Bimekizumab Inhibited Radiographic Progression Regardless of Baseline Characteristics in bDMARD-Naïve Patients with Active Psoriatic Arthritis: 3-Year Results from a Phase 3 Study and Its Open-Label Extension

Philipp Sewerin,[1] Laura C. Coates,[2] Philip J. Mease,[3] M. Elaine Husni,[4] Mitsumasa Kishimoto,[5] Proton Rahman,[6] Enrique R. Soriano,[7] David Nicholls,[8] Nadine Goldammer,[9] Jason Coarse,[10] Peter Nash[11]

[1]Rheumazentrum Ruhrgebiet, University Hospital of the Ruhr University Bochum, Herne, Germany; [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]Department of Rheumatology, Providence-Swedish Medical Center and University of Washington, Seattle, USA; [4]Department of Rheumatic and Immunologic Diseases, Cleveland Clinic, Cleveland, USA; [5]Department of Nephrology and Rheumatology, Kyorin University School of Medicine, Tokyo, Japan; [6]Division of Rheumatology, Craig L. Dobbin Genetics Research Centre, Discipline of Medicine, Memorial University of Newfoundland, St John's, Canada; [7]Rheumatology Section, Internal Medicine Service, Hospital Italiano de Buenos Aires and University Hospital Italiano de Buenos Aires, Buenos Aires, Argentina; [8]Clinical Trials Unit, University of the Sunshine Coast, Queensland, Australia; [9]UCB, Monheim am Rhein, Germany; [10]UCB, Morrisville, USA; [11]School of Medicine, Griffith University, Brisbane, Australia.

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Objective

To explore the impact of bimekizumab (BKZ) on radiographic progression at 3 years in biological disease-modifying antirheumatic drug (bDMARD)-naïve patients with psoriatic arthritis (PsA), both overall and across predefined subgroups.

Background

- Persistent inflammation in PsA can drive structural joint damage, which may contribute to physical impairment and reduced quality of life.[1]
- Radiographic damage has been linked to disease duration, age, sex and disease activity,[2] highlighting the importance of evaluating whether treatments can durably suppress progression across clinically relevant subgroups.
- BKZ, a humanised IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has previously demonstrated sustained inhibition of radiographic progression in patients with PsA up to 2 years.[3]

Methods

- BE OPTIMAL (NCT03895203), placebo (PBO)-controlled to Week 16, assessed subcutaneous BKZ 160 mg every 4 weeks (Q4W) in bDMARD-naïve patients with PsA.
- PBO patients switched to BKZ at Week 16 (PBO/BKZ).
- Week 52 completers could enter BE VITAL (open-label extension; NCT04009499), in which all patients received BKZ 160 mg Q4W.
- This post hoc analysis assessed radiographic progression using plain radiographs of the hands and feet, scored with the van der Heijde modified Total Sharp Score (vdHmTSS; range: 0–528; higher scores indicate greater joint damage).
- Radiographs taken at baseline and 3 years (Week 148) were centrally read by two independent, experienced, treatment-blinded readers; discrepancies of ≥8 units were resolved by a third adjudicator, as per the charter.
- Subgroup analyses included risk status (at-risk [high-sensitivity C-reactive protein (hs-CRP) ≥6 mg/L and/or ≥1 bone erosion at baseline], not at-risk), PsA disease duration (<1, 1–5, >5 years), age (<45, ≥45 years), sex (male, female) and swollen joint count (SJC) (≤4 ['oligo'], >4).
- Outcomes reported at Week 148 for the BKZ Total group (PBO/BKZ and BKZ-randomised patients):
  - Proportions of patients with no radiographic progression (defined as vdHmTSS change from baseline [CfB] ≤0.5 or ≤0.0)
  - CfB in vdHmTSS, vdH joint space narrowing (JSN) and vdH erosion
- Cumulative probability of vdHmTSS CfB is additionally reported for the overall radiographic set and risk status subgroups.
- Analyses were descriptive and based on observed cases (OC) for patients with radiographs at Week 148 in the overall radiographic set and across subgroups.

Results

- Of 712 patients in the BKZ Total group, 579 had radiographs at baseline and ≥1 post-baseline visit, forming the overall radiographic set; of these, 524 had radiographs available at Week 148.
  - Baseline demographics and characteristics were similar to the overall BE OPTIMAL study BKZ Total population (**Table**).[4]
- At Week 148, most patients in the overall radiographic set had no radiographic progression (**Figure 1**).
- High proportions of patients across subgroups also experienced no radiographic progression at Week 148 according to both thresholds (**Figure 1**).
  - Greater proportions of patients not at-risk vs at-risk at baseline had no radiographic progression at Week 148.
  - Greater proportions of patients with a shorter disease duration at baseline had no radiographic progression at Week 148.
  - Greater proportions of patients aged <45 vs ≥45 years had no radiographic progression.
  - Comparable proportions of males and females had no radiographic based on vdHmTSS CfB ≤0.5, although a slightly smaller proportion of males met the more stringent threshold of ≤0.0.
  - A slightly higher proportion of patients with SJC ≤4 vs >4 at baseline experienced no radiographic progression.
- Patients at-risk, with disease duration >5 years, aged ≥45 years, male sex and SJC >4 at baseline had higher baseline vdHmTSS, vdH JSN and vdH erosion scores compared with their respective counterparts. However, radiographic progression at Week 148 was minimal, both in the overall radiographic set and across subgroups (**Figure 2**).
- The cumulative probability of structural progression remained minimal, with most patients showing no progression (**Figure 3**). These findings were consistent with those reported at 2 years.[3]

Conclusions

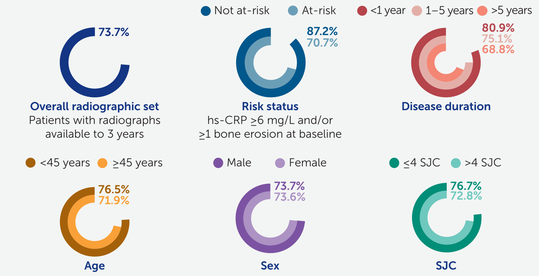
Bimekizumab treatment was associated with minimal radiographic progression over 3 years in bDMARD-naïve patients with PsA, with consistent efficacy across clinically relevant subgroups. The highest proportions of patients with no radiographic progression were those not at-risk, with a shorter disease duration, aged <45 years and with SJC ≤4. Overall, the likelihood of meaningful structural progression remained low over the 3-year treatment period.

Summary

Persistent inflammation in patients with **PsA** can lead to irreversible **structural damage**, reducing quality of life.

Radiographic progression was assessed at **3 years** with **bimekizumab** treatment in **bDMARD-naïve patients** with **PsA** using the **vdHmTSS**.

Most patients experienced **no radiographic progression[a] at Week 148**, overall and across subgroups (OC):



Bimekizumab treatment was associated with **minimal radiographic progression** over **3 years** in **bDMARD-naïve** patients with **PsA**, which was consistent across **clinically relevant subgroups**; highest proportions were seen among those not at-risk, with a disease duration <1 year, aged <45 years and with SJC ≤4.

[a] Defined as vdHmTSS change from baseline ≤0.5.

Table

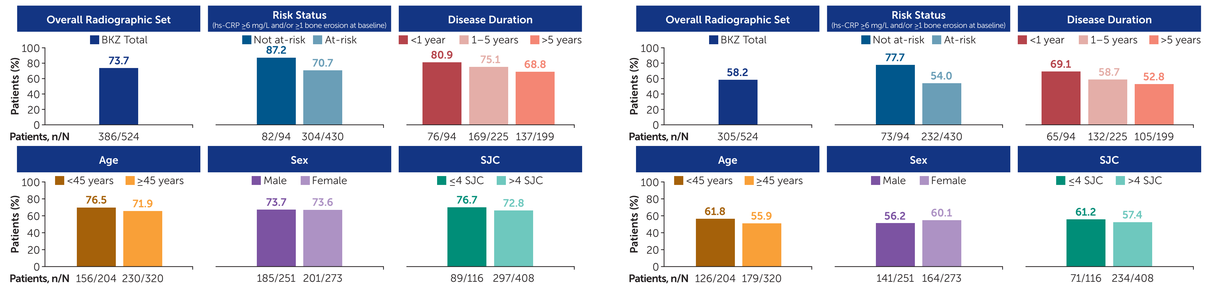
Demographics and baseline characteristics for the overall radiographic set

	BKZ 160 mg Q4W Total (n=579)
Age, years, mean (SD)	48.1 (12.0)
Sex, male, n (%)	277 (47.8)
BMI, kg/m², mean (SD)	29.1 (6.1)
Race,[a] n (%)	
American Indian/Alaskan native	1 (0.2)
Asian	22 (3.8)
Black	1 (0.2)
Native Hawaiian or other Pacific Islander	0
White	549 (94.8)
Other/mixed	5 (0.9)
Time since PsA diagnosis, years, mean (SD)	5.8 (6.7)[b]
Any csDMARD at baseline	413 (71.3)
Concomitant methotrexate, n (%)	348 (60.1)
Affected BSA ≥3%, n (%)	297 (51.3)
PASI, mean (SD)	8.2 (6.5)
Enthesitis (LEI >0), n (%)	179 (30.9)[c]
LEI score, mean (SD)	2.6 (1.5)
Dactylitis (LDI >0), n (%)	76 (13.1)[c]
LDI score, mean (SD)	47.2 (51.1)
Nail psoriasis (mNAPSI >0), n (%)	341 (58.9)[d]
mNAPSI score, mean (SD)	4.1 (2.3)

Radiographic set. BKZ Total includes both PBO/BKZ patients and BKZ-randomised patients. Baseline data reported for all patients with radiographs available at baseline and ≥1 post-baseline timepoint. **[a]** Data missing for 1 patient; **[b]** Data missing for 8 patients; **[c]** Data missing for 5 patients; **[d]** Data missing for 6 patients.

Figure 1

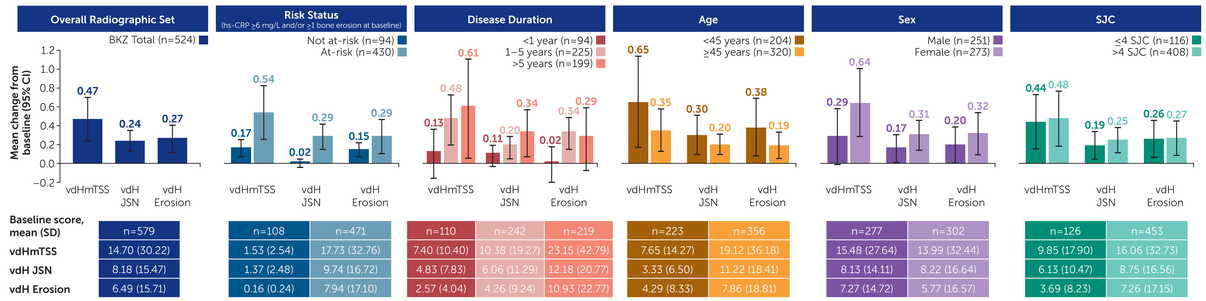
Proportion of BKZ Total patients with no radiographic progression at Week 148 (OC)



Radiographic set. BKZ Total group includes both PBO/BKZ patients and BKZ-randomised patients. Data are reported as observed case for all patients with radiographs available at baseline and Week 148.

Figure 2

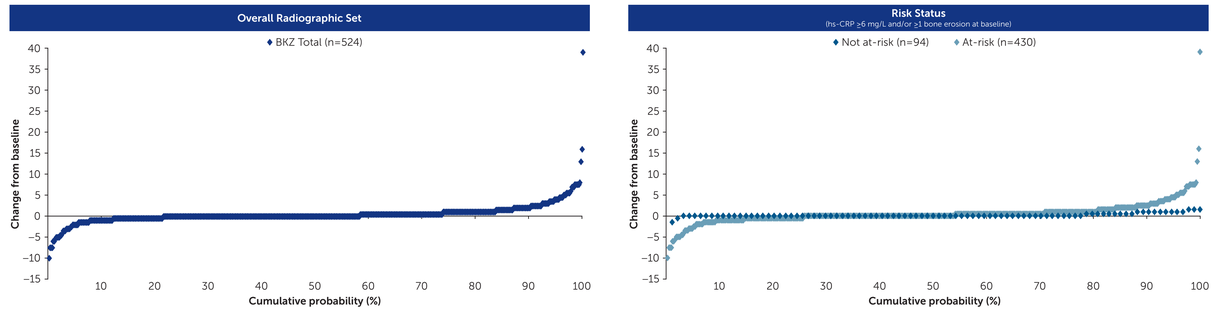
Mean CfB in radiographic outcomes in BKZ Total patients at Week 148 (OC)



Radiographic set. BKZ Total includes both PBO/BKZ patients and BKZ-randomised patients. Baseline values are reported for all patients with radiographs available at baseline and ≥1 post-baseline timepoint. Data at Week 148 are reported as observed case for all patients with radiographs available at baseline and Week 148.

Figure 3

Cumulative probability of vdHmTSS change from baseline in BKZ Total patients at Week 148 (OC)



Radiographic set. BKZ Total includes both PBO/BKZ patients and BKZ-randomised patients. Data are reported as observed case for all patients with radiographs available at baseline and Week 148.

bDMARD: biologic disease-modifying antirheumatic drug; **BKZ:** bimekizumab; **BMI:** body mass index; **BSA:** body surface area; **CfB:** change from baseline; **CI:** confidence interval; **csDMARD:** conventional synthetic disease-modifying antirheumatic drug; **hs-CRP:** high-sensitivity C-reactive protein; **IL:** interleukin; **JSN:** joint space narrowing; **LDI:** Leeds Dactylitis Index; **LEI:** Leeds Enthesitis Index; **mNAPSI:** modified Nail Psoriasis Severity Index; **OC:** observed case; **OLE:** open-label extension; **PASI:** Psoriasis Area and Severity Index; **PBO:** placebo; **PsA:** psoriatic arthritis; **Q4W:** every 4 weeks; **SD:** standard deviation; **SJC:** swollen joint count; **vdHmTSS:** van der Heijde modified Total Sharp Score.

References: [1]van der Heijde D. Arthritis Res Ther 2020;22:18; [2]Koc GH. RMD Open 2024;10:e004080; [3]Coates LC. Ann Rheum Dis 2025;84:1309–10; [4]Gossec L. Rheumatology 2026; keag118.

Author Contributions: Substantial contributions to study conception/design; or acquisition/analysis/interpretation of data: **PS**, **LC**, **PM**, **MEH**, **MK**, **PR**, **ERS**, **DN**, **NG**, **JC**, **PN**; Drafting of the publication, or reviewing it critically for important intellectual content: **PS**, **LC**, **PM**, **MEH**, **MK**, **PR**, **ERS**, **DN**, **NG**, **JC**, **PN**. Final approval of the publication: **PS**, **LC**, **PM**, **MEH**, **MK**, **PR**, **ERS**, **DN**, **NG**, **JC**, **PN**. **Author Disclosures: PS:** Speakers bureau for AbbVie, Amgen, AXIOM Health, Biogen, BMS, Celgene, Chugai Pharma Marketing Ltd./Chugai Europe, Deutscher Psoriasis-Bund, Gilead Sciences, Hexal Pharma, Janssen-Cilag, Johnson & Johnson, Lilly/Lilly Europe/Lilly Global, medi-login, Mediri GmbH, Novartis Pharma, Onkowissen GmbH, Pfizer, Roche Pharma, Rheumazentrum Rhein-Ruhr, Sanofi-Genzyme, Spirit Medical Communication, Swedish Orphan Biovitrum and UCB; consultant for AbbVie, Amgen, AXIOM Health, Biogen, BMS, Celgene, Chugai Pharma Marketing Ltd./Chugai Europe, Deutscher Psoriasis-Bund, Gilead Sciences, Hexal Pharma, Janssen-Cilag, Johnson & Johnson, Lilly/Lilly Europe/Lilly Global, medi-login, Mediri GmbH, Novartis Pharma, Onkowissen GmbH, Pfizer, Roche Pharma, Rheumazentrum Rhein-Ruhr, Sanofi-Genzyme, Spirit Medical Communication, Swedish Orphan Biovitrum and UCB; **LCC:** Grant/research support from AbbVie, Amgen, Celgene, Eli Lilly, Gilead, Janssen, Novartis, Pfizer and UCB; consultant for AbbVie, Amgen, BMS, Boehringer Ingelheim, Celgene, Domain, Eli Lilly, Galapagos, Gilead, Janssen, Moonlake Immunotherapeutics, Novartis, Pfizer and UCB; speaking fees from AbbVie, Amgen, Biogen, Celgene, Eli Lilly, Galapagos, Gilead, GSK, Janssen, medac, Novartis, Pfizer and UCB. **PJM:** Research grants from AbbVie, Acelyrin, Amgen, BMS, Eli Lilly and Company, Johnson & Johnson Innovative Medicine, Novartis, Pfizer, Sana and UCB; consulting fees from AbbVie, Acelyrin, Amgen, BMS, Century, Cullinan, Eli Lilly and Company, Inmagene, Johnson & Johnson Innovative Medicine, MoonLake Immunotherapeutics, Novartis, Pfizer, Spyre, Takeda and UCB; speakers bureau fees from AbbVie, Amgen, Eli Lilly and Company, Johnson & Johnson Innovative Medicine, Novartis, Pfizer and UCB. **MEH:** Advisory board member and consultant for AbbVie, Amgen, BMS, Eli Lilly, Janssen, Novartis, Pfizer and UCB. **MK:** Speakers bureau fees from AbbVie, Amgen, Asahi-Kasei Pharma, Ayumi Pharma, BMS, Chugai, Daiichi Sankyo, Eisai, Gilead, Janssen, Lilly, Novartis, Tanabe-Mitsubishi and UCB; consultant for AbbVie, Amgen, Asahi-Kasei Pharma, Ayumi Pharma, BMS, Chugai, Gilead, Janssen, Lilly, Novartis, Takeda, Tanabe-Mitsubishi and UCB. **PR:** Consulting fees from Abbott, AbbVie, Amgen, BMS, Celgene, Eli Lilly and Company, Janssen, Novartis, Pfizer and UCB; research grants from Janssen and Novartis. **ERS:** Grants for research and clinical trials and honoraria for advice and lectures on behalf of AbbVie, BMS, Eli Lilly, GSK, Johnson & Johnson, Novartis, Pfizer, Raffo and UCB. **DN:** Research support from AbbVie, BMS, Eli-Lilly, Gilead, Incannex, Janssen, Novartis, Pfizer, Servatus, Sun Pharma, UCB; advisory board or speaker fees from AbbVie, AstraZeneca, Janssen, Novartis, Pfizer, Sandoz and UCB. **NG**, **JC:** Employee and shareholder of UCB. **PN:** Speakers bureau fees from AbbVie, AstraZeneca, BMS, Janssen, Lilly, Novartis, Pfizer and UCB; consultant for AbbVie, AstraZeneca, BMS, Janssen, Lilly, Novartis, Pfizer, Servatus, UCB and Xencor; grant/research support from AbbVie, Amgen, AstraZeneca, BMS, Janssen, Lilly, Novartis, Pfizer, Servatus, UCB and Xencor. **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 Lyes Derouchie, PhD, UCB, for editorial review and publication coordination, Becky Sainty, MSc, Costello Medical, Cambridge, UK for medical writing and editorial assistance, and the Costello Medical Creative team for design support. Funded by UCB. All costs associated with development of this presentation were funded by UCB.

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