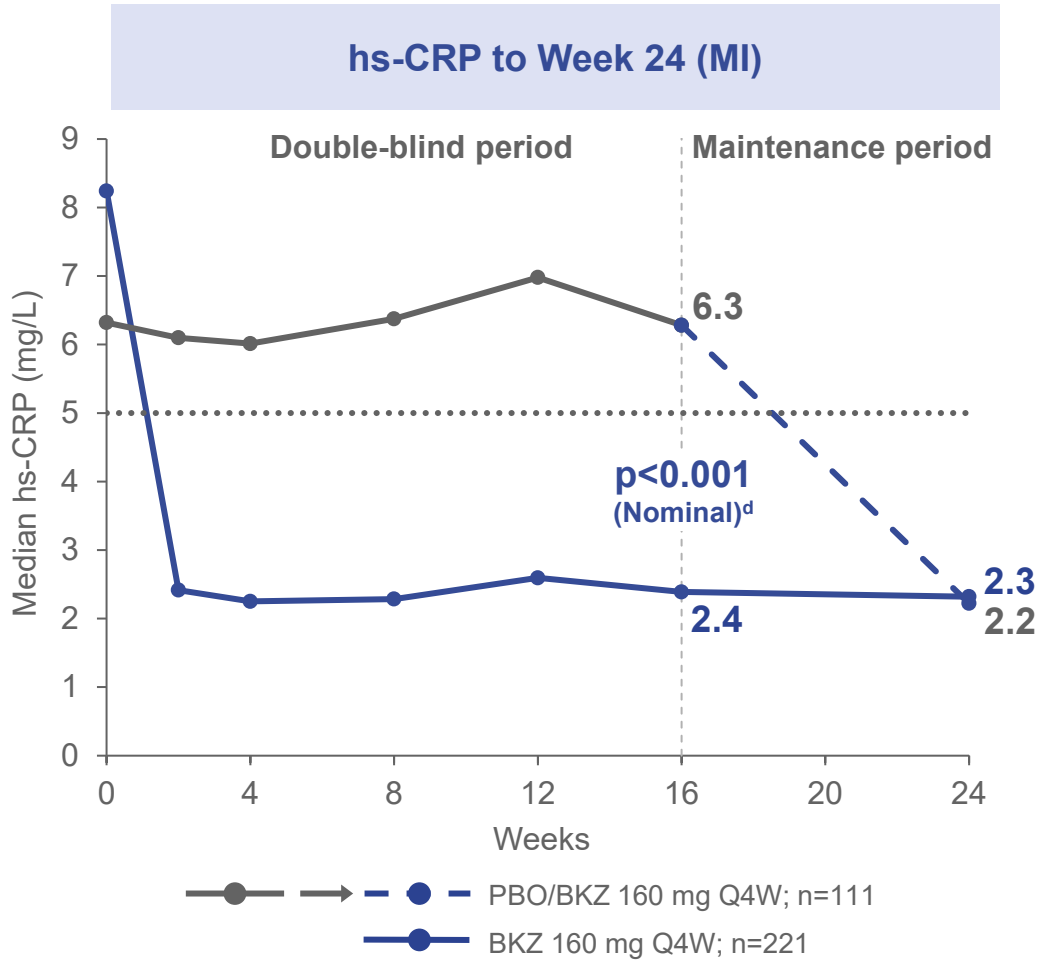


Randomised set. [a] Nominal p values were not controlled for multiplicity. p value was obtained by ANCOVA with treatment, prior TNFi exposure and region as fixed effects, and baseline values as covariates. For ASDAS-CRP CfB, MI was based on the missing at random assumption. VHD: ASDAS >3.5; HD: ASDAS ≥2.1–≤3.5; LD: ASDAS ≥1.3–<2.1; ID: ASDAS <1.3. ANCOVA: analysis of covariance; ASDAS: Ankylosing Spondylitis Disease Activity Score; BKZ: bimekizumab; CfB: change from baseline; CRP: C-reactive protein; HD: high disease; ID: inactive disease; LD: low disease; M/D: missing data; MI: multiple imputation; OC: observed case; PBO: placebo; Q4W: every four weeks; SE: standard error; VHD: very high disease.

Reduction in Objective Signs of Inflammation with BKZ

Exploratory endpoints: Change from baseline in MRI spine Berlin score and SPARCC MRI SIJ score, and median hs-CRP with BKZ compared to PBO





Randomised set. [a] Only patients enrolled in the SIJ and spine MRI sub-study are included in this analysis; [b] At baseline, n=45 (PBO) and n=82 (BKZ), at Week 16, n=43 (PBO) and n=79 (BKZ); [c] At baseline, n=45 (PBO) and n=83 (BKZ), at Week 16, n=43 (PBO) and n=79 (BKZ); [d] Nominal p values were not controlled for multiplicity. MRI spine Berlin score ranges from 0 to 69 with lower scores indicating less spinal inflammation, and a negative change representing improvement. SPARCC MRI SIJ score ranges from 0 to 72 with lower scores indicating less SIJ inflammation, and a negative change representing improvement. For hs-CRP, MI was based on the missing at random assumption. p values were obtained by ANCOVA with treatment, prior TNFi exposure and region as fixed effects, and baseline values as covariates. ANCOVA: analysis of covariance; BKZ: bimekizumab; CfB: change from baseline; hs-CRP: high-sensitivity C-reactive protein; MI: multiple imputation; MRI: magnetic resonance imaging; OC: observed case; PBO: placebo; Q4W: every 4 weeks; SIJ: sacroiliac joint; SPARCC: Spondyloarthritis Research Consortium of Canada; TNFi: tumour necrosis factor inhibitor.

Safety Overview

n (%)	Double-blind period (Weeks 0–16)		Overall (Weeks 0–24)
	PBO n=111	BKZ 160 mg Q4W n=221	BKZ 160 mg Q4W Total[a] N=330
Any treatment-emergent adverse event (TEAE)	48 (43.2)	120 (54.3)	183 (55.5)
Most frequently reported TEAEs[b]			
Nasopharyngitis	4 (3.6)	17 (7.7)	21 (6.4)
Diarrhoea	1 (0.9)	7 (3.2)	13 (3.9)
Headache	5 (4.5)	9 (4.1)	12 (3.6)
Oral candidiasis[c]	0	9 (4.1)	10 (3.0)
Serious TEAEs	1 (0.9)	4 (1.8)	12 (3.6)
Study discontinuation due to TEAEs	0	6 (2.7)	11 (3.3)
Drug-related TEAEs	19 (17.1)	65 (29.4)	96 (29.1)
Severe TEAEs	0	3 (1.4)	9 (2.7)
Fungal infections	0	13 (5.9)	21 (6.4)
Systemic fungal infections	0	0	0
Adjudicated IBD[d]			
Definite Crohn's disease	0	1 (0.5)	1 (0.3)
Probable ulcerative colitis	0	1 (0.5)	1 (0.3)
Uveitis[e,f]	5 (4.5)	0	2 (0.6)

- All fungal infections were mild or moderate, localised, and mucocutaneous; few led to treatment discontinuation (2 patients: 1 oral and 1 oesophageal candidiasis)
- A case of herpes zoster occurred in 1 (0.9%) patient in the placebo group; no cases were reported with bimekizumab
- No active tuberculosis, adjudicated MACE or deaths were reported
- Overall, safety was consistent with prior studies[1,2]

1. van der Heijde D. Ann Rheum Dis 2020;79:595–604; 2. Gensler L. Arthritis Rheumatol 2021;73(suppl 10):0491. Safety set. MedDRA (Version 19.0). [a] Includes patients who switched from PBO to BKZ (events after switch only); [b] TEAEs >3% in either BKZ are reported by preferred term; [c] All oral candidiasis cases were mild to moderate; [d] Neither patient had a medical history of IBD; [e] At baseline, 24/111 (21.6%) patients on PBO and 33/221 (14.9%) patients on BKZ had a medical history of uveitis; [f] Includes the preferred terms autoimmune uveitis, uveitis, iridocyclitis and iritis. BKZ: bimekizumab; IBD: inflammatory bowel disease; MACE: major adverse cardiovascular event; n: number of patients reporting at least one TEAE in that category; PBO: placebo; Q4W: every 4 weeks; TEAE: treatment-emergent adverse event.

Conclusions

The BE MOBILE 2 phase 3 study, evaluating dual inhibition of IL-17A and IL-17F with bimekizumab in patients with AS, met all its primary and secondary endpoints.

Patients with active AS treated with bimekizumab showed rapid and clinically meaningful reductions in key signs and symptoms of disease, with ≥50% patients achieving ASDAS <2.1 by Week 24. Consistent ASAS40 response rates were observed between TNFi-naïve and TNFi-experienced patients.

Objective signs of inflammation were markedly reduced in bimekizumab-treated patients, as measured by CRP level and MRI inflammation of the sacroiliac joints and spine.

The results presented here from the BE MOBILE 2 study in patients with AS (i.e. radiographic axial spondyloarthritis) are consistent with findings from the BE MOBILE 1 study in patients with non-radiographic axial spondyloarthritis (nr-axSpA).[1]

The safety profile was consistent with prior studies, with no new safety signals observed.[2,3]

1. Deodhar A. EULAR 2022;POS0939; 2. van der Heijde D. Ann Rheum Dis 2020;79:595–604; 3. Gensler L. Arthritis Rheumatol 2021;73(suppl 10):0491. AS: ankylosing spondylitis; ASAS40: Assessment of Spondyloarthritis international Society 40% response; ASDAS: Ankylosing Spondylitis Disease Activity Score; CRP: C-reactive protein; IL: interleukin; MRI: magnetic resonance imaging; nr-axSpA: non-radiographic axial spondyloarthritis; TNFi: tumour necrosis factor inhibitor.

Presentation POS0939

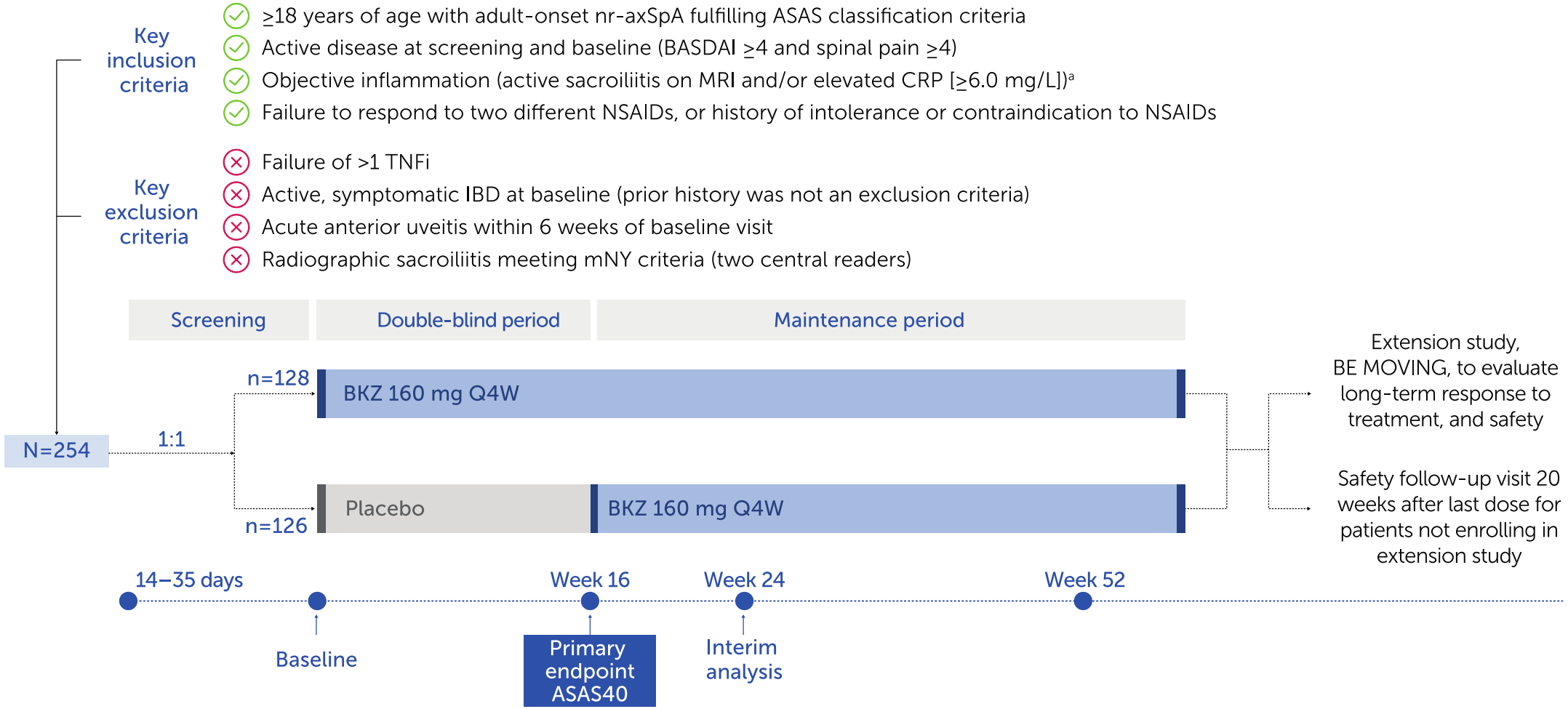
Bimekizumab in Patients with Active Non-Radiographic Axial Spondyloarthritis: 24-Week Efficacy & Safety from BE MOBILE 1, a Phase 3, Multicentre, Randomised, Placebo Controlled Study

A. Deodhar, D. van der Heijde, LS. Gensler, H. Xu,
K. Gaffney, H. Dobashi, W P. Maksymowych, M. Rudwaleit,
M. Magrey, D. Elewaut, M. Oortgiesen, C. Fleurinck,
AM. Ellis, T. Vaux, J. Shepherd-Smith, X. Baraliakos

Bimekizumab is currently in clinical development and is not authorised for use by any regulatory authority worldwide for axSpA or PsA; therefore, this document discusses unlicensed indications and contains off-label information

GL-N-BK-AS-2200005
Date of preparation: May 2022

Study design



Enrolled patients were eligible to receive non-biologic rescue therapy from Week 20, at the discretion of the investigator, while continuing to receive BKZ. [a] Patients who are MRI negative must have elevated CRP and be HLA-B27 positive at screening. ASAS: Assessment in Spondyloarthritis international Society; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BKZ: bimekizumab; CRP: C-reactive protein; IBD: inflammatory bowel disease; MRI: magnetic resonance imaging; mNY: modified New York; nr-axSpA: non-radiographic axial spondyloarthritis; NSAID: non-steroidal anti-inflammatory drug; Q4W: every 4 weeks; TNFi: tumour necrosis factor inhibitor.

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Patient Demographics and Baseline Characteristics

	PBO n=126	BKZ 160 mg Q4W n=128
Age, years, mean (SD)	39.4 (11.8)	39.5 (11.1)
Sex, male, n (%)	65 (51.6%)	73 (57.0%)
HLA-B27 positive, n (%)	94 (74.6%)	103 (80.5%)
Symptom duration, years, mean (SD)	9.0 (9.0)	9.1 (8.7)
Time since first diagnosis, years, mean (SD)	3.6 (5.4)	3.7 (6.2)
MRI/CRP status,[a] n (%)		
MRI+/CRP+	39 (31.0%)	39 (30.5%)
MRI+/CRP–	56 (44.4%)	53 (41.4%)
MRI–/CRP+	31 (24.6%)	36 (28.1%)
ASDAS, mean (SD)	3.7 (0.7)	3.7 (0.8)
BASDAI, mean (SD)	6.7 (1.3)	6.9 (1.2)
hs-CRP, mg/L, median (min, max)	6.5 (0.1, 56.1)	6.1 (0.1, 79.1)
hs-CRP >ULN,[b] n (%)	71 (56.3%)	70 (54.7%)
Total spinal pain, mean (SD)	7.1 (1.6)	7.3 (1.5)
SPARCC MRI SIJ score,[c] mean (SD) [Nsub]	10.5 (13.8) [68]	8.5 (10.3) [79]
Patients with MASES >0, n (%)	92 (73.0%)	94 (73.4%)
Prior TNFi exposure, n (%)	17 (13.5%)	10 (7.8%)

Randomised set. [a] Patients categorised by the stratum to which they belong, which may differ from the stratum they were randomised to; [b] ULN value for hs-CRP is 5 mg/L; [c] Only patients enrolled in the MRI sub-study are included in this analysis. ASDAS: Ankylosing Spondylitis Disease Activity Score; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BKZ: bimekizumab; CRP: C-reactive protein; csDMARD: conventional synthetic disease-modifying antirheumatic drug; HLA-B27: human leukocyte antigen-B27; hs-CRP: high-sensitivity C-reactive protein; MASES: Maastricht Ankylosing Spondylitis Enthesitis Score; MRI: magnetic resonance imaging; PBO: placebo; Q4W: every 4 weeks; SD: standard deviation; SIJ: sacroiliac joint; SPARCC: Spondyloarthritis Research Consortium of Canada; TNFi: tumour necrosis factor inhibitor; ULN: upper limit of normal.

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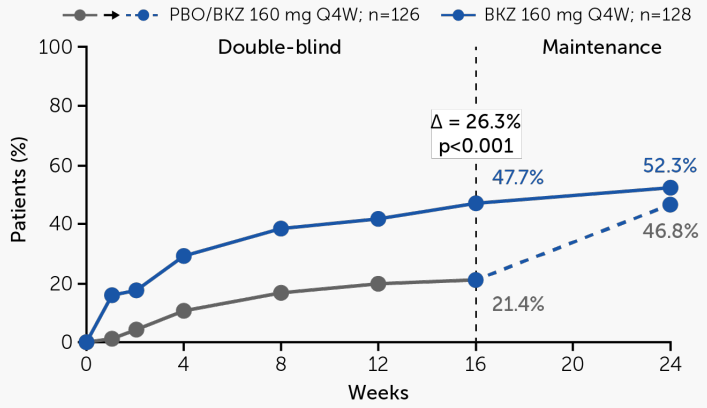
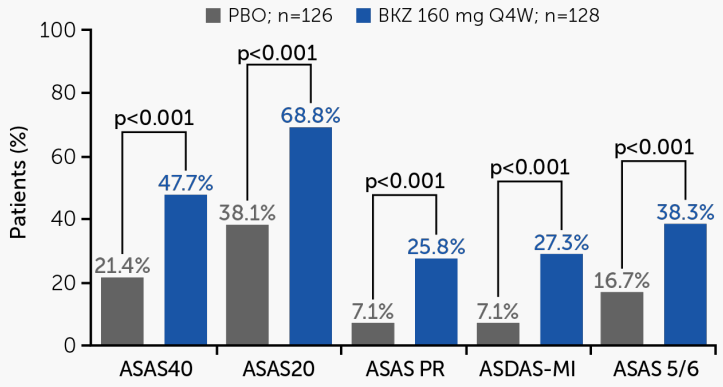
Primary and All Ranked Secondary Endpoints were Met at Week 16[a]

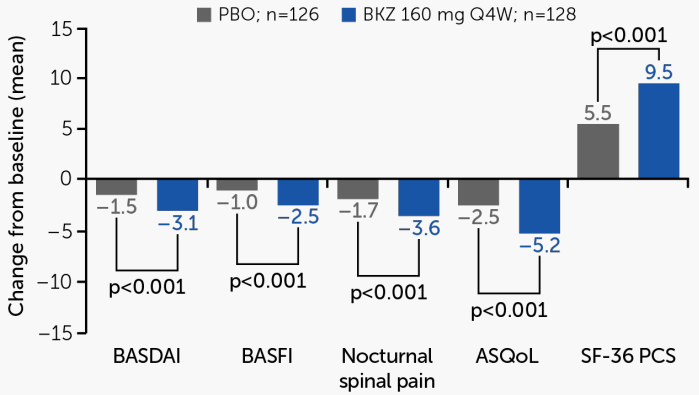
ASAS40 to Week 24 (NRI)



Response rates at Week 16 for binary endpoints (NRI)



Change from baseline in continuous endpoints at Week 16 (RBMI)



Randomised set. Missing data were imputed using non-responder imputation for binary endpoints and reference-based multiple imputation for continuous endpoints (based on data from the PBO group). [a] All tests performed at a 2-sided alpha level of 0.05 (for binary variables, p values were calculated by logistic regression with treatment, MRI/CRP classification and region as factors; for continuous variables, p values were obtained by ANCOVA with treatment, MRI/CRP classification and region as fixed effects, and baseline values as covariates). ANCOVA: analysis of covariance; ASAS: Assessment in Spondyloarthritis international Society; ASDAS: Ankylosing Spondylitis Disease Activity Score; ASQoL: Ankylosing Spondylitis Quality of Life; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BASFI: Bath Ankylosing Spondylitis Functional Index; CRP: C-reactive protein; MI: major improvement; MRI: magnetic resonance imaging; NRI: non-responder imputation; PBO: placebo; PCS: Physical Component Summary; PR: partial remission; Q4W: every 4 weeks; RMBI: reference-based multiple imputation; SF-36: Short-Form 36-item Health Survey.

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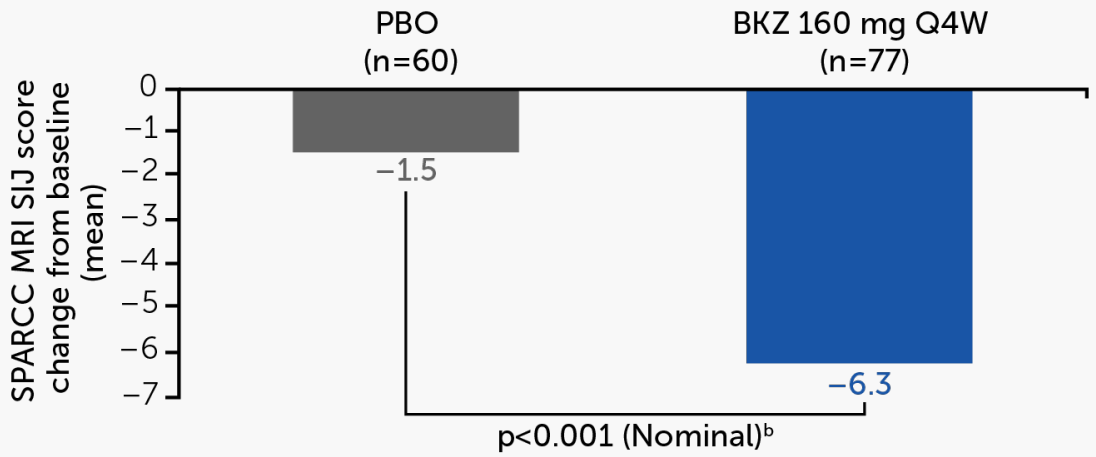
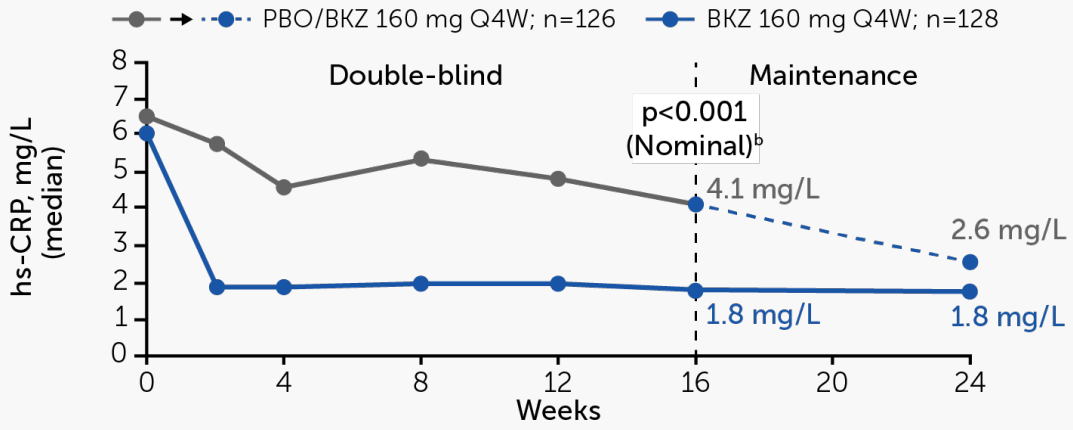
Substantial Reductions of MRI SIJ Inflammation by Week 16 and hs-CRP by Week 2 were Achieved with BKZ vs. Placebo[a]

Change from baseline in SPARCC MRI SIJ score at Week 16 (OC)



Change in median hs-CRP Weeks 0–24 (MI)



Randomised set. MRI data are reported as observed case; for hs-CRP, missing data were imputed using multiple imputation (based on the missing at random assumption). SPARCC MRI SIJ score ranges from 0 to 72 with lower scores indicating less SIJ inflammation, and a negative change representing improvement. [a] Only patients enrolled in the sacroiliac joint and spine MRI sub-study are included in this analysis; [b] Nominal p values were not controlled for multiplicity and were obtained by ANCOVA with treatment, MRI/CRP classification and region as fixed effects, and baseline values as covariates'. BKZ: bimekizumab; CfB: change from baseline; hs-CRP: high-sensitivity C-reactive protein; MRI: magnetic resonance imaging; PBO: placebo; Q4W: every 4 weeks; SIJ: sacroiliac joint; SPARCC: Spondyloarthritis Research Consortium of Canada.

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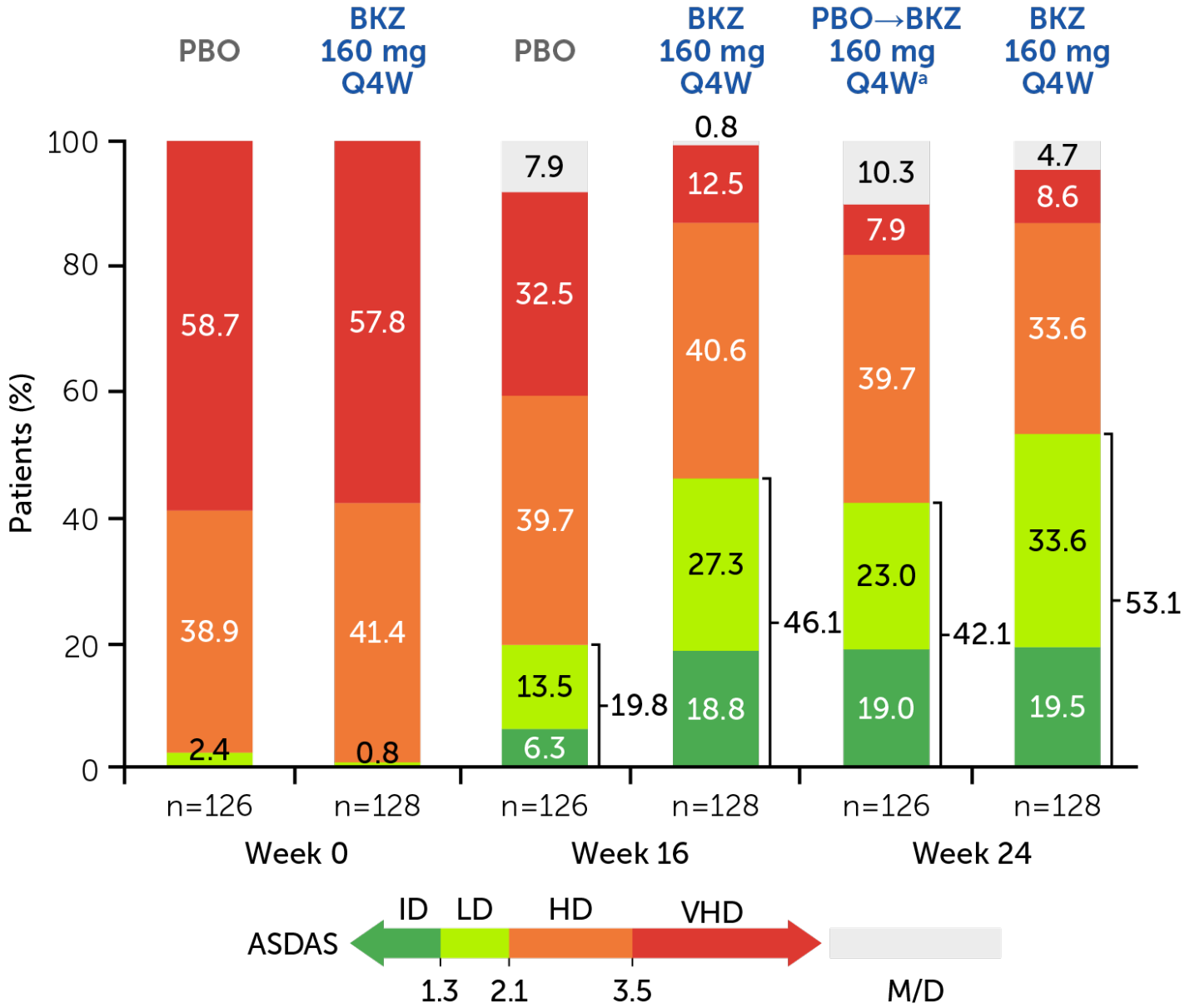
At Week 24, >50% of Patients Initially Randomized to BKZ had Achieved ASDAS<2.1



Randomised set. Data reported as observed case. [a] At Week 16, patients on PBO switched to BKZ. VHD: ASDAS >3.5; HD: ASDAS ≥2.1–≤3.5; LD: ASDAS ≥1.3–<2.1; ID: ASDAS <1.3. ASDAS: Ankylosing Spondylitis Disease Activity Index; BKZ: bimekizumab; HD: high disease; ID: inactive disease; LD: low disease; M/D: missing data; PBO: placebo; Q4W: every 4 weeks; VHD: very high disease.

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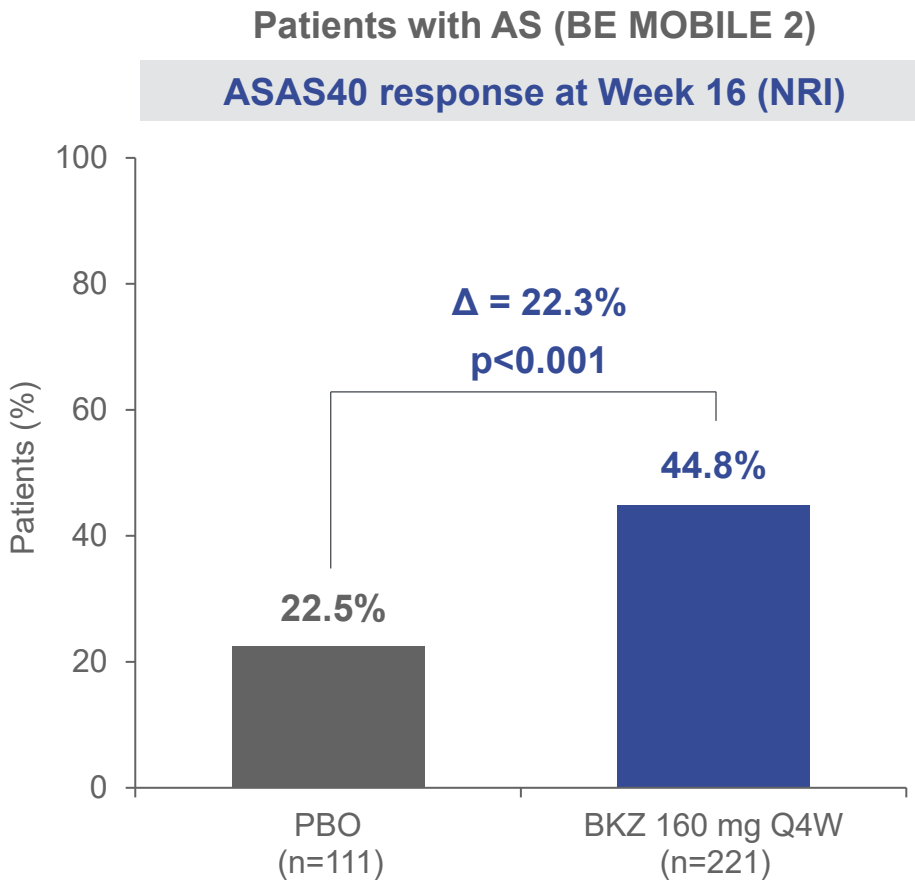
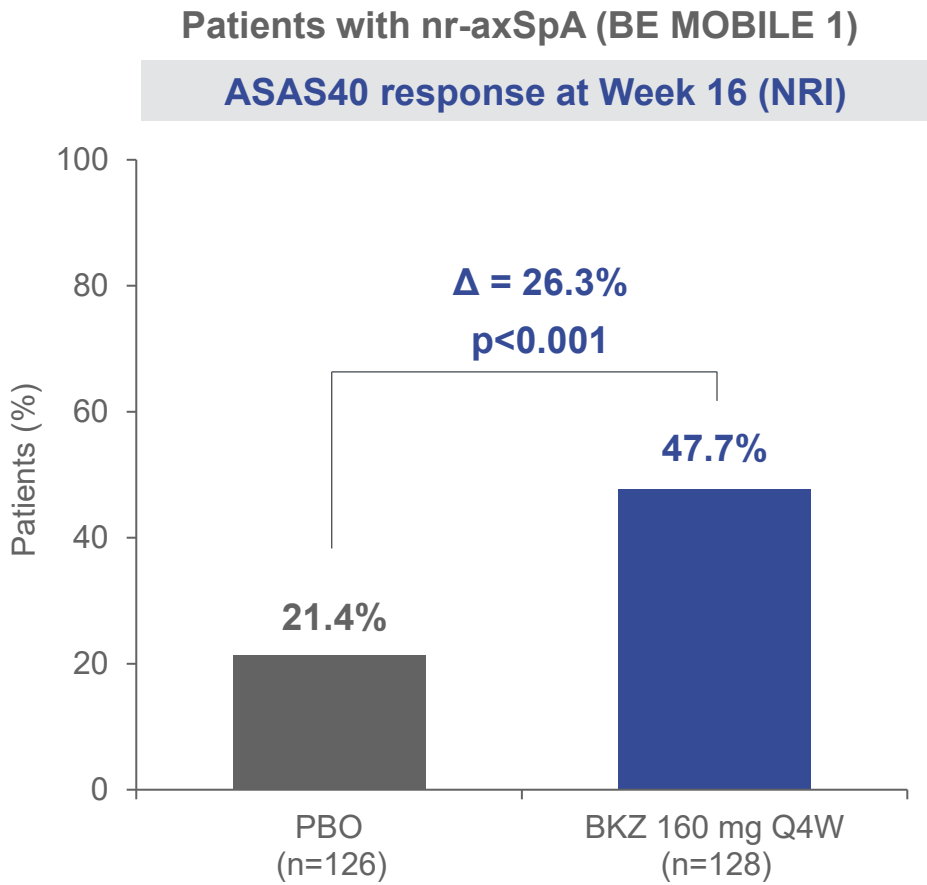
Consistency of BKZ Across the Spectrum of Axial Spondyloarthritis

Results from the BE MOBILE 2 study in patients with AS (i.e. radiographic axial spondyloarthritis) were consistent with findings from the BE MOBILE 1 study in patients with non-radiographic axial spondyloarthritis (nr-axSpA).[1]





1. Deodhar A. EULAR 2022;POS0939. Randomised set. In BE MOBILE 2, p value was calculated using logistic regression with treatment, prior TNFi exposure and region as factors. In BE MOBILE 1, p value was calculated using logistic regression with treatment, MRI/CRP classification and region as factors. AS: ankylosing spondylitis; ASAS40: Assessment of Spondyloarthritis international Society 40% response; BKZ: bimekizumab; CRP: C-reactive protein; MRI: magnetic resonance imaging; NRI: non-responder imputation; nr-axSpA: non-radiographic axial spondyloarthritis; PBO: placebo; Q4W: every 4 weeks; TNFi: tumour necrosis factor inhibitor.

Safety Overview

n (%)	Double-blind period (Weeks 0-16) PBO n=126	Double-blind period (Weeks 0-16) BKZ 160 mg Q4W n=128	Overall (Weeks 0-24) BKZ 160 mg Q4W Total[a] N=244
Any TEAE	71 (56.3)	80 (62.5)	124 (50.8)
Most frequently reported TEAEs (>3%) by preferred term			
Upper respiratory tract infection	9 (7.1)	9 (7.0)	17 (7.0)
Nasopharyngitis	6 (4.8)	12 (9.4)	16 (6.6)
Pharyngitis	1 (0.8)	4 (3.1)	7 (2.9)
Oral candidiasis[b]	0	4 (3.1)	7 (2.9)
Serious TEAEs	1 (0.8)	0	1 (0.4)
Study discontinuation due to TEAEs	5 (4.0)	2 (1.6)	2 (0.8)[c]
Drug-related TEAEs	18 (14.3)	32 (25.0)	53 (21.7)
Severe TEAEs	1 (0.8)	0	1 (0.4)
Deaths	0	0	0
Adjudicated MACE	0	0	0
Adjudicated IBD[d]			
Definite ulcerative colitis	1 (0.8)	0	0
Uveitis[e,f]	6 (4.8)	2 (1.6)	2 (0.8)

Safety set. MedDRA (Version 19.0). [a] Includes patients who switched from PBO to BKZ (events after switch only); [b] All case of oral candidiasis were non-severe and non-systemic, and none led to study discontinuation; [c] Of the 2 discontinuations from BKZ, 1 had neurological signs and symptoms NEC and 1 had psychiatric evaluation abnormal; [d] Definite or probable IBD reported, patient had no medical history of IBD; [e] At baseline, 21/126 (16.7%) patients on PBO and 19/128 (14.8%) patients on BKZ had a medical history of uveitis; [f] Includes the preferred terms uveitis, autoimmune uveitis, iridocyclitis and iritis. BKZ: bimekizumab; IBD: inflammatory bowel disease; MACE: major adverse cardiovascular events; NEC: not elsewhere classified; PBO: placebo; Q4W: every 4 weeks; TEAE: treatment-emergent adverse events. Deodhar D et al. EULAR 2022. Presentation POS0939.

Summary

In patients with active nr-axSpA, subcutaneous BKZ 160 mg Q4W achieved the primary and all ranked secondary endpoints.

BKZ resulted in clinically meaningful improvements in:

Disease activity
ASDAS, BASDAI, ASDAS-MI, ASDAS <2.1

Objective signs of inflammation
SPARCC MRI SIJ score, hs-CRP

Signs and symptoms
ASAS40, ASAS20, ASAS PR, ASAS 5/6, nocturnal spinal pain, MASES

Quality of life
ASQoL, SF-36 PCS

Physical function
BASFI

Safety
No new safety signals were observed

ASAS: Assessment in Spondyloarthritis international Society; ASDAS: Ankylosing Spondylitis Disease Activity Score; ASQoL: Ankylosing Spondylitis Quality of Life; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BASFI: Bath Ankylosing Spondylitis Functional Index; BKZ: bimekizumab; hs-CRP: high-sensitivity C-reactive protein; MASES: Maastricht Ankylosing Spondylitis Enthesitis Score; MI: major improvement; MRI: magnetic resonance imaging; PCS: Physical Component Summary; PR: partial remission; SF-36: Short-Form 36-item Health Survey; SIJ: sacroiliac joint; SPARCC: Spondyloarthritis Research Consortium of Canada.

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Bimekizumab in bDMARD-Naïve Patients with Psoriatic Arthritis: 24-Week Efficacy & Safety from BE OPTIMAL, a Phase 3, Multicentre, Randomised, Placebo-Controlled, Active Reference Study

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[1]Institute of Infection, Immunity and Inflammation, University of Glasgow, Glasgow, UK; [2]Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Diseases, University of Oxford and Oxford Biomedical Research Centre, Oxford University Hospitals NHS Trust, Oxford, UK; [3]Amsterdam Rheumatology & Clinical Immunology Center, Amsterdam, and Zuyderland MC, Heerlen, The Netherlands; [4]Swedish Medical Center and Providence St. Joseph Health and University of Washington, Seattle, Washington, USA; [5]Department of Medicine, University of Rochester, Rochester, New York, USA; [6]The First Department of Internal Medicine, University of Occupational and Environmental Health, Japan, Kitakyushu, Fukuoka; [7]Department of Dermatology, The Jikei University School of Medicine, Tokyo, Japan; [8]Sorbonne Université, Pitié Salpêtrière Hospital, Paris, France; [9]Department of Dermatology; The Icahn School of Medicine at Mt Sinai, New York, New York, USA; [10]Dermatology Centre, Salford Royal NHS Foundation Trust, Manchester NIHR Biomedical Research Centre, The University of Manchester, Manchester, UK; [11]UCB Pharma, Slough, UK; [12]UCB Pharma, Raleigh, North Carolina, USA; [13]Harvard Medical School, Brigham and Women's Hospital, Boston, Massachusetts, USA.

Bimekizumab is currently in clinical development and is not authorised for use by any regulatory authority worldwide for axSpA or PsA; therefore, this document discusses unlicensed indications and contains off-label information

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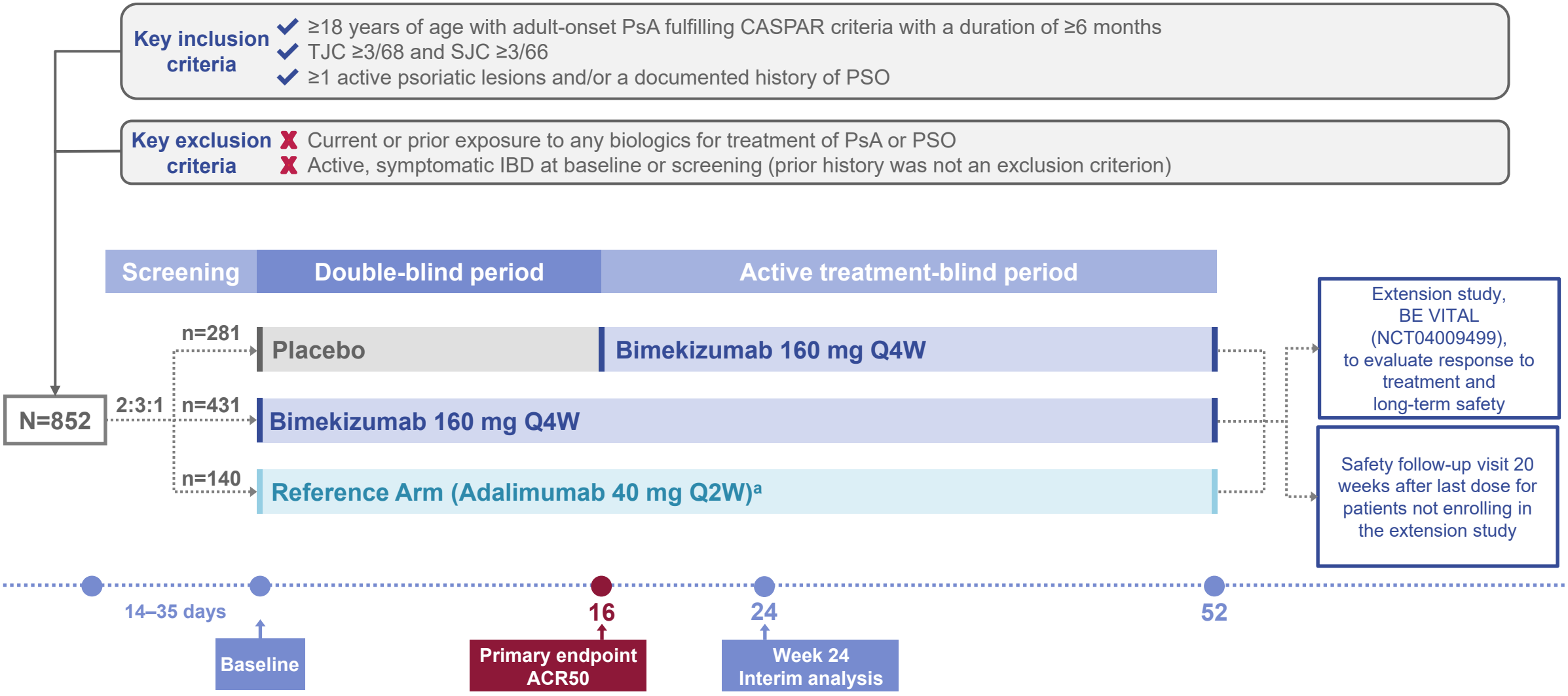
Date of preparation: May 2022

Presentation number: LB0001

Study Design



[a] The adalimumab 40mg Q2W treatment arm served as an active reference. The study was not powered for statistical comparisons of adalimumab to bimekizumab or adalimumab to placebo.
ACR: American College of Rheumatology; CASPAR: Classification Criteria for Psoriatic Arthritis; IBD: inflammatory bowel disease; PsA: psoriatic arthritis; PSO: psoriasis; SJC: swollen joint count; TJC: tender joint count; Q2W: every 2 weeks; Q4W: every 4 weeks.

Primary, Secondary and Other Endpoints

Primary endpoint

- **ACR50 response at Week 16**

Ranked secondary endpoints

- HAQ-DI CfB at Week 16
- PASI90 response at Week 16
- SF-36 PCS CfB at Week 16
- MDA response at Week 16
- vdHmTSS CfB at Week 16 in patients with hs-CRP ≥6 mg/L and/or ≥1 bone erosion at baseline
- Pooled enthesitis resolution (LEI) at Week 16[a]
- Pooled dactylitis resolution (LDI) at Week 16[a]
- vdHmTSS CfB at Week 16 in the overall population

Secondary and other efficacy endpoints

- ACR20 and ACR70 response at Week 16
- PASI75 and PASI100 response at Week 16
- TJC and SJC CfB at Week 16
- Proportion of patients with a decrease in HAQ-DI ≥0.35 at Week 16

Safety endpoints

- Incidence of TEAEs, treatment-emergent SAEs and TEAEs leading to withdrawal

Interim data results; final results at trial completion. [a] Data pooled from BE OPTIMAL and BE COMPLETE studies. ACR20/50/70: American College of Rheumatology criteria ≥20/50/70% response; CfB: change from baseline; HAQ-DI: Health Assessment Questionnaire-Disability Index; hs-CRP: high-sensitivity C-reactive protein; LDI: Leeds Dactylitis Index; LEI: Leeds Enthesitis Index; MDA: minimal disease activity; PASI: Psoriasis Area and Severity Index; PASI75/90/100: ≥75/90/100% improvement in PASI; PCS: Physical Component Summary; SAE: serious adverse event; SF-36: Short-Form 36-item Health Survey; SJC: swollen joint count; TEAE: treatment-emergent adverse event; TJC: tender joint count; vdHmTSS: van der Heijde-modified Total Sharp Score.

Patient Demographics and Baseline Disease Characteristics

	Placebo n=281	BKZ 160 mg Q4W n=431	Reference Arm (ADA 40 mg Q2W) n=140
Age, years, mean (SD)	48.7 (11.7)	48.5 (12.6)	49.0 (12.8)
Sex, male, n (%)	127 (45.2)	201 (46.6)	71 (50.7)
BMI, kg/m^2, mean (SD)	29.6 (6.1)	29.2 (6.8)	28.4 (5.9)
PsA duration,[a] years, mean (SD)	5.6 (6.5)	6.0 (7.3)	6.1 (6.8)
Concomitant methotrexate, n (%)	162 (57.7)	252 (58.5)	82 (58.6)
TJC (of 68 joints), mean (SD)	17.1 (12.5)	16.8 (11.8)	17.5 (13.1)
SJC (of 66 joints), mean (SD)	9.5 (7.3)	9.0 (6.2)	9.6 (7.1)
hs-CRP ≥6 mg/L, n (%)	121 (43.1)	158 (36.7)	44 (31.4)
Psoriasis BSA ≥3%, n (%)	140 (49.8)	217 (50.3)	68 (48.6)
PASI score,[b] mean (SD)	7.9 (5.6)	8.2 (6.8)	8.5 (7.6)
HAQ-DI,[c] mean (SD)	0.9 (0.6)	0.8 (0.6)	0.9 (0.5)
SF-36 PCS,[c] mean (SD)	36.9 (9.7)	38.1 (9.4)	37.6 (8.8)
vdHmTSS (at risk subgroup),[d,e] mean (SD)	6.7 (12.7)	6.6 (16.1)	7.0 (12.3)
vdHmTSS (overall),[d,f] mean (SD)	13.3 (25.2)	13.4 (30.1)	14.6 (27.9)
Enthesitis,[g] n (%) Score, mean (SD)	70 (24.9) 2.9 (1.5)	143 (33.2) 2.5 (1.5)	36 (25.7) 2.3 (1.6)
Dactylitis,[h] n (%) Score, mean (SD)	33 (11.7) 47.3 (41.1)	56 (13.0) 46.7 (54.3)	11 (7.9) 49.7 (31.9)

Randomised set. [a] Listed as time since diagnosis of PsA, placebo n=279, BKZ n=423, ADA n=139; [b] In patients with ≥3% BSA with PSO at baseline; [c] data missing for 1 BKZ patient; [d] Radiographic set; [e] At-risk subgroup defined as patients with elevated hs-CRP (≥6 mg/L) and/or ≥1 bone erosion at baseline, placebo n=221, BKZ n=357, ADA n=108; [f] placebo n=261, BKZ n=416, ADA n=131; [g] Leeds Enthesitis Index >0; [h] Leeds Dactylitis Index >0. ADA: adalimumab; BKZ: bimekizumab; BMI: body mass index; BSA: body surface area; HAQ-DI: Health Assessment Questionnaire-Disability Index; hs-CRP: high-sensitivity C-reactive protein; PASI: Psoriasis Area and Severity Index; PCS: Physical Component Summary; PsA: psoriatic arthritis; Q2W: every 2 weeks; Q4W: every 4 weeks; SD: standard deviation; SF-36: Short-Form 36-item Health Survey; SJC: swollen joint count; TJC: tender joint count; vdHmTSS: van der Heijde-modified Total Sharp Score.

BE OPTIMAL Met Primary and All Ranked Secondary Endpoints (Week 16)

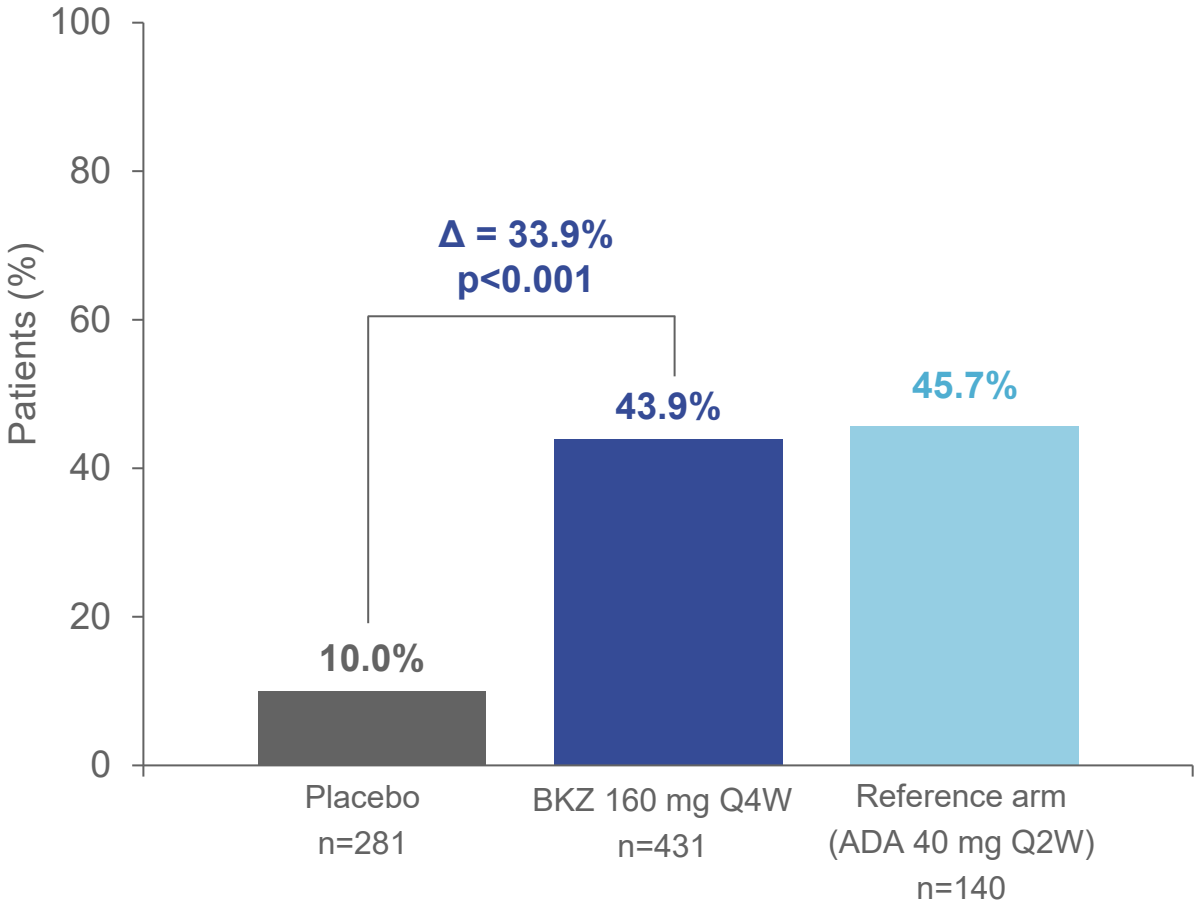
	Efficacy endpoint	p value[a]	Statistically significant	Odds ratio[b] BKZ vs placebo (95% CI)	Least squares mean difference[b] BKZ vs placebo (95% CI)
1	ACR50 (NRI)	<0.001	Yes	7.1 (4.6, 11.0)	–
2	HAQ-DI Change from Baseline (RBMI)	<0.001	Yes	–	−0.2 (−0.3, −0.1)
3	PASI90 (NRI)[c]	<0.001	Yes	62.4 (22.0, 176.9)	–
4	SF-36 PCS Change from Baseline (RBMI)	<0.001	Yes	–	+4.3 (+3.2, +5.5)
5	MDA Response (NRI)	<0.001	Yes	5.5 (3.7, 8.1)	–
6	vdHmTSS Change from Baseline (at risk subgroup) (RBMI)[d]	<0.001	Yes	–	−0.3 (−0.5, −0.1)
7	Pooled Resolution of Enthesitis (LEI) (NRI)[e]	0.008	Yes	1.9 (1.2, 3.1)	–
8	Pooled Resolution of Dactylitis (LDI) (NRI)[f]	0.002	Yes	3.4 (1.6, 7.6)	–
9	vdHmTSS Change from Baseline (overall population) (RMBI)	0.001	Yes	–	−0.3 (−0.5, −0.1)

Interim data results; final results at trial completion. Randomised set. For binary variables, p values were obtained from logistic regression with treatment, bone erosion at baseline and region as factors (for endpoints 7 and 8, study was included as a factor and bone erosion at baseline was excluded). For continuous variables, p values were obtained from ANCOVA with treatment, bone erosion at baseline and region as fixed effects and the baseline value as covariate. The study was not powered for statistical comparisons of adalimumab to bimekizumab or placebo. [a] All tests performed at a 2-sided alpha level of 0.05; [b] Odds ratio for binary variables and least squares mean difference BKZ vs placebo for continuous variables; [c] In patients with ≥3% BSA with PSO at baseline; [d] In patients with hs-CRP ≥6 mg/L and/or ≥1 bone erosion at baseline; [e] In patients with LEI>0 at baseline in pooled BE OPTIMAL/BE COMPLETE randomised sets; [f] In patients with LDI>0 at baseline in pooled BE OPTIMAL/BE COMPLETE randomised sets. ACR50: American College of Rheumatology criteria ≥50% response; BKZ: bimekizumab; BSA: body surface area; CI: confidence interval; HAQ-DI: Health Assessment Questionnaire-Disability Index; hs-CRP: high-sensitivity C-reactive protein; LDI: Leeds Dactylitis Index; LEI: Leeds Enthesitis Index; MDA: Minimal Disease Activity; NRI: non-responder imputation; PASI: Psoriasis Area and Severity Index; PASI90: ≥90% improvement in PASI; PCS: Physical Component Summary; PSO: psoriasis; RBMI: reference-based multiple imputation; SF-36: Short-Form 36-item Health Survey; vdHmTSS: van der Heijde-modified Total Sharp Score.

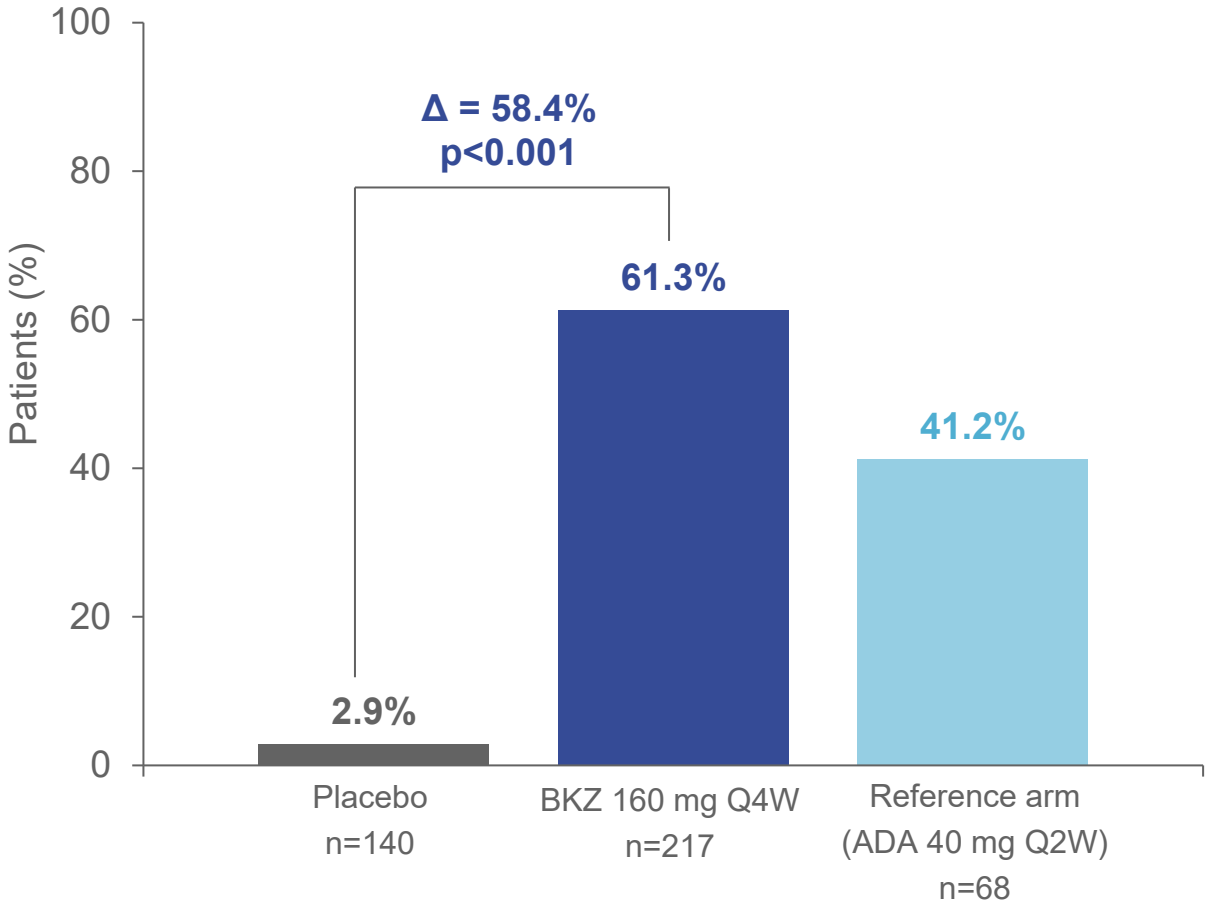
Efficacy: ACR50 and PASI90 Responses at Week 16 (NRI)

BKZ demonstrated superiority vs placebo in improvements in joint and skin outcomes at Week 16

Primary Endpoint: ACR50



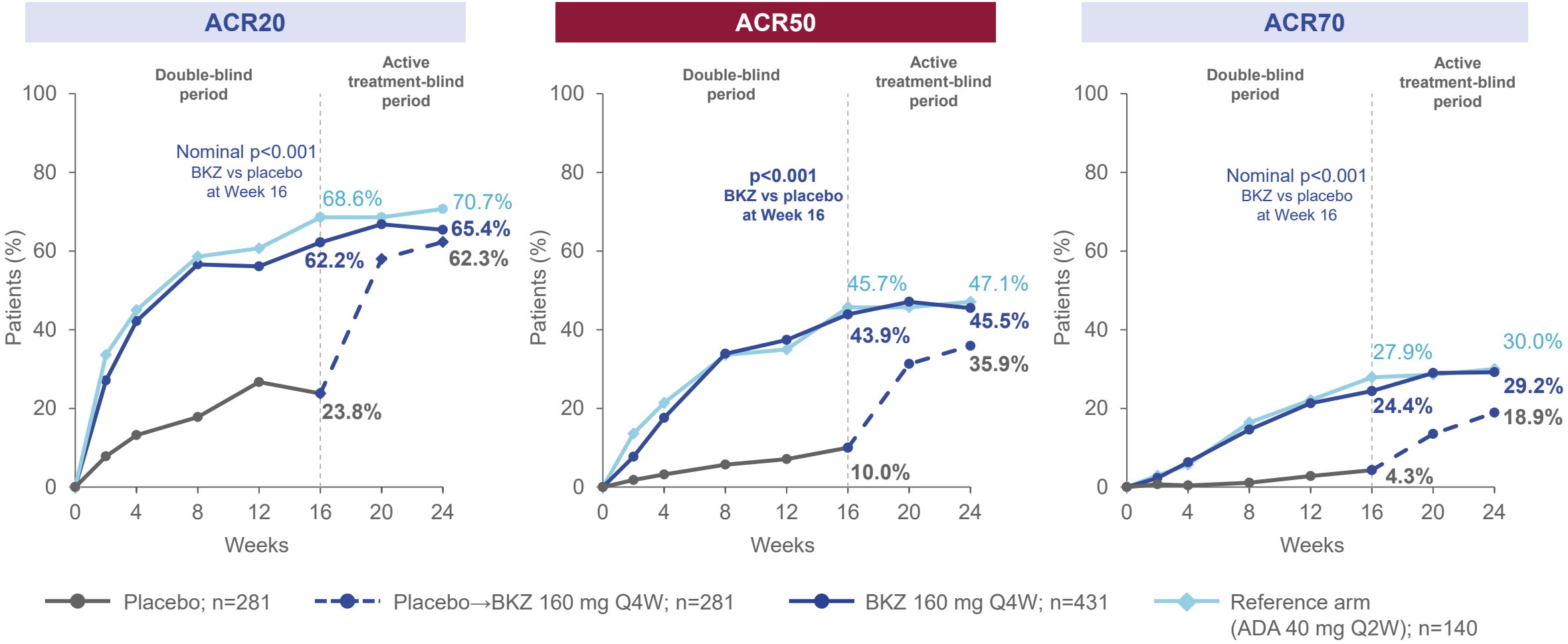
PASI90[a]



Randomised set. p values BKZ vs placebo were obtained from logistic regression with treatment, bone erosion at baseline and region as factors. The study was not powered for statistical comparisons of adalimumab to bimekizumab or adalimumab to placebo. [a] Patients with PSO involving ≥3% of BSA at baseline. ACR50: American College of Rheumatology criteria ≥50% response; ADA: adalimumab; BKZ: bimekizumab; BSA: body surface area; NRI: non-responder imputation; PASI: Psoriasis Area and Severity Index; PASI90: ≥90% improvement in PASI; PSO: psoriasis; Q2W: every 2 weeks; Q4W: every 4 weeks.

Efficacy: ACR Response Criteria to Week 24 (NRI)

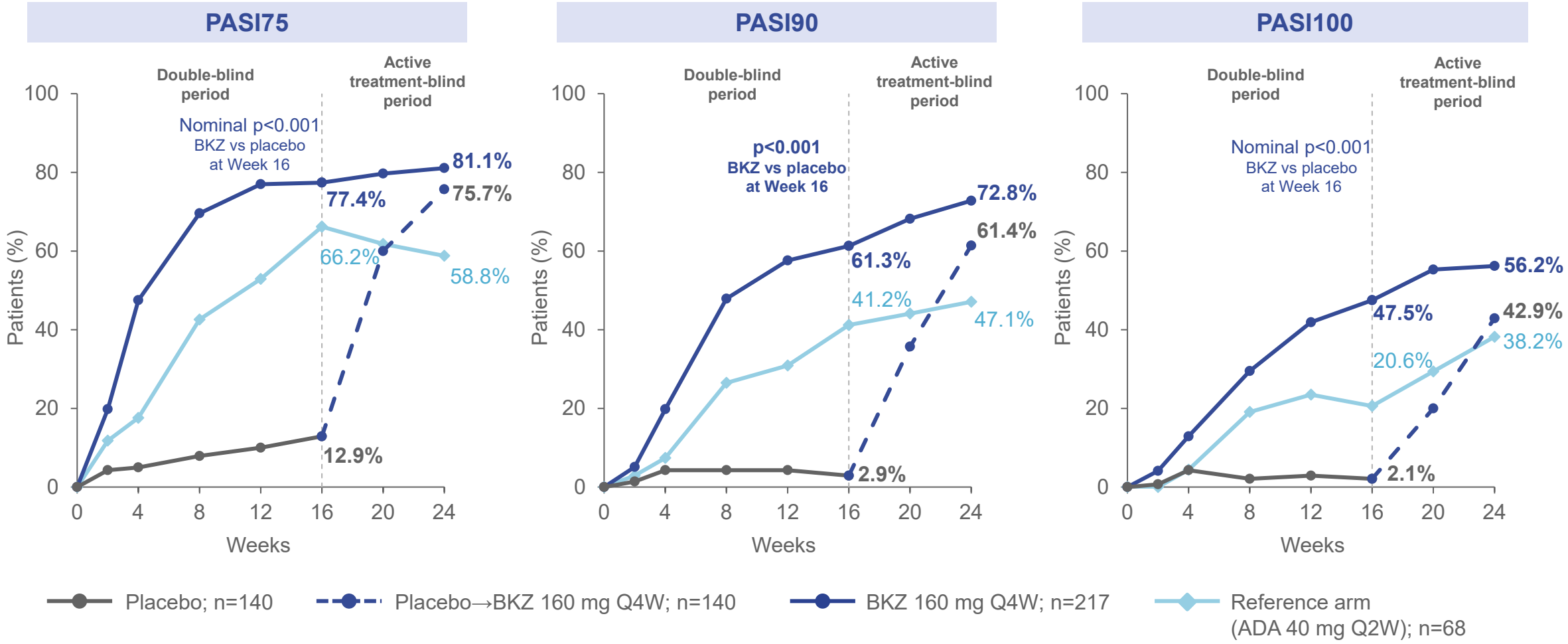
BKZ demonstrated improvements vs placebo in achievement of ACR response criteria at Week 16



Randomised set. p values BKZ vs placebo were obtained from logistic regression with treatment, bone erosion at baseline and region as factors. Nominal p values were not adjusted for multiplicity. The study was not powered for statistical comparisons of adalimumab to bimekizumab or adalimumab to placebo. ACR20/50/70: American College of Rheumatology criteria ≥20/50/70% response; ADA: adalimumab; BKZ: bimekizumab; NRI: non-responder imputation; Q2W: every 2 weeks; Q4W: every 4 weeks.

Efficacy: Psoriasis Area and Severity Index to Week 24 (NRI)

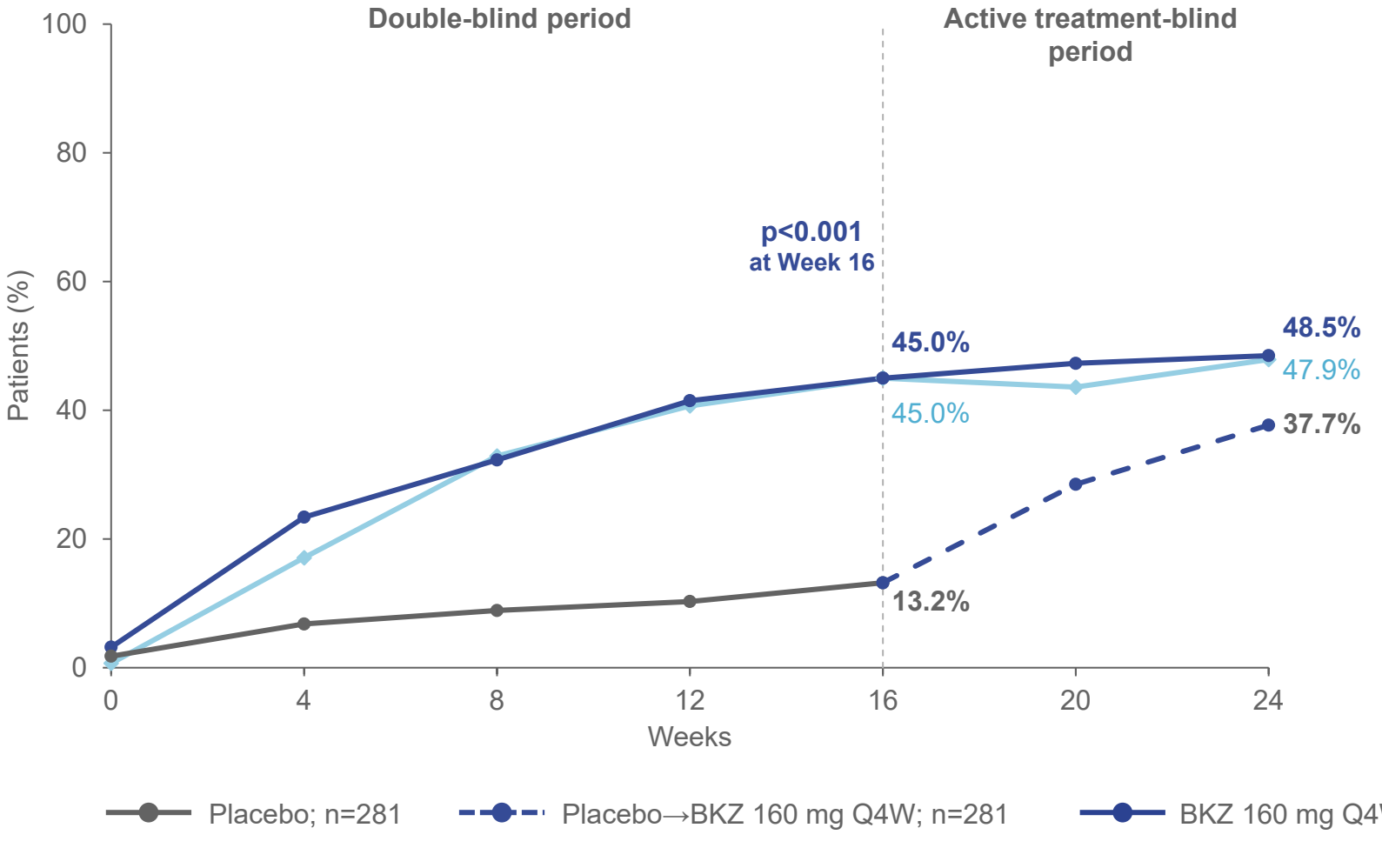
Over half of BKZ patients achieved complete skin clearance by Week 24



Randomised set, in patients with PSO involving ≥3% of BSA at baseline. p values BKZ vs placebo were obtained from logistic regression with treatment, bone erosion at baseline and region as factors. Nominal p values were not adjusted for multiplicity. The study was not powered for statistical comparisons of adalimumab to bimekizumab or adalimumab to placebo. ADA: adalimumab; BKZ: bimekizumab; BSA: body surface area; NRI: non-responder imputation; PASI: Psoriasis Area and Severity Index; PASI75/90/100: 75/90/100% improvement in PASI; PSO: psoriasis; Q2W: every 2 weeks; Q4W: every 4 weeks.

Efficacy: Proportion of Patients Achieving MDA to Week 24 (NRI)

BKZ demonstrated superiority vs placebo in achievement of MDA response (composite index) at Week 16



MDA response defined as achievement of at least 5 of the 7 following criteria:

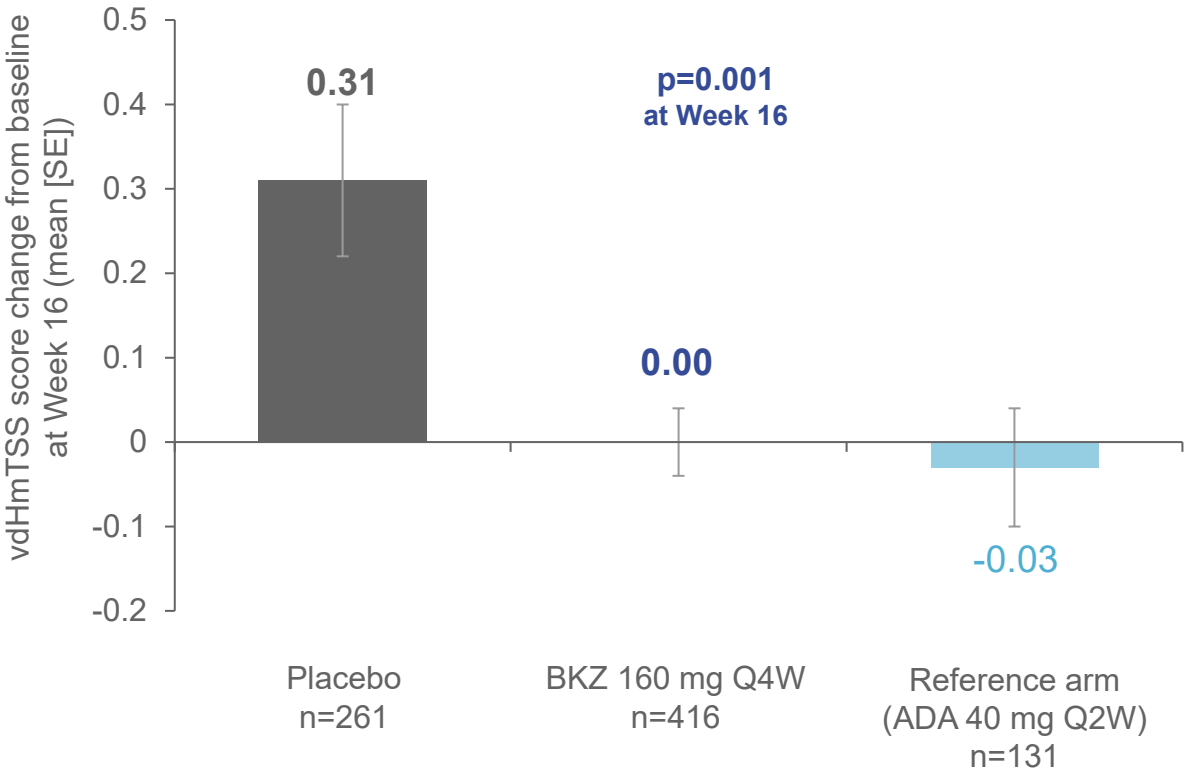
- Tender joint count ≤1
- Swollen joint count ≤1
- Psoriasis Area and Severity Index ≤1[a] or body surface area ≤3%[b]
- Patient's Assessment of Arthritis Pain ≤15 mm
- Patient global assessment-PsA ≤20 mm
- Health Assessment Questionnaire–Disability Index ≤0.5
- Tender entheseal points ≤1

Randomised set. p value BKZ vs placebo was obtained from logistic regression with treatment, bone erosion at baseline and region as factors. The study was not powered for statistical comparisons of adalimumab to bimekizumab or adalimumab to placebo. [a] For patients with PSO involving ≥3% of BSA at baseline. [b] Subjects with BSA <3% at baseline will always meet the criteria PASI ≤1 or BSA ≤3% except in the cases where a BSA score >3% is observed. ACR: American College of Rheumatology; ADA: adalimumab; BKZ: bimekizumab; BSA: body surface area; MDA: Minimal Disease Activity; NRI: non-responder imputation; PASI: Psoriasis Area and Severity Index; PsA: psoriatic arthritis; PSO: psoriasis; Q2W: every 2 weeks; Q4W: every 4 weeks.

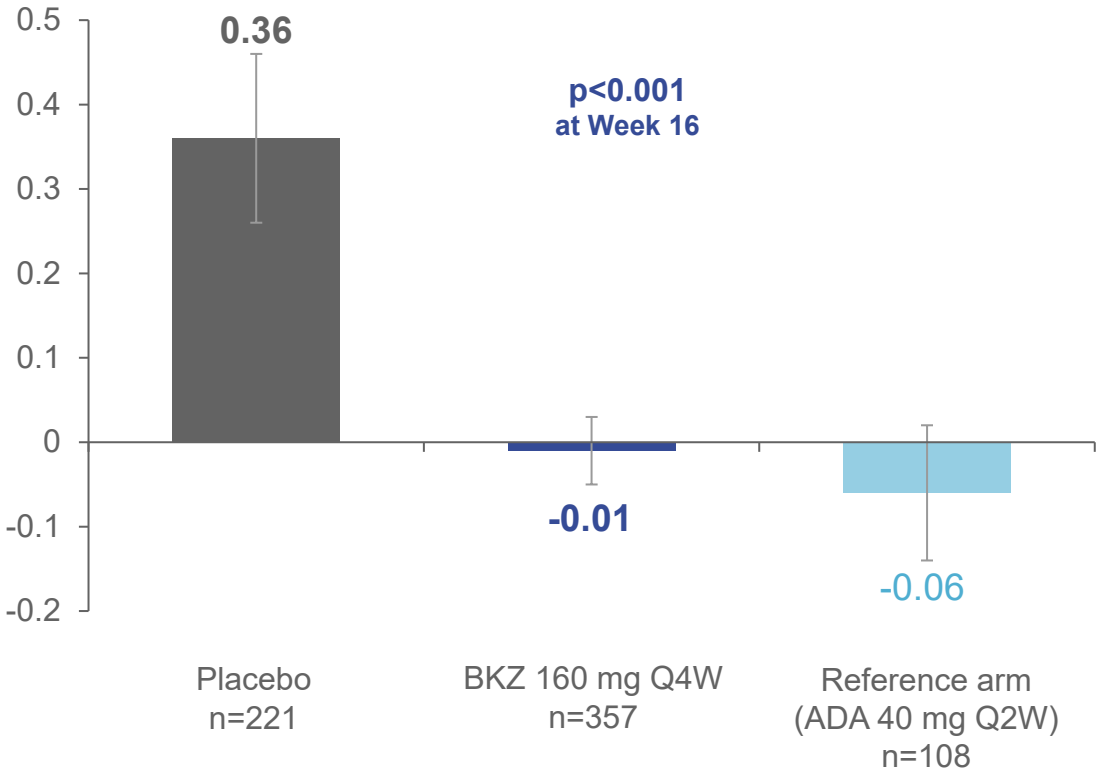
Efficacy: Radiographic Outcomes at Week 16 (MI)

BKZ demonstrated superiority vs placebo in inhibition of structural progression at Week 16

Overall Population
(Radiographic Set)



At-Risk Population
(hs-CRP ≥6 mg/L and/or ≥1 Bone Erosion at Baseline)



Radiographic set. p values BKZ vs placebo were obtained from ANCOVA with treatment, bone erosion at baseline and region as fixed effects and the baseline value as covariate. The study was not powered for statistical comparisons of adalimumab to bimekizumab or adalimumab to placebo. ADA: adalimumab; BKZ: bimekizumab; CfB: change from baseline; hs-CRP: high-sensitivity C-reactive protein; MI: multiple imputation; Q2W: every 2 weeks; Q4W: every 4 weeks; SE: standard error; vdHmTSS: van der Heijde-modified Total Sharp Score.

Safety: Overall

n (%)	Week 0–16			Week 0–24	
	Placebo n=281	BKZ 160 mg Q4W n=431	Reference Arm (ADA 40 mg Q2W) n=140	BKZ 160 mg Q4W Total n=702[a]	Reference Arm (ADA 40 mg Q2W) n=140
Any TEAE	139 (49.5)	258 (59.9)	83 (59.3)	395 (56.3)	96 (68.6)
Serious TEAEs	3 (1.1)	7 (1.6)	2 (1.4)	20 (2.8)	5 (3.6)
Discontinuation due to TEAEs	3 (1.1)	8 (1.9)	3 (2.1)	12 (1.7)	7 (5.0)
Drug-related TEAEs	35 (12.5)	101 (23.4)	34 (24.3)	149 (21.2)	43 (30.7)
Severe TEAEs	0	4 (0.9)	3 (2.1)	10 (1.4)	3 (2.1)
Deaths	0	0	0	0	0
Most frequently reported TEAEs[b] (≥3% in any treatment arm)					
Nasopharyngitis	13 (4.6)	40 (9.3)	7 (5.0)	58 (8.3)	12 (8.6)
Upper respiratory tract infection	18 (6.4)	21 (4.9)	3 (2.1)	31 (4.4)	5 (3.6)
Headache	7 (2.5)	20 (4.6)	2 (1.4)	26 (3.7)	3 (2.1)
Diarrhoea	7 (2.5)	16 (3.7)	5 (3.6)	21 (3.0)	5 (3.6)
Hypertension	11 (3.9)	12 (2.8)	4 (2.9)	19 (2.7)	4 (2.9)
ALT elevation	2 (0.7)	3 (0.7)	7 (5.0)	5 (0.7)	8 (5.7)
Oral herpes	3 (1.1)	5 (1.2)	3 (2.1)	7 (1.0)	6 (4.3)
Injection site erythema	0	1 (0.2)	4 (2.9)	2 (0.3)	5 (3.6)
Fungal Infections[c]	4 (1.4)	20 (4.6)	1 (0.7)	40 (5.7)	1 (0.7)
Candida infections[d]	2 (0.7)	11 (2.6)	0	22 (3.1)	0
Adjudicated MACE	0	0	0	1 (0.1)	0
Adjudicated IBD	0	0	0	1 (0.1)[e]	0

Safety set, MedDRA (Version 19.0). [a] Includes patients who switched from placebo to BKZ (events after switch only); [b] TEAEs ≥3% in any treatment arm are reported by preferred term; [c] No fungal infections were systemic; [d] All infections were mild to moderate and none were serious, 1 BKZ patient discontinued; [e] one case of probable IBD in a patient with no prior history of IBD. ADA: adalimumab; ALT: alanine aminotransferase; BKZ: bimekizumab; IBD: inflammatory bowel disease; MACE: major adverse cardiovascular event; n: number of patients reporting at least one TEAE in that category; Q2W: every 2 weeks; Q4W: every 4 weeks; TEAE: treatment-emergent adverse event.

Conclusions

The BE OPTIMAL phase 3 study, evaluating dual inhibition of IL-17A and IL-17F with bimekizumab in bDMARD-naïve patients with PsA, met all its primary and secondary endpoints.

Bimekizumab-treated bDMARD-naïve patients with PsA showed improvements in joint and skin outcomes, as well as in the composite outcome of minimal disease activity, reflecting the efficacy of dual inhibition across PsA disease manifestations.

Bimekizumab treatment resulted in the inhibition of structural progression in both the overall population and the subgroup of patients with elevated hs-CRP and/or ≥1 bone erosion at baseline.

Bimekizumab was well tolerated; the safety profile was consistent with prior studies with no unexpected safety findings.[1,2]

1. Ritchlin CT Lancet 2020;395(10222):427–40; 2. Coates LC Ann Rheum Dis 2021;80:779–80(POS1022). bDMARD: biologic disease-modifying antirheumatic drug; hs-CRP: high-sensitivity C-reactive protein; IL: interleukin; PsA: psoriatic arthritis; TNFi-IR: tumour necrosis factor inhibitor – inadequate response.

Bimekizumab in Patients with Active Psoriatic Arthritis and an Inadequate Response to Tumour Necrosis Factor Inhibitors: 16-Week Efficacy and Safety from BE COMPLETE, a Phase 3, Multicentre, Randomised, Placebo-Controlled Study

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Bimekizumab is currently in clinical development and is not authorised for use by any regulatory authority worldwide for axSpA or PsA; therefore, this document discusses unlicensed indications and contains off-label information

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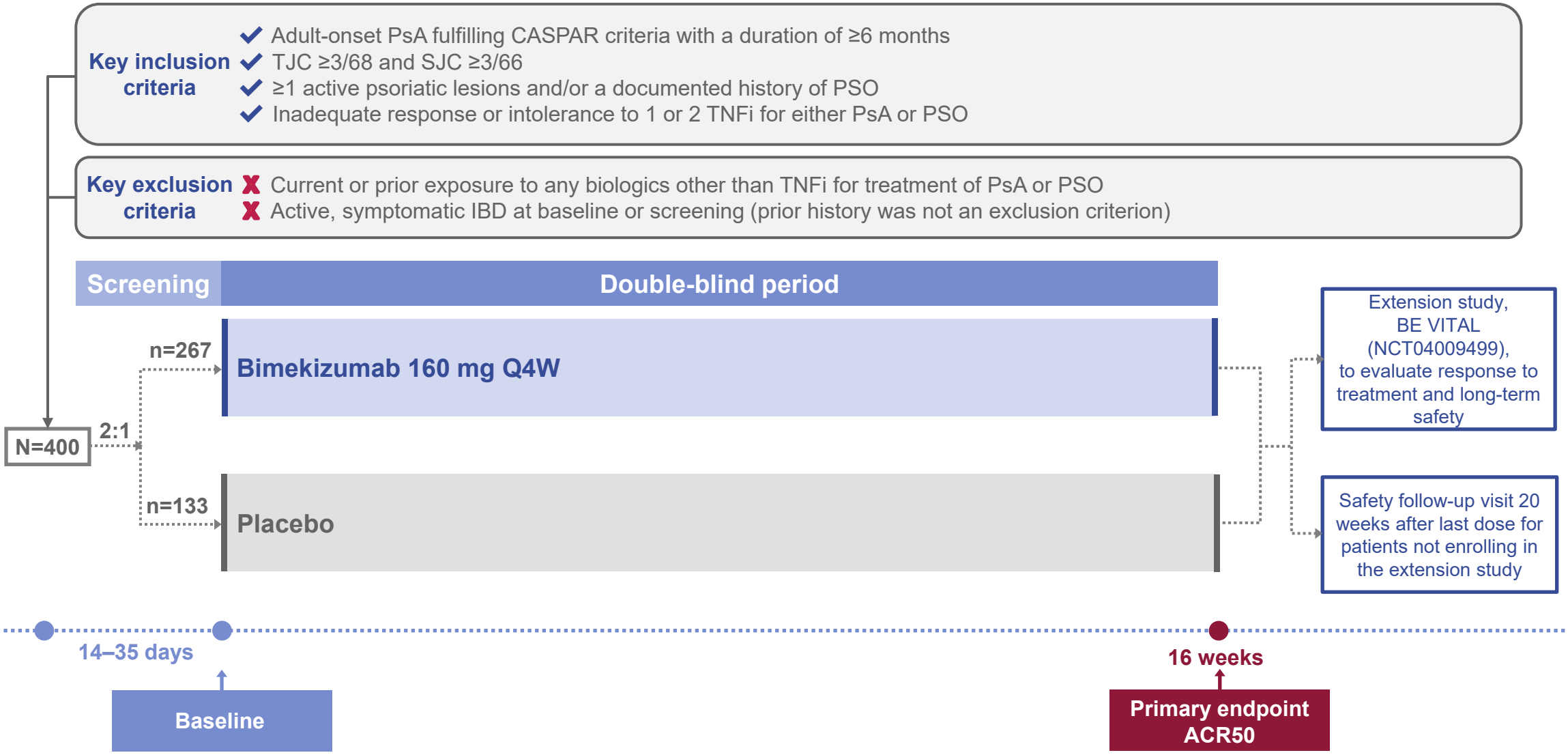
Date of preparation: May 2022

Study Design



ACR: American College of Rheumatology; CASPAR: Classification Criteria for Psoriatic Arthritis; IBD: inflammatory bowel disease; PsA: psoriatic arthritis; PSO: psoriasis; SJC: swollen joint count; TJC: tender joint count; TNFi: tumour necrosis factor inhibitor; Q4W: every 4 weeks.

GL-N-BK-AS-2200005
Date of preparation: May 2022

Primary, Secondary and Other Endpoints

Primary endpoint

- ACR50 response at Week 16

Ranked secondary endpoints

- HAQ-DI CfB at Week 16
- PASI90 response at Week 16
- SF-36 PCS CfB at Week 16
- MDA response at Week 16

Secondary and other efficacy endpoints

- ACR20 and ACR70 response at Week 16
- PASI75 and PASI100 response at Week 16
- TJC and SJC CfB at Week 16
- Proportion of patients with a decrease in HAQ-DI ≥0.35 at Week 16

Safety endpoints

- Incidence of TEAEs, treatment-emergent SAEs and TEAEs leading to withdrawal

ACR20/50/70: American College of Rheumatology criteria ≥20/50/70% response; CfB: change from baseline; HAQ-DI: Health Assessment Questionnaire-Disability Index; MDA: minimal disease activity; PASI75/90/100: ≥75/90/100% improvement in PASI; PCS: Physical Component Summary; SAE: serious adverse event; SF-36: Short-Form 36-item Health Survey; SJC: swollen joint count; TEAE: treatment-emergent adverse event; TJC: tender joint count.

Patient Demographics and Baseline Disease Characteristics

	Placebo n=133	BKZ 160 mg Q4W n=267
Age, years, mean (SD)	51.3 (12.9)	50.1 (12.4)
Sex, male, n (%)	60 (45.1)	130 (48.7)
BMI, kg/m^2, mean (SD)	29.0 (5.4)	30.1 (6.5)
PsA duration,[a] years, mean (SD)	9.2 (8.1)	9.6 (9.9)
Concomitant methotrexate, n (%)	51 (38.3)	119 (44.6)
Prior TNFi exposure, n (%) Inadequate response to 1 TNFi Inadequate response to 2 TNFi Intolerance to TNFi	 103 (77.4) 15 (11.3) 15 (11.3)	 204 (76.4) 29 (10.9) 34 (12.7)
TJC (of 68 joints), mean (SD)	19.3 (14.2)	18.4 (13.5)
SJC (of 66 joints), mean (SD)	10.3 (8.2)	9.7 (7.5)
hs-CRP ≥6 mg/L, n (%)	59 (44.4)	118 (44.2)
Psoriasis BSA ≥3%, n (%)	88 (66.2)	176 (65.9)
PASI score,[b] mean (SD)	8.5 (6.6)	10.1 (9.1)
HAQ-DI, mean (SD)	1.0 (0.7)	1.0 (0.6)
PtAAP,[c] mean (SD)	61.7 (24.6)	58.3 (24.2)
SF-36 PCS, mean (SD)	35.9 (0.9)	36.4 (0.5)
Enthesitis,[d] n (%) Score, mean (SD)	36 (27.1) 2.9 (1.6)	106 (39.7) 2.6 (1.5)
Dactylitis,[e] n (%) Score, mean (SD)	14 (10.5) 66.4 (127.6)	34 (12.7) 72.7 (114.4)

Randomised set. [a] Listed as time since diagnosis of PsA, data missing for one patient receiving placebo and one patient receiving BKZ; [b] In patients with PSO involving ≥3% BSA at baseline; [c] PtAAP VAS 0–100; [d] Leeds Enthesitis Index >0; [e] Leeds Dactylitis Index >0. BKZ: bimekizumab; BMI: body mass index; BSA: body surface area; HAQ-DI: Health Assessment Questionnaire-Disability Index; hs-CRP: high-sensitivity C-reactive protein; PASI: Psoriasis Area and Severity Index; PCS: Physical Component Summary; PsA: psoriatic arthritis; PSO: psoriasis; PtAAP: Patient's Assessment of Arthritis Pain; Q4W: every 4 weeks; SD: standard deviation; SF-36: Short-Form 36-item Health Survey; SJC: swollen joint count; TJC: tender joint count; TNFi: tumour necrosis factor inhibitor; VAS: visual analogue scale.

BE COMPLETE Met Primary and All Ranked Secondary Endpoints (Week 16)

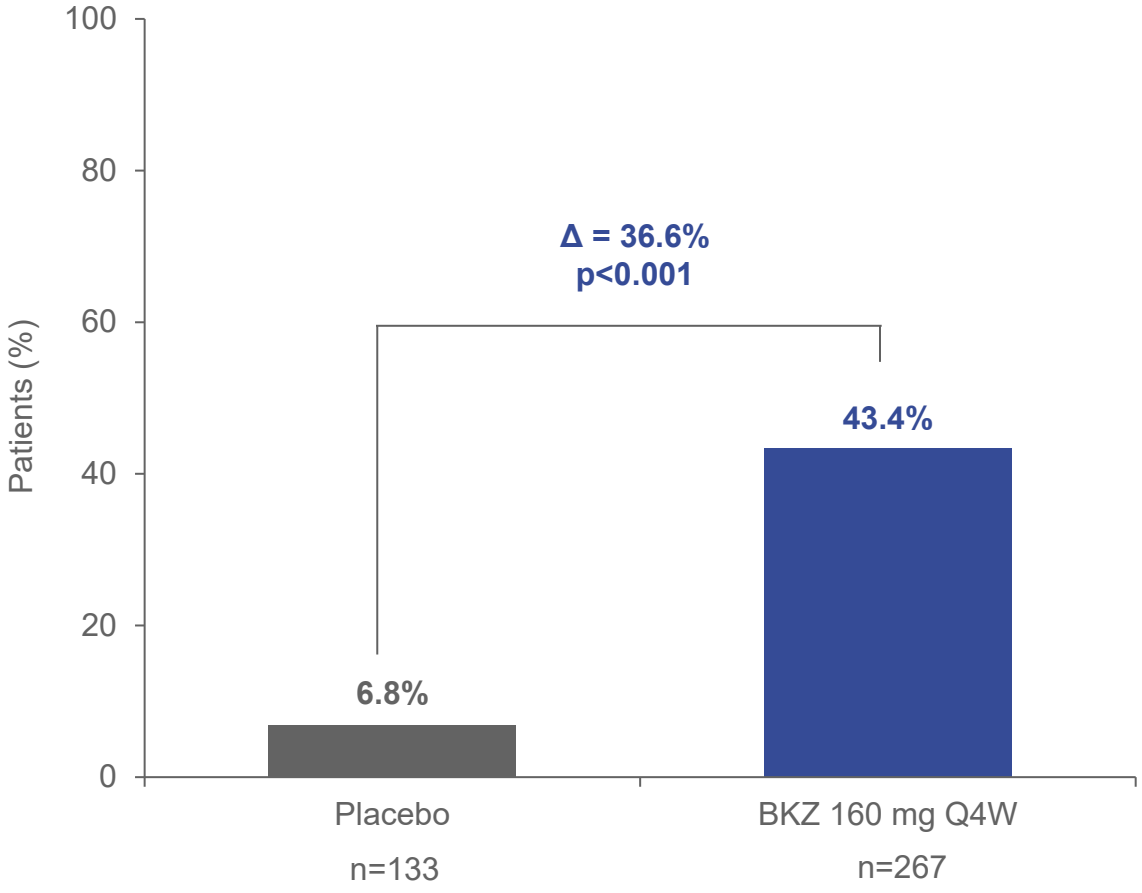
	Efficacy endpoint	p value[a]	Statistically significant	Odds ratio[a] BKZ vs placebo (95% CI)[b]	Least squares mean difference BKZ vs placebo (95% CI)[b]
1	**ACR50 (NRI)**	<0.001	Yes	11.1 (5.4, 22.9)	–
2	**HAQ-DI CfB (RBMI)**	<0.001	Yes	–	–0.3 (–0.4, –0.2)
3	**PASI90 (NRI)[c]**	<0.001	Yes	30.2 (12.4, 73.9)	–
4	**SF-36 PCS CfB (RBMI)**	<0.001	Yes	–	+6.0 (+4.4, +7.7)
5	**MDA Response (NRI)**	<0.001	Yes	13.0 (6.1, 27.9)	–

Randomised set. For binary variables, p values were obtained from logistic regression with treatment, prior TNF inhibitor exposure and region as factors. For continuous variables, p values were obtained from ANCOVA with treatment, prior TNF inhibitor exposure and region as fixed effects and the baseline value as covariate [a] Tests performed at a 2-sided alpha level of 0.05. [b] Odds ratio for binary variables and least squares mean difference BKZ vs placebo for continuous variables. [c] In patients with PSO involving ≥3% BSA at baseline. ACR50: American College of Rheumatology criteria ≥50% response; ANCOVA: Analysis of Covariance; BKZ: bimekizumab; BSA: body surface area; CfB: change from baseline; CI: confidence interval; HAQ-DI: Health Assessment Questionnaire-Disability Index; MDA: Minimal Disease Activity; NRI: non-responder imputation; PASI90: ≥90% improvement in PASI; PCS: Physical Component Summary; PSO: psoriasis; RBMI: reference-based multiple imputation; SF-36: Short-Form 36-item Health Survey; TNF: tumour necrosis factor.

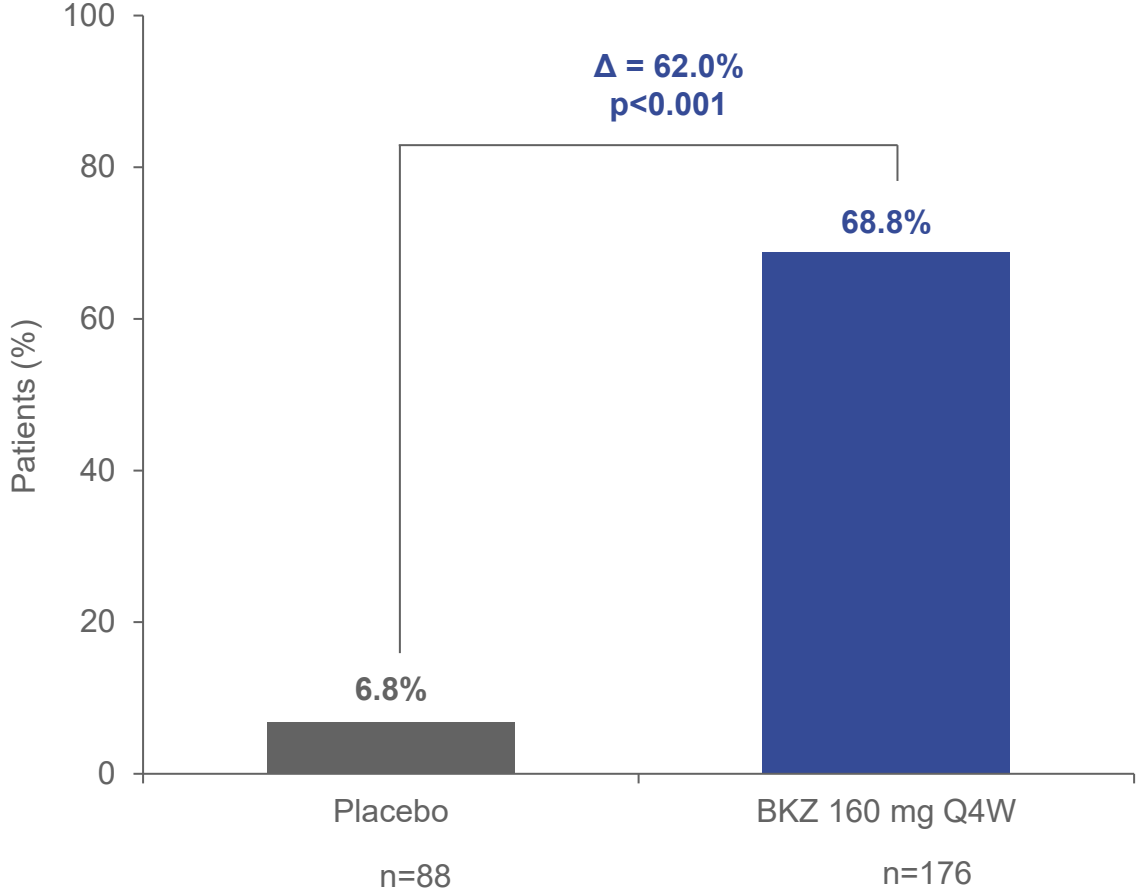
Efficacy: ACR50 and PASI90 Responses at Week 16 (NRI)

BKZ demonstrated superiority vs placebo in improvements in joint and skin outcomes at Week 16

Primary Endpoint: ACR50



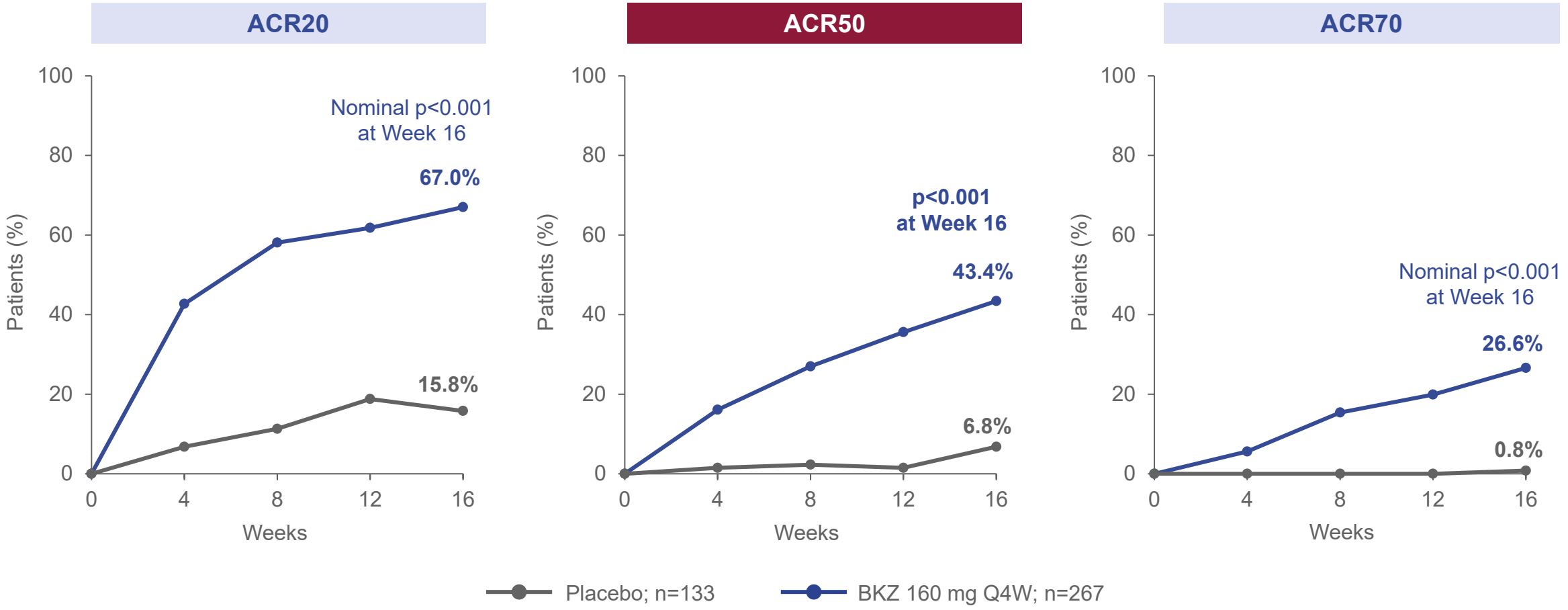
PASI90[a]



Randomised set. p values were obtained from logistic regression with treatment, prior TNF inhibitor exposure and region as factors. [a] In patients with PSO involving ≥3% BSA at baseline. ACR50: American College of Rheumatology criteria ≥50% response; BKZ: bimekizumab; BSA: body surface area; NRI: non-responder imputation; PASI90: ≥90% improvement in PASI; PSO: psoriasis; Q4W: every 4 weeks.

Efficacy: ACR Response Criteria to Week 16 (NRI)

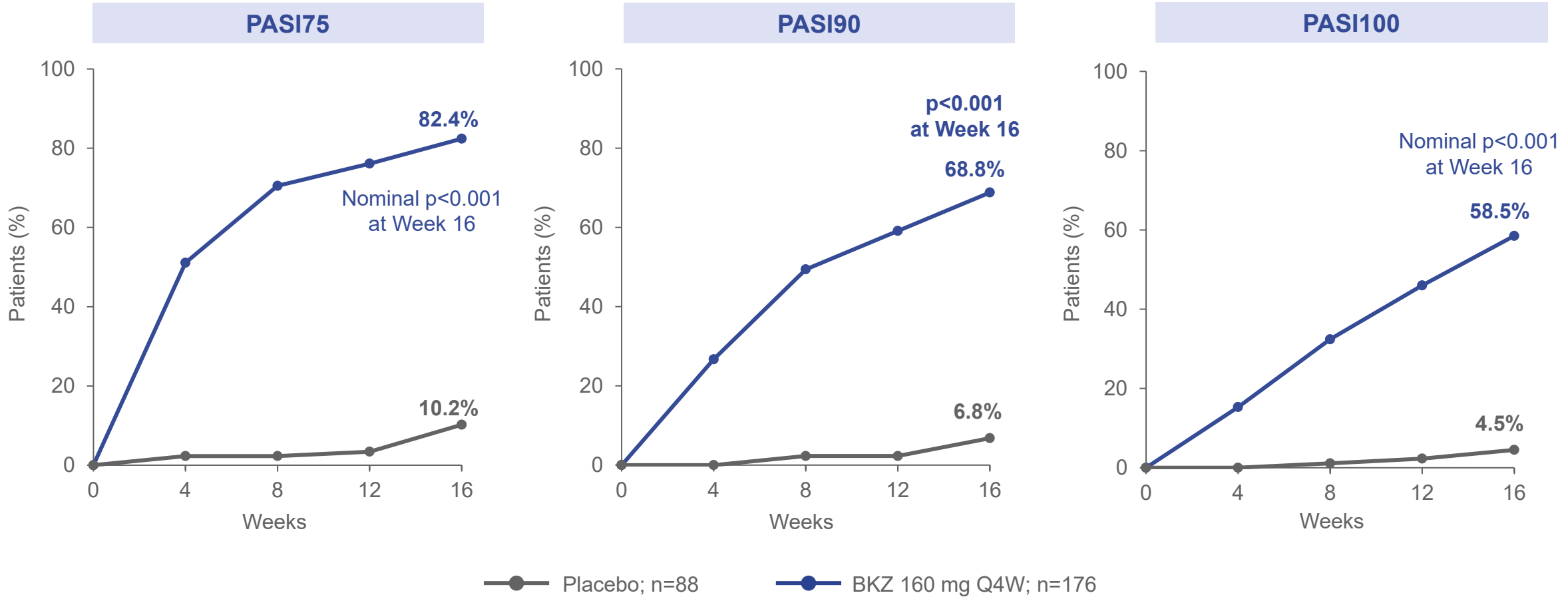
BKZ demonstrated improvements vs placebo in achievement of all ACR response criteria at Week 16



Randomised set. p values were obtained from logistic regression with treatment, prior TNF inhibitor exposure and region as factors. Nominal p values were not adjusted for multiplicity. ACR20/50/70: American College of Rheumatology criteria ≥20/50/70% response; BKZ: bimekizumab; NRI: non-responder imputation; Q4W: every 4 weeks; TNF: tumour necrosis factor.

Efficacy: Psoriasis Area and Severity Index to Week 16 (NRI)

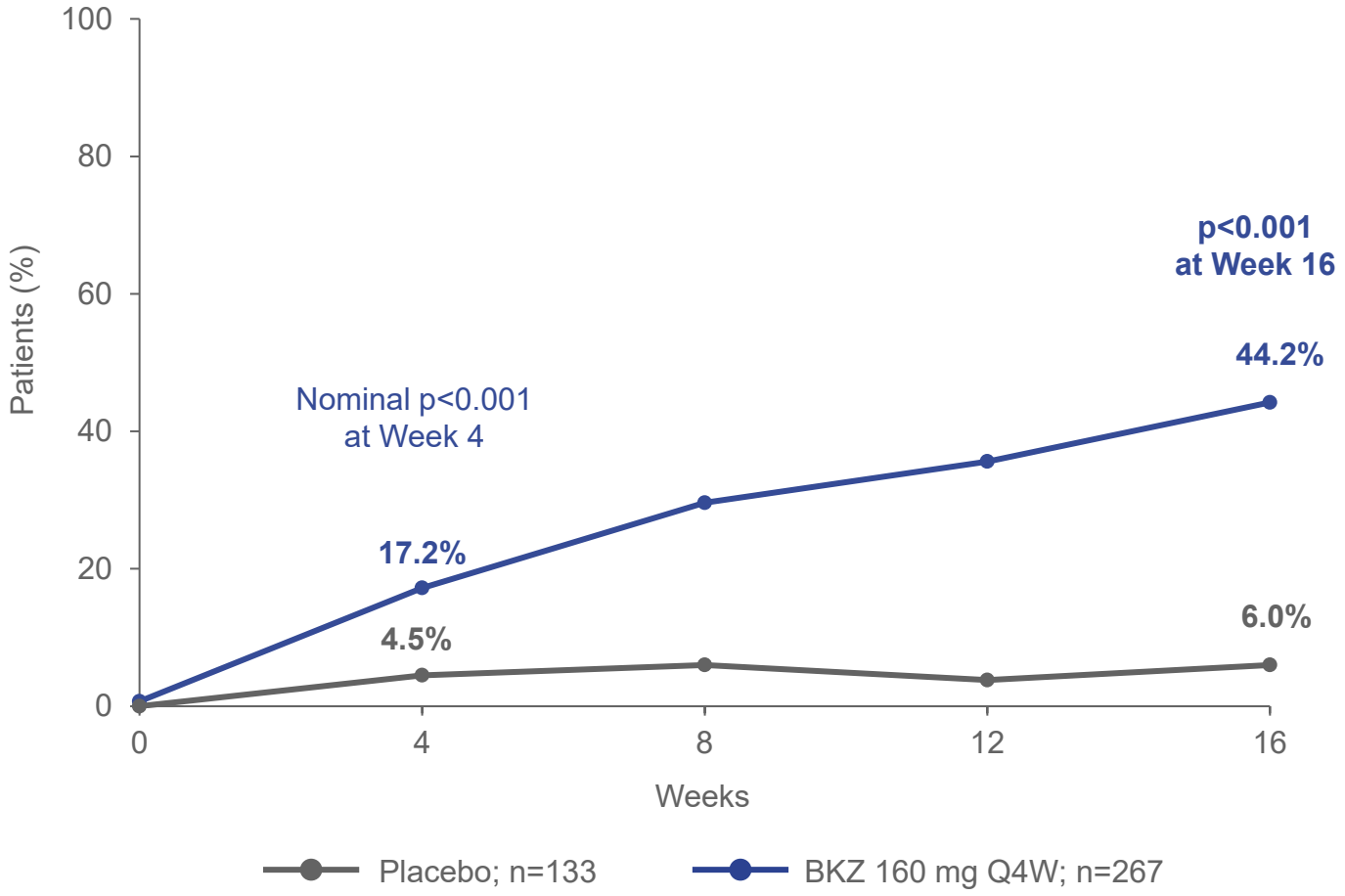
Over half of BKZ patients achieved complete skin clearance at Week 16



Randomised set, in patients with PSO involving ≥3% BSA at baseline. p values were obtained from logistic regression with treatment, prior TNF inhibitor exposure and region as factors. Nominal p values were not adjusted for multiplicity. BKZ: bimekizumab; BSA: body surface area; NRI: non-responder imputation; PASI: Psoriasis Area and Severity Index; PASI75/90/100: ≥75/90/100% improvement in PASI; PSO: psoriasis; Q4W: every 4 weeks; TNF: tumour necrosis factor.

Efficacy: Proportion of Patients Achieving MDA to Week 16 (NRI)

BKZ demonstrated superiority vs placebo in achievement of MDA response (composite index) at Week 16



MDA response defined as achievement of at least 5 of the 7 following criteria:

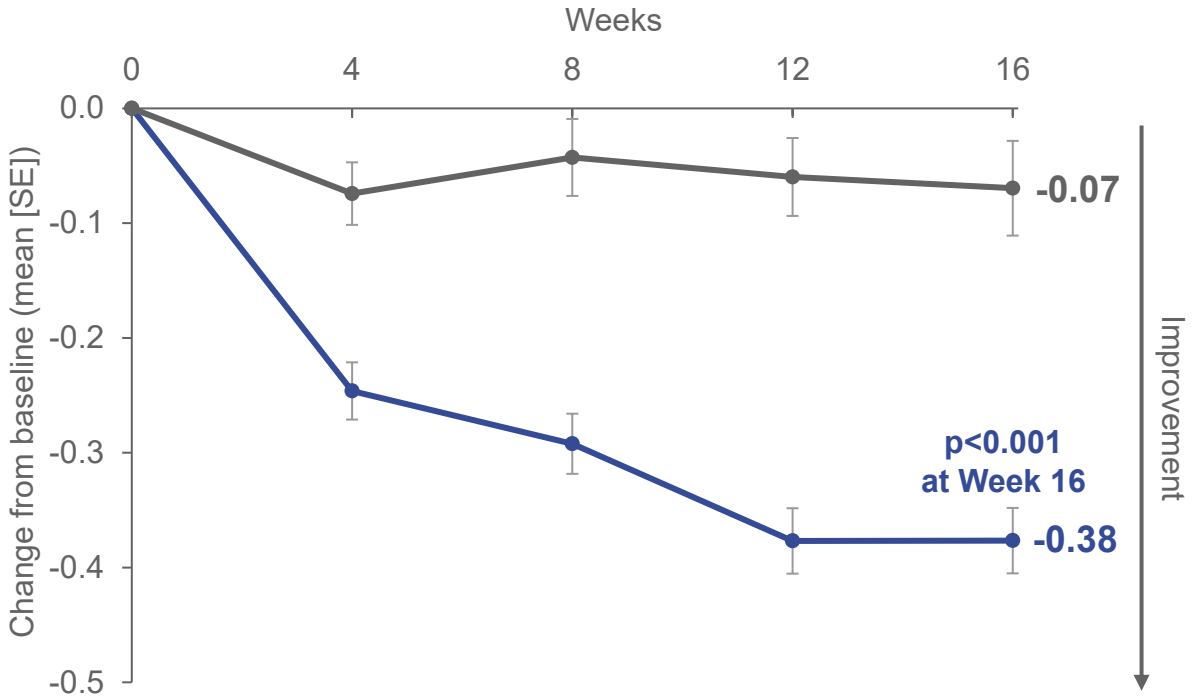
- Tender joint count ≤1
- Swollen joint count ≤1
- Psoriasis Area and Severity Index ≤1[a] or body surface area ≤3%[b]
- Patient's Assessment of Arthritis Pain ≤15 mm
- Patient's Global Assessment-PsA ≤20 mm
- Health Assessment Questionnaire-Disability Index ≤0.5
- Leeds Enthesitis Index ≤1

Randomised set. p value obtained from logistic regression with treatment, prior TNF inhibitor exposure and region as factors. Nominal p values were not adjusted for multiplicity. [a] For patients with PSO involving ≥3% of BSA at baseline. [b] Subjects with PSO involving <3% of BSA at baseline will always meet the criteria PASI ≤1 or BSA ≤3% except in the cases where a BSA score ≥3% is observed. BKZ: bimekizumab; BSA: body surface area; MDA: minimal disease activity; NRI: non-responder imputation; PASI: Psoriasis Area and Severity Index; PsA: psoriatic arthritis; PSO: psoriasis; Q4W: every 4 weeks.

Efficacy: Physical Functioning to Week 16 (MI)

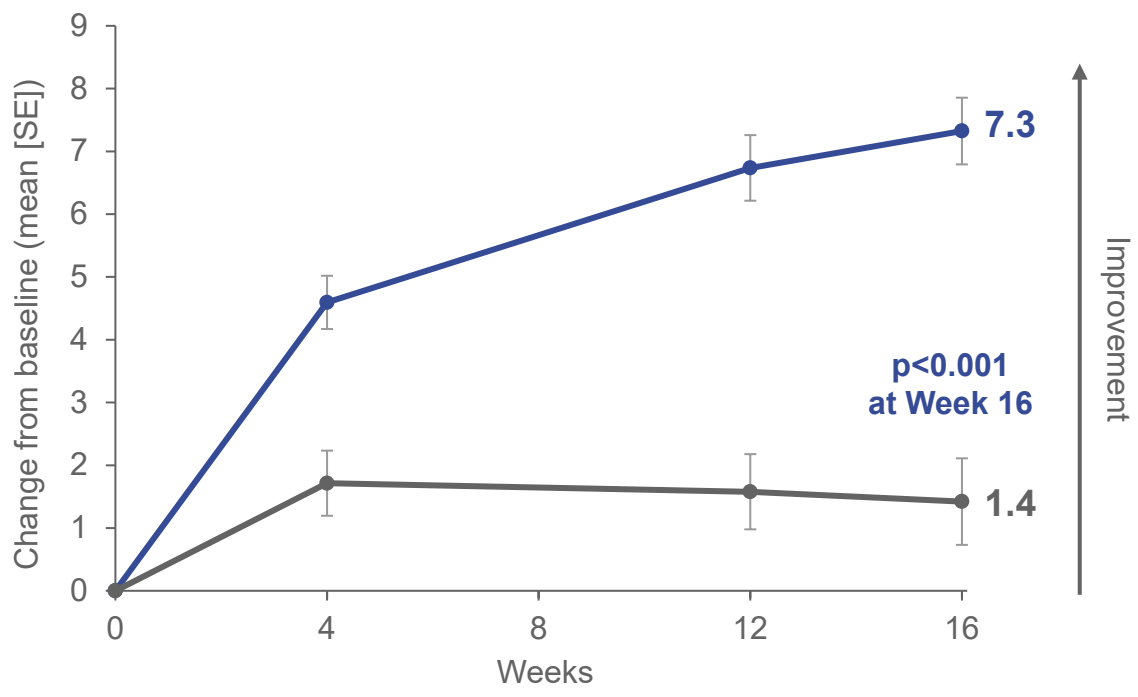
BKZ demonstrated superiority vs placebo in improvements in physical functioning at Week 16

HAQ-DI CfB



BL HAQ-DI, mean (SD)	1.0 (0.7)	1.0 (0.6)

SF-36 PCS CfB



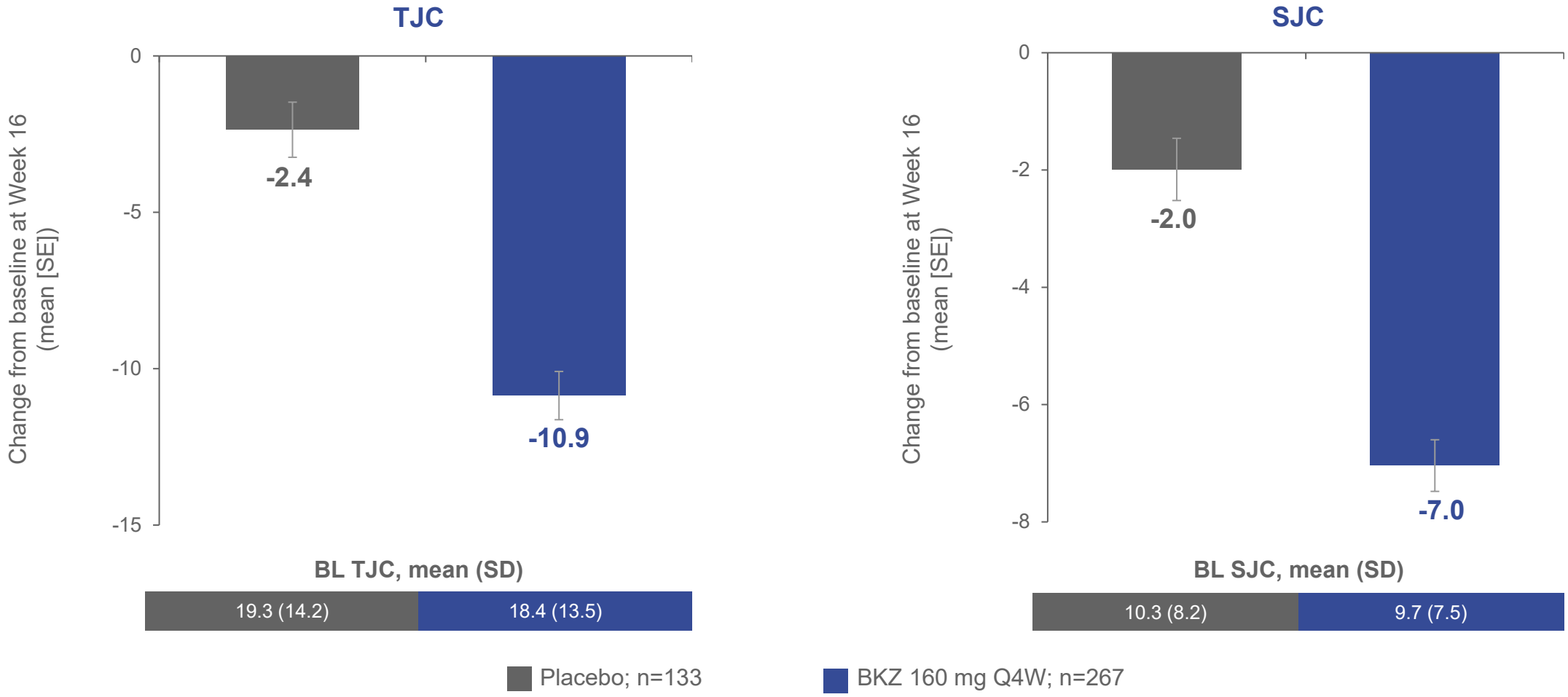
BL SF-36, mean (SD)	35.9 (10.2)	36.4 (9.0)

Placebo; n=133 BKZ 160 mg Q4W; n=267

Randomised set. p value obtained from logistic regression with treatment, prior TNF inhibitor exposure and region as factors. BKZ: bimekizumab; BL: baseline; CfB: change from baseline; HAQ-DI: Health Assessment Questionnaire-Disability Index; MI: multiple imputation; PCS: Physical Component Summary; Q4W: every 4 weeks; SF-36: Short-Form 36-item Health Survey.

Efficacy: TJC and SJC CfB at Week 16 (MI)

BKZ demonstrated numerically greater reduction of tender and swollen joints at Week 16



Randomised set. BKZ: bimekizumab; BL: baseline; CfB: change from baseline; MI: multiple imputation; Q4W: every 4 weeks; SD: standard deviation; SE: standard error; SJC: swollen joint count; TJC: tender joint count.

Safety: Overall

n (%)	Placebo n=132[a]	BKZ 160 mg Q4W n=267
Any TEAE	44 (33.3)	107 (40.1)
Serious TEAEs	0	5 (1.9)
Discontinuation due to TEAEs	0	2 (0.7)
Drug-related TEAEs	4 (3.0)	35 (13.1)
Severe TEAEs	0	5 (1.9)
Deaths	0	0
Most frequently reported TEAEs on the BKZ arm		
Nasopharyngitis	1 (0.8)	10 (3.7)
Oral candidiasis[b]	0	7 (2.6)
Upper respiratory tract infection	2 (1.5)	6 (2.2)
Fungal infections[c]	0	12 (4.5)
Systemic fungal infections	0	0
Neutropenia[d]	0	4 (1.5)
Hypersensitivity	1 (0.8)	7 (2.6)
Anaphylactic reactions	0	0
Dermatitis and eczema	0	4 (1.5)
Injection site reactions	0	3 (1.1)
Liver function test changes/enzyme elevations		
ALT >3x ULN	0	2 (0.7)
AST or ALT >3x ULN	0	4 (1.5)
Biochemistry Hy's Law[e]	0	0

Safety set. [a] One patient included in the randomised set was not counted in the safety set. [b] 6 out of 7 cases classified by investigator as mild in intensity, 1 out of 7 cases classified as moderate in intensity; one case resulted in discontinuation. [c] All fungal infections were mild to moderate; there were no cases of systemic/disseminated *Candida* infection. [d] Neutropenia were generally transient and not associated with serious infections; 3 patients had neutropenia and 1 had decreased neutrophil count. [e] Patient must experience the elevation in bilirubin and ALT or AST (and the absence of ALP elevation, if applicable) at the same visit. ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BKZ: bimekizumab; MACE: major adverse cardiovascular event; n: number of patients reporting at least one TEAE in that category; Q4W: every 4 weeks; SIB: suicidal ideation behaviour; TEAE: treatment emergent adverse event; ULN: upper limit of normal.

BE COMPLETE Conclusions

The BE COMPLETE phase 3 study, evaluating dual inhibition of IL-17A and IL-17F with bimekizumab in patients with PsA with inadequate response or intolerance to TNFi, met all its primary and secondary endpoints.

- Bimekizumab-treated patients with PsA and inadequate response or intolerance to TNFi showed improvements in joint, skin and HRQoL-related outcomes up to Week 16, compared with placebo.

- Furthermore, bimekizumab treatment resulted in improvements in the composite outcome of minimal disease activity, reflecting the efficacy of dual inhibition across PsA disease manifestations.

- Bimekizumab treatment led to rapid improvements in signs and symptoms of PsA, with separation from placebo observed by Week 4.

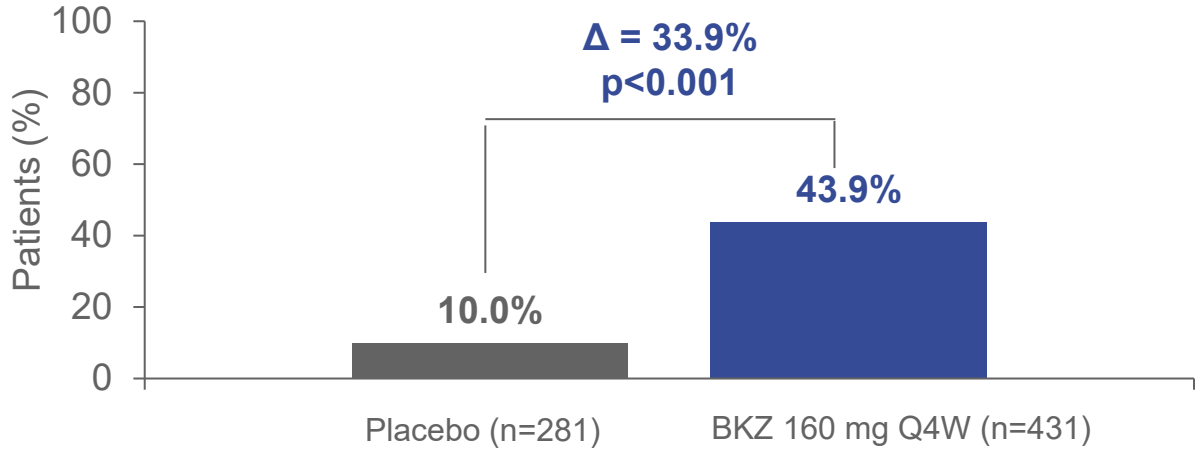
- Bimekizumab was well tolerated; the safety profile was consistent with prior studies with no unexpected safety findings.[1,2]

1. Ritchlin CT Lancet 2020;395(10222):427–40; 2. Coates LC Ann Rheum Dis 2021;80:779–80(POS1022). HRQoL: health-related quality of life; IL: interleukin; PsA: psoriatic arthritis; TNFi: tumour necrosis factor inhibitor.

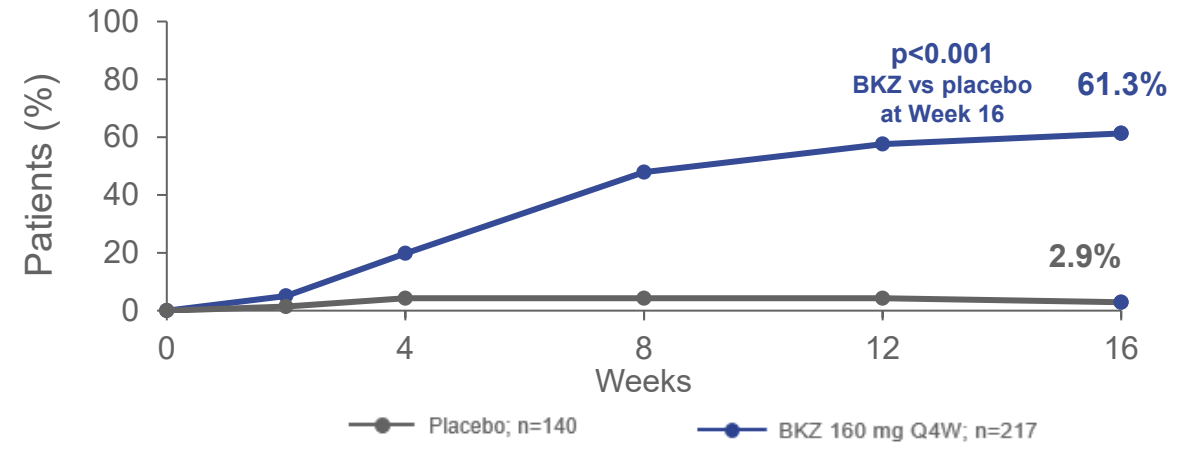
Consistency of BKZ Across Psoriatic Arthritis Patient Populations

BE OPTIMAL (bDMARD-naïve patients)

ACR50 at Week 16 (NRI)

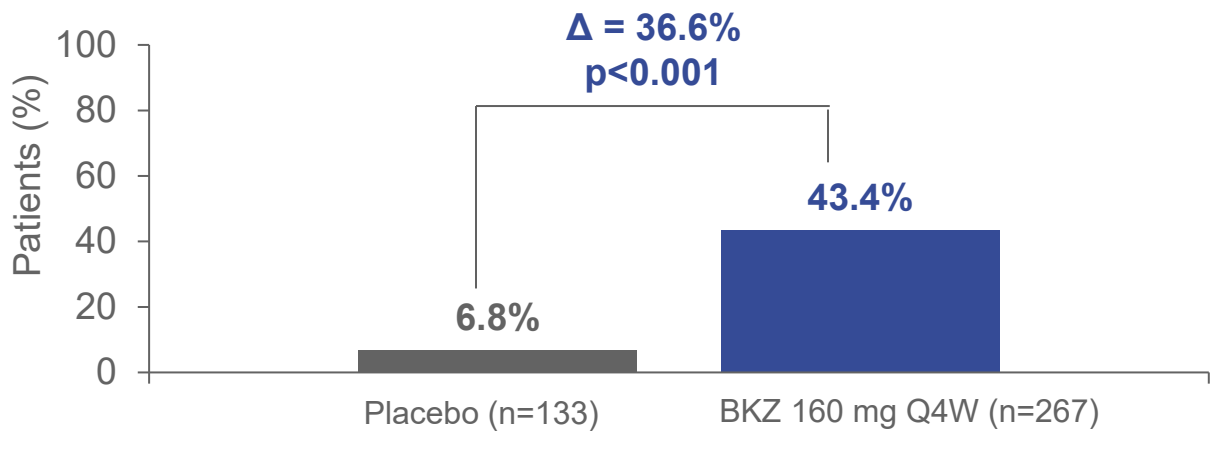


PASI90 at Week 16

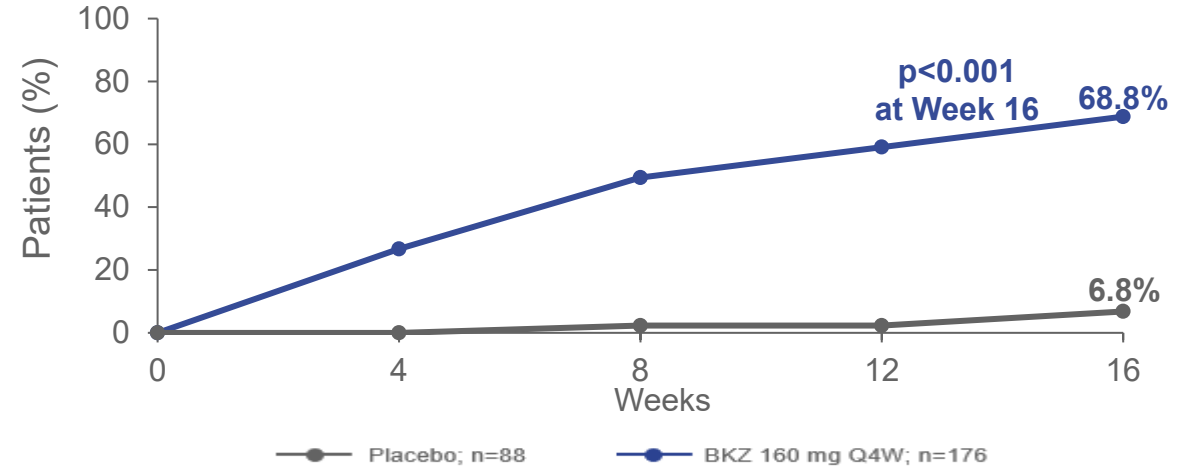


BE COMPLETE (TNF-IR patients)

ACR50 at Week 16 (NRI)



PASI90 at Week 16



Randomised set. p value for BE OPTIMAL was obtained from logistic regression with treatment, bone erosion at baseline and region as factors. p value for BE COMPLETE was obtained from logistic regression with treatment, prior TNF inhibitor exposure and region as factors. ACR50: American College of Rheumatology criteria ≥50% response; bDMARD: biologic disease-modifying antirheumatic drug; BKZ: bimekizumab; BSA: body surface area; NRI: non-responder imputation; PSO: psoriasis; Q4W: every 4 weeks; Randomised set, in patients with PSO involving ≥3% BSA at baseline. p values were obtained from logistic regression with treatment, prior TNF inhibitor exposure and region as factors; TNF-IR: Tumour necrosis factor inhibitor – inadequate response.; PASI: Psoriasis Area and Severity Index; PASI90: 90 improvement in PASI

Q&A

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Thank you

Inspired by **patients.**
Driven by **science.**

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