Dual Inhibition of IL-17A and IL-17F with Bimekizumab Demonstrated Long-Term Safety and Efficacy in Patients with Active Psoriatic Arthritis and Prior Inadequate Response to Tumour Necrosis Factor Inhibitors: Final 3-Year Results from the Phase 3 BE COMPLETE Study and its Open-Label Extension

POS0105

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Objective

To assess the 3-year efficacy and safety of bimekizumab (BKZ) in patients with psoriatic arthritis (PsA) who had prior inadequate response or intolerance to tumour necrosis factor inhibitors (TNFi-IR).

Background

- BKZ is a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.
- Patients with PsA and TNFi-IR typically experience reduced efficacy compared with patients who are biologic disease-modifying antirheumatic drug (bDMARD)-naïve.[1,2]
- Rapid, deep and sustained high levels of response with BKZ treatment were demonstrated up to 2 years which were consistent across TNFi-IR and bDMARD-naïve patients with PsA.[3]

Methods

- In BE COMPLETE (NCT03896581), TNFi-IR patients were randomised 2:1 to subcutaneous BKZ 160 mg every 4 weeks (Q4W) or placebo (PBO).
- Patients completing Week 16 could enter BE VITAL (open-label extension; NCT04009499) for up to 140 weeks. PBO patients entering BE VITAL switched to BKZ (PBO/BKZ).
- Efficacy outcomes are reported to Week 156 for patients in the BKZ Total group (PBO/BKZ and BKZ-randomised [BKZ]).
- Missing data were imputed using modified non-responder (mNRI; binary) or multiple (MI; continuous) imputation. mNRI considered all visits following discontinuation due to adverse events or lack of efficacy as non-response; all other missing data were imputed with MI and the response derived from the imputed values.
- Safety data are reported to Week 156 for all BKZ-treated patients (≥1 dose). All treatment-emergent adverse events (TEAEs) were classified using the MedDRA v19.0.

Results

Patient characteristics

- Of 400 randomised patients, 299 (74.8%) completed to Week 156. Select baseline characteristics are summarised in **Table 1**.

Efficacy

- Patients demonstrated sustained clinical responses across all assessed efficacy outcomes from 1 year through 3 years.
- ≥50% improvement from baseline in American College of Rheumatology response criteria (ACR50) was sustained from 50.4% at Week 52 to 55.2% at Week 156 (**Figure 1A**).
- Among those with baseline psoriasis (≥3% body surface area), complete skin clearance (Psoriasis Area and Severity Index [PASI]100) was sustained from 66.2% at Week 52 to 67.5% at Week 156 (**Figure 1B**).
- Similar sustained responses from Week 52 to Week 156 were observed for minimal disease activity (MDA), resolution of swollen joint count (SJC=0; a clinical measure of inflammation) and additional clinical and patient-reported efficacy outcomes (**Figure 1C–D; Table 2**).

Safety

- Safety data up to 3 years for BKZ-treated patients are presented in **Table 3**.
- Over 3 years, the incidence rate (exposure-adjusted incidence rate [EAIR]/100 patient years [PY]) for ≥1 TEAE was 88.6.
- One death was reported up to 3 years (Week 0–52), deemed unrelated to the study treatment by the investigator.
- The three most frequent TEAEs by preferred term were SARS-CoV-2 (COVID-19) infection, nasopharyngitis and upper respiratory tract infection.
- Up to 3 years, all fungal infections were localised and the majority were identified as *Candida* infections; most *Candida* infections were oral candidiasis.
- All *Candida* infections were mild/moderate in severity and the number of *Candida* infections leading to study discontinuations was low (4; EAIR/100 PY: 0.4).
- One case of serious hypersensitivity reaction (dermatitis) and no cases of active tuberculosis were reported.
- No new safety signals were observed with BKZ with an additional year of treatment.[3]

Conclusions

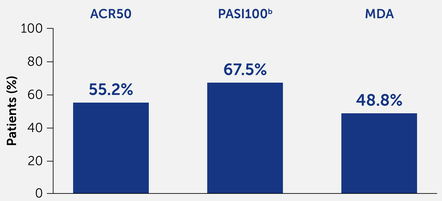
Efficacy results from BE COMPLETE and its open-label extension demonstrated that bimekizumab treatment resulted in sustained clinical efficacy up to 3 years in patients with PsA who had prior TNFi-IR. Bimekizumab was well tolerated and no new safety signals were observed.[3,4]

Summary

The **3-year efficacy** and safety of **bimekizumab** treatment was assessed in patients with **active psoriatic arthritis** who had prior **TNFi-IR (BE COMPLETE)**.

Sustained efficacy from **1 to 3 years** was observed in **joint**, **skin** and **composite outcomes**.

Proportion of patients achieving efficacy responses at 3 years:[a]



Resolution of inflammation was sustained from 1 year, with **59.1%** of patients achieving SJC=0 at 3 years

Bimekizumab was well tolerated to 3 years with no new safety signals observed

Patients with active PsA who had prior **TNFi-IR** experienced **sustained high levels of response** up to **3 years with bimekizumab treatment**.

Responses were **consistent** with those observed in patients who were bDMARD-naive (BE OPTIMAL). ACR50 responses at 3 years: **55.2% TNFi-IR** and **53.2% bDMARD-naïve**.[5]

[a] Values shown here are mNRI; **[b]** In patients with psoriasis involving ≥3% BSA at baseline (n=264).

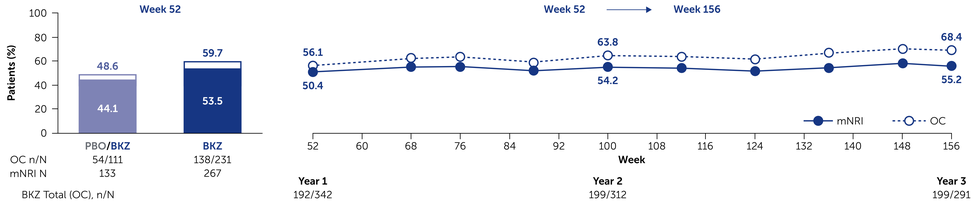
Table 1 Select baseline patient demographics and disease characteristics

	BE COMPLETE (TNFi-IR) BKZ 160 mg Q4W Total[a] (N=400)
Age, years, mean (SD)	50.5 (12.5)
Sex, male, n (%)	190 (47.5)
Time since PsA diagnosis,[b] years, mean (SD)	9.5 (9.3)
Any cDMARD at baseline, n (%)	202 (50.5)
Concomitant methotrexate, n (%)	170 (42.5)
SJC (of 66 joints), mean (SD)	9.9 (7.7)
TJC (of 68 joints), mean (SD)	18.7 (13.8)
≥3% BSA affected by psoriasis, n (%)	264 (66.0)
≥3–≤10%	172 (43.0)
>10%	92 (23.0)
PASI score,[c] mean (SD)	9.6 (8.4)
Enthesitis (LEI >0),[d] n (%)	142 (35.5)
LEI score,[e] mean (SD)	2.7 (1.5)
Dactylitis (LDI >0),[d] n (%)	48 (12.0)
LDI score,[f] mean (SD)	70.9 (117.0)
HAQ-DI score, mean (SD)	0.99 (0.62)
FACIT-Fatigue score, mean (SD)	35.6 (10.3)
PsAID-12 total score, mean (SD)	4.5 (2.0)
Pain VAS score,[g] mean (SD)	59.5 (24.3)

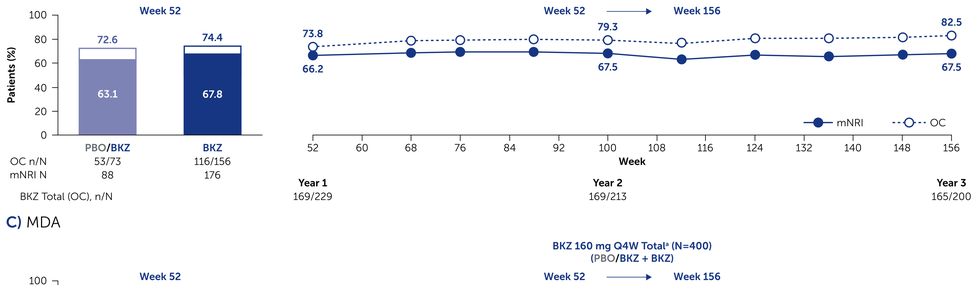
Randomised set. **[a]** BKZ Total group includes BKZ-randomised patients and PBO-randomised patients who switched to BKZ at Week 16; **[b]** Data missing for 2 patients; **[c]** In patients with psoriasis involving ≥3% BSA at baseline (n=264); **[d]** Data missing for 1 patient; **[e]** In patients with enthesitis at baseline (LEI >0); **[f]** In patients with dactylitis at baseline (LDI >0); **[g]** Pain VAS was assessed using Patient's Assessment of Arthritis Pain VAS, which ranges from 0 (no pain) to 100 (most severe pain).

Figure 1 Proportion of TNFi-IR patients achieving ACR50, PASI100, MDA and SJC=0 over time to Week 156 in BE COMPLETE (mNRI, OC)

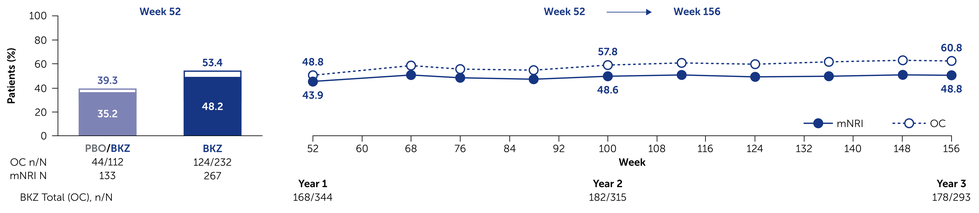
A) ACR50



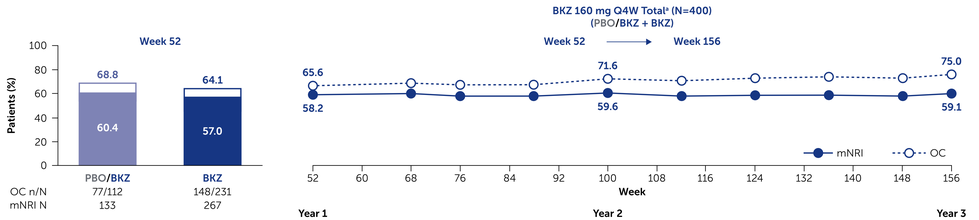
B) PASI100[b]



C) MDA



D) SJC=0[c]



Randomised set. Data reported through Year 1 (Week 52) to Year 2 (Week 100) and Year 3 (Week 156). **[a]** BKZ Total group includes BKZ-randomised patients and PBO-randomised patients who switched to BKZ at Week 16; **[b]** In patients with psoriasis involving ≥3% BSA at baseline (n=264); **[c]** SJC=0 was assessed in 66 joints.

Table 2 Summary of additional efficacy results at Week 156

	BE COMPLETE (TNFi-IR) BKZ 160 mg Q4W Total[a] (N=400)	
	mNRI, %	**OC, % (n/N)**
ACR20	71.7	85.6 (249/291)
ACR70	37.4	47.6 (139/292)
PASI75[b]	84.6	96.5 (193/200)
PASI90[b]	77.3	89.5 (179/200)
Nail psoriasis resolution[c]	67.1	80.5 (153/190)
ACR50+PASI100[b]	48.3	60.5 (121/200)
VLDA	23.6	30.6 (89/291)
DAPSA disease state [MI],[d] % (95% CI)		
REM+LDA	67.3 (62.2, 72.3)	
REM	30.6 (25.9, 35.3)	
TJC=0 (of 68 joints)	33.0	40.1 (117/292)
Enthesitis resolution[e]	59.9	77.5 (79/102)
Dactylitis resolution[f]	70.8 [NRI][g]	94.4 (34/36)
HAQ-DI MCID[h]	55.7	66.8 (165/247)
FACIT-Fatigue MCID[i]	54.2	63.3 (171/270)
PsAID-12 ≥3-point decrease[j]	50.8	62.1 (133/214)
Pain VAS ≥50% improvement[k,l]	59.4	72.7 (213/293)

Randomised set. mNRI and OC unless otherwise stated. **[a]** BKZ Total group includes BKZ-randomised patients and PBO-randomised patients who switched to BKZ at Week 16; **[b]** In patients with psoriasis involving ≥3% BSA at baseline (n=264); **[c]** In patients with nail psoriasis at baseline (mNAPSI >0; n=242); **[d]** DAPSA REM defined as a DAPSA score of ≤4, DAPSA REM+LDA as a DAPSA score of ≤14; **[e]** In patients with enthesitis at baseline (LEI >0; n=142); **[f]** In patients with dactylitis at baseline (LDI >0; n=48); **[g]** In cases where MI did not converge and mNRI was not available, missing data were imputed using NRI; **[h]** HAQ-DI MCID defined as a decrease from baseline ≥0.35 in patients with HAQ-DI ≥0.35 at baseline (n=341); **[i]** FACIT-Fatigue MCID defined as an increase from baseline ≥4 in patients with FACIT-Fatigue ≤48 at baseline (n=371); **[j]** Defined as clinically meaningful within-patient improvement.[6] Reported in patients with PsAID-12 ≥3 at baseline (n=299); **[k]** Pain VAS assessed using the Patient's Assessment of Arthritis Pain VAS which ranges from 0 to 100, 0 representing 'no pain' and 100 'most severe pain'; **[l]** Pain VAS ≥50% represents a substantial improvement in patient-reported pain.[7]

Table 3 Safety at Week 156

	BE COMPLETE (TNFi-IR) BKZ-Treated Patients (BKZ 160 mg Q4W)[a] (n=388); 985.3 PY
n (%) [EAIR/100 PY]	
Any TEAEs	318 (82.0) [88.6]
Serious TEAEs	52 (13.4) [5.7]
Study discontinuation due to TEAEs	27 (7.0) [2.8]
Drug-related TEAEs[b]	130 (33.5) [17.1]
Severe TEAEs	35 (9.0) [3.7]
Deaths	1 (0.3) [0.1][c]
Most frequent TEAEs[d]	
SARS-CoV-2 (COVID-19) infection	68 (17.5) [7.6]
Nasopharyngitis	44 (11.3) [4.8]
Upper respiratory tract infection	38 (9.8) [4.1]
Safety topics of interest	
Serious infections	13 (3.4) [1.3]
Opportunistic infections	3 (0.8) [0.3]
Active tuberculosis	0
Fungal infections	52 (13.4) [5.8]
Candida infections	37 (9.5) [4.0]
Oral candidiasis	34 (8.8) [3.6]
Fungal infections NEC	18 (4.6) [1.9]
Tinea infections	6 (1.5) [0.6]
Neutropenia	13 (3.4) [1.4][e]
Serious hypersensitivity reaction	1 (0.3) [0.1][f]
Administration/injection site reaction[g]	8 (2.1) [0.8]
Definite or probable adjudicated IBD	1 (0.3) [0.1]
Uveitis	0
Adjudicated suicidal ideation and behaviour	0
Adjudicated MACE	2 (0.5) [0.2]
Elevated liver enzymes[h]	37 (9.5) [4.0]
>3x ULN ALT or AST	17 (4.4) [1.8]
Malignancies, excluding non-melanoma skin cancer	10 (2.6) [1.0]

Safety set. **[a]** Safety events reported whilst receiving BKZ. BKZ-Treated group includes BKZ-randomised patients and PBO-randomised patients who switched to BKZ at Week 16, includes events after switch only; **[b]** Per study investigator assessment; **[c]** One sudden death (Week 0–52), deemed unrelated to treatment; **[d]** Most frequent TEAEs are the top three adverse events occurring in all BKZ-treated subjects; **[e]** 8 neutropenia; 6 neutrophil count decreased; **[f]** One case of dermatitis, classified as serious due to the patient needing hospitalisation; **[g]** Includes the high-level terms "administration site reactions NEC" and "injection site reactions"; **[h]** Elevated liver enzymes includes the following preferred terms reported as adverse events: increased/abnormal levels of ALT, AST, blood bilirubin, gamma-glutamyltransferase, hepatic enzymes, liver function test, total bile acids, or transaminases.

ACR20/50/70: ≥20/50/70% improvement from baseline in American College of Rheumatology response criteria; **ALT:** alanine aminotransferase; **AST:** aspartate aminotransferase; **bDMARD:** biologic disease-modifying antirheumatic drug; **BKZ:** bimekizumab; **BSA:** body surface area; **CI:** confidence interval; **cDMARD:** conventional disease-modifying antirheumatic drug; **DAPSA:** Disease Activity in Psoriatic Arthritis; **EAIR:** exposure-adjusted incidence rate; **FACIT-Fatigue:** Functional Assessment of Chronic Illness Therapy-Fatigue; **HAQ-DI:** Health Assessment Questionnaire-Disability Index; **IBD:** inflammatory bowel disease; **LDA:** low disease activity; **LDI:** Leeds Dactylitis Index; **LEI:** Leeds Enthesitis Index; **MACE:** major adverse cardiovascular event; **MCID:** minimal clinically important difference; **MedDRA:** Medical Dictionary for Regulatory Activities; **MDA:** minimal disease activity; **MI:** multiple imputation; **mNAPSI:** modified Nail Psoriasis Severity Index; **mNRI:** modified non-responder imputation; **NEC:** not elsewhere classified; **NRI:** non-responder imputation; **OC:** observed case; **OLE:** open-label extension; **PASI:** Psoriasis Area and Severity Index; **PASI75/90/100:** ≥75/90/100% improvement from baseline in Psoriasis Area and Severity Index; **PBO:** placebo; **PsA:** psoriatic arthritis; **PsAID-12:** 12-item Psoriatic Arthritis Impact of Disease; **PY:** patient-years; **Q4W:** every four weeks; **REM:** remission; **SD:** standard deviation; **SJC:** swollen joint count; **TEAE:** treatment-emergent adverse event; **TJC:** tender joint count; **TNFi-IR:** inadequate response or intolerance to tumour necrosis factor inhibitors; **ULN:** upper limit of normal; **VAS:** visual analogue scale; **VLDA:** very low disease activity.

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Author Contributions: Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **IBM**, **JFM**, **LCC**, **LG**, **RL**, **FP**, **YT**, **AA**, **BI**, **RB**, **JC**, **PJM**; Drafting of the publication, or reviewing it critically for important intellectual content: **IBM**, **JFM**, **LCC**, **LG**, **RL**, **FP**, **YT**, **AA**, **BI**, **RB**, **JC**, **PJM**; Final approval of the publication: **IBM**, **JFM**, **LCC**, **LG**, **RL**, **FP**, **YT**, **AA**, **BI**, **RB**, **JC**, **PJM**.

Author Disclosures: IBM: Consulting fees and honoraria from AbbVie, AstraZeneca, BMS, Boehringer Ingelheim, Cabaletta, Causeway Therapeutics, Celgene, Evelo, Janssen, Eli Lilly and Company, MoonLake Immunotherapeutics, Novartis and UCB; research support from BMS, Boehringer Ingelheim, Celgene, Janssen, Novartis and UCB. **JFM:** Consultant and/or investigator for AbbVie, Amgen, AstraZeneca, Biogen, BMS, Boehringer Ingelheim, Dermavant, Eli Lilly and Company, Incyte, Janssen, LEO Pharma, MoonLake Immunotherapeutics, Novartis, Pfizer, Sanofi-Regeneron, Sun Pharma and UCB. **LCC:** Grants/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. **LG:** Received grants or contracts from AbbVie, Biogen, Lilly, Novartis and UCB; consulting fees from AbbVie, Amgen, BMS, Celltrion, Janssen, Lilly, MoonLake Immunotherapeutics, MSD, Novartis, Pfizer, Stada and UCB. **RL:** Consultancy fees from AbbVie, AstraZeneca, BMS, Novartis, Pfizer, Eli Lilly and UCB; research grants from AbbVie, Pfizer, Novartis and UCB; owner of Rheumatology Consultancy BV, an AMS company under Dutch law. **FP:** Grant/research support from Eli Lilly and Company, Novartis and UCB; consultancy fees and speakers bureau from AbbVie, Amgen, BMS, Celgene, Eli Lilly and Company, Galapagos, Hexal, Janssen, Medscape, MoonLake Immunotherapeutics, MSD, Novartis, Pfizer, Roche and UCB. **YT:** Speaker fees and/or honoraria from AbbVie, AstraZeneca, BMS, Boehringer Ingelheim, Chugai, Daiichi-Sankyo, Eisai, Eli Lilly, Gilead, GSK, IQVIA, Otsuka, Taisho and UCB. **AA:** Honoraria and/or research grants from AbbVie, Amgen, BMS, Boehringer Ingelheim, Eisai, Eli Lilly, Janssen, Kyowa Kirin, LEO Pharma, Maruho, Mitsubishi Tanabe Pharma, Novartis, Pfizer, Sun Pharma, Taiho Pharma, Torii Pharmaceutical Co. and UCB. **BI:** Employee of UCB; shareholder of AbbVie, GSK and UCB. **RB, JC:** Employees and shareholders of 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.

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, Smyrna, Georgia, USA, for publication coordination; Alice Di Vincenzo, MSc, Costello Medical, Manchester, 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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