# 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



**Iain B. McInnes,**[1] Laura C. Coates,[2] Robert Landewé,[3] Philip J. Mease,[4] Christopher T. Ritchlin,[5] Yoshiya Tanaka,[6] Akihiko Asahina,[7] Laure Gossec,[8] Alice B. Gottlieb,[9] Richard B. Warren,[10] Barbara Ink,[11] Deepak Assudani,[11] Jason Coarse,[12] Rajan Bajracharya,[11] Joseph F. Merola[13]

[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.

**EULAR 2022 | Congress | 1–4 June 2022**

**Presentation number: LB0001**

# Disclosures & Acknowledgements

## Disclosures

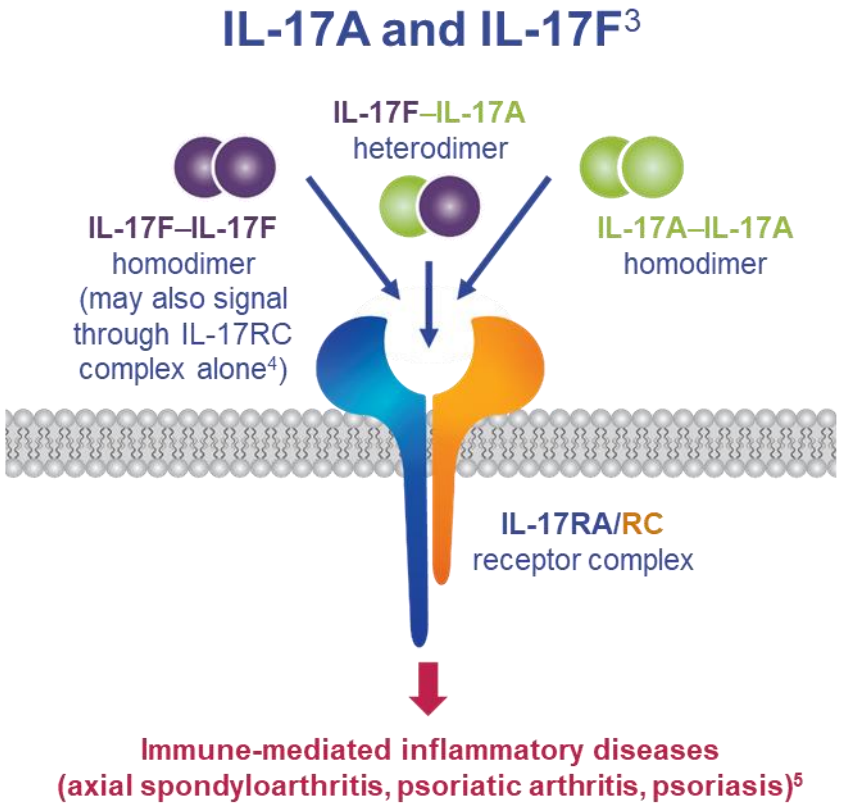
**IBM:** Consulting fees and honoraria from AbbVie, Celgene, BMS, Boehringer Ingelheim, Janssen, Novartis, Lilly, and UCB Pharma; Research support from BMS, Boehringer Ingelheim, Celgene, Janssen, and UCB Pharma. **LCC:** Grants/research support from AbbVie, Amgen, Celgene, Eli Lilly, Gilead, Janssen, Novartis, Pfizer and UCB Pharma; Paid consultant for AbbVie, Amgen, BMS, Boehringer Ingelheim, Celgene, Domain, Eli Lilly, Gilead, Galapagos, Janssen, Moonlake, Novartis, Pfizer and UCB Pharma; Paid as a speaker for AbbVie, Amgen, Biogen, Celgene, Eli Lilly, Galapagos, Gilead, GSK, Janssen, Medac, Novartis, Pfizer and UCB Pharma. **RL:** Consultancy fees from Abbott, Ablynx, Amgen, AstraZeneca, BMS, Centocor, GSK, Novartis, Merck, Pfizer, Roche, Schering-Plough, UCB Pharma, and Wyeth; Research grants from Abbott, Amgen, Centocor, Novartis, Pfizer, Roche, Schering-Plough, UCB Pharma, and Wyeth; Speaker's bureau from Abbott, Amgen, BMS, Centocor, Merck, Pfizer, Roche, Schering-Plough, UCB Pharma, and Wyeth. **PJM:** Member of the speaker's bureau for AbbVie, Amgen, Eli Lilly, Janssen, Novartis, Pfizer, and UCB Pharma; Consultancy fees from AbbVie, Amgen, BMS, Boehringer Ingelheim, Eli Lilly, Galapagos, Gilead, GSK, Janssen, Novartis, Pfizer, Sun Pharma, and UCB Pharma; Research grants from AbbVie, Amgen, BMS, Eli Lilly, Gilead, Janssen, Novartis, Pfizer, Sun Pharma, and UCB Pharma. **CTR:** Research grants from AbbVie, Amgen, and UCB Pharma; Consultant for AbbVie, Amgen, Eli Lilly, Gilead, Janssen, Novartis, Pfizer, and UCB Pharma. **YT:** Member of the speaker's bureaus for AbbVie, Amgen, Astellas, AstraZeneca, BMS, Boehringer-Ingelheim, Chugai, Eisai, Eli Lilly, Gilead, Mitsubishi-Tanabe, and YL Biologics; Research Grants for AbbVie, Asahi-Kasei, Boehringer-Ingelheim, Chugai, Corrona, Daiichi-Sankyo, Eisai, Kowa, Mitsubishi-Tanabe, and Takeda; Consultant fee for AbbVie, Ayumi, Daiichi-Sankyo, Eli Lilly, GSK, Sanofi, and Taisho. **AA:** Honoraria and/or research grants from AbbVie, Amgen, Eisai, Eli Lilly, Janssen, Kyowa Kirin, LEO Pharma, Maruho, Mitsubishi Tanabe Pharma, Pfizer, Sun Pharma, Taiho Pharma, Torii Pharmaceutical, and UCB Pharma. **LG:** Research grants from Amgen, Galapagos, Lilly, Pfizer, Sandoz, and UCB Pharma; Consulting fees from: AbbVie, Amgen, BMS, Celltrion, Galapagos, Gilead, GSK, Janssen, Lilly, Novartis, Pfizer, and UCB Pharma. **ABG:** Honoraria as an advisory board member and consultant for: Amgen, AnaptsysBio, Avotres Therapeutics, BMS, Boehringer Ingelheim, Dermavant, Eli Lilly, Janssen, Novartis, Pfizer, Sanofi, Sun Pharma, UCB Pharma, and Xbiotech (stock options for an RA project). ABG has received research/educational grants from: AnapytsysBio, Janssen, Novartis, Ortho, Sun Pharma, and UCB Pharma: all funds go to Mount Sinai Medical School. **RBW:** Consulting fees from AbbVie, Almirall, Amgen, Arena, Astellas, Avillion, Biogen, BMS, Boehringer Ingelheim, Celgene, Eli Lilly, GSK, Janssen, LEO Pharma, Novartis, Pfizer, Sanofi, and UCB Pharma; Research grants to his institution from AbbVie, Almirall, Janssen, LEO Pharma, Novartis, and UCB Pharma; Honoraria from Astellas, DiCE, GSK, and Union. **BI:** Employee of UCB Pharma and a shareholder of GSK and UCB Pharma. **DA**, **JC**, **RB:** Employees and stockholders of UCB Pharma. **JFM:** Consultant and/or investigator for AbbVie, Amgen, Bayer, Biogen, BMS, Celgene, Dermavant, Eli Lilly, Janssen, Leo Pharma, Novartis, Pfizer, Sanofi-Regeneron, Sun Pharma, and UCB Pharma.

## Acknowledgements

We would like to thank the patients and their caregivers in addition to all the investigators and their teams who contributed to this study. The authors acknowledge Heather Edens, PhD, UCB Pharma, Smyrna, Georgia, USA, for publication coordination, Luke Green, PhD, Costello Medical, London, UK for medical writing and editorial assistance, and the Costello Medical Design Team for design support. This study was funded by UCB Pharma. All costs associated with development of this presentation were funded by UCB Pharma.

# Background & Objective

- **Bimekizumab** is a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.
- Bimekizumab has shown rapid and sustained efficacy and was well tolerated up to 152 weeks in a phase 2b study in patients with active psoriatic arthritis (PsA).[1,2]



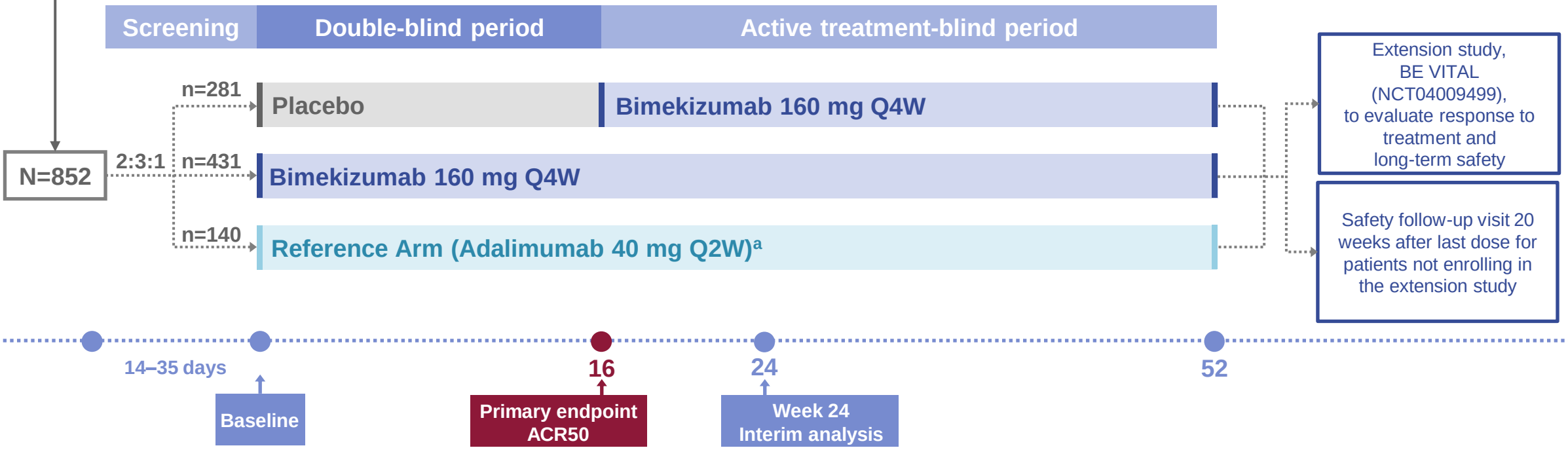

**OBJECTIVE:** To assess efficacy and safety of subcutaneous bimekizumab vs placebo in biologic disease-modifying antirheumatic drug (bDMARD)-naïve patients with active PsA up to Week 24 in the pivotal phase 3 study, BE OPTIMAL

1. Ritchlin CT Lancet 2020;395(10222):427–40; 2. Coates LC Ann Rheum Dis 2021;80:779–80(POS1022); 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.

# 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)




[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 (%)<br>Score, mean (SD) | 70 (24.9)<br>2.9 (1.5) | 143 (33.2)<br>2.5 (1.5) | 36 (25.7)<br>2.3 (1.6) |
| **Dactylitis**,[h] n (%)<br>Score, mean (SD) | 33 (11.7)<br>47.3 (41.1) | 56 (13.0)<br>46.7 (54.3) | 11 (7.9)<br>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)

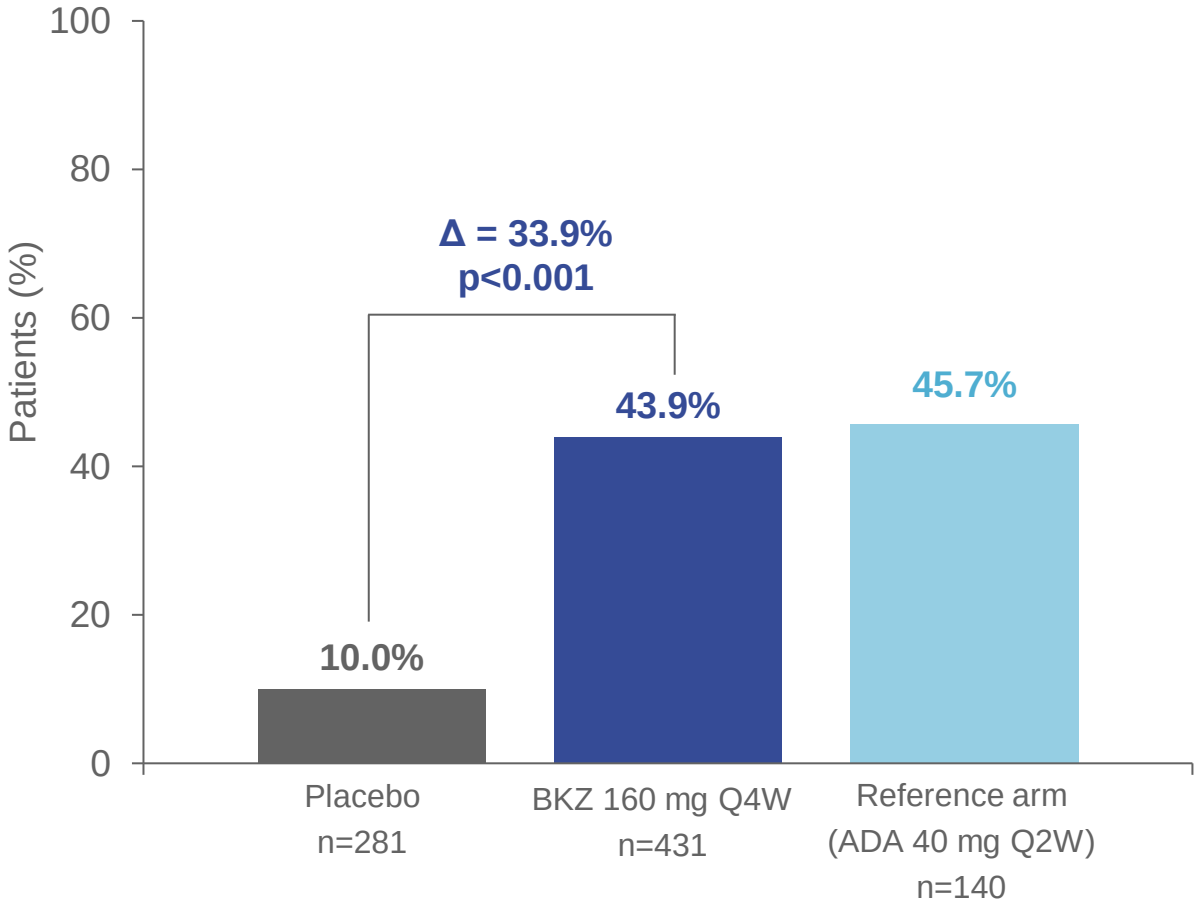
| | Efficacy endpoint | p value[a] | Statistically significant | Odds ratio[b] BKZ vs placebo (95% CI) | Least squares mean difference[b] BKZ vs placebo (95% CI) |
|---|---|---|---|---|---|
| 1 | ACR50 (NRI) | <0.001 | Yes | 7.1 (4.6, 11.0) | – |
| 2 | HAQ-DI Change from Baseline (RBMI) | <0.001 | Yes | – | −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.

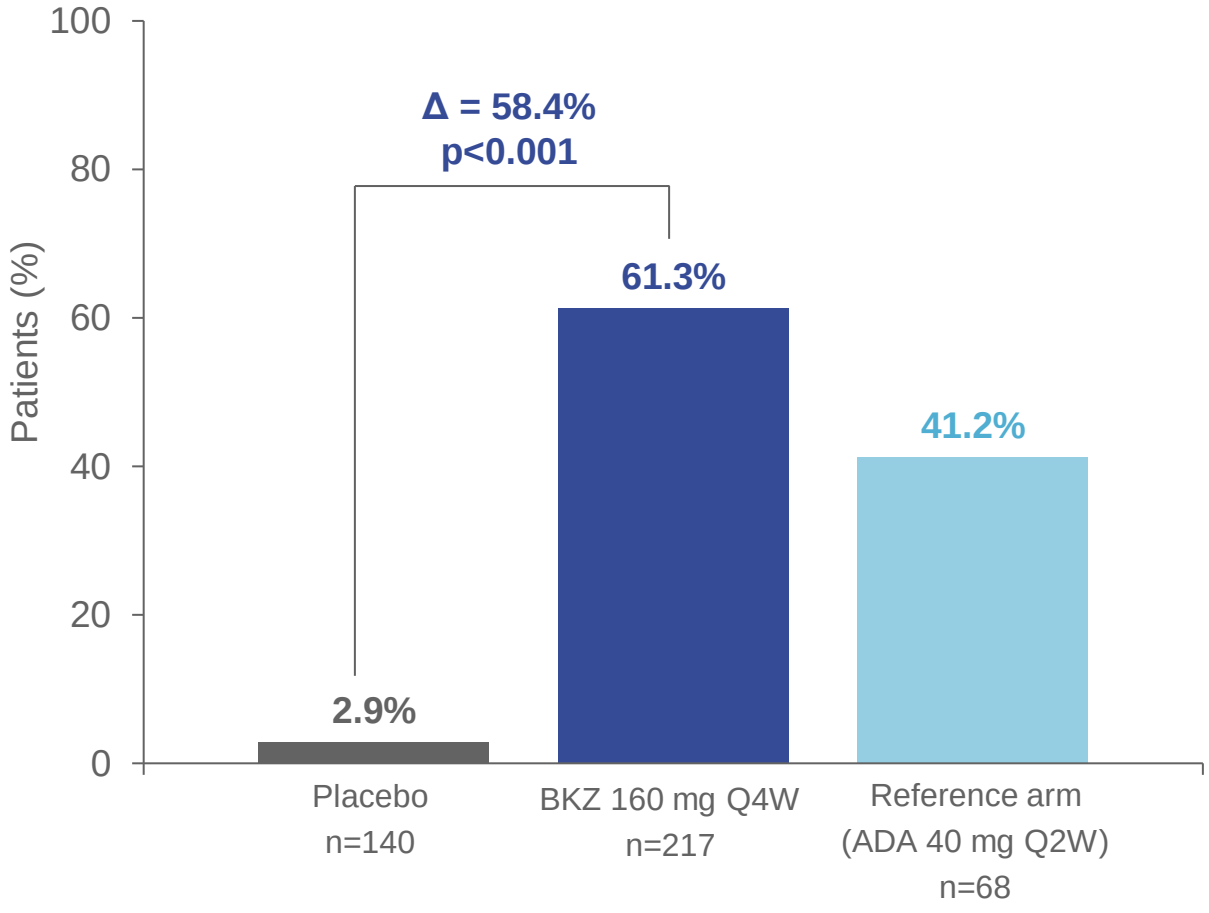
# Efficacy: ACR50 and PASI90 Responses at Week 16 (NRI)

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

## Primary Endpoint: ACR50



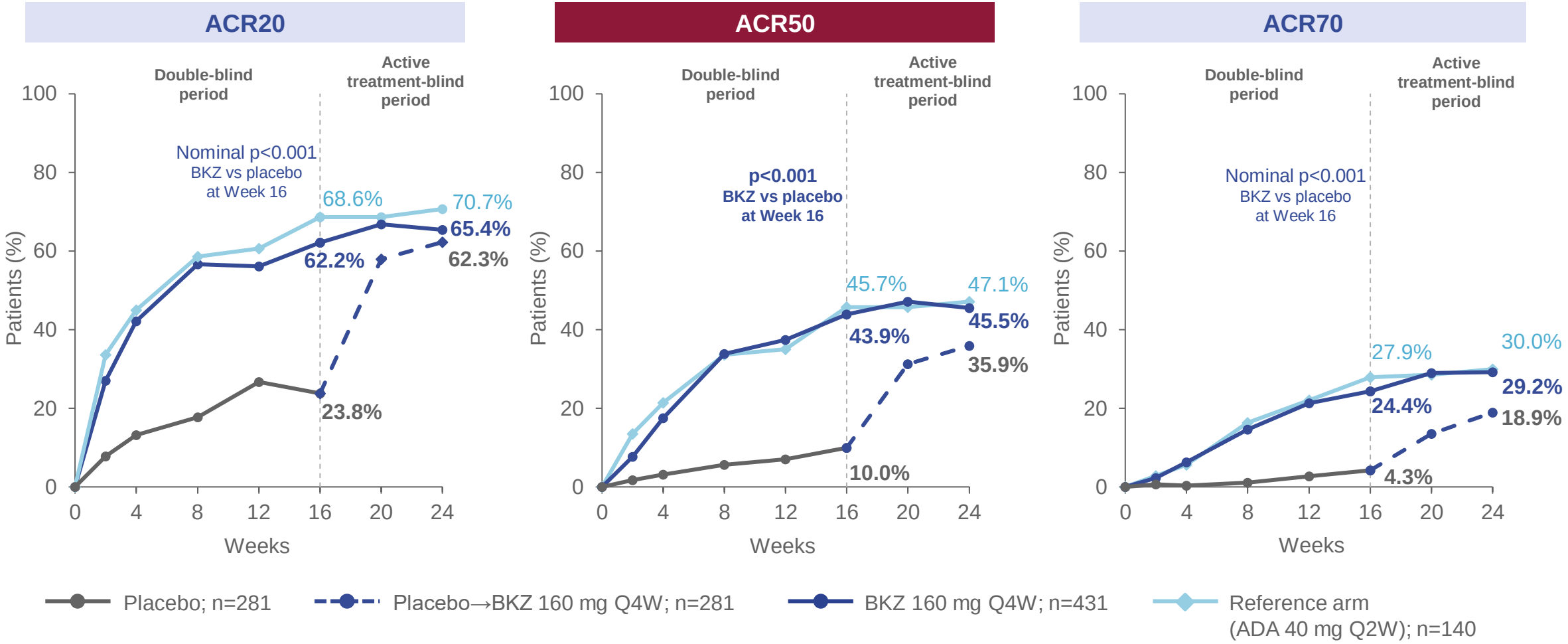

## PASI90[a]




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)

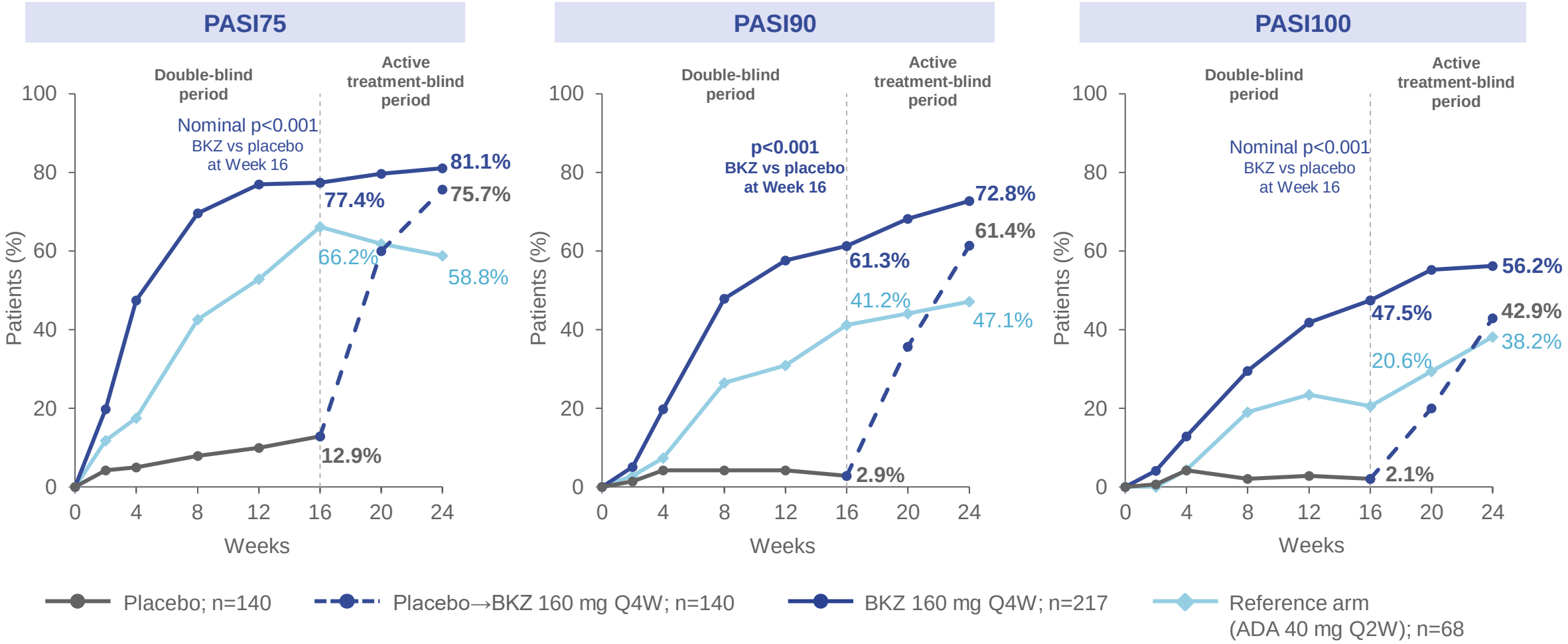
**BKZ demonstrated improvements vs placebo in achievement of ACR response criteria at Week 16**




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)

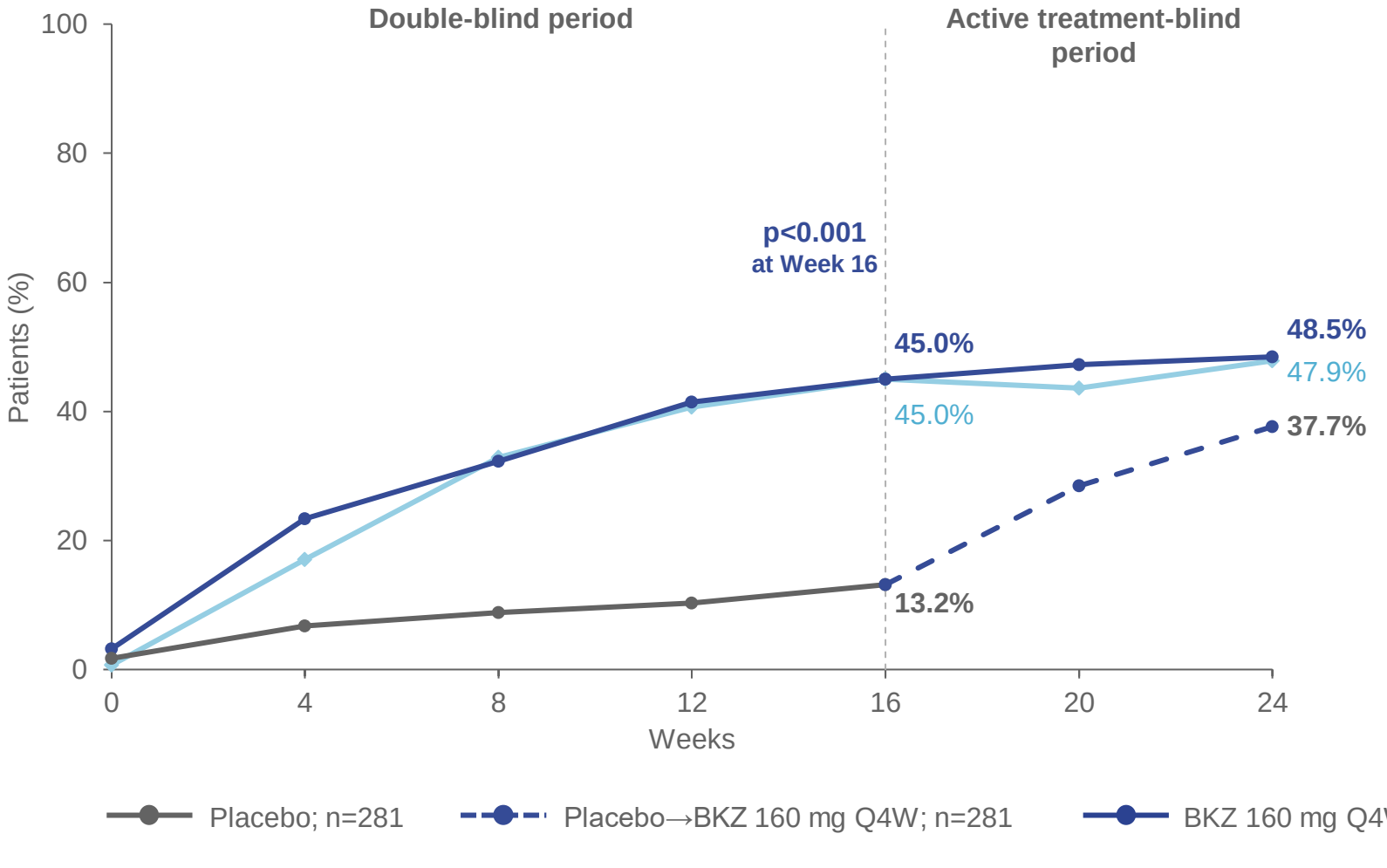
**Over half of BKZ patients achieved complete skin clearance by Week 24**




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:**

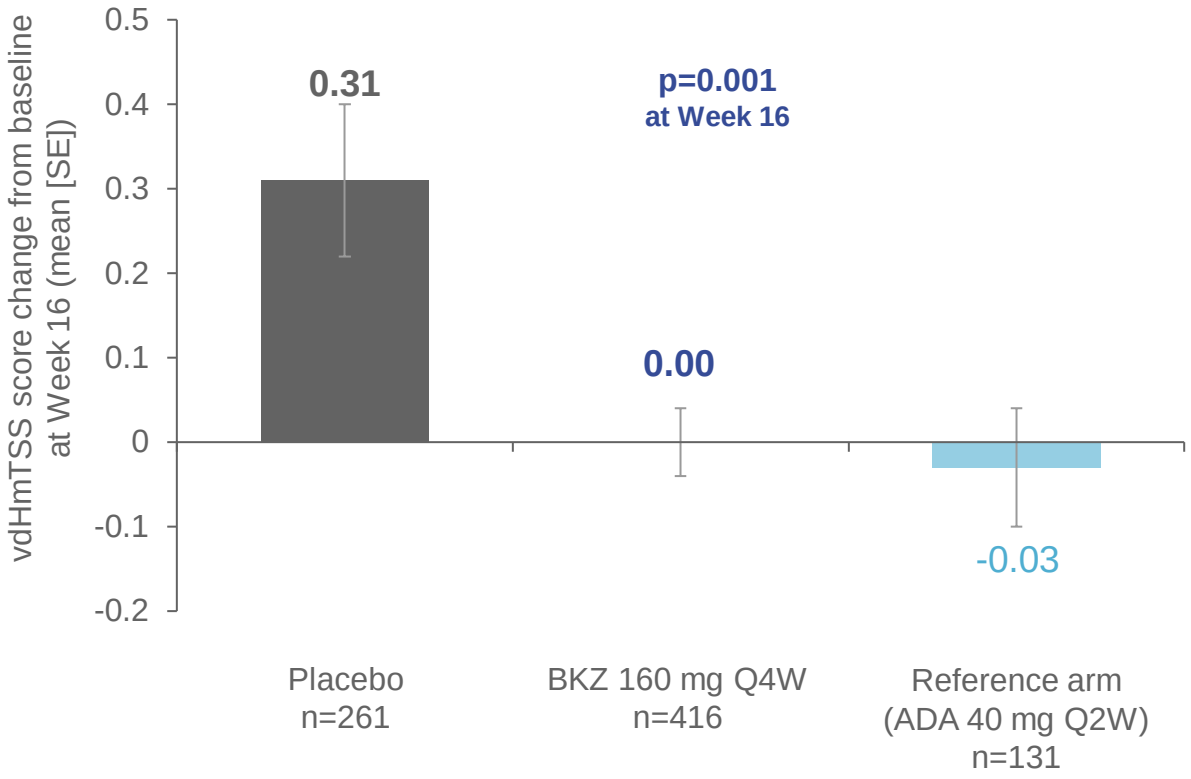
- Tender joint count ≤1
- Swollen joint count ≤1
- Psoriasis Area and Severity Index ≤1[a] or body surface area ≤3%[b]
- Patient's Assessment of Arthritis Pain ≤15 mm
- Patient global assessment-PsA ≤20 mm
- Health Assessment Questionnaire–Disability Index ≤0.5
- Tender entheseal points ≤1

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.

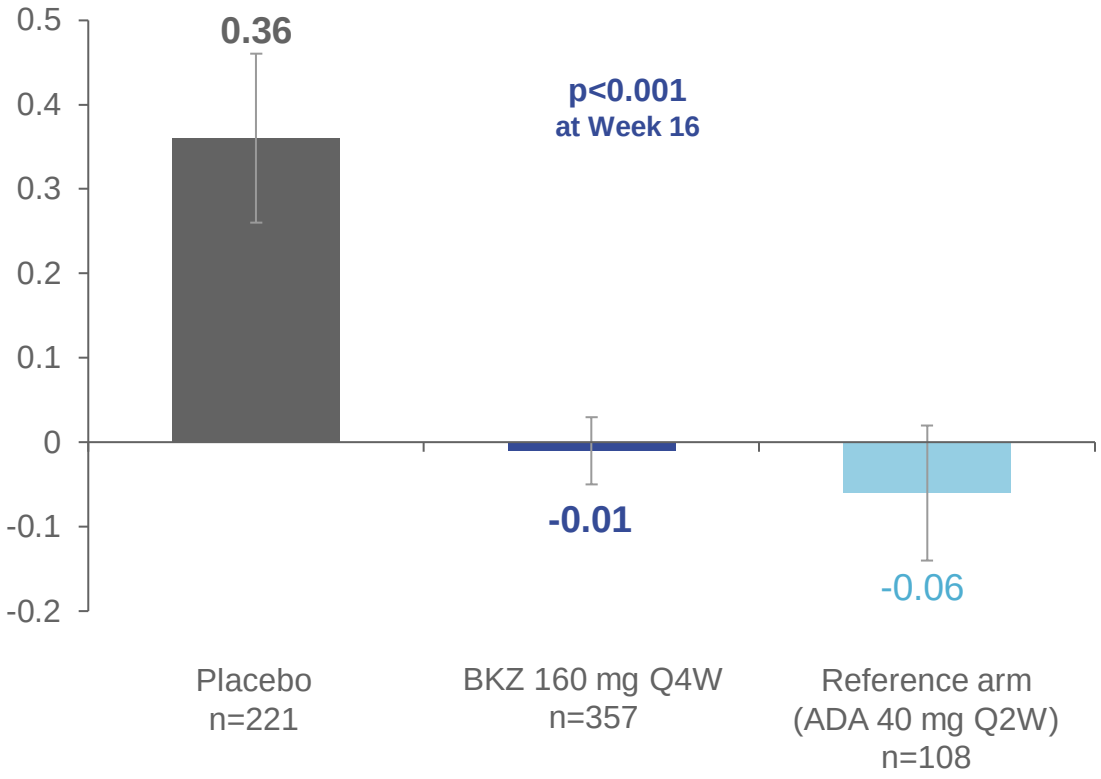
# Efficacy: Radiographic Outcomes at Week 16 (MI)

**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 |

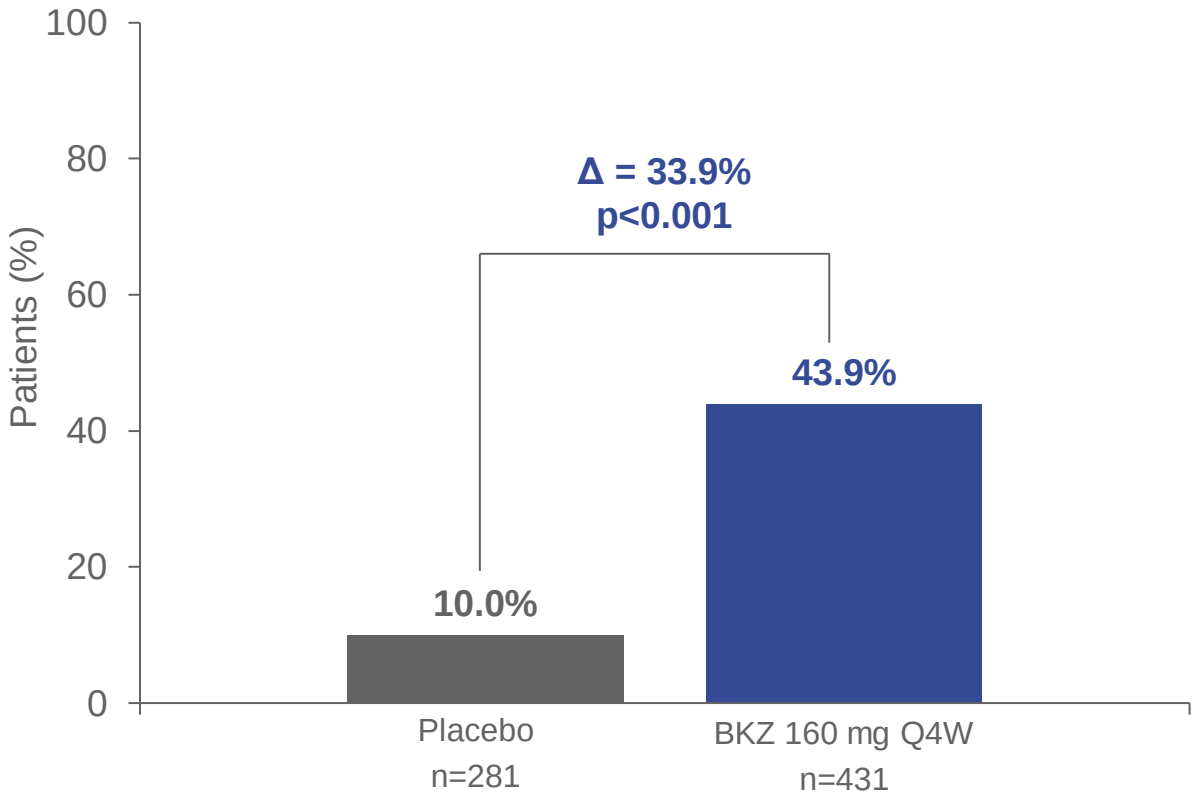
Safety set, MedDRA (Version 19.0). [a] Includes patients who switched from placebo to BKZ (events after switch only); [b] TEAEs ≥3% in any treatment arm are reported by preferred term; [c] No fungal infections were systemic; [d] All infections were mild to moderate and none were serious, 1 BKZ patient 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.

# Consistency of BKZ Across Psoriatic Arthritis Patient Populations

**Results from BE OPTIMAL (bDMARD-naïve) were consistent with those from BE COMPLETE (TNFi-IR)[1]**

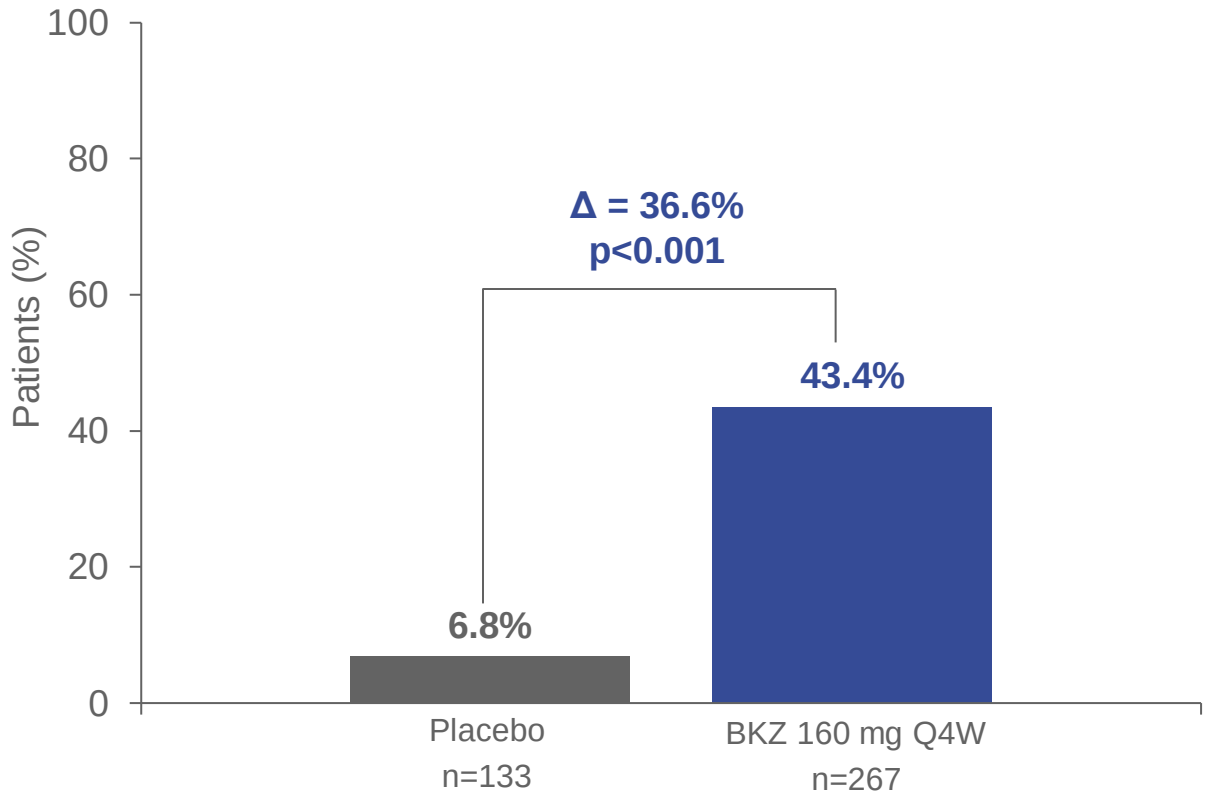
## BE OPTIMAL (bDMARD-naïve patients)

**ACR50 at Week 16 (NRI)**




## BE COMPLETE (TNF-IR patients)

**ACR50 at Week 16 (NRI)**




1. Merola JF. Ann Rheum Dis 2022; OP0255. 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; ADA: adalimumab; bDMARD: biologic disease-modifying antirheumatic drug; BKZ: bimekizumab; BSA: body surface area; NRI: non-responder imputation; PSO: psoriasis; Q2W: every 2 weeks; Q4W: every 4 weeks; TNF-IR: Tumour necrosis factor inhibitor – inadequate response.

# 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]

Consistent levels of response were observed in patients in BE OPTIMAL (bDMARD-naïve) compared to BE COMPLETE (TNF-IR patients), suggesting that bimekizumab treatment leads to improvements in joint and skin outcomes, irrespective of prior bDMARD use.

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.

# Thank You

Any Questions?