UCB VIRTUAL BRIEFING:

52-week data from bimekizumab Phase 3 Studies in Psoriatic Arthritis (PsA) and Axial Spondyloarthritis (axSpA)

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.
Bimekizumab is not approved for any indication by the U.S. Food and Drug Administration

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

GL-N-BK-axSpA-2200111
Date of preparation: November 2022

Intended Audience

- This presentation is intended for analysts, investors and U.S. medical/trade journalists invited by UCB to this closed educational event.

- The efficacy and safety of investigational bimekizumab **in the treatment of psoriatic arthritis (PsA), non-radiographic axial spondyloarthritis (nr-axSpA) and ankylosing spondylitis (AS)** have not been established and it is not approved for the treatment of PsA, nr-axSpA and AS by any regulatory authority worldwide.

- 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.

- Bimekizumab is **not approved for any indication by the U.S. Food and Drug Administration.**

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Introduction

Emmanuel Caeymaex

Executive Vice President, Immunology Solutions
and Head of US, UCB

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Head of Medical Affairs, Rheumatology, UCB

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Director, Rheumatology Research, Swedish Medical Center/Providence St. Joseph Health
Clinical Professor, University of Washington School of Medicine
Seattle, WA, USA

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In IL-17 mediated diseases, bimekizumab has delivered 8 consecutive positive Phase 3 studies to-date

Psoriasis

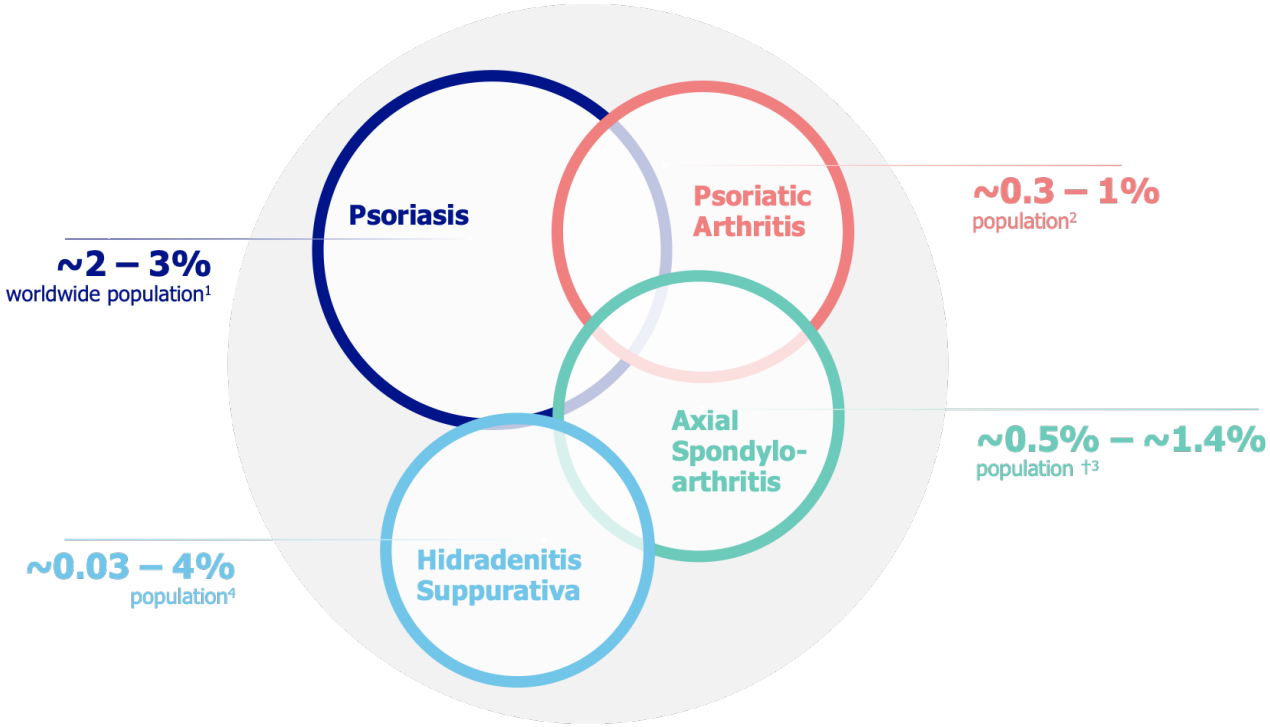
- **BE VIVID** (PS0009) NCT03370133 (vs ustekinumab*)
- **BE READY** (PS0013) NCT03410992 (vs placebo)
- **BE SURE** (PS0008) NCT03412747 (vs adalimumab)
- **BE RADIANT** (PS0015) NCT03536884 (vs secukinumab)

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: November 2022; 2. Gladman D D et al. Ann Rheum Dis. 2005. 64 (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.

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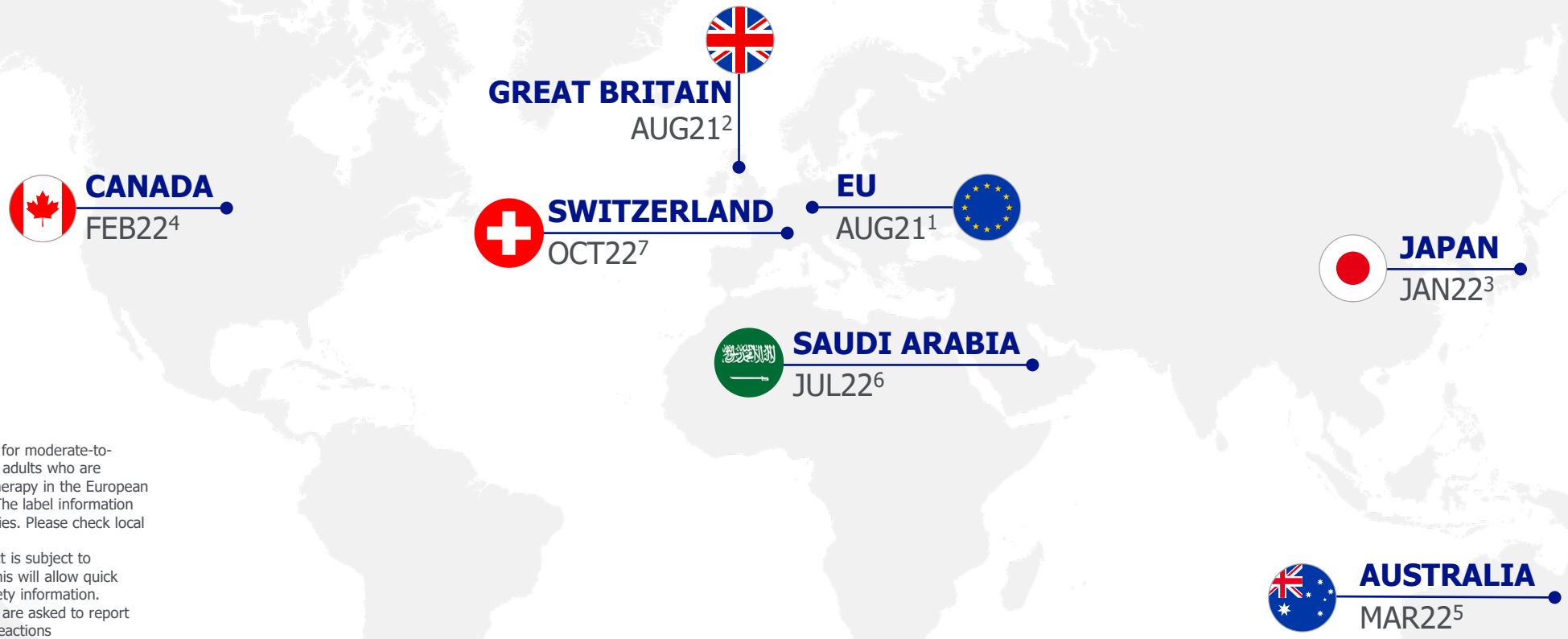
Bimekizumab, marketed under the tradename BIMZELX®▼, is now approved for psoriasis by seven regulatory authorities worldwide



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. EU: https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf Last accessed: NOV22; 2. GB: https://www.medicines.org.uk/emc/product/12834/smpc https://www.medicines.org.uk/emc/product/12833/smpc Last accessed: NOV22; 3. JP: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html Last accessed: NOV22. 4. CA: https://pdf.hres.ca/dpd_pm/00064702.PDF Last accessed: NOV22; 5. AUS: https://www.tga.gov.au/resources/auspmd/bimzelx Last accessed NOV22; 6. KSA: Saudi Food & Drug Authority. https://www.sfda.gov.sa/en last accessed: NOV2022; 7. CH: Swissmedic Available at https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/authorisations/new-medicines/bimzelx-injlsg-fertigspritzebimekizumabum.html Last accessed: NOV2022.

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Overview: Bimekizumab Phase 3 studies in axSpA and PsA

Dr. John Ioannou BMedSci, MB BS, PhD, FRCP

Head of Medical Affairs, Rheumatology, UCB

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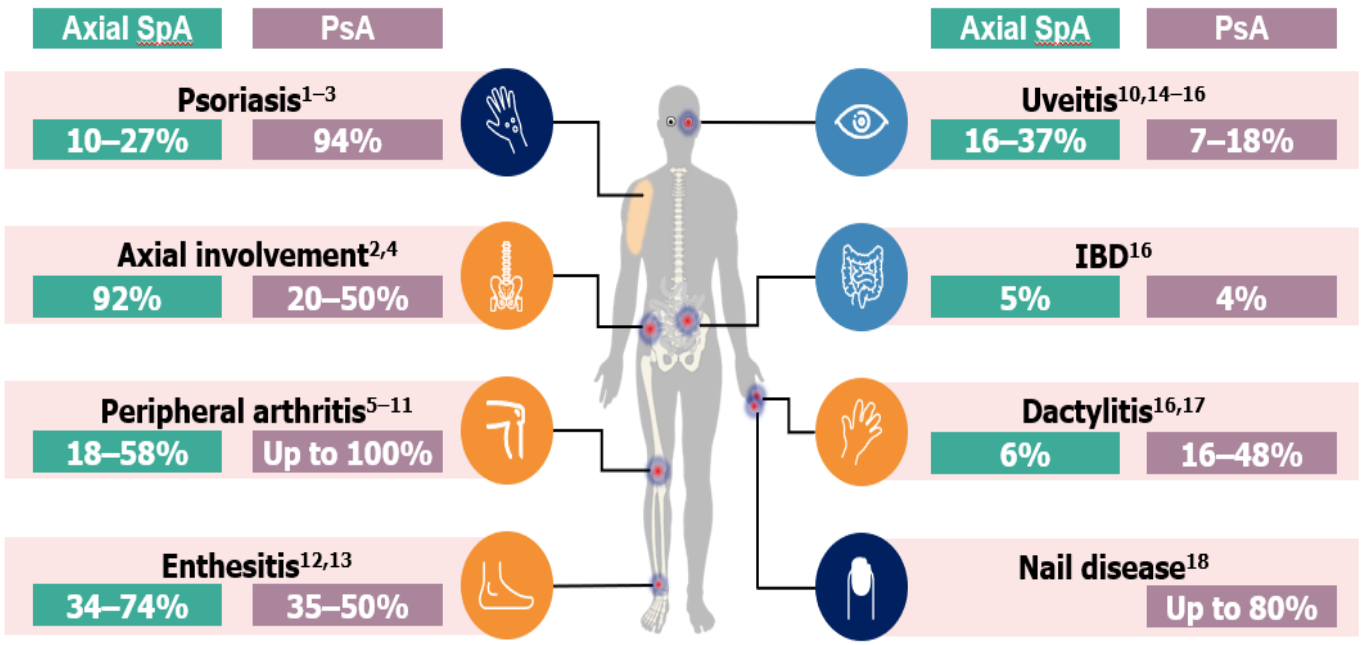
PsA and axSpA have many overlapping clinical features



Treatment goals and reality

Guidelines recommend treatment should be aimed at reaching the **target of remission,** or **low disease activity**[19,20,21]*

Approximately one third of patients achieve these goals within the first six months of taking a biologic*[22,23]

*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 1. Kane D, et al. Rheumatology. 2003;42:1460–8; 2. Lucasson F, et al. RMD Open. 2022;8:e001986; 3. Navarro-Compán V, et al. Ann Rheum Dis 2021;80:1511–21; 4. McGagh D & Coates LC. Rheumatology. 2020;59:i29–36; 5. Moll JM and Wright V. Semin Arthritis Rheum. 1973;3:55–78; 6. Torre-Alonso JC, et al. Br J Rheumatol. 1991;30:245–50; 7. Helliwell PS and Taylor W. Ann Rheum Dis. 2005;64(Suppl 2):ii3–8; 8. Gladman DD. Ann Rheum Dis. 2006;65(Suppl 3):iii22–4; 9. Acosta-Felquer ML and FitzGerald O. Clin Exp Rheumatol. 2015;33(Suppl 93):S26–30; 10. de Winter JJ, et al. Arthritis Res Ther. 2016;18:196; 11. López-Medina C, et al. Arthritis Res Ther. 2019;21:139; 12. Kaeley GS, et al. Semin Arthritis Rheum. 2018;48:35–43; 13. D'Agostino MA, et al. Arthritis Rheum. 2003;48(2):523–33; 14. Chen H and Chou C. Curr Rheumatol Rev 2008;4:111–14; 15. Roche D, et al. Arthritis Res Ther. 2021;23:192; 16. López-Medina C, RMD Open. 2021;7:e001450; 17. Helliwell PS, et al. J Rheumatol. 2005;32:1745–50; 18. Sobolewski P, et al. Reumatologia. 2017;55:131–5. 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. Ramiro S, et al. Ann Rheum Dis 2022;0:1–16 22. Zardin-Moraes M, et al. J Rheumatol. 2020;47(6):839–46; 23. Ørnbjerg LM, et al. Ann Rheum Dis. 2019;78:1536–44.

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The Phase 3 clinical development program in PsA and axSpA has high threshold endpoints aimed at elevating standards of care

Phase 3 studies	**BE** OPTIMAL[1] Phase 3 double-blind study in patients with active **PsA who were biologic naive**	**BE** COMPLETE[2] 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 52** analysis	

Phase 3 studies	**BE** MOBILE 1[3] Phase 3 double-blind study in patients with active **non-radiographic axSpA (nr-axSpA)**	**BE** MOBILE 2[4] 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 52** analysis	**Week 52** analysis

References:
1. 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. Ann. Rheum Dis 2022; 81 (suppl 1); 206-207; 2. 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. Ann. Rheum Dis 2022; 81 (suppl 1); 167-169; 3. 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. Ann. Rheum Dis 2022; 81 (suppl 1); 772; 4. 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. Ann. Rheum Dis 2022; 81 (suppl 1); 12-13

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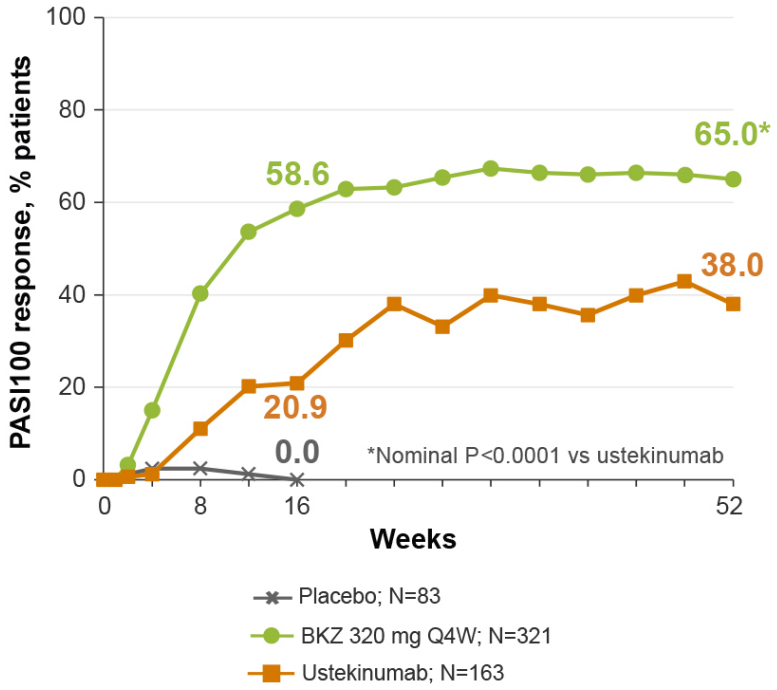
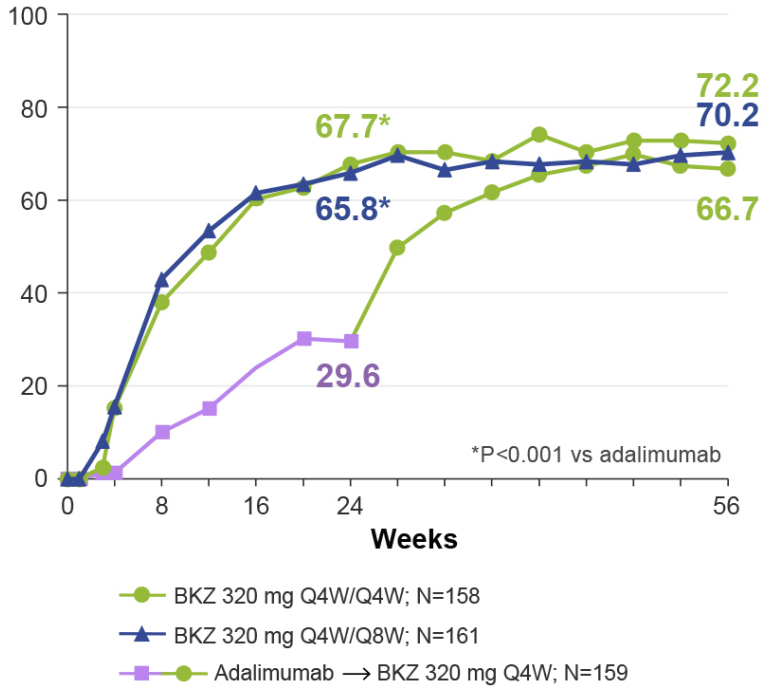
In Phase 3 psoriasis studies, bimekizumab consistently demonstrated high levels of complete skin clearance across studies

PASI100 during Year 1 with bimekizumab vs active comparators (NRI)

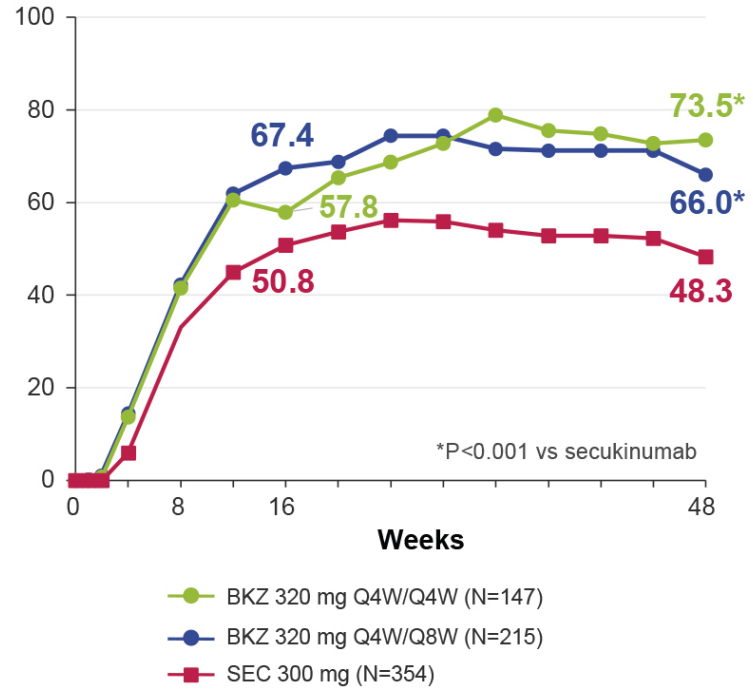
BE VIVID[1]



BE SURE[2,3]



BE RADIANT[†4,5]



In BE SURE, PASI100 at Week 24 was a ranked secondary endpoint. In BE RADIANT, PASI100 at Week 48, was a ranked secondary endpoint. In BE SURE, patients in the BKZ Q4W/Q8W arm switched at Week 16 from Q4W to BKZ Q8W, and patients in the Adalimumab → BKZ Q4W arm switched at Week 24 from adalimumab to BKZ Q4W. †These data are taken from the maintenance set. All figures adapted from the cited reference(s).

1. Reich et al. Lancet 2021;397:487–98; 2. Warren et al. N Engl J Med 2021;385:130–41; 3. Warren et al. Presented at EADV 2020; 4. Reich et al. N Engl J Med 2021;385:142–52; 5. PS0015. Table 6.3.1.9.

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Psoriatic Arthritis: 52-week data from BE OPTIMAL

Axial Spondyloarthritis: 52-week data from BE MOBILE 1 and BE MOBILE 2

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L02

Bimekizumab Treatment in Biologic DMARD-Naïve Patients with Active Psoriatic Arthritis: 52-Week Efficacy and Safety Results from a Phase 3, Randomized, Placebo-Controlled, Active Reference Study

Christopher T. Ritchlin, Laura C. Coates, Iain B. McInnes, Philip J. Mease, Joseph F. Merola, Yoshiya Tanaka, Akihiko Asahina, Laure Gossec, Alice B. Gottlieb, Diamant Thaçi, Barbara Ink, Deepak Assudani, Rajan Bajracharya, Vish Shende, Jason Coarse, Robert Landewé

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Disclosures & Acknowledgements

Disclosures

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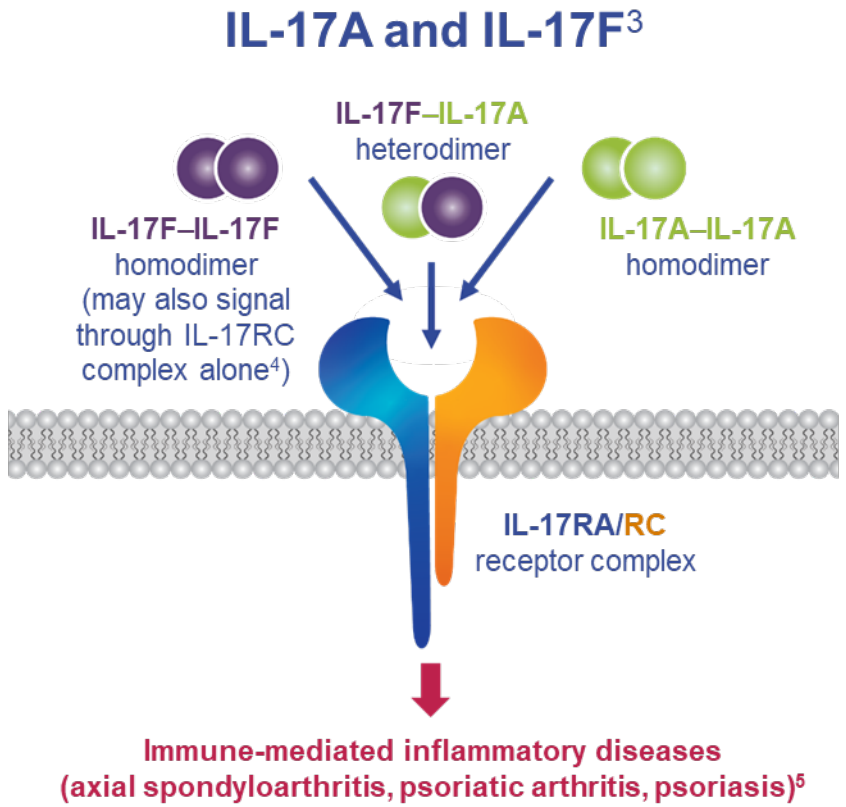
Background and objective

Bimekizumab is a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.

Results (up to week 24) from the pivotal phase 3 study, BE OPTIMAL, and results (up to 152 weeks) from the phase 2b study in patients with active psoriatic arthritis (PsA) have been previously presented.[1,2]

OBJECTIVE
To assess the long-term efficacy and safety of subcutaneous bimekizumab in biologic disease-modifying antirheumatic drug (bDMARD)-naïve patients with active PsA up to Week 52 in the pivotal phase 3 study, BE OPTIMAL (NCT03895203)



1. McInnes IB. Ann Rheum Dis 2022;81:206–7; 2. Coates LC. Arthritis & Rheum 2022;10.1002/art.42280; 3. Yang XO. J Exp Med 2008;1063–75; 4. Goepfert A. Immunity 2020;52(3):499–512.e5; 5. Glatt S. Ann Rheum Dis 2018;77:523–32.
bDMARD: biologic disease-modifying antirheumatic drug; Ig: immunoglobulin; IL: interleukin; PsA: psoriatic arthritis; RA: receptor A; RC: receptor C.

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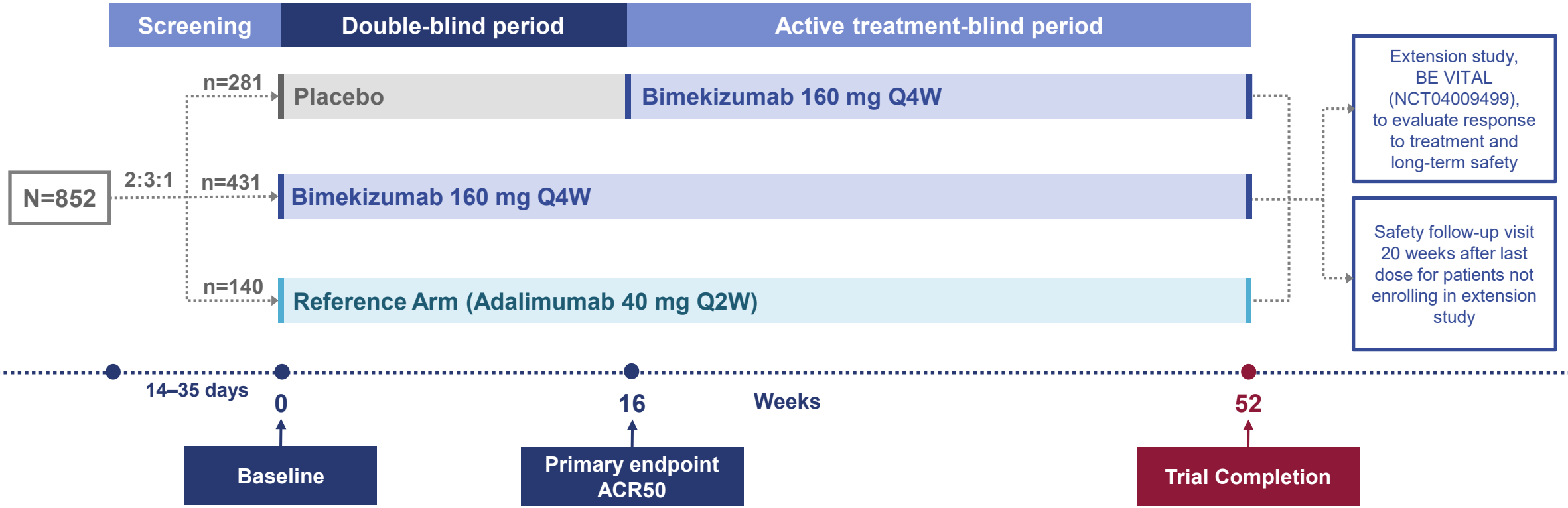
BE OPTIMAL Study Design



Key inclusion criteria

- ≥18 years of age with adult-onset PsA fulfilling CASPAR criteria with a duration of ≥6 months
- TJC ≥3/68 and SJC ≥3/66
- ≥1 active psoriatic lesions and/or a documented history of PSO

Key exclusion criteria

- Current or prior exposure to any biologics for treatment of PsA or PSO
- Active, symptomatic IBD at baseline or screening (prior history was not an exclusion criterion)

BKZ-treated patients were eligible to receive rescue therapy from Week 16 at the discretion of the investigator, while continuing to receive BKZ. ACR: American College of Rheumatology response criteria; BKZ: bimekizumab; CASPAR: Classification Criteria for Psoriatic Arthritis; IBD: inflammatory bowel disease; PsA: psoriatic arthritis; PSO: psoriasis; Q2W: every 2 weeks; Q4W: every 4 weeks; SJC: swollen joint count; TJC: tender joint count.

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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 (%)	163 (58.0)	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)	0.89 (0.61)	0.82 (0.59)	0.86 (0.54)
SF-36 PCS,[d] mean (SD)	36.9 (9.7)	38.1 (9.4)	37.6 (8.8)
vdHmTSS (at risk subgroup),[e,f] mean (SD)	14.5 (23.9)	14.4 (32.0)	16.5 (28.4)
vdHmTSS (overall),[e,g] mean (SD)	12.3 (22.5)	12.5 (30.0)	13.8 (26.5)
Enthesitis,[h] 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,[i] 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)

Randomized set. [a] Listed as time since diagnosis of PsA, data missing for 2 placebo patients, 8 BKZ patients, 1 ADA patient; [b] In patients with psoriasis involving ≥3% BSA at baseline; [c] Data missing for 1 BKZ patient; [d] Data missing for 1 BKZ patient and 1 ADA patient; [e] Radiographic set; [f] At-risk subgroup defined as patients with elevated hs-CRP (≥6 mg/L) and/or ≥1 bone erosion at baseline, placebo n=227, BKZ n=361, ADA n=112; [g] Placebo n=269, BKZ n=420, ADA n=135; [h] Leeds Enthesitis Index >0; data missing for 6 BKZ patients, 1 ADA patient; [i] Leeds Dactylitis Index >0; data missing for 1 placebo patient, 7 BKZ patients, 1 ADA patient. 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.

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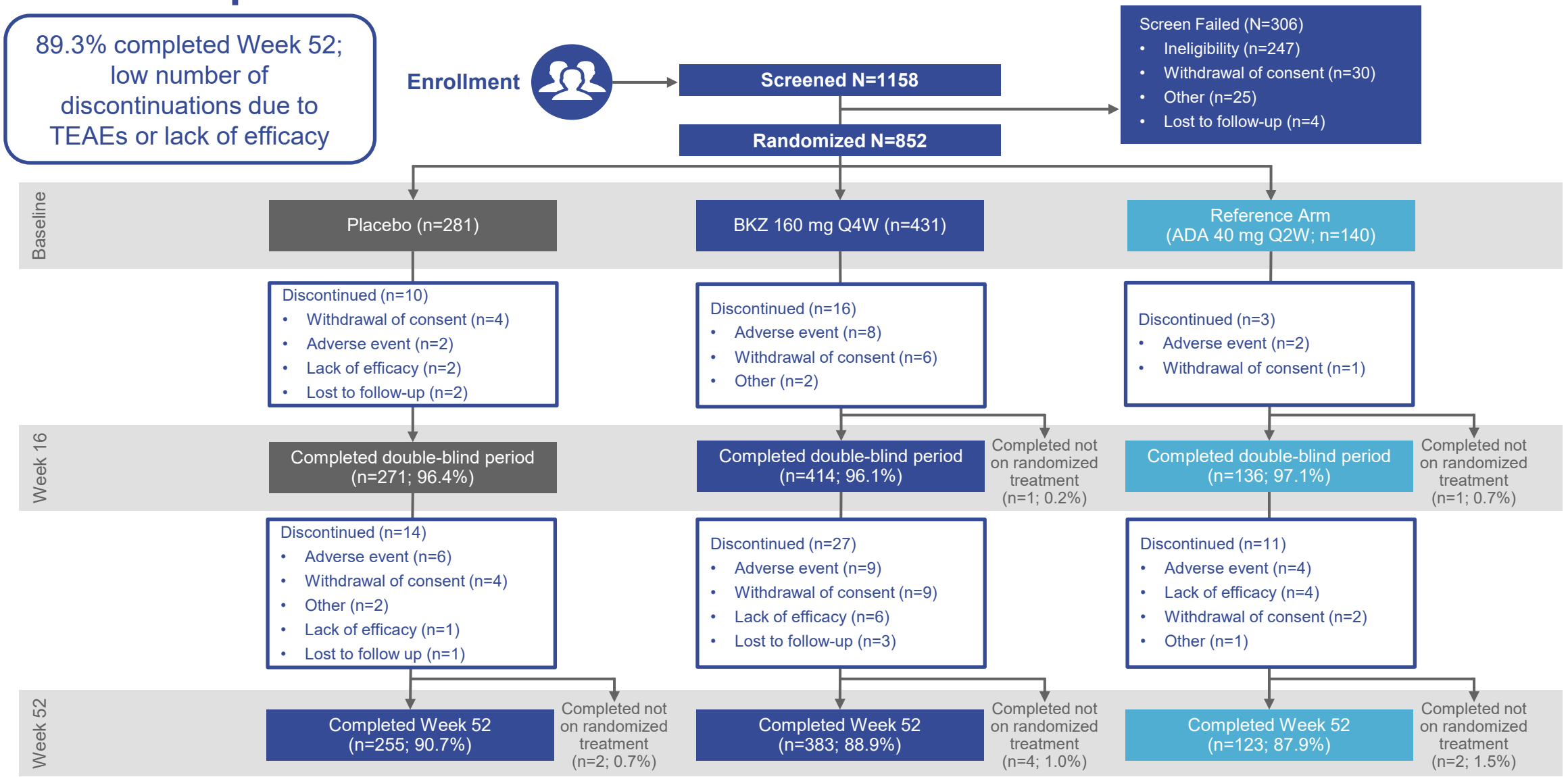
Patient Disposition to Week 52

89.3% completed Week 52; low number of discontinuations due to TEAEs or lack of efficacy



Patients who withdrew from the study medication but returned for all scheduled visits up to Week 16 or 52 were considered as having completed the treatment period not on randomized treatment.

ADA: adalimumab; BKZ: bimekizumab; Q2W: every 2 weeks; Q4W: every 4 weeks; TEAE: treatment-emergent adverse event.

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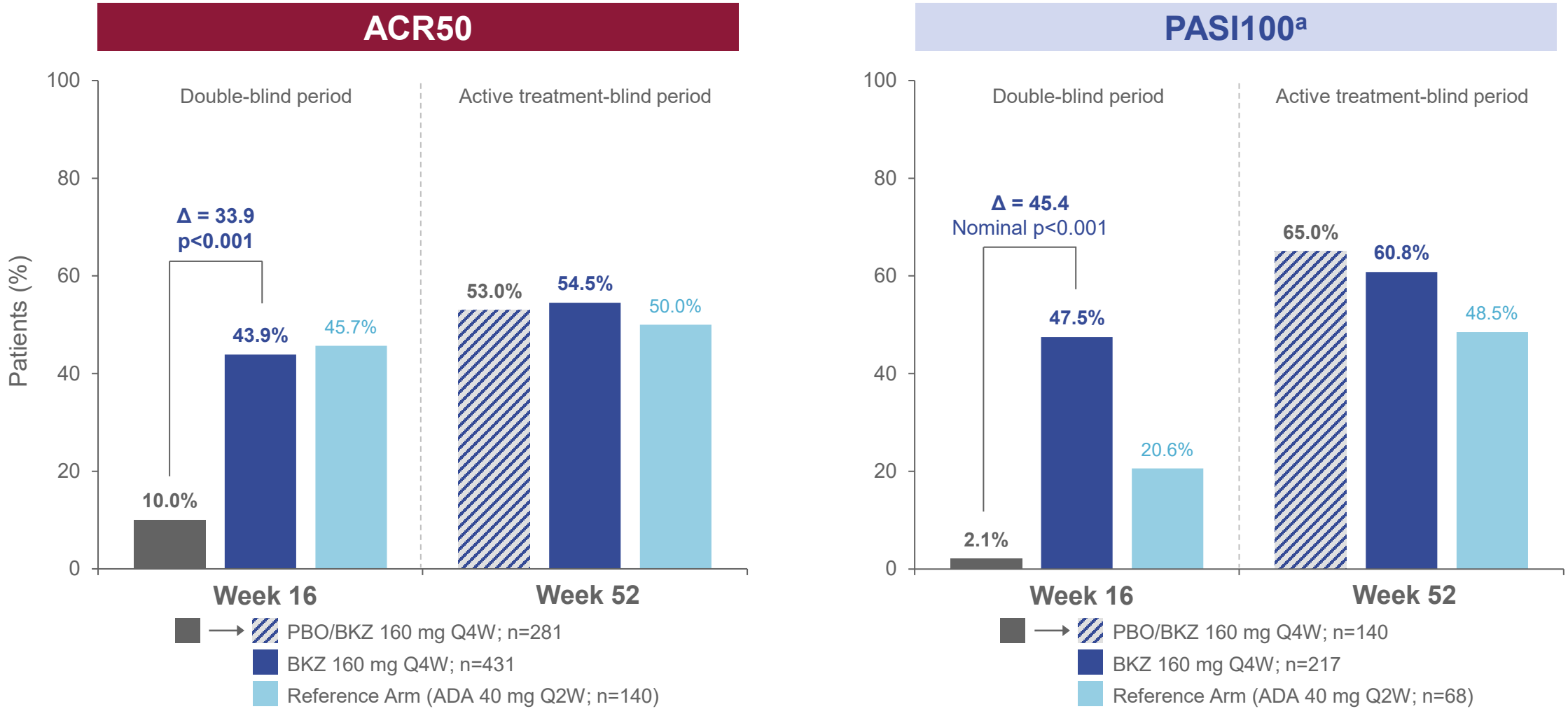
Joint and Skin Responses were Sustained to Week 52 (NRI)



Randomized set. p value was calculated using a logistic regression model with treatment, bone erosion at baseline, and region as stratification factors. Nominal p values are not powered or adjusted for multiplicity and should not be used to assess statistical significance. The study was not powered for statistical comparisons of ADA to BKZ or PBO. [a] In patients with PSO involving ≥3% BSA at baseline. ACR50: American College of Rheumatology criteria ≥50% response; ADA: adalimumab; BKZ: bimekizumab; BSA: body surface area; NRI: non-responder imputation; PASI100: 100% improvement in Psoriasis Area and Severity Index; PBO: placebo; PsA: psoriatic arthritis; PSO: psoriasis; Q2W: every 2 weeks; Q4W: every 4 weeks.

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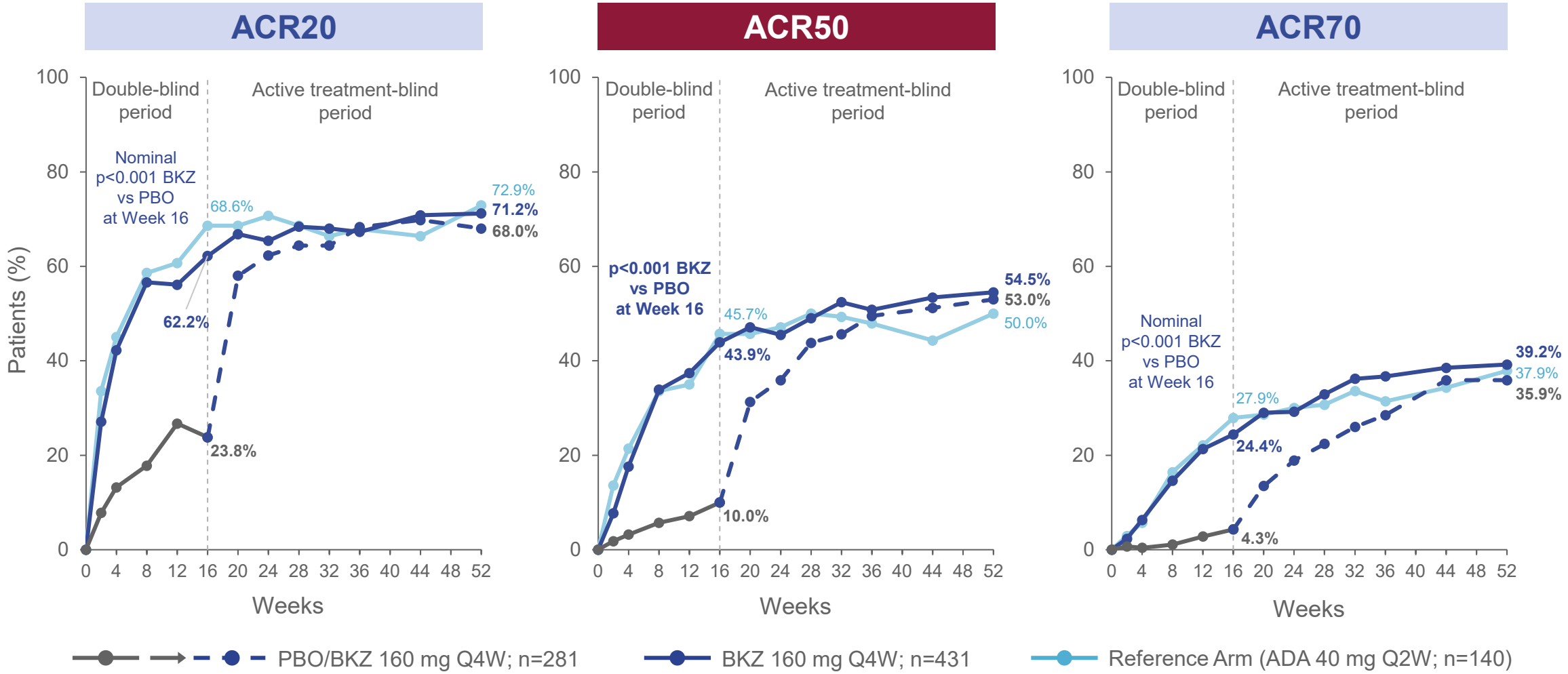
Joint Responses were Sustained to Week 52 (NRI)



Randomized set. p value was calculated using a logistic regression model with treatment, bone erosion at baseline, and region as stratification factors. Nominal p values are not powered or adjusted for multiplicity and should not be used to assess statistical significance. The study was not powered for statistical comparisons of ADA to BKZ or PBO. ACR20/50/70: American College of Rheumatology criteria ≥20/50/70% response; ADA: adalimumab; BKZ: bimekizumab; NRI: non-responder imputation; PBO: placebo; PsA: psoriatic arthritis; Q2W: every 2 weeks; Q4W: every 4 weeks.

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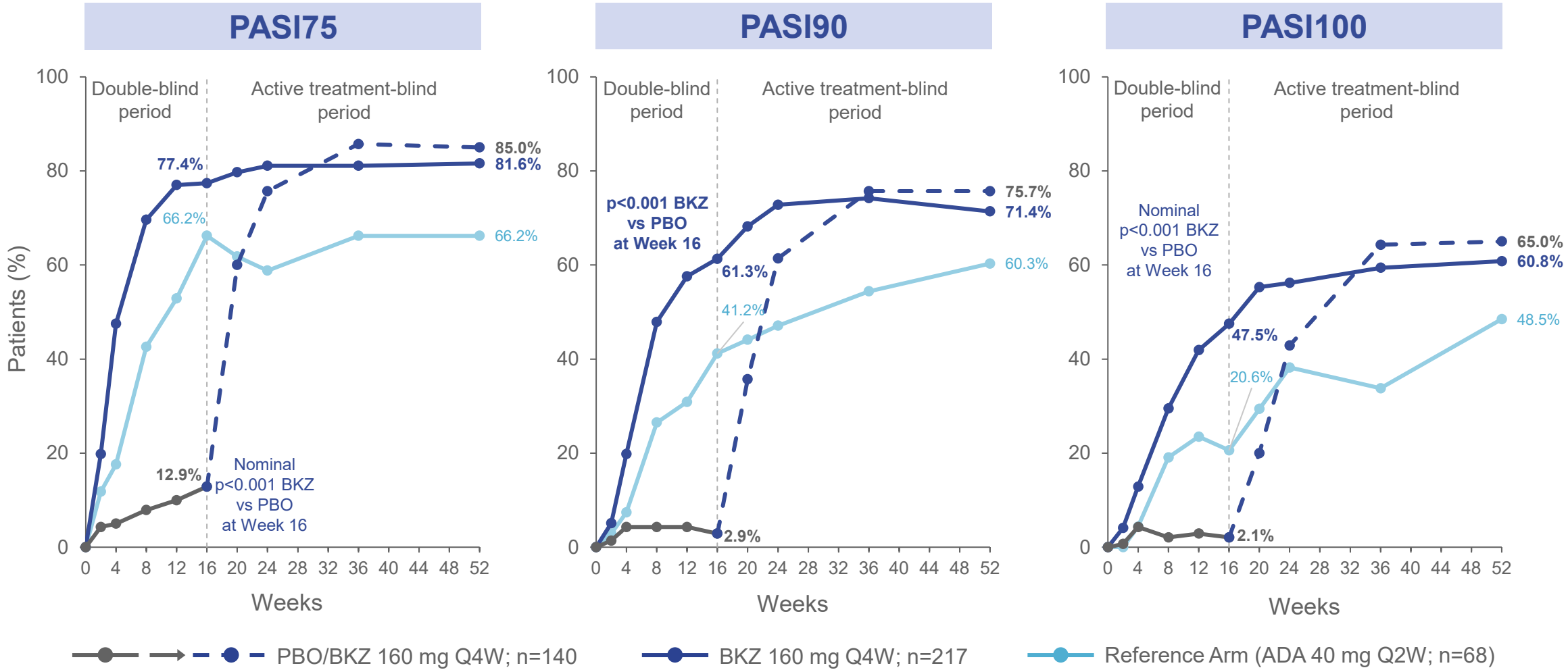
Skin Responses were Sustained to Week 52 (NRI)



Randomized set, in patients with PSO involving ≥3% BSA at baseline. p value was calculated using a logistic regression model with treatment, bone erosion at baseline, and region as stratification factors. Nominal p values are not powered or adjusted for multiplicity and should not be used to assess statistical significance. The study was not powered for statistical comparisons of ADA to BKZ or PBO. ADA: adalimumab; BKZ: bimekizumab; BSA: body surface area; NRI: non-responder imputation; PASI75/90/100: ≥75/90/100% improvement in Psoriasis Area and Severity Index; PBO: placebo; PsA: psoriatic arthritis; PSO: psoriasis; Q2W: every 2 weeks; Q4W: every 4 weeks.

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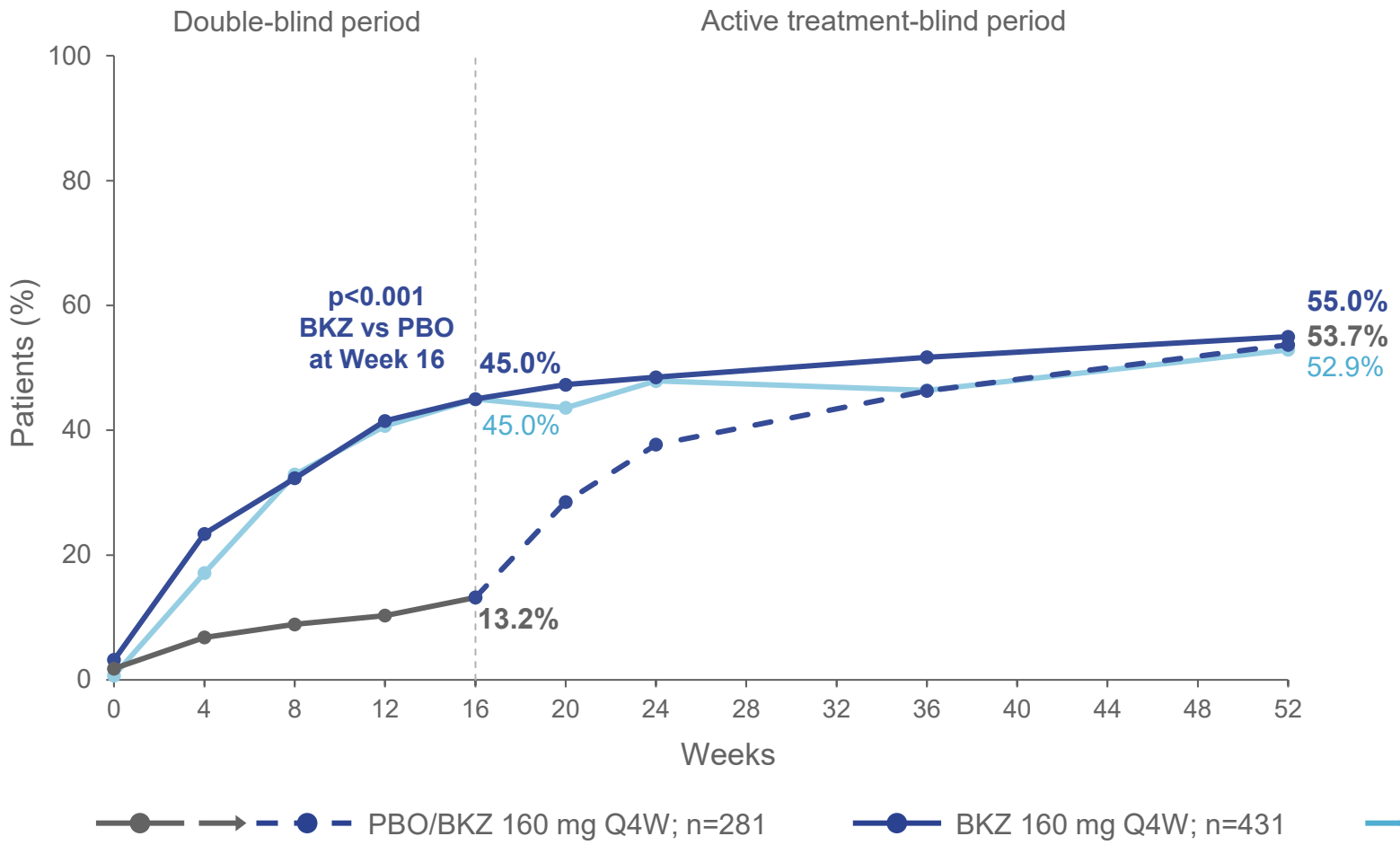
Sustained Improvements in MDA to Week 52 (NRI)



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 (VAS) ≤15 mm
- Patient global assessment-PsA (VAS) ≤20 mm
- Health Assessment Questionnaire Disability Index ≤0.5
- Tender entheseal points ≤1

Randomized set. p value was calculated using a logistic regression model with treatment, bone erosion at baseline, and region as stratification factors. The study was not powered for statistical comparisons of ADA to BKZ or PBO. [a] For patients with PSO involving ≥3% of BSA at baseline; [b] Patients 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. ADA: adalimumab; BKZ: bimekizumab; MDA: Minimal Disease Activity; NRI: non-responder imputation; PBO: placebo; PsA: psoriatic arthritis; PSO: psoriasis; Q2W: every 2 weeks; Q4W: every 4 weeks; VAS: visual analog scale.

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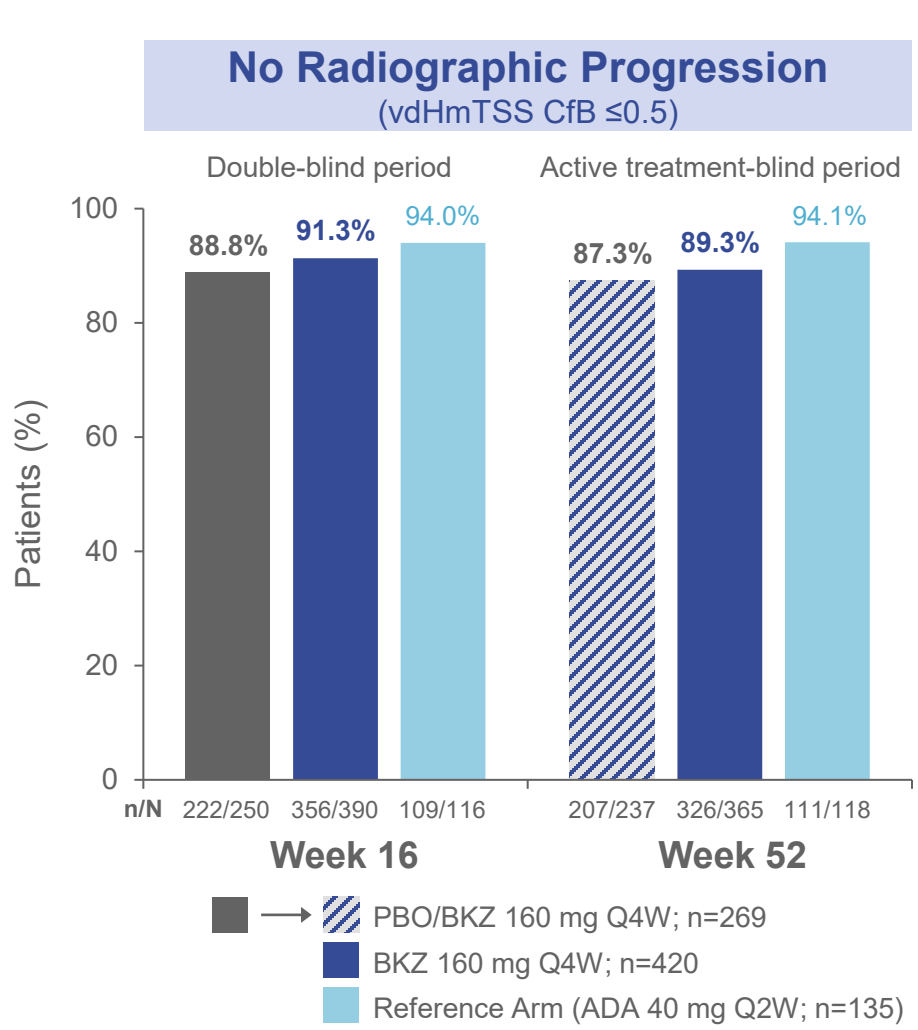
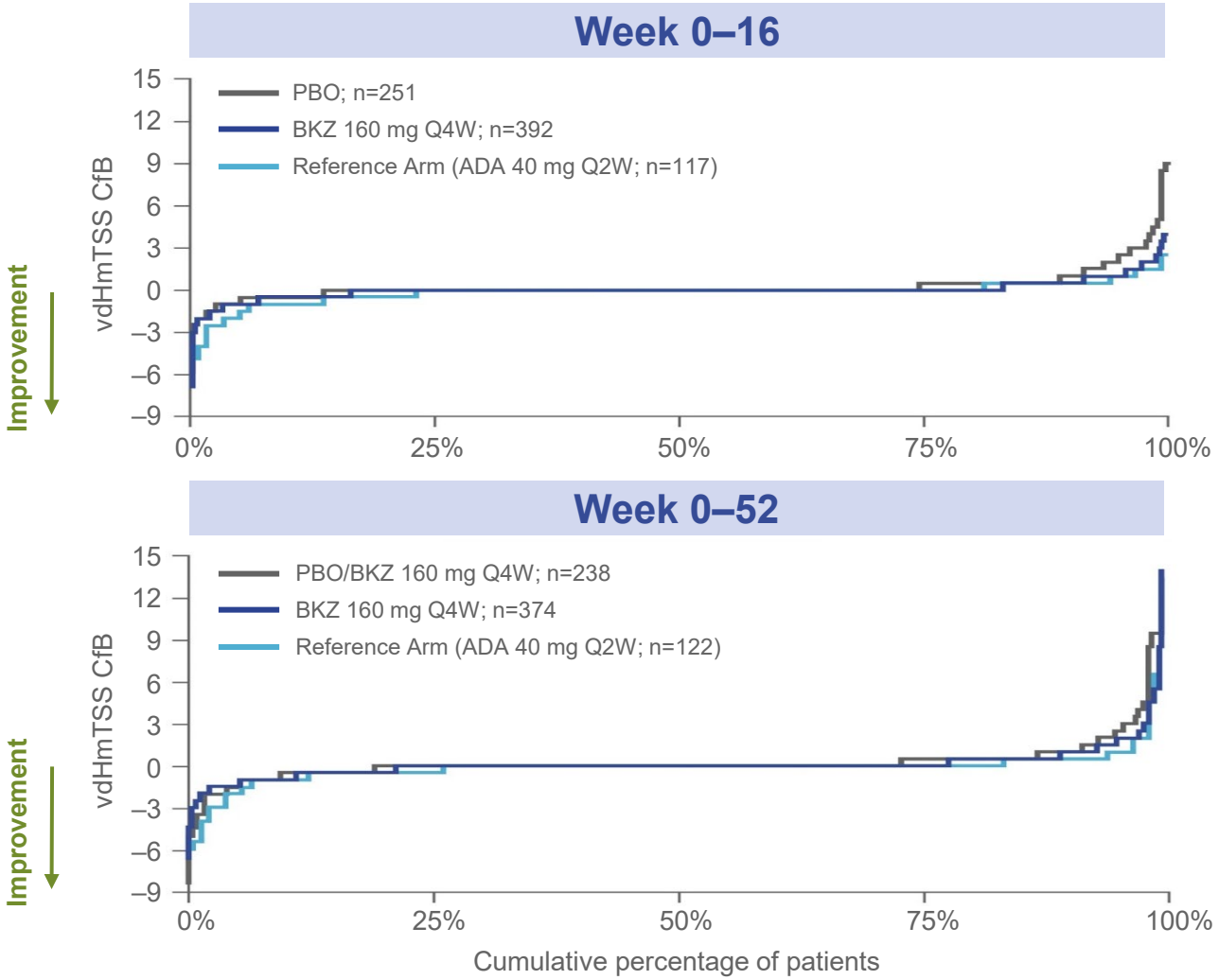
Bimekizumab Treatment Inhibited Radiographic Progression to Week 52 (OC)





Radiographic set consists of patients in the randomized set with valid radiographic imaging of hands and feet at screening, assessed by ≥2 reviewers. ADA: adalimumab; BKZ: bimekizumab; CfB: change from baseline; hs-CRP: high-sensitivity C-reactive protein; OC: observed case; PBO: placebo; Q2W: every 2 weeks; Q4W: every 4 weeks; vdHmTSS: van der Heijde-modified Total Sharp Score.

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Adverse Events to Week 16 and Week 52

n (%)	Week 0–16			Week 0–52	
	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)	257 (59.6)	83 (59.3)	555 (79.1)	113 (80.7)
Serious TEAEs	3 (1.1)	8 (1.9)	2 (1.4)	46 (6.6)	10 (7.1)
Discontinuation due to TEAEs	3 (1.1)	8 (1.9)	3 (2.1)	21 (3.0)	7 (5.0)
Drug-related TEAEs	35 (12.5)	100 (23.2)	34 (24.3)	224 (31.9)	54 (38.6)
Severe TEAEs	0	4 (0.9)	3 (2.1)	23 (3.3)	9 (6.4)
Deaths	0	0	0	1 (0.1)[b]	0
Most frequently reported TEAEs (≥5% in any treatment arm)[c]					
Nasopharyngitis	13 (4.6)	40 (9.3)	7 (5.0)	84 (12.0)	12 (8.6)
Upper respiratory tract infection	18 (6.4)	22 (5.1)	3 (2.1)	50 (7.1)	8 (5.7)
Urinary tract infection	4 (1.4)	9 (2.1)	3 (2.1)	43 (6.1)	5 (3.6)
Headache	7 (2.5)	19 (4.4)	2 (1.4)	41 (5.8)	6 (4.3)
Oral candidiasis[d]	0	9 (2.1)	0	38 (5.4)	1 (0.7)
Diarrhea	7 (2.5)	16 (3.7)	5 (3.6)	36 (5.1)	7 (5.0)
Hypertension	11 (3.9)	12 (2.8)	4 (2.9)	29 (4.1)	9 (6.4)
ALT elevation	2 (0.7)	3 (0.7)	7 (5.0)	16 (2.3)	11 (7.9)
AST elevation	2 (0.7)	1 (0.2)	4 (2.9)	14 (2.0)	7 (5.0)
Injection site erythema	0	1 (0.2)	4 (2.9)	6 (0.9)	7 (5.0)
TEAEs of special interest					
Candida infections[d]	2 (0.7)	11 (2.6)	0	54 (7.7)	1 (0.7)
Serious Infections	0	1 (0.2)	1 (0.7)	6 (0.9)	2 (1.4)
Adjudicated MACE	0	0	0	4 (0.6)[f]	0
Definite adjudicated IBD	0	0	0	2 (0.3)[g]	0
Malignancies	1 (0.4)	1 (0.2)	0	7 (1.0)	0
Non-melanoma skin cancer	0	1 (0.2)	0	4 (0.6)	0

Safety set, MedDRA (Version 19.0). [a] Includes patients who switched from placebo to BKZ (events after switch only); [b] Motorcycle accident; [c] TEAEs ≥5% in any treatment arm are reported by preferred term; [d] All infections were mild to moderate and none were serious, 1 BKZ patient discontinued; [e] No fungal infections were systemic; [f] 1 myocardial infarction; 1 cerebrovascular accident; 1 ischemic stroke; 1 thrombotic cerebral infarction; [g] Both ulcerative colitis; one in a patient with a prior history of IBD, the other de novo. ADA: adalimumab; ALT: alanine aminotransferase; AST: aspartate 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.

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Summary

The phase 3 BE OPTIMAL study demonstrated long-term response of IL-17A and IL-17F inhibition with bimekizumab treatment in bDMARD-naïve patients with PsA.

Bimekizumab-treated patients with PsA demonstrated response across both joint and skin outcomes, which were sustained from Week 16 to Week 52.

Bimekizumab treatment inhibited radiographic progression to Week 52.

Bimekizumab was generally well-tolerated, and the adverse event profile was consistent with prior studies.[1–3]

1. Coates LC. Arthritis & Rheum 2022;10.1002/art.42280; 2. McInnes IB. Ann Rheum Dis 2022;81:206–7; 3. Merola JF Ann Rheum Dis 2022;81:167–8.
bDMARD: biologic disease-modifying antirheumatic drug; IL: interleukin; PsA: psoriatic arthritis.

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Poster L14 (Ignite Talk)

Bimekizumab Maintains Improvements in Efficacy Endpoints and has a Consistent Safety Profile Through 52 Weeks in Patients with Non-Radiographic Axial Spondyloarthritis and Ankylosing Spondylitis: Results from Two Parallel Phase 3 Studies

X. Baraliakos, A. Deodhar, D. van der Heijde, M. Magrey, WP. Maksymowych, T. Tomita, H. Xu, M. Oortgiesen, U. Massow, C. Fleurinck, AM. Ellis, T. Vaux, J. Shepherd-Smith, A. Marten, LS. Gensler

Introduction

Objective

To report efficacy and safety of bimekizumab (BKZ) in patients with active non-radiographic axial spondyloarthritis (nr-axSpA) and ankylosing spondylitis (AS) up to Week 52 in the pivotal phase 3 studies, BE MOBILE 1 and 2, respectively

Methods

- BE MOBILE 1 (NCT03928704; nr-axSpA) and 2 (NCT03928743; AS) were conducted in parallel; each comprised a 16-week double blind, PBO-controlled period followed by a 36-week maintenance period
- Primary and secondary efficacy endpoints were assessed at Week 16 and are presented in this analysis to Week 52 (randomized set)
- Treatment-emergent adverse events (TEAs; MedDRA v19.0) following first BKZ exposure are reported at the Week 52 data cut (safety set)

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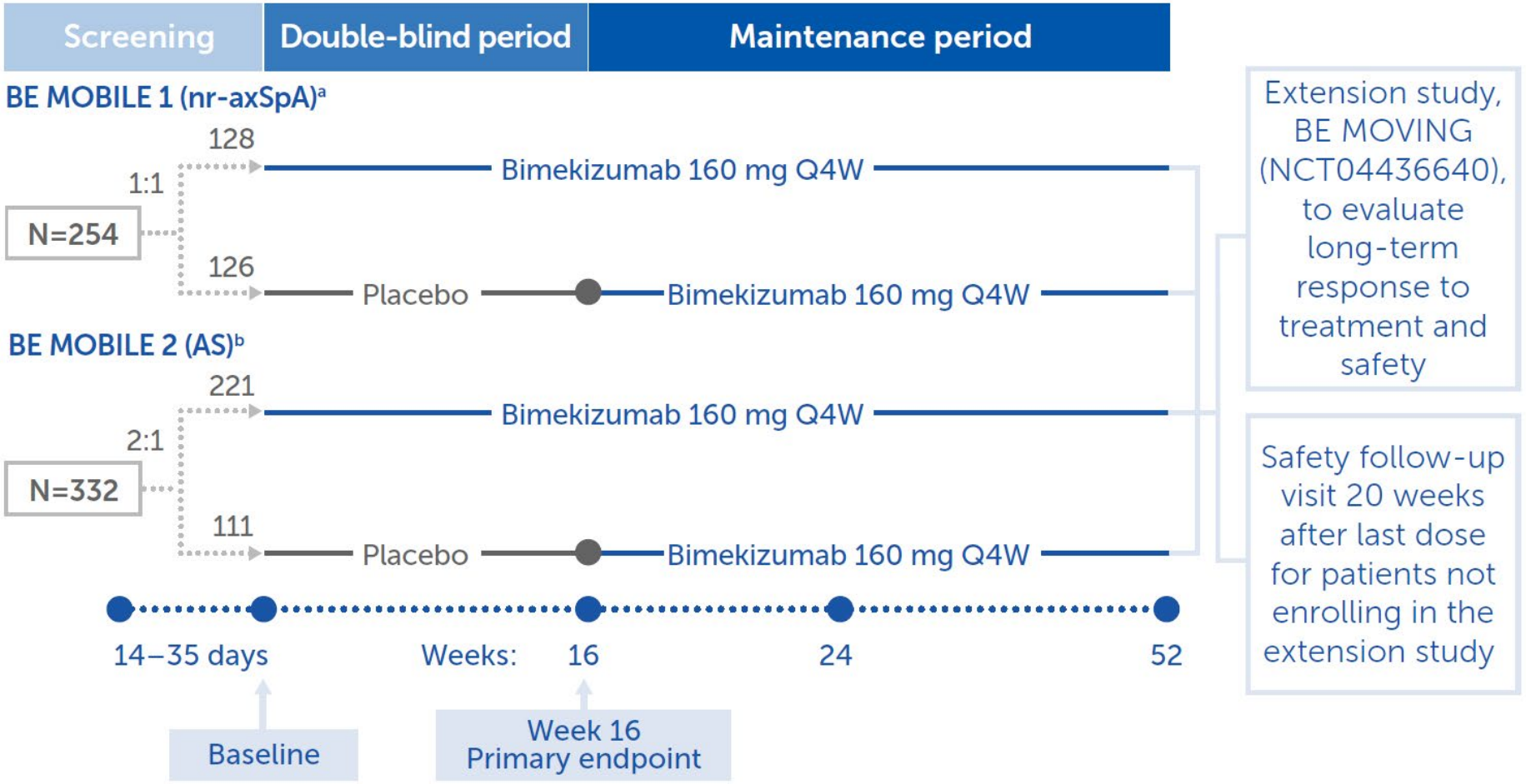
Study Designs



Patients were eligible to receive non-biologic rescue therapy from Week 20 at the discretion of the investigator, while continuing to receive BKZ. All patients had active nr-axSpA or AS at baseline (BASDAI ≥4 and spinal pain ≥4). [a] Included patients had adult-onset nr-axSpA fulfilling ASAS classification criteria and objective signs of inflammation (active sacroiliitis on MRI and/or elevated CRP [≥6 mg/L]). [b] Included patients had radiographic evidence of AS fulfilling Modified New York criteria.

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Baseline Characteristics

	BE MOBILE 1 (nr-axSpA) N=254	BE MOBILE 2 (AS) N=332
Age, mean (SD)	39.4 (11.5)	40.4 (12.3)
Sex, male, n (%)	138 (54.3)	240 (72.3)
HLA-B27 positive, n (%)	197 (77.6)	284 (85.5)
Symptom duration, years, mean (SD)	9.0 (8.8)	13.5 (10.3)
Time since first diagnosis of nr-axSpA/AS, years, mean (SD)	3.6 (5.8)	6.4 (7.9)
ASDAS, mean (SD)	3.7 (0.7)	3.7 (0.8)[a]
BASDAI, mean (SD)	6.8 (1.3)	6.5 (1.3)
hs-CRP, mg/L, median (min, max)	6.3 (0.1, 79.1)	7.4 (0.1, 105.4)
hs-CRP >ULN, [b] n (%)	141 (55.5)	204 (61.4)
Total spinal pain score, mean (SD)	7.2 (1.5)	7.2 (1.5)
BASFI, mean (SD)	5.4 (2.3)	5.2 (2.1)
Prior TNFi exposure, n (%)	27 (10.6)	54 (16.3)

Randomized set. [a] n=331; [b] ULN value for hs-CRP is 5 mg/L.

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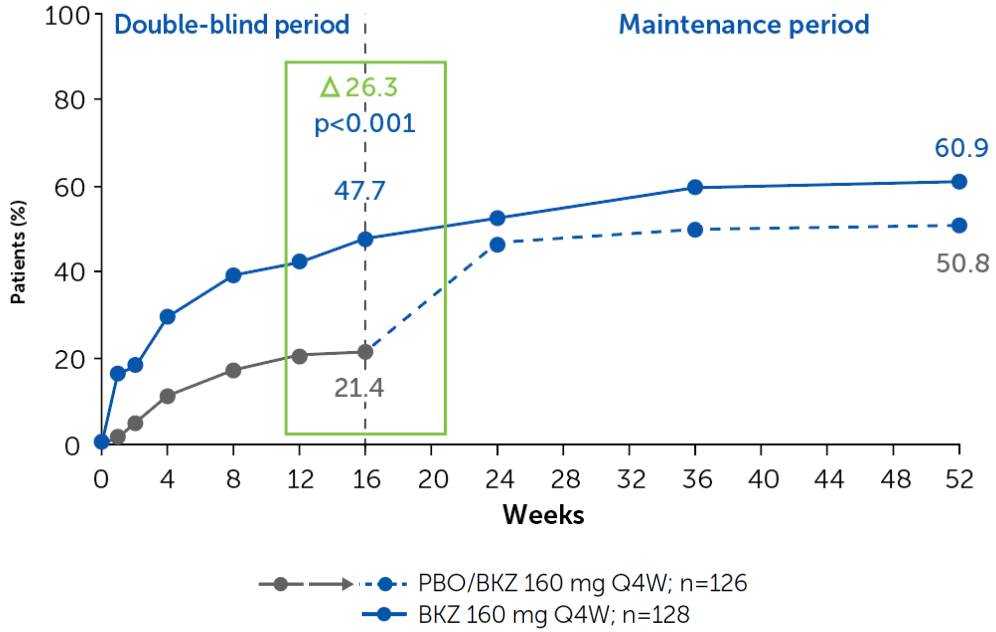
Sustained ASAS40 Response to Week 52

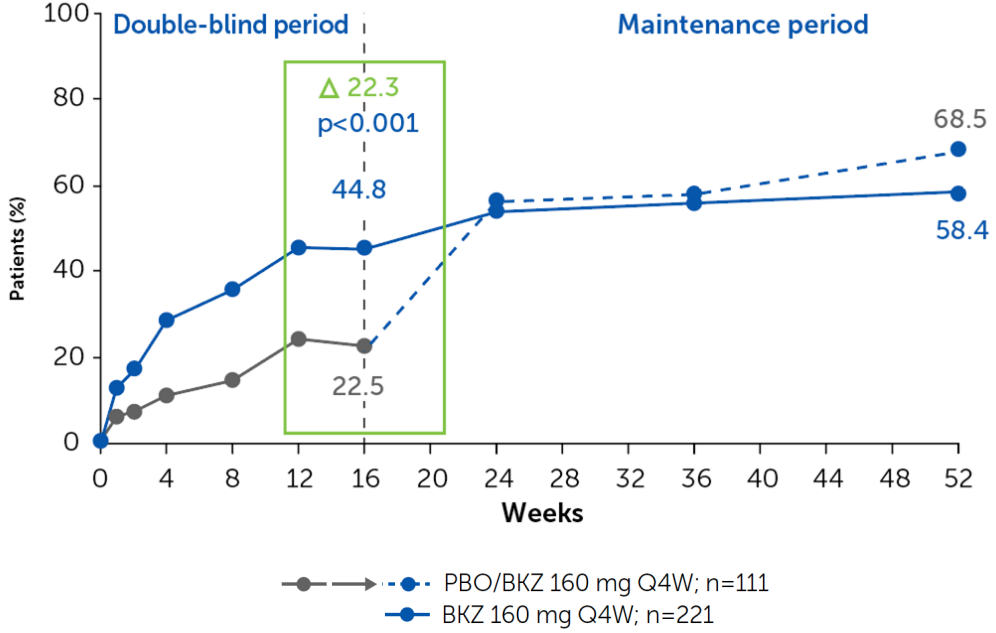
BE MOBILE 1

nr-axSpA (NRI)



BE MOBILE 2

AS (NRI)



Missing data were imputed using NRI. Randomized set.
p values were calculated using logistic regression with treatment, prior MRI/CRP status (BE MOBILE 1) or TNFi exposure (BE MOBILE 2), and region as factors.

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Sustained Clinical Responses to Week 52 Across the Spectrum of Disease

	BE MOBILE 1 (nr-axSpA)		BE MOBILE 2 (AS)	
	WEEK 52		WEEK 52	
	PBO → BKZ 160 mg Q4W N=126	BKZ 160 mg Q4W N=128	PBO → BKZ 160 mg Q4W N=111	BKZ 160 mg Q4W N=221
ASAS40* [NRI], n (%)	64 (50.8)	78 (60.9)	76 (68.5)	129 (58.4)
ASAS40 in TNFi-naïve‡ [NRI], n (%)	58 (53.2)[a]	73 (61.9)[b]	67 (71.3)[c]	108 (58.7)[d]
ASAS40 in TNFi-IR[e] [NRI], n (%)	6 (35.3)[f]	5 (50.0)[g]	9 (52.9)[f]	21 (56.8)[h]
ASAS20†‡ [NRI], n (%)	88 (69.8)	94 (73.4)	89 (80.2)	158 (71.5)
ASAS PR†‡ [NRI], n (%)	38 (30.2)	38 (29.7)	41 (36.9)	66 (29.9)
ASAS 5/6†‡ [NRI], n (%)	65 (51.6)	71 (55.5)	74 (66.7)	124 (56.1)
BASDAI CfB†‡ [MI], mean (SE)	-3.5 (0.2)	-3.9 (0.2)	-4.0 (0.2)	-3.6 (0.1)
BASFI CfB†‡ [MI], mean (SE)	-2.6 (0.2)	-3.0 (0.2)	-2.8 (0.2)	-2.8 (0.1)
ASDAS-MI†‡ [NRI], n (%)	37 (29.4)	47 (36.7)	49 (44.1)	71 (32.1)
ASDAS-CRP CfB [MI], mean (SE)	-1.6 (0.1)	-1.8 (0.1)	-1.9 (0.1)	-1.7 (0.1)
Nocturnal spinal pain CfB†‡ [MI], mean (SE)	-4.1 (0.2)	-4.3 (0.3)	-4.6 (0.3)	-4.1 (0.2)
ASQoL CfB†‡ [MI], mean (SE)	-5.3 (0.4)	-5.9 (0.4)	-5.6 (0.4)	-5.7 (0.3)
SF-36 PCS CfB†‡ [MI], mean (SE)	11.4 (0.9)	12.2 (0.9)	12.3 (0.9)	12.0 (0.6)
BASMI CfB†‡ [MI], mean (SE)	-0.4 (0.1)	-0.6 (0.1)	-0.7 (0.1)	-0.7 (0.1)

Missing data were imputed using NRI for binary endpoints and MI (based on the missing at random assumption) for all continuous endpoints, for which a reference-based MI approach was applied for the Week 16 timepoint (based on data from the placebo group). Randomized set.
* Primary endpoint; † Secondary endpoint in BE MOBILE 1; ‡ Secondary endpoint in BE MOBILE 2. [a] n=109; [b] n=118; [c] n=94; [d] n=184;
[e] Patients received maximum of one TNFi; [f] n=17; [g] n=10; [h] n=37. Tables report mean absolute values

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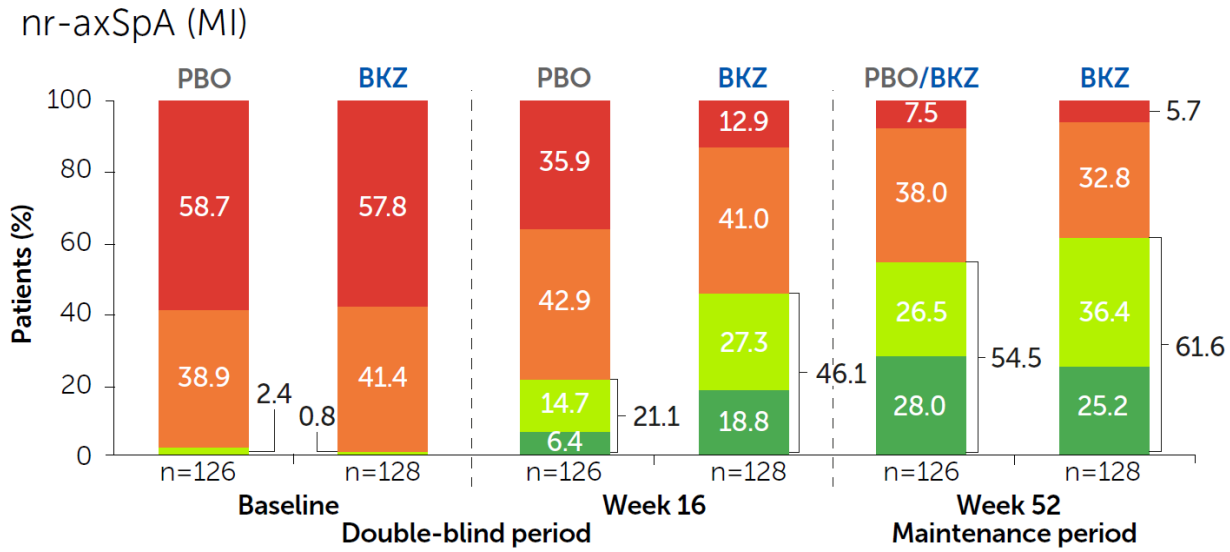
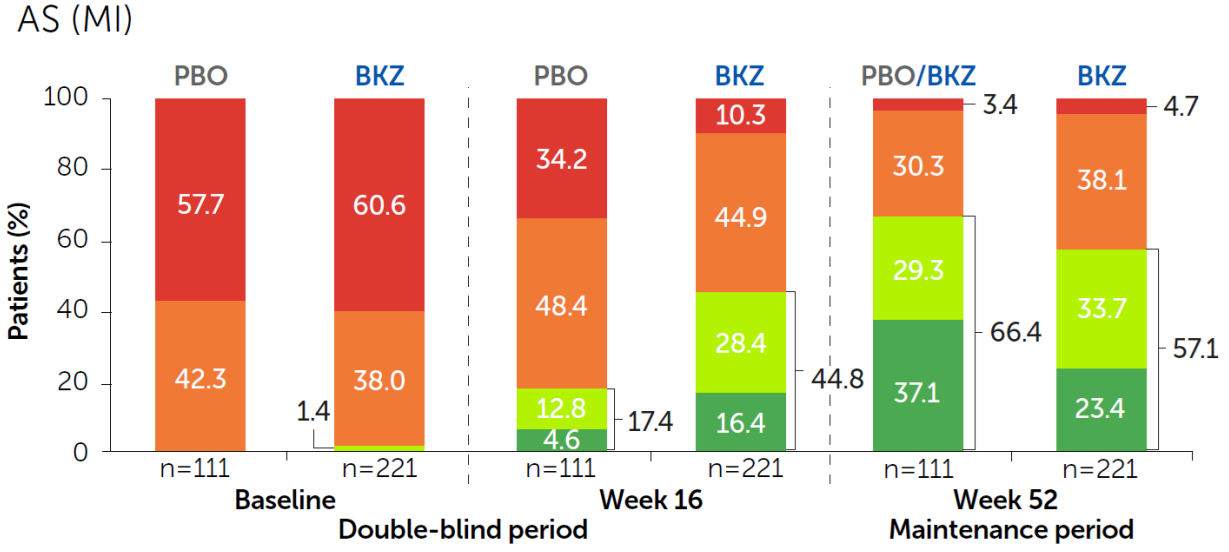
ASDAS States Over Time

At week 52, in the continued bimekizumab arm 61.6% nr-axSpA patients and 57.1% AS patients achieved ASDAS<2.1

BE MOBILE 1



BE MOBILE 2



Data reported using MI where patients that discontinued treatment due to loss of efficacy or safety were considered as non-responders. Randomized set. 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. AS: ankylosing spondylitis.

Inspired by patients. Driven by science.

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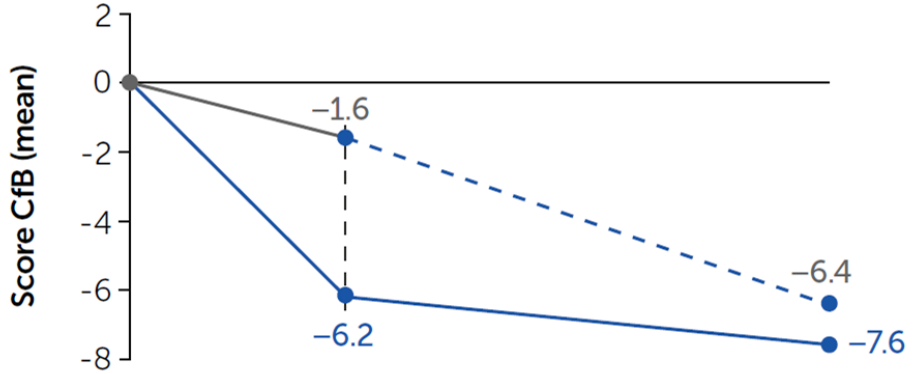
Reductions in MRI were Sustained through Week 52

SPARCC MRI SIJ score CfB

BE MOBILE 1

SPARCC MRI SIJ score CfB, nr-axSpA (OC)[a,b]

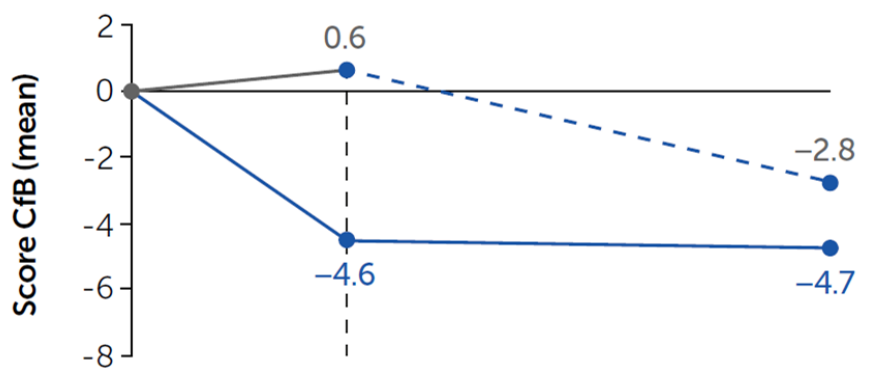
mean	Baseline	Week 16	Week 52
PBO/BKZ	9.8	9.0	1.9
BKZ	8.0	2.0	1.0



BE MOBILE 2

SPARCC MRI SIJ score CfB, AS (OC)[a,e]

mean	Baseline	Week 16	Week 52
PBO/BKZ	3.8	4.5	0.9
BKZ	5.4	1.4	0.8



Data reported using OC. Randomized set.
Tables report mean absolute values. [a.] Only includes pts enrolled in the SIJ and spine MRI sub-study; [b.] At baseline n=70 (PBO/BKZ), n=82 (BKZ); [e.] At baseline n=48 (PBO/BKZ), n=90 (BKZ)

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Adverse Event Overview

n (%) [EAIR]	BE MOBILE 1 (nr-axSpA) BKZ 160 mg Q4W Total[a] n=244	BE MOBILE 2 (AS) BKZ 160 mg Q4W Total[a] n=330
Any TEAE	183 (75.0) [202.1]	249 (75.5) [200.8]
Most frequently reported TEAEs[b]		
Nasopharyngitis	30 (12.3) [15.7]	30 (9.1) [11.0]
Upper respiratory tract infection	23 (9.4) [11.9]	21 (6.4) [7.5]
Oral candidiasis	18 (7.4) [9.0]	20 (6.1) [7.2]
Severe TEAEs	8 (3.3)	14 (4.2)
Serious TEAEs[c]	9 (3.7) [4.4]	20 (6.1) [7.1]
Study discontinuation due to TEAEs	6 (2.5) [2.9]	15 (4.5) [5.2]
Drug-related TEAEs	81 (33.2)	135 (40.9)
Any fungal infections	37 (15.2) [19.6]	40 (12.1) [14.9]
Adjudicated IBD[d]	2 (0.8) [1.0]	3 (0.9) [1.0]
Crohn's disease	1 (0.4) [0.5]	2 (0.6) [0.7]
Ulcerative colitis	1 (0.4) [0.5]	1 (0.3) [0.3]
Uveitis event[e,f]	3 (1.2) [1.5]	7 (2.1) [2.4]

Most incidences of fungal infection were *candidiasis* and mild to moderate (none were serious or systemic); two patients with nr-axSpA and two with AS discontinued the study due to *Candida* infections

No major adverse cardiovascular events, active tuberculosis cases, or deaths were reported.

Safety set. MedDRA (Version 19.0). [a]Includes patients who switched from PBO to BKZ (events after switch only); [b]TEAEs >5% in patients receiving BKZ are reported by preferred term; [c]Includes TEAEs that are fatal; life threatening; requiring in-patient hospitalisation or prolongation of existing hospitalisation; resulting in persistent or significant disability or incapacity; or any other medically important serious event; [d]At baseline, 4/244 (1.6%) patients with nr-axSpA, and 4/330 (1.2%) patients with AS had a medical history of IBD; [e]At baseline, 39/244 (16.0%) patients with nr-axSpA and 56/330 (17.0%) patients with AS had a medical history of uveitis; [f]Includes the preferred terms autoimmune uveitis, uveitis, iridocyclitis and iritis. Tables report mean absolute values

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Summary

Across the full axSpA disease spectrum, dual inhibition of IL-17F in addition to IL-17A with bimekizumab resulted in sustained response, including suppression of inflammation and improvements in function and quality of life, to Week 52. No new safety signals were observed, consistent with the adverse event profile established in prior studies.

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.
Bimekizumab is not approved for any indication by the U.S. Food and Drug Administration

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Summary

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Executive Vice President, Immunology Solutions and Head of US, UCB

Summary

Patient needs

- Within six months of taking a biologic, the majority of patients with PsA and axSpA do not achieve remission or low disease activity*[1,2]

Bimekizumab PsA Phase 3 data

- In both Phase 3 studies, a greater proportion of bimekizumab patients achieved high levels of joint and skin clearance vs placebo[3,4]
- Outcomes were consistent across biologic-naïve & TNF-IR populations (week 16)[3,4]
- Clinical responses were sustained to week 52 in BE OPTIMAL[5]

Bimekizumab axSpA Phase 3 data

- In both Phase 3 studies, a greater proportion of bimekizumab patients achieved clinically meaningful improvements in signs and symptoms vs placebo at week 16[6,7]
- Outcomes were consistent across nr-axSpA and AS populations (wks 16 & 52)[6,7,8]
- Clinical responses were sustained to week 52 across the full spectrum of axSpA[8]

The science of bimekizumab

- Phase 3 findings in PsA and axSpA highlight the meaningful clinical outcomes achieved by targeting IL-17F in addition to IL-17A

The adverse event profile of bimekizumab to week 52 in PsA, nr-axSpA and AS is consistent with previous observations with no new safety signals[5,8]

*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

References: 1. Zardin-Moraes M, et al. J Rheumatol. 2020;47(6):839–47; 2. Ørnbjerg LM, et al. Ann Rheum Dis. 2019;78:1536–44; 3 study. EULAR 2022 – Presentation OP0019; 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. Ann. Rheum Dis 2022; 81 (suppl 1); 206-207; 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. Ann. Rheum Dis 2022; 81 (suppl 1); 167-169; 5. Ritchlin C et al. #L02 Presented at ACR Convergence 2022; 6. 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. Ann. Rheum Dis 2022; 81 (suppl 1); 772; 7. 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. Ann. Rheum Dis 2022; 81 (suppl 1); 12-13; 8. Baraliakos X, et al. #L14 Presented at ACR Convergence 2022.

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Q&A

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Thank you

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

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