Bimekizumab-Treated Patients with Active PsA Showed Sustained Improvement in Disease Symptoms Assessed by the PsA Impact of Disease (PsAID)-12 Questionnaire: 1-Year Results Reported from Two Phase 3 Studies

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Objective

To report the impact of bimekizumab (BKZ) treatment on patient-reported symptoms and health-related quality of life (HRQoL), assessed by the Psoriatic Arthritis Impact of Disease-12 (PsAID-12) questionnaire, in patients who were biologic DMARD (bDMARD)-naïve or had intolerance or inadequate response to TNF inhibitors (TNFi-IR).

Background

- The PsAID-12 questionnaire is a patient-reported outcome measure assessing the impact of psoriatic arthritis (PsA) on 12 physical, social, and psychological domains.
- GRAPPA-OMERACT has provisionally endorsed PsAID-12 as a core outcome measure for HRQoL in clinical trials.[1]
- BKZ, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated efficacy and tolerability to 52 weeks in patients with active PsA.[2,3]

Methods

- The phase 3 BE OPTIMAL (NCT03895203) and BE COMPLETE (NCT03896581) trials assessed BKZ 160 mg every 4 weeks in patients with PsA who were bDMARD-naïve or TNFi-IR, respectively (**Figure 1**).
- Patients completing BE OPTIMAL at Week 52 or BE COMPLETE at Week 16 could enter BE VITAL (open-label extension [OLE]; NCT04009499); BE COMPLETE plus BE VITAL is referred to as 'BE COMPLETE' hereafter.
- In both BE OPTIMAL and BE COMPLETE, placebo (PBO) patients switched to BKZ treatment at Week 16 (PBO/BKZ). Data reported here for up to 52 weeks of therapy from both trials.
- PsAID-12 total and single-item domain scores range from 0–10; higher scores indicate worse status.
- Here, we report PsAID-12 change from baseline (CfB) and clinically meaningful within-patient improvement responses (≥3-point decrease from baseline when respective PsAID-12 score ≥3 at baseline) up to 1 year (collected to Week 40 in BE COMPLETE).
- Missing data were imputed using multiple imputation (MI) for continuous and non-responder imputation (NRI) for binary outcomes.

Results

- 770/852 (90.4%) patients completed Week 52 of BE OPTIMAL and 360/400 (90.0%) patients completed Week 40 of BE COMPLETE.*
- Baseline characteristics were generally similar across treatment arms within trials (**Table 1**).
- BKZ-treated patients demonstrated numerically greater mean improvements in PsAID-12 total score at Week 16 compared with PBO patients (**Figure 2**).
- Improvements were sustained to Week 52/40 for BKZ-treated patients; PBO/BKZ patients achieved similar improvements to BKZ-randomized patients at this timepoint.
- In both trials, improvements from baseline in PsAID-12 single-item domain scores were observed across all domains at Week 16 and sustained to Week 52/40 on BKZ; greatest improvements were observed in domains with highest impact at baseline, including pain, fatigue, skin problems, and functional capacity (**Figure 3**).
- Greater proportions of BKZ-randomized patients demonstrated clinically meaningful within-patient improvement compared with PBO patients at Week 16; by Week 52/40, similar proportions of BKZ-randomized and PBO/BKZ patients achieved clinically meaningful within-patient improvement responses across single-item domains (**Figure 4**).

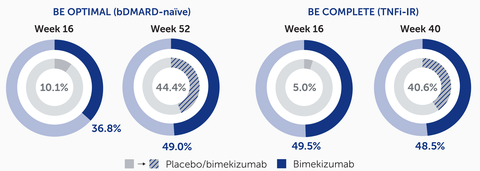
Conclusions

Improvements in PsAID-12 total and single-item domain scores at Week 16 were sustained up to 1 year with BKZ treatment. Results were similar between the two trials, demonstrating consistent responses in bDMARD-naïve and TNFi-IR patients with active PsA.

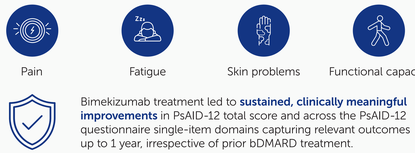
Summary

The **impact of bimekizumab treatment** on patient-reported symptoms and health-related quality of life was assessed using the **PsA-specific PsAID-12 questionnaire** in patients with **active PsA** across **BE OPTIMAL (bDMARD-naïve)** and **BE COMPLETE (TNFi-IR)**.

Proportion of patients that achieved clinically meaningful response in PsAID-12 total score:



Improvements were observed with bimekizumab treatment in **domains that patients reported to be most impactful** at baseline, including:



Bimekizumab treatment led to **sustained, clinically meaningful improvements** in PsAID-12 total score and across the PsAID-12 questionnaire single-item domains capturing relevant outcomes up to 1 year, irrespective of prior bDMARD treatment.

Table 1 Baseline patient characteristics, disease activity, and PsAID-12 total and single-item domain scores

	BE OPTIMAL (bDMARD-naïve)		BE COMPLETE (TNFi-IR)	
	Placebo (n=281)	BKZ 160 mg Q4W (n=431)	Placebo (n=133)	BKZ 160 mg Q4W (n=267)
Patient characteristics				
Age, years, mean (SD)	48.7 (11.7)	48.5 (12.6)	51.3 (12.9)	50.1 (12.4)
Male, n (%)	127 (45.2)	201 (46.6)	60 (45.1)	130 (48.7)
Time since first PsA diagnosis, years, mean (SD)	5.6 (6.5)[a]	6.0 (7.3)[b]	9.2 (8.1)[c]	9.6 (9.9)[d]
Disease activity				
BSA affected by psoriasis ≥3%, n (%)	140 (49.8)	217 (50.3)	88 (66.2)	176 (65.9)
PASI score,[e] mean (SD)	7.9 (5.6)	8.2 (6.8)	8.5 (6.6)	10.1 (9.1)
TJC (of 68 joints), mean (SD)	17.1 (12.5)	16.8 (11.8)	19.3 (14.2)	18.4 (13.5)
SJC (of 66 joints), mean (SD)	9.5 (7.3)	9.0 (6.2)	10.3 (8.2)	9.7 (7.5)
PsAID-12 scores,[f] mean (SD)				
Total score	4.1 (1.9)	3.9 (1.9)	4.4 (2.0)	4.5 (2.1)
Pain	5.5 (2.2)	5.3 (2.3)	5.9 (2.4)	5.8 (2.3)
Fatigue	4.8 (2.5)	4.6 (2.5)	4.9 (2.6)	5.2 (2.5)
Skin problems	4.4 (2.8)	4.4 (2.8)	5.4 (2.6)	5.1 (2.8)
Work and/or leisure activities	4.5 (2.5)	4.4 (2.6)	4.8 (2.6)	4.8 (2.6)
Functional capacity	4.6 (2.5)	4.6 (2.5)	5.1 (2.7)	5.0 (2.5)
Discomfort	4.3 (2.7)	4.3 (2.6)	4.8 (2.7)	4.9 (2.7)
Sleep disturbance	3.8 (3.0)	3.4 (2.9)	3.7 (3.0)	4.0 (2.8)
Coping	3.9 (2.4)	3.6 (2.4)	4.2 (2.4)	4.1 (2.5)
Anxiety, fear and uncertainty	2.5 (2.5)	2.1 (2.3)	2.0 (2.4)	2.3 (2.6)
Embarrassment and/or shame	2.5 (2.7)	2.3 (2.5)	2.7 (2.8)	2.8 (3.0)
Social participation	2.7 (2.7)	2.5 (2.6)	3.2 (2.8)	3.1 (2.8)
Depression	1.4 (2.2)	1.1 (1.8)	1.4 (2.3)	1.8 (2.5)

Randomized set. PsAID-12 scores range from 0–10; higher scores indicate worse status. [a] n=279; [b] n=423; [c] n=132; [d] n=266; [e] In patients with psoriasis involving at least 3% of BSA at baseline; [f] Data missing for one BKZ-randomized patient in BE OPTIMAL (n=430).

Figure 1 BE OPTIMAL and BE COMPLETE study designs

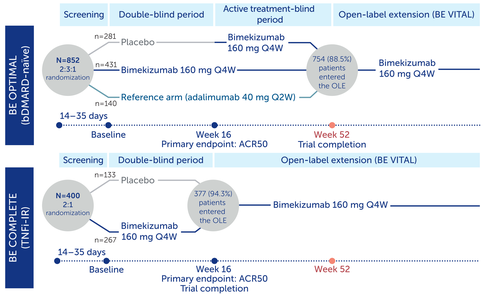
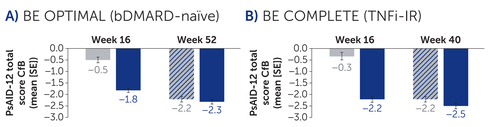
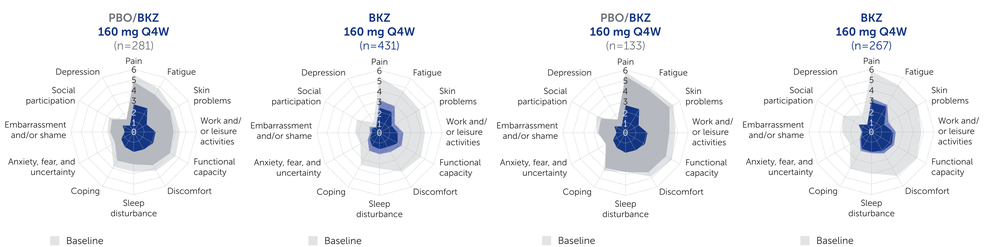


Figure 2 Change from baseline in PsAID-12 total score at Week 16 and Week 52/40 (MI)



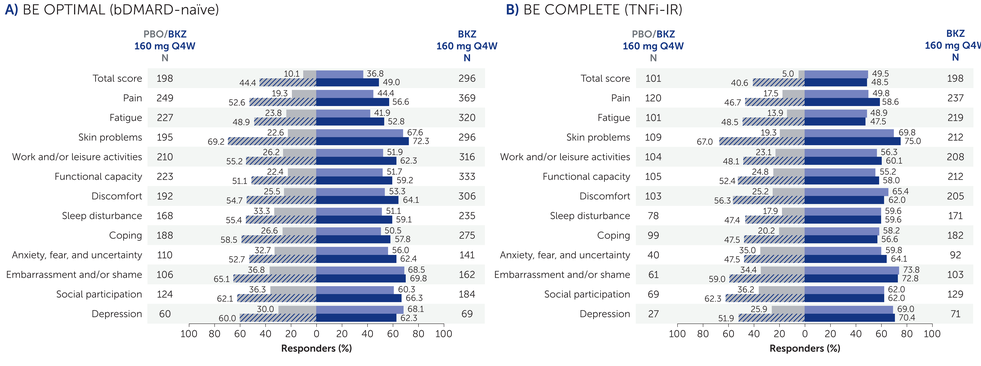
Randomized set. PsAID-12 scores range from 0–10; higher scores indicate worse status. Data collected to Week 40 for BE COMPLETE.

Figure 3 PsAID-12 single-item domain mean scores at baseline, Week 16, and Week 52/40 (MI)



Randomized set. PsAID-12 scores range from 0–10; higher scores indicate worse status. Data collected to Week 40 for BE COMPLETE.

Figure 4 Proportion of patients achieving a clinically meaningful within-patient improvement[a] in PsAID-12 total and single-item domain scores at Week 16 and Week 52/40 (NRI)



Randomized set, in patients with a total or item score of ≥3 at baseline. Data collected to Week 40 for BE COMPLETE. [a] Decrease of ≥3 from baseline.

*Including patients not on randomized treatment (BE OPTIMAL: 9; BE COMPLETE: 4). **ACR50:** ≥50% improvement in the American College of Rheumatology response criteria; **bDMARD:** biologic disease-modifying antirheumatic drug; **BKZ:** bimekizumab; **BSA:** body surface area; **CfB:** change from baseline; **GRAPPA:** Group for Research and Assessment of Psoriasis and Psoriatic Arthritis; **IL:** interleukin; **MI:** multiple imputation; **NRI:** non-responder imputation; **OLE:** open-label extension; **PASI:** Psoriasis Area Severity Index; **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; **SJC:** swollen joint count; **TJC:** tender joint count; **TNFi-IR:** intolerance or inadequate response to TNF inhibitor.

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References: [1]Orbai AM. J Rheumatol 2019;46:990–5; [2]Ritchlin CT. Arthritis Rheumatol 2022; 74 (S9). [3]Coates L. Ann Rheum Dis 2023; 82 (S1) **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **DDG, LCC, MdW, ARO, AMO, BI, VT, JL, LG**. Drafting of the publication, or reviewing it critically for important intellectual content: **DDG, LCC, MdW, ARO, AMO, BI, VT, JL, LG**. Final approval of the publication: **DDG, LCC, MdW, ARO, AMO, BI, VT, JL, LG**. **Author Disclosures: DDG:** Consultant and/or received grant support from Abbvie, Amgen, BMS, Eli Lilly, Gilead, Galapagos, Janssen, Novartis, Pfizer, and UCB Pharma; **LCC:** Grants/research support from AbbVie, Amgen, Celgene, Eli Lilly, Gilead, Janssen, Novartis, Pfizer, and UCB Pharma; consultant for AbbVie, Amgen, BMS, Boehringer Ingelheim, Celgene, Domain, Eli Lilly, Galapagos, Gilead, Janssen, Moonlake Pharma, Novartis, Pfizer, and UCB Pharma; speaking fees from AbbVie, Amgen, Biogen, Celgene, Eli Lilly, Galapagos, Gilead, GSK, Janssen, medac, Novartis, Pfizer, 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, Janssen, Pfizer, and UCB Pharma; **ARO:** Grant/research support from AbbVie, Amgen, Janssen, Novartis and Pfizer, consultant of AbbVie, Amgen, BMS, Celgene, CorEvitas, Eli Lilly, GSK, Gilead, Janssen, Novartis, Pfizer, Takeda, and UCB Pharma; **AMO:** Research grants to Johns Hopkins University from AbbVie, Amgen, and Janssen; consulting fees from BMS, Janssen, Sanofi, and UCB Pharma; **BI:** Employee of UCB Pharma and shareholder of AbbVie, GSK, and UCB Pharma; **VT, JL:** Employee and shareholder of UCB Pharma; **LG:** Grants from AbbVie, Biogen, Lilly, Novartis, Sandoz, and UCB Pharma; personal fees from AbbVie, Amgen, BMS, Celltrion, Galapagos, Janssen, Lilly, MSD, Novartis, Pfizer, Sandoz, 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, for publication coordination, Aditi Mehta, MSc, Costello Medical, London, 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.

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