Bimekizumab reduced psoriatic arthritis impact in patients with psoriasis: Up to 2-year results from two phase 3 studies

Laure Gossec,[1] Dafna D Gladman,[2] Paolo Gisondi,[3] Maarten de Wit,[4] Alexis Ogdie,[5] Barbara Ink,[6] Vanessa Taieb,[7] Jérémy Lambert,[7] Laura C Coates[8]

Objective

To assess the efficacy of bimekizumab (BKZ) treatment on disease impact up to 2 years, using the Psoriatic Arthritis Impact of Disease-12 (PsAID-12) questionnaire, in patients with active psoriatic arthritis (PsA) and baseline psoriasis affecting 3%–10%, or >10% body surface area (BSA).

Background

- PsA negatively impacts health-related quality of life; patients with concomitant psoriasis may further be impacted.[1]
- The patient-reported PsAID-12 questionnaire assesses the physical, social, and psychological impact of PsA.[2]
- BKZ, a humanised monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated sustained reductions in disease impact to 1 year in patients with active PsA from the phase 3 BE OPTIMAL and BE COMPLETE studies.[3–5]

Methods

- BE OPTIMAL (NCT03895203; biologic disease-modifying antirheumatic drug [bDMARD]-naïve) and BE COMPLETE (NCT03896581; tumour necrosis factor inhibitor inadequate response/intolerance [TNFi-IR]) assessed subcutaneous BKZ 160 mg every 4 weeks (Q4W) in patients with active PsA.[3,4]
- In BE OPTIMAL, patients were randomised 3:2:1 to BKZ 160 mg Q4W, placebo (PBO) and reference arm (adalimumab [ADA] 40 mg Q2W). In BE COMPLETE, patients were randomised 2:1 to BKZ 160 mg Q4W and PBO. In both studies, PBO patients switched to BKZ at Week 16 (PBO/BKZ). In BE OPTIMAL, patients receiving ADA switched to BKZ at Week 52 (ADA/BKZ) with no washout period between treatments.
- PsAID-12 total and single-item domain scores range from 0–10; higher scores indicate worse status.[2]
- Change from baseline (CfB), clinically meaningful improvement response rates (≥3-point decrease from baseline in patients with baseline PsAID-12 score ≥3) and symptom or impact severity based on PsAID-12 total score[6] were assessed for patients with baseline psoriasis affecting ≥3%–≤10% and >10% BSA to Week 104 of BE OPTIMAL and Week 88 of BE COMPLETE.
- Data are reported as observed case (OC) and using multiple imputation (MI; continuous) or non-responder imputation (NRI; binary).

Results

- Of patients with baseline psoriasis BSA ≥3%, 365/425 (85.9%) bDMARD-naïve and 221/264 (83.7%) TNFi-IR patients completed Week 104/88 of BE OPTIMAL and BE COMPLETE, respectively. Baseline characteristics were generally comparable across BSA subgroups and treatment arms within trials (**Supplementary Table 1**, accessible via the QR code).
- Baseline PsAID-12 total scores were numerically higher in the >10% BSA subgroup than the ≥3%–≤10% BSA subgroup across both treatment groups and studies (**Figure 1A**).
- In both BSA subgroups, improvements in PsAID-12 total score and achievement of clinically meaningful improvement response rate were sustained to Week 104/88 in bDMARD-naïve and TNFi-IR patients with baseline psoriasis (**Figure 1**). Improvements in disease impact were generally numerically greater in the >10% BSA subgroup compared with the ≥3%–≤10% BSA subgroup, possibly due to greater disease severity at baseline.
  - Across BSA subgroups, ADA/BKZ patients sustained Week 52 outcomes to Week 104 following the switch to BKZ.
- Similarly, improvements in pain, fatigue, skin problems and functional capacity domains with BKZ treatment were sustained to Week 104/88 across the ≥3%–≤10% and >10% BSA subgroups (**Figure 2**). These domains were most impacted at baseline and showed the greatest improvements at Week 104/88. All PsAID-12 single-item domains are reported in **Supplementary Table 2–3**, accessible via the QR code.
  - ADA/BKZ patients sustained improvements from Week 52 to Week 104 after switching to BKZ, with further reductions in impact observed in the skin problems domain.
- Proportions of patients achieving no or low symptom or impact severity in the ≥3%–≤10% and >10% BSA subgroups at Week 52/40 were sustained to Week 104/88 across both bDMARD-naïve and TNFi-IR patients (**Figure 3**).
- A limitation of this analysis is the small patient numbers in some subgroups, which may limit interpretation of these results.

Conclusions

BKZ treatment resulted in clinically meaningful improvements in patient-reported disease impact that were sustained up to 2 years in patients with PsA and psoriasis. Results were consistent between BSA subgroups and across bDMARD-naïve and TNFi-IR patients.

Summary

The **longer-term efficacy** of **BKZ** treatment on **disease impact** was assessed, using the **PsAID-12** questionnaire, up to 2 years in patients with **active PsA** and **baseline psoriasis** who were **bDMARD-naïve (BE OPTIMAL)** or **TNFi-IR (BE COMPLETE)**.

Patients achieving no or low symptom impact
(PsAID-12 total score ≤1.95)

In **BKZ-randomised** patients with **psoriasis** affecting **≥3%–≤10%** BSA

bDMARD-naïve (BE OPTIMAL at Week 104)	TNFi-IR (BE COMPLETE at Week 88)
57.6%	58.7%

In **BKZ-randomised** patients with **psoriasis** affecting **>10%** BSA

bDMARD-naïve (BE OPTIMAL at Week 104)	TNFi-IR (BE COMPLETE at Week 88)
56.2%	53.7%

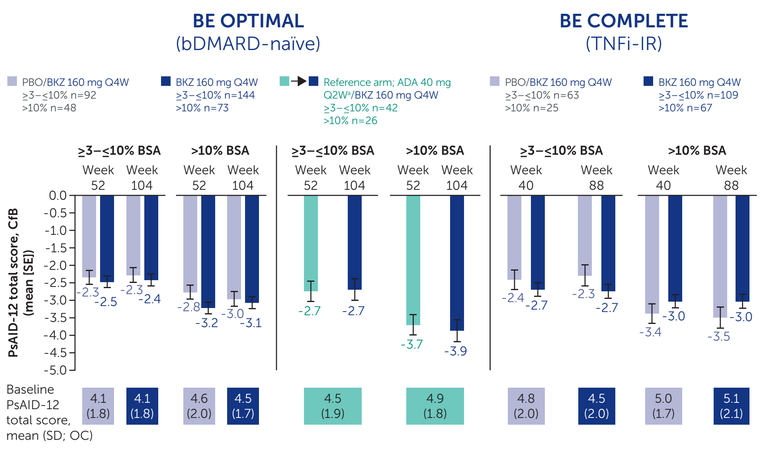
Observed improvements were sustained to 2 years with BKZ treatment in domains that patients reported to be most impactful at baseline, including:

Pain · Fatigue · Skin problems · Functional capacity

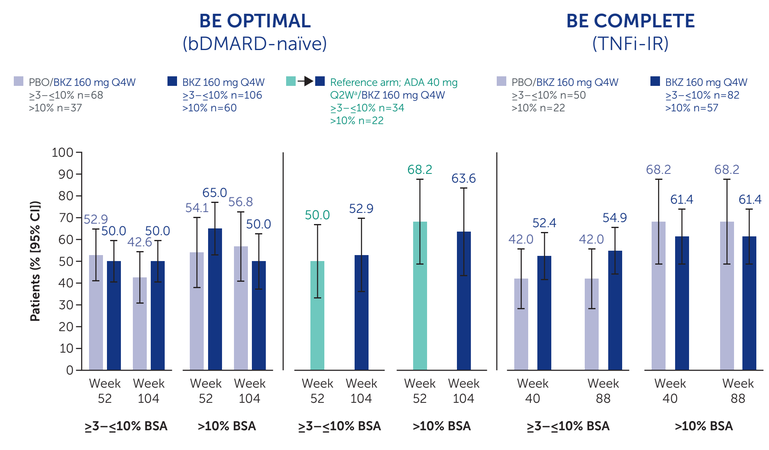
BKZ treatment demonstrated **sustained, clinically meaningful reductions** in **disease impact** up to 2 years in patients with **PsA and baseline psoriasis** who were **bDMARD-naïve** or **TNFi-IR**

Figure 1 PsAID-12 total score (A) change from baseline and (B) clinically meaningful improvement response rate in patients with baseline psoriasis ≥3% BSA at Week 52/40 and Week 104/88 (MI, NRI, OC)

A) PsAID-12 total score change from baseline (MI, OC)



B) PsAID-12 total score clinically meaningful improvement response rate[b] (NRI)

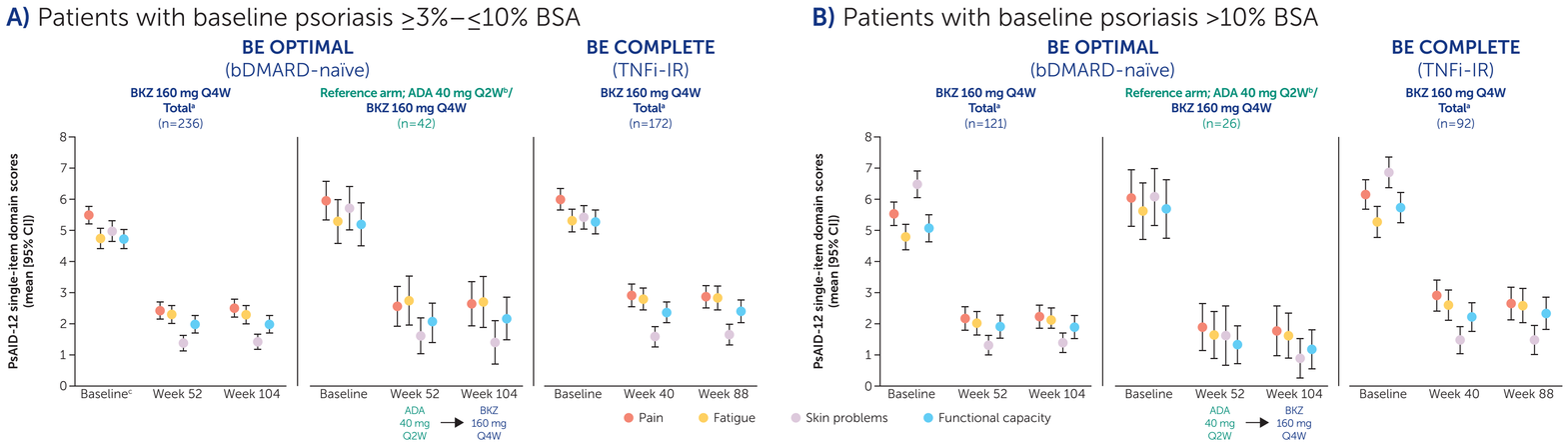


Randomised set, in patients with psoriasis involving ≥3%–≤10% and >10% BSA at baseline. PsAID-12 scores range from 0–10; higher scores indicate worse status.[2] [a] Reference arm; study not powered for statistical comparisons of ADA to BKZ or PBO; [b] Clinically meaningful improvement response: ≥3 point decrease from baseline in patients with baseline PsAID-12 score ≥3.

Figure 2 Pain, fatigue, skin problems and functional capacity domain mean scores at baseline, Week 52/40 and Week 104/88 (MI, OC)

A) Patients with baseline psoriasis ≥3%–≤10% BSA

B) Patients with baseline psoriasis >10% BSA

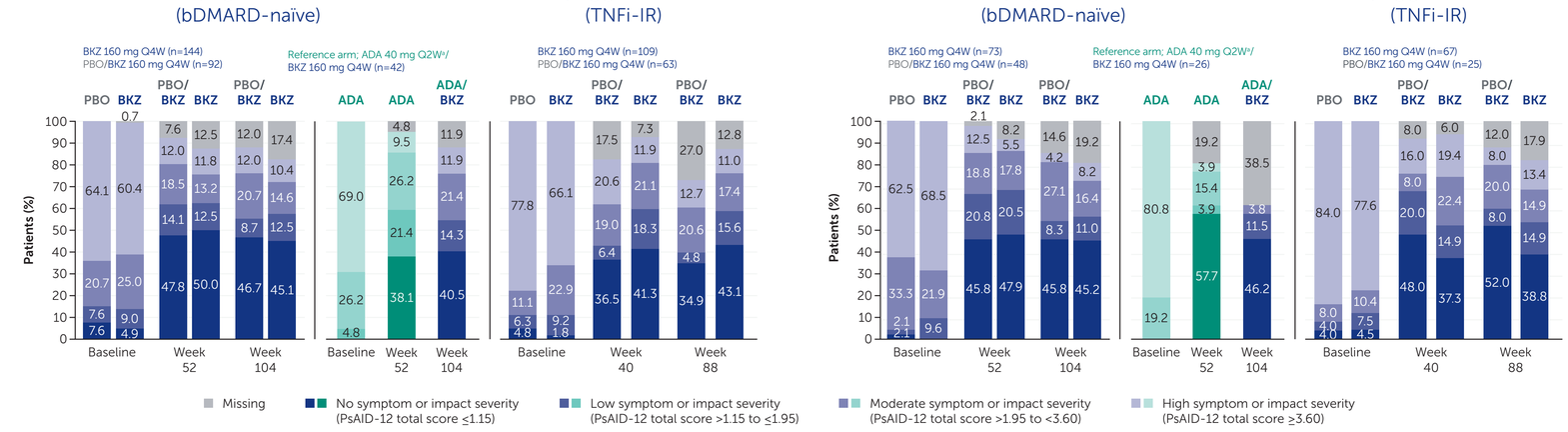


Randomised set. PsAID-12 scores range from 0–10; higher scores indicate worse status.[2] Baseline data are reported as OC; Week 52/40 and Week 104/88 data are reported using MI. [a] Includes patients who switched from PBO to BKZ; [b] Reference arm; study not powered for statistical comparisons of ADA to BKZ or PBO; [c] OC: n=235. All PsAID-12 single-item domain scores at baseline and change from baseline at Week 52/40 and Week 104/88 are presented by treatment arm in **Supplementary Table 2–3**, accessible via the QR code.

Figure 3 Symptom or impact severity by visit for PsAID-12 total score at baseline, Week 52/40 and Week 104/88 (no imputation)

A) Patients with baseline psoriasis ≥3%–≤10% BSA

B) Patients with baseline psoriasis >10% BSA



Randomised set. [a] Reference arm; study not powered for statistical comparisons of ADA to BKZ or PBO.

ADA: adalimumab; **bDMARD:** biologic disease-modifying antirheumatic drug; **BKZ:** bimekizumab; **BSA:** body surface area; **CfB:** change from baseline; **CI:** confidence interval; **IL:** interleukin; **MI:** multiple imputation; **NRI:** non-responder imputation; **OC:** observed case; **PBO:** placebo; **PsA:** psoriatic arthritis; **PsAID-12:** Psoriatic Arthritis Impact of Disease-12; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks; **SD:** standard deviation; **SE:** standard error; **TNFi-IR:** prior inadequate response/intolerance to tumour necrosis factor inhibitors.

Institutions: [1]Sorbonne Universite and Pitie-Salpetriere Hospital, Paris, France; [2]Schroeder Arthritis Institute, Krembil Research Institute, Toronto Western Hospital, University Health Network, University of Toronto, Ontario, Canada; [3]Section of Dermatology and Venereology, Department of Medicine, University of Verona, Verona, Italy; [4]Patient Research Partner, Stichting Tools, Amsterdam, The Netherlands; [5]Department of Medicine, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, Pennsylvania, USA; [6]UCB Pharma, Slough, UK; [7]UCB Pharma, Colombes, France; [8]Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Diseases, University of Oxford and Oxford Biomedical Research Centre, Oxford University Hospitals NHS Trust, Oxford, UK.

References: [1]Walsh JA et al. Joint Bone Spine 2023;90:105534; [2]Orbai AM et al. J Rheumatol 2019;46:990–5; [3]Ritchlin CT et al. Ann Rheum Dis 2023;82:1404–14; [4]Coates LC et al. RMD Open 2024;10: e003855; [5]Gladman DD et al. Arthritis Rheumatol 2023;75(suppl 9); [6]Gossec L et al. RMD Open 2024;10:e003548.

Author Contributions: Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **LG**, **DDG**, **PG**, **MdW**, **AO**, **BI**, **VT**, **JL**, **LCC**; Drafting of the publication, or reviewing it critically for important intellectual content: **LG**, **DDG**, **PG**, **MdW**, **AO**, **BI**, **VT**, **JL**, **LCC**; Final approval of the publication: **LG**, **DDG**, **PG**, **MdW**, **AO**, **BI**, **VT**, **JL**, **LCC**. **Author Disclosures: LG:** Grants or contracts from AbbVie, Biogen, Eli Lilly and Company, Novartis, and UCB Pharma; Consulting fees from AbbVie, BMS, Celltrion, Janssen, Novartis, Pfizer, and UCB Pharma; Honoraria for lectures from AbbVie, Amgen, BMS, Celltrion, Eli Lilly and Company, Janssen, MSD, Novartis, Pfizer, Stada, and UCB Pharma; Received support for attending meetings and/or travel from MSD, Novartis, Pfizer; Received medical writing support from AbbVie, Amgen, Galapagos, Janssen, Pfizer, and UCB Pharma; Membership on an entity's Board of Directors or advisory committees: EULAR Treasurer. **DDG:** Consultant and/or received grant support from AbbVie, Amgen, BMS, Eli Lilly and Company, Gilead, Galapagos, Janssen, Novartis, Pfizer, and UCB Pharma. **PG:** Consultant for AbbVie, Abiogen, Almirall, Celgene, Eli Lilly and Company, Janssen, LEO Pharma, Merck, MSD, Novartis, Otsuka, Pfizer, Pierre Fabre, Sanofi, and UCB Pharma. **MdW:** Over the last five years Stichting Tools has received fees for lectures or consultancy provided by MdW from Celgene, Eli Lilly and Company, Janssen-Cilag, Pfizer, and UCB Pharma. **AO:** Grant/research support from AbbVie, Amgen, Janssen, Novartis, and Pfizer; Consultant of AbbVie, Amgen, BMS, Celgene, CorEvitas, Eli Lilly and Company, GSK, Gilead, Janssen, Novartis, Pfizer, Takeda, and UCB Pharma. **BI:** Employee of UCB Pharma; Shareholder of AbbVie, GSK, and UCB Pharma. **VT**, **JL:** Employees and shareholders of UCB Pharma. **LCC:** Grants/research support from AbbVie, Amgen, Celgene, Eli Lilly and Company, Gilead, Janssen, Novartis, Pfizer, and UCB Pharma; Consultant for AbbVie, Amgen, BMS, Boehringer Ingelheim, Celgene, Domain, Eli Lilly and Company, Galapagos, Gilead, Janssen, Moonlake Immunotherapeutics, Novartis, Pfizer, and UCB Pharma; Speaking fees from AbbVie, Amgen, Biogen, Celgene, Eli Lilly and Company, Galapagos, Gilead, GSK, Janssen, medac, Novartis, Pfizer, 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 these studies. The authors acknowledge Heather Edens, PhD, UCB Pharma, Smyrna, Georgia, USA for publication coordination, David Morgan, PhD, Costello Medical, Manchester, UK for medical writing and editorial assistance, and the Costello Medical Creative team for design support. These studies were funded by UCB Pharma. All costs associated with development of this presentation were funded by UCB Pharma.

To receive a copy of this poster, scan the QR code or visit:
UCBposters.com/IFPA2024
Poster ID: 81
Link expiration: 13 July 2024