Achieving complete skin clearance was associated with cumulative benefits on disease impact up to 2 years in patients with psoriatic arthritis and psoriasis treated with bimekizumab

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Objective

To assess how achieving complete skin clearance (100% improvement from baseline in Psoriasis Area and Severity Index [PASI100]) in patients with psoriatic arthritis (PsA) and baseline psoriasis treated with bimekizumab (BKZ) influences patient-reported disease impact over 2 years, using the PsA Impact of Disease-12 (PsAID-12) questionnaire and area under the curve (AUC) analyses.

Introduction

- Control of inflammation to reduce symptoms and disease impact is an important treatment goal for patients with psoriatic disease.[1–3]
- The patient-reported PsAID-12 questionnaire assesses the impact of PsA on 12 physical, social, and psychological domains; scores for each domain range from 0–10 with higher scores indicating worse status.[4,5]
- One of the PsAID-12 single-item domains specifically examines the severity of skin problems due to PsA, including itching, in the prior week.[4]

Methods

- This post hoc analysis examined patients with PsA and psoriasis (≥3% body surface area [BSA]) at baseline in the phase 3 trials BE OPTIMAL (NCT03895203; biologic disease-modifying antirheumatic drug-naïve [biologic-naïve]), BE COMPLETE (NCT03896581; tumour necrosis factor inhibitor inadequate response/intolerance [TNFi-IR]), and the open-label extension (OLE) BE VITAL (NCT04009499) (**Figure 1**).[6]
- Only patients randomised to BKZ 160 mg every 4 weeks at baseline were included in this analysis; patients were grouped based on achievement of complete skin clearance (PASI100) at Week 16.
- The PsAID-12 questionnaire was administered up to Week 104 in BE OPTIMAL and Week 88 in BE COMPLETE.
- Proportion of patients achieving PsAID-12 remission/low disease impact of the total score (≤1.95) or skin domain score (≤2),[5] are reported at Weeks 16, 52 and 104 for BE OPTIMAL patients and Weeks 16, 40 and 88 for BE COMPLETE.
- Cumulative benefit on disease impact, assessed using remission/low disease impact in PsAID-12 total score and skin domain,[5] were estimated using AUC through Week 104/88 (biologic-naïve/TNFi-IR).
  - $AUC_{0–104/88}$ was used to calculate the estimated number of days, and subsequently percent of the study period, during which patients were in PsAID-12 remission/low disease impact (**Figure 2**).
- Missing data were imputed using non-responder imputation (NRI).

Results

- At Week 16, 103/217 (47.5%) biologic-naïve and 103/176 (58.5%) TNFi-IR patients with baseline BSA ≥3% achieved PASI100; mean absolute PASI and PASI100 response rate at Week 16 are presented in the **Table**.
- At Week 104/88 (biologic-naïve/TNFi-IR), a higher proportion of Week 16 PASI100 responders achieved PsAID-12 total score remission/low disease impact than Week 16 PASI100 non-responders (**Figure 3**).
- A similar trend was observed for PsAID-12 skin domain remission/low disease impact at Week 104/88 (biologic-naive/TNFi-IR; **Figure 4**).
- The cumulative number of days over a period of up to 2 years ($AUC_{0–104/88}$; biologic-naive/TNFi-IR) in remission/low disease impact for Week 16 PASI100 responders was greater than for non-responders for PsAID-12 total score (**Figure 3**) and skin domain (**Figure 4**).
- Up to 2 years of BKZ treatment, patients with PsA and baseline psoriasis achieving complete skin clearance (PASI100) at Week 16 experienced approximately 3–4 more cumulative months in PsAID-12 total score or skin domain remission/low disease impact than those not achieving complete skin clearance at Week 16.

Conclusions

In biologic-naive and TNFi-IR patients with PsA and baseline psoriasis, complete skin clearance at Week 16 of bimekizumab treatment was associated with greater cumulative benefit on patient-reported disease impact over 2 years of treatment.

Summary

Control of inflammation to reduce symptoms and disease impact is an important treatment goal for patients with psoriatic disease.

Cumulative days of disease impact up to 2 years of BKZ treatment was assessed in patients with PsA and baseline psoriasis using **PsAID-12** and **AUC analyses.**

PsAID-12 Questionnaire Domains[4]

1. Pain
2. Fatigue
3. **Skin problems**
4. Work and/or leisure activities
5. Functional capacity
6. Discomfort
7. Sleep disturbance
8. Anxiety
9. Coping
10. Embarrassment
11. Social participation
12. Depression

Total and domain scores range from **0–10**; higher scores indicate worse disease impact

Patients with **complete skin clearance (PASI100) at Week 16** had a **greater proportion of days in remission/low disease impact** up to 2 years of BKZ treatment versus Week 16 PASI100 non-responders:

PsAID-12 Total Score (≤1.95)

Biologic-naïve		TNFi-IR	
65.2%	48.3%	61.1%	44.2%

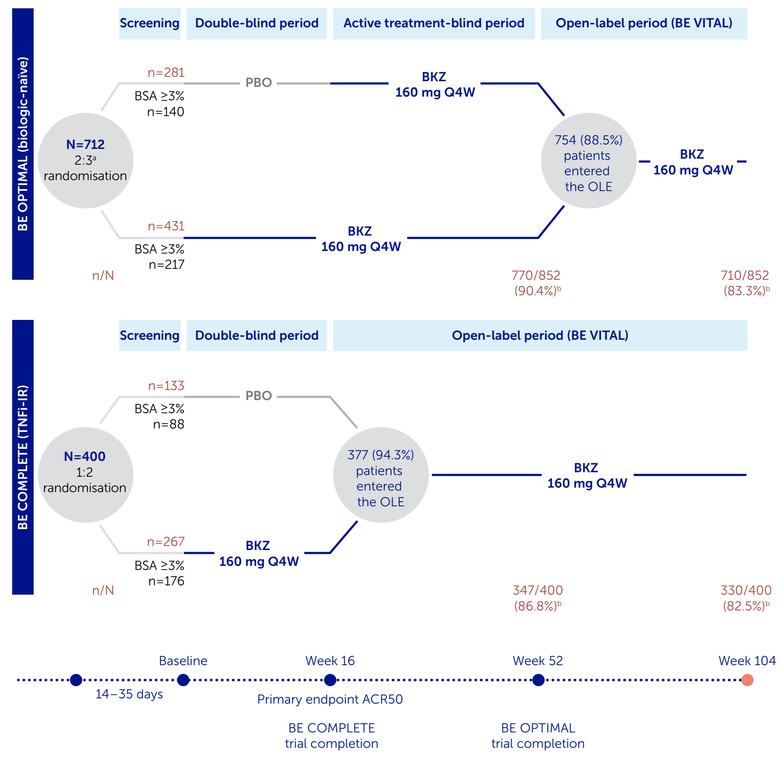
PsAID-12 Skin Domain (≤2)

Biologic-naïve		TNFi-IR	
76.4%	59.2%	78.0%	57.4%

■ Week 16 PASI100 responders ■ Week 16 PASI100 non-responders

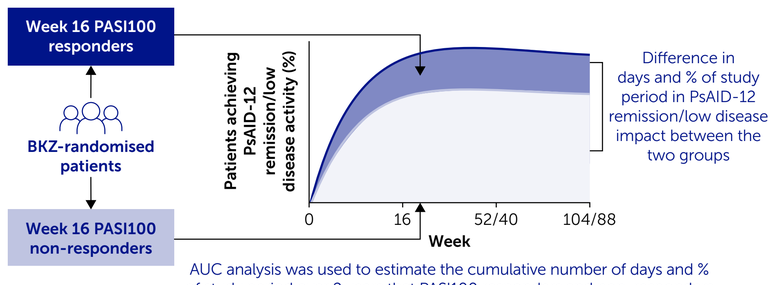
Complete skin clearance with BKZ at Week 16 was associated with **greater cumulative benefits on patient-reported disease impact** over 2 years in patients with PsA and baseline psoriasis.

Figure 1 BE OPTIMAL, BE COMPLETE and BE VITAL (OLE) study designs



The number of patients with BSA ≥3% at baseline considered in this analysis are shown. Disposition data are presented for the overall trial population. **[a]** BE OPTIMAL also included a standard-of-care reference arm (adalimumab 40 mg Q2W); data not shown; **[b]** Completion rates include patients that completed to Week 52/104 in BE OPTIMAL and Week 52/88 in BE COMPLETE not on randomised treatment; not including 1 ongoing patient at Week 88 in BE COMPLETE. There were no ongoing patients in BE OPTIMAL at Week 104.

Figure 2 Method for estimating cumulative disease impact based on Week 16 PASI100 response



AUC analysis was used to estimate the cumulative number of days and % of study period over 2 years that PASI100 responders and non-responders were in PsAID-12 remission/low disease impact ($AUC_{0–104/88}$)

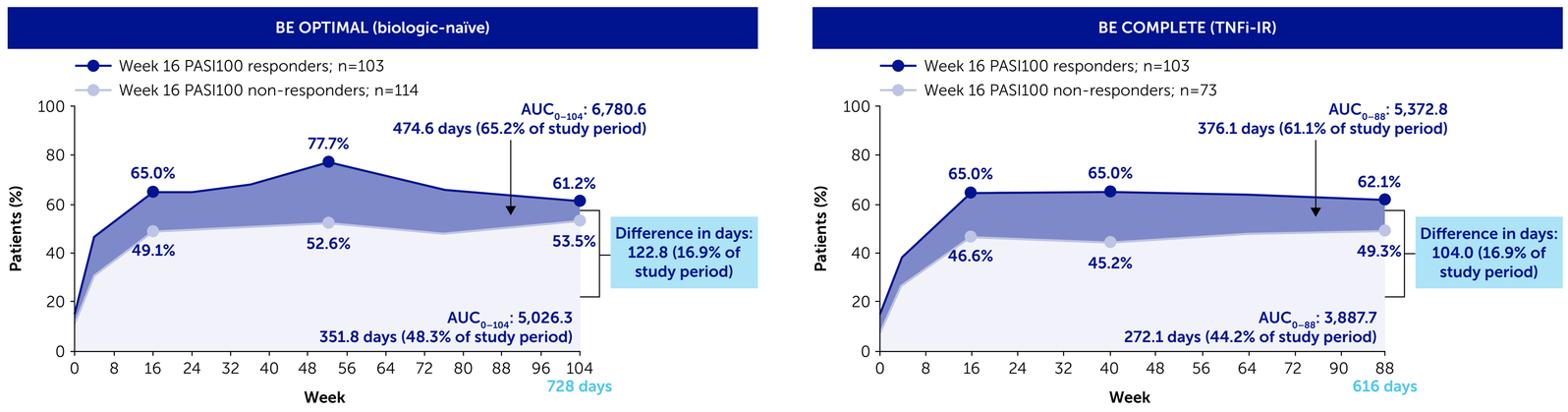
PASI100 responders imputed using NRI. AUC analysis was used to calculate the cumulative number of days in PsAID-12 remission/low disease impact; the cumulative number of days was used to calculate the percentage of study period based on the total study duration in days.

Table Proportion of patients who were Week 16 PASI100 responders or non-responders (NRI, OC)

	BE OPTIMAL (biologic-naïve)	BE COMPLETE (TNFi-IR)
	BKZ 160 mg Q4W n=217	BKZ 160 mg Q4W n=176
Responders, n (%), NRI	103 (47.5)	103 (58.5)
Non-responders, n (%), NRI	114 (52.5)	73 (41.5)
PASI at Week 16, mean (SD), OC	1.5 (1.7)[a]	2.4 (3.3)[b]

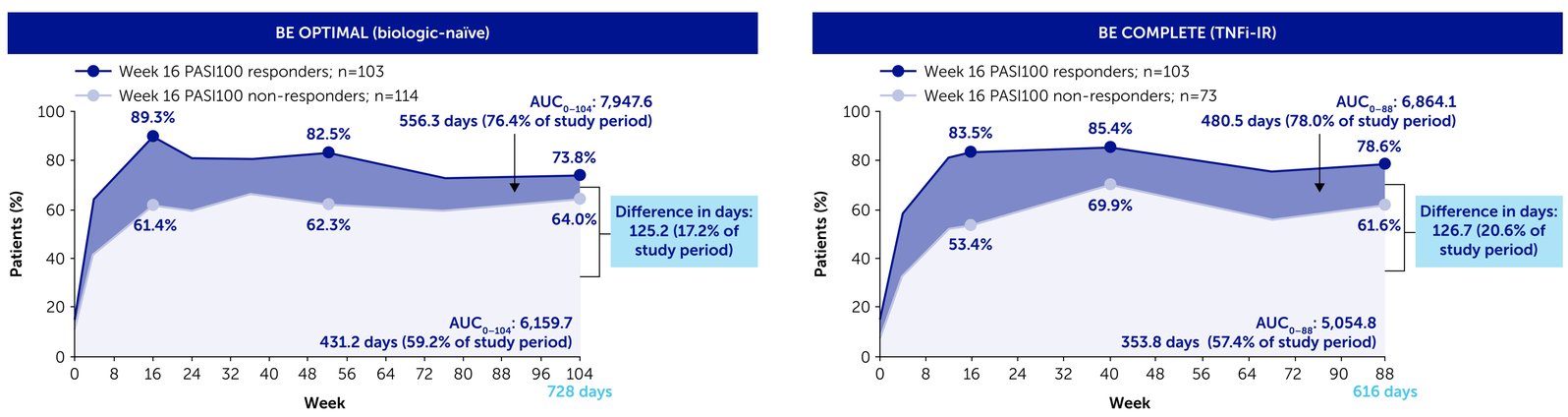
In patients with psoriasis involving ≥3% BSA at baseline. **[a]** n=104; **[b]** n=69.

Figure 3 Patients with **PsAID-12 total score remission/low disease impact** to 2 years by Week 16 PASI100 response (NRI)



In patients with psoriasis involving ≥3% BSA at baseline treated with BKZ (BE OPTIMAL: n=217; BE COMPLETE: n=176). Percentage of days manually calculated based on AUC data. Number of days and percentage of study period rounded to the nearest 1 decimal place. PsAID-12 total score remission/low disease impact (score ≤1.95).

Figure 4 Patients with **PsAID-12 skin domain remission/low disease impact** to 2 years by Week 16 PASI100 response (NRI)



In patients with psoriasis involving ≥3% BSA at baseline treated with BKZ (BE OPTIMAL: n=217; BE COMPLETE: n=176). Percentage of days manually calculated based on AUC data. Number of days and percentage of study period rounded to the nearest 1 decimal place. PsAID-12 skin domain remission/low disease impact (score ≤2).

AUC: area under the curve; **biologic-naïve:** biologic disease-modifying antirheumatic drug-naïve; **BKZ:** bimekizumab; **BSA:** body surface area; **NRI:** non-responder imputation; **OLE:** open-label extension; **PASI:** Psoriasis Area and Severity Index; **PASI100:** 100% improvement from baseline in PASI; **PBO:** placebo; **PsA:** psoriatic arthritis; **PsAID-12:** PsA Impact of Disease-12; **SD:** standard deviation; **TNFi-IR:** prior inadequate response or intolerance to tumour necrosis factor inhibitors; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks.

References: [1]Ritchlin CT et al. Ann Rheum Dis 2023;82:1404–14; [2]Gudu T & Gossec L. Expert Rev Clin Immunol 2018;14:405–17; [3]Coates LC et al. Nat Rev Rheumatol 2022;18:465-79; [4]Gossec L et al. Ann Rheum Dis 2014;73:1012–19; [5]Gossec L et al. RMD Open 2024:10:e003548; [6]Mease PJ et al. Rheumatol Ther 2024;11:1363–82. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **JFM**, **WT, RBW**, **IBM**, **LG**, **PH**, **JL**, **HE**, **KBG**; Drafting of the publication, or reviewing it critically for important intellectual content: **JFM**, **WT, RBW**, **IBM**, **LG**, **PH**, **JL**, **HE**, **KBG**; Final approval of the publication: **JFM**, **WT, RBW**, **IBM**, **LG**, **PH**, **JL**, **HE**, **KBG**. **Author Disclosures: JFM:** Consultant and/or investigator for AbbVie, Amgen, AstraZeneca, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Eli Lilly and Company, Incyte, Janssen, LEO Pharma, MoonLake Immunotherapeutics, Novartis, Pfizer, Sanofi-Regeneron, Sun Pharma, and UCB. **WT:** Research grants, consulting fees, speaking fees and/or honoraria from AbbVie, Amgen, Bristol Myers Squibb, Celgene, Eli Lilly and Company, GSK, Janssen, MSD, Novartis, Ono Pharma, Pfizer, Takeda, and UCB. **RBW:** Consulting fees from AbbVie, Almirall, Amgen, Arena, Astellas, Avillion, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, DICE Therapeutics, Eli Lilly and Company, GSK, Janssen, LEO Pharma, Meiji Pharma, Novartis, Pfizer, RAPT Therapeutics, Sanofi, Sun Pharma, UCB, and Union; research grants to his institution from AbbVie, Almirall, Amgen, Celgene, Eli Lilly and Company, Janssen, LEO Pharma, Novartis, Pfizer, and UCB; honoraria from AbbVie, Almirall, Bristol Myers Squibb, Eli Lilly and Company, Galderma, Janssen, and Novartis. **IBM:** Consulting fees and honoraria from AbbVie, AstraZeneca, Boehringer Ingelheim, Bristol Myers Squibb, Cabaletta, Causeway Therapeutics, Celgene, Eli Lilly and Company, Evelo, Janssen, MoonLake Immunotherapeutics, Novartis, and UCB; research support from Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Janssen, Novartis, and UCB. **LG:** Received grants or contracts from AbbVie, Biogen, Lilly, Novartis, and UCB; consulting fees from AbbVie, Amgen, Bristol Myers Squibb, Celltrion, Janssen, Lilly, MSD, Novartis, Pfizer, and UCB. **PH**, **JL:** Employees and shareholders of UCB. **HE:** Employee of UCB; shareholder of Abbott, and UCB. **KBG:** Consulting fees from AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Dermira, Eli Lilly and Company, Janssen, Novartis, Pfizer, Sun Pharma, and UCB; research support from AbbVie, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Janssen, Novartis, and UCB. **Acknowledgements:** This study was funded by UCB. We thank the patients and their caregivers in addition to the investigators and their teams who contributed to this study. The authors acknowledge Heather Edens, PhD, UCB, Smyrna, Georgia, USA, for publication coordination, Orla Woodward, PhD, Costello Medical, London, UK for medical writing and editorial assistance and the Costello Medical Creative team for design support. All costs associated with development of this poster were funded by UCB.

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