Bimekizumab, a Dual Inhibitor of IL-17A and IL-17F, Demonstrated Long-Term Safety and Efficacy in Biologic DMARD-Naïve Patients with Active Psoriatic Arthritis: Final 3-Year Results from the Phase 3 BE OPTIMAL Study and its Open-Label Extension

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Objective

To assess the 3-year efficacy and safety of bimekizumab (BKZ) in patients with active psoriatic arthritis (PsA) who were biologic disease-modifying antirheumatic drug (bDMARD)-naïve.

Background

- BKZ is a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.
- BKZ treatment has demonstrated rapid, deep and sustained efficacy across multiple domains of disease up to 2 years in patients with PsA, with consistent levels of response observed in patients who were bDMARD-naïve or had prior inadequate response or intolerance to tumour necrosis factor inhibitors (TNFi-IR).[1]

Methods

- In BE OPTIMAL (NCT03895203), patients with PsA who were bDMARD-naïve were randomised 3:2:1 to subcutaneous BKZ 160 mg every 4 weeks (Q4W), placebo (PBO) or a reference arm (adalimumab [ADA] 40 mg Q2W).
- PBO-randomised patients switched to BKZ at Week 16 (PBO/BKZ); ADA patients switched to BKZ at Week 52 with no washout between treatments (ADA/BKZ). Week 52 completers were eligible for entry into BE VITAL (open-label extension [OLE]; NCT04009499).
- Efficacy outcomes are reported to Week 160 for patients in the BKZ Total group (PBO- and BKZ-randomised patients).
- 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 Patients [PBO/BKZ, BKZ and ADA/BKZ]) and patients in the BKZ Total group. All treatment-emergent adverse events (TEAEs) were classified using the MedDRA v19.0.

Results

Patient characteristics

- Of the 712 patients randomised to the BKZ Total group, 546 (76.7%) completed Week 160. Select baseline characteristics are presented in **Table 1**.

Efficacy

- Across all efficacy outcomes, patients in the BKZ Total group demonstrated sustained clinical responses from 1 year through 3 years.
- ≥50% improvement from baseline in American College of Rheumatology response criteria (ACR50) was sustained from 56.1% at Week 52 to 53.2% at Week 160 (**Figure 1A**).
- In patients with baseline psoriasis (≥3% body surface area), complete skin clearance (Psoriasis Area and Severity Index [PASI100]) was sustained from 64.7% at Week 52 to 61.9% at Week 160 (**Figure 1B**).
- A similar sustained response was observed to Week 160 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**).
- Patients in the reference arm (ADA/BKZ) who switched to BKZ at Week 52 demonstrated sustained clinical responses across all efficacy outcomes, with an increase in skin and nail clearance, through 3 years (data not shown).

Safety

- Safety data up to 3 years are presented in **Table 3**.
- Over 3 years, the incidence rate (exposure-adjusted incidence rate [EAIR]/100 patient years [PY]) for all patients receiving ≥1 dose of BKZ (All Patients) reporting ≥1 TEAE was 164.2.
- Three deaths were reported (1 Week 0–52; 1 Week 52–104; 1 Week 104–156), all deemed unrelated to 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.
- All fungal infections were localised and the majority identified as *Candida* infections; majority of cases were mild or moderate in severity. Most *Candida* infections were oral candidiasis. Over 3 years, the number of all BKZ treated patients discontinuing study due to *Candida* infections remained low (7; EAIR/100 PY: 0.4). One case of a serious *Candida* infection (oropharyngeal candidiasis) was reported up to 3 years.
- No cases of serious hypersensitivity reaction or active tuberculosis were reported.
- No new safety signals were observed with BKZ with an additional year of treatment.

Conclusions

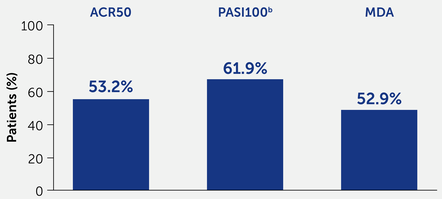
Efficacy results from BE OPTIMAL and its open-label extension demonstrated that bimekizumab treatment resulted in deep and sustained clinical efficacy up to 3 years in patients with PsA who were bDMARD-naïve. Bimekizumab was well tolerated with a favourable safety profile and no new safety signals were observed.[1,2]

Summary

The **3-year efficacy** and **safety** of **bimekizumab** treatment was assessed in patients with **active psoriatic arthritis** who were **bDMARD-naïve (BE OPTIMAL)**.

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 **59.5%** of patients achieving SJC=0 at 3 years

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

Bimekizumab treatment demonstrated **deep and sustained clinical efficacy** up to **3 years** in patients with **active PsA** who were **bDMARD-naïve**.

Responses were **consistent** with those observed in patients who were TNFi-IR (BE COMPLETE). ACR50 responses at 3 years: **53.2% bDMARD-naïve** and **55.2% TNFi-IR**.[2]

[a] Values shown here are mNRI; **[b]** In patients with psoriasis involving ≥3% BSA at baseline (n=357).

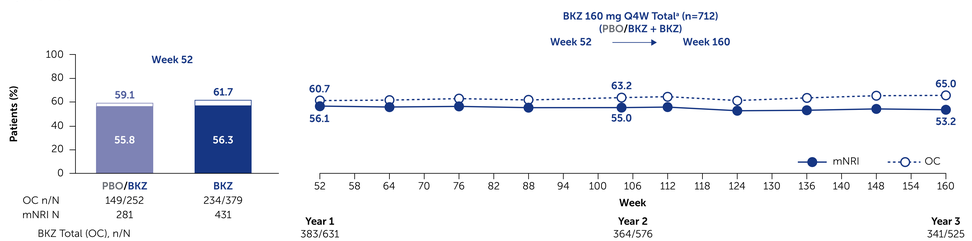
Table 1 Select baseline patient demographics and disease characteristics

	BE OPTIMAL (bDMARD-naïve) BKZ 160 mg Q4W Total[a] (n=712)
Age, years, mean (SD)	48.6 (12.2)
Sex, male, n (%)	328 (46.1)
Time since PsA diagnosis,[b] years, mean (SD)	5.8 (7.0)
Any csDMARD at baseline, n (%)	495 (69.5)
Concomitant methotrexate, n (%)	415 (58.3)
SJC (of 66 joints), mean (SD)	9.2 (6.6)
TJC (of 68 joints), mean (SD)	16.9 (12.1)
≥3% BSA affected by psoriasis, n (%)	357 (50.1)
≥3–≤10%	236 (33.1)
>10%	121 (17.0)
PASI score,[c] mean (SD)	8.1 (6.4)
Enthesitis (LEI >0),[d] n (%)	213 (29.9)
LEI score,[e] mean (SD)	2.6 (1.5)
Dactylitis (LDI >0),[f] n (%)	89 (12.5)
LDI score,[g] mean (SD)	47.0 (49.6)
HAQ-DI score,[h] mean (SD)	0.85 (0.59)
FACIT-Fatigue score,[h] mean (SD)	37.1 (9.9)
PsAID-12 total score,[h] mean (SD)	4.0 (1.9)
Pain VAS score,[h,i] mean (SD)	54.9 (23.9)

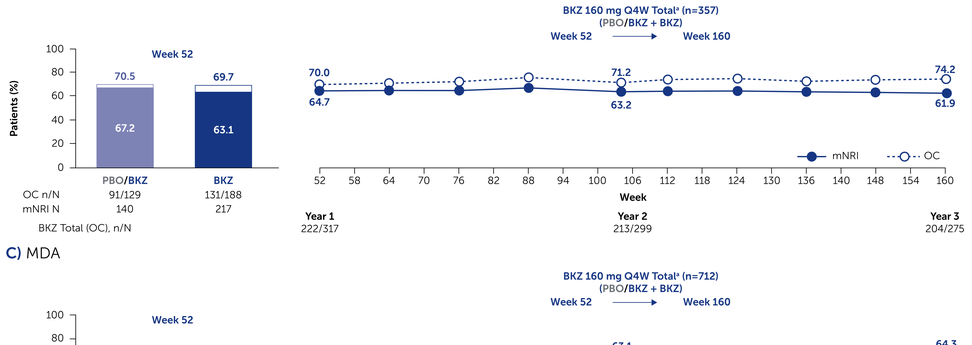
Randomised set. **[a]** BKZ Total group includes BKZ-randomised patients and PBO-randomised patients who switched to BKZ at Week 16. **[b]** Data missing for 10 patients; **[c]** In patients with psoriasis involving ≥3% BSA at baseline (n=357); **[d]** Data missing for 6 patients; **[e]** In patients with enthesitis at baseline (LEI >0); **[f]** Data missing for 7 patients; **[g]** In patients with dactylitis at baseline (LDI >0); **[h]** Data missing for 1 patient; **[i]** 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 bDMARD-naïve patients achieving ACR50, PASI100, MDA and SJC=0 over time to Week 160 in BE OPTIMAL (mNRI, OC)

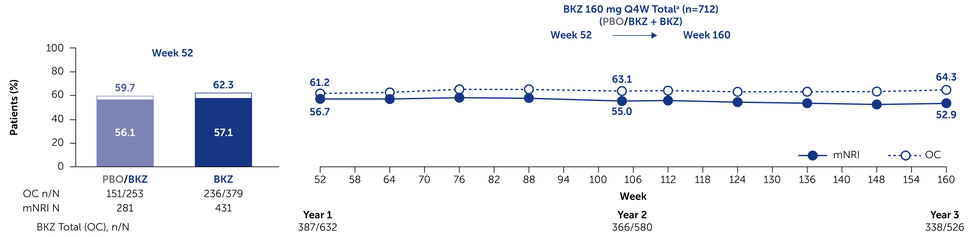
A) ACR50



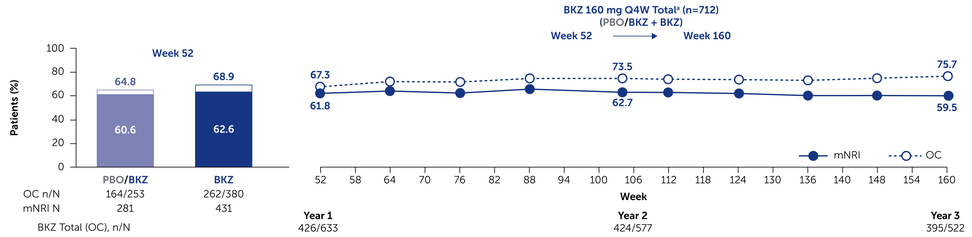
B) PASI100[b]



C) MDA



D) SJC=0[c]



Randomised set. Efficacy data reported from Year 1 (Week 52) through Year 2 (Week 104) and Year 3 (Week 160). **[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=357); **[c]** Resolution of swollen joint count (SJC=0) was assessed in 66 joints.

Table 2 Summary of additional efficacy results at Week 160

	BE OPTIMAL (bDMARD-naïve) BKZ 160 mg Q4W Total[a] (n=712)	
	mNRI, %	**OC, % (n/N)**
ACR20	67.6	80.1 (419/523)
ACR70	40.0	50.1 (263/525)
PASI75[b]	84.2	93.8 (258/275)
PASI90[b]	76.4	88.0 (242/275)
Nail psoriasis resolution[c]	65.6	78.2 (244/312)
ACR50+PASI100[b]	44.1	54.4 (149/274)
VLDA	30.0	38.3 (202/527)
DAPSA disease state (MI),[d] % (95% CI)		
REM+LDA	71.5 (67.9, 75.0)	
REM	38.2 (34.4, 42.0)	
TJC=0 (of 68 joints)	36.9	45.8 (239/522)
Enthesitis resolution[e]	59.6	76.4 (120/157)
Dactylitis resolution[f]	66.3 [NRI][g]	96.7 (59/61)
HAQ-DI MCID[h]	54.4	63.9 (260/407)
FACIT-Fatigue MCID[i,j]	51.5	59.6 (288/483)
PsAID-12 ≥3-point decrease[j,k]	45.6	54.2 (202/373)
Pain VAS ≥50% improvement[j,m]	55.2	65.3 (346/530)

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=357); **[c]** In patients with nail psoriasis at baseline (mNAPSI >0; n=400); **[d]** DAPSA REM defined as a DAPSA score of ≤4. REM+LDA defined as a DAPSA score of ≤14; **[e]** In patients with enthesitis at baseline (LEI >0; n=213); **[f]** In patients with dactylitis at baseline (LDI >0; n=89); **[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 decrease from baseline ≥0.35 in patients with HAQ-DI ≥0.35 at baseline (n=539); **[i]** FACIT-Fatigue MCID defined as increase from baseline ≥4 in patients with FACIT-Fatigue ≤48 at baseline (n=643); **[j]** Reported to Week 148; **[k]** Defined as clinically meaningful within patient improvement.[3] Reported in patients with PsAID-12 ≥3 at baseline (n=494); **[l]** Pain VAS was assessed using Patient's Assessment of Arthritis Pain VAS, which ranges from 0 (no pain) to 100 (most severe pain); **[m]** Pain VAS ≥50% represents a substantial improvement in patient-reported pain.[4]

Table 3 Safety at Week 156

n (%) [EAIR/100 PY]	BE OPTIMAL (bDMARD-naïve) BKZ 160 mg Q4W Total[a] (n=702); 1794.3 PY	All Patients[a] (N=823); 2022.1 PY
Any TEAEs	650 (92.6) [168.1]	755 (91.7) [164.2]
Serious TEAEs	114 (16.2) [6.9]	122 (14.8) [6.5]
Study discontinuation due to TEAEs	60 (8.5) [3.4]	65 (7.9) [3.3]
Drug-related TEAEs[b]	324 (46.2) [27.4]	365 (44.3) [26.9]
Severe TEAEs	61 (8.7) [3.5]	66 (8.0) [3.4]
Deaths	2 (0.3) [0.1][c]	3 (0.4) [0.2][c,d]
Most frequent TEAEs[e]		
SARS-CoV-2 (COVID-19) infection	191 (27.2) [12.2]	223 (27.1) [12.7]
Nasopharyngitis	125 (17.8) [8.0]	139 (16.9) [7.8]
Upper respiratory tract infection	102 (14.5) [6.2]	113 (13.7) [6.1]
Safety topics of interest		
Serious infections	25 (3.6) [1.4]	28 (3.4) [1.4]
Opportunistic infections	20 (2.8) [1.1]	21 (2.6) [1.1]
Active tuberculosis	0	0
Fungal infections	144 (20.5) [9.2]	163 (19.8) [9.2]
Candida infections	97 (13.8) [5.9]	106 (12.9) [5.7]
Oral candidiasis	73 (10.4) [4.3]	82 (10.0) [4.3]
Fungal infections NEC	61 (8.7) [3.6]	71 (8.6) [3.7]
Tinea infections	11 (1.6) [0.6]	12 (1.5) [0.6]
Neutropenia	22 (3.1) [1.3][f]	22 (2.7) [1.1][f]
Serious hypersensitivity reaction	0	0
Administration/injection site reaction[g]	24 (3.4) [1.4]	28 (3.4) [1.4]
Definite or probable adjudicated IBD	5 (0.7) [0.3]	7 (0.9) [0.4]
Uveitis[h]	4 (0.6) [0.2][i]	4 (0.5) [0.2][i]
Adjudicated suicidal ideation and behaviour	2 (0.3) [0.1][j]	2 (0.2) [0.1][j]
Adjudicated MACE	7 (1.0) [0.4]	9 (1.1) [0.5]
Elevated liver enzymes[k]	71 (10.1) [4.3]	80 (9.7) [4.2]
>3× ULN ALT or AST, n/N (%) [EAIR]	34/701 (4.9) [2.0]	39/822 (4.7) [2.0]
Malignancies, excluding non-melanoma skin cancer	9 (1.3) [0.5]	9 (1.1) [0.5]

Safety set. **[a]** Safety events reported whilst receiving BKZ. BKZ Total group includes BKZ-randomised patients and PBO patients who switched to BKZ at Week 16, includes events after switch only. All Patients also includes ADA/BKZ switchers, includes events after switch only; **[b]** Per study investigator assessment; **[c]** One death due to traumatic shock (motorcycle accident), unrelated to treatment (Week 0–52). One death due to cardiac arrest, unrelated to treatment (Week 104–156); **[d]** One death due to acute myocardial infarction, unrelated to treatment (Week 52–104); **[e]** Most frequent TEAEs are the top three adverse events occurring in all patients; **[f]** 20 cases of neutropenia; 2 neutrophil count decreased; **[g]** Includes the high-level terms "administration site reactions NEC" and "injection site reactions"; **[h]** Includes the preferred terms "autoimmune uveitis", "iridocyclitis", "iritis"and "uveitis"; **[i]** 2 iridocyclitis; 2 uveitis; **[j]** One event reported Week 52–104; one event reported Week 104–156; **[k]** 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; **ADA:** adalimumab; **ALT:** alanine aminotransferase; **AST:** aspartate aminotransferase; **bDMARD:** biologic disease-modifying antirheumatic drug; **BKZ:** bimekizumab; **BSA:** body surface area; **CI:** confidence interval; **csDMARD:** conventional synthetic 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; **IL:** interleukin; **LDA:** low disease activity; **LDI:** Leeds Dactylitis Index; **LEI:** Leeds Enthesitis Index; **MACE:** major adverse cardiovascular event; **MCID:** minimal clinically important difference; **MDA:** minimal disease activity; **MedDRA:** Medical Dictionary for Regulatory Activities; **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; **Q2W:** every 2 weeks; **Q4W:** every 4 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.

References: [1]Mease PJ. Rheumatol Ther 2024;11:1363–82. [2]McInnes IB. EULAR 2025. POS0105; [3]Gossec L. RMD Open 2024;10:e003548; [4]Dworkin RH. J Pain 2008;9:105–21.

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