Efficacy and safety of bimekizumab to 2 years in patients with psoriatic arthritis by baseline psoriasis severity

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Disclosures

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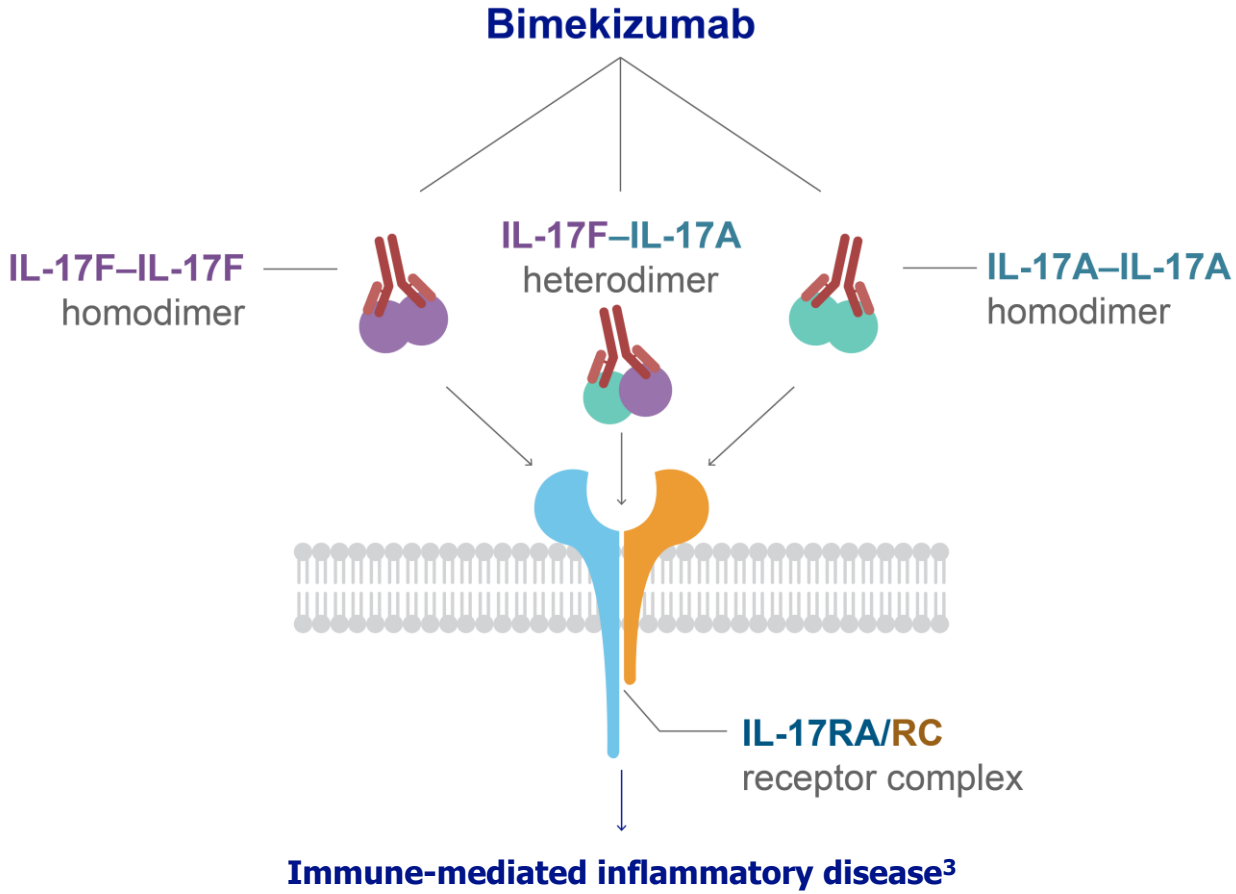
Introduction

- Evaluating the long-term efficacy and safety of treatments in patients with psoriatic arthritis (PsA) and varying levels of skin psoriasis is clinically important.
- Bimekizumab, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated sustained efficacy in patients with PsA to 2 years and in patients with PsA and concomitant psoriasis to 1 year.[1,2]

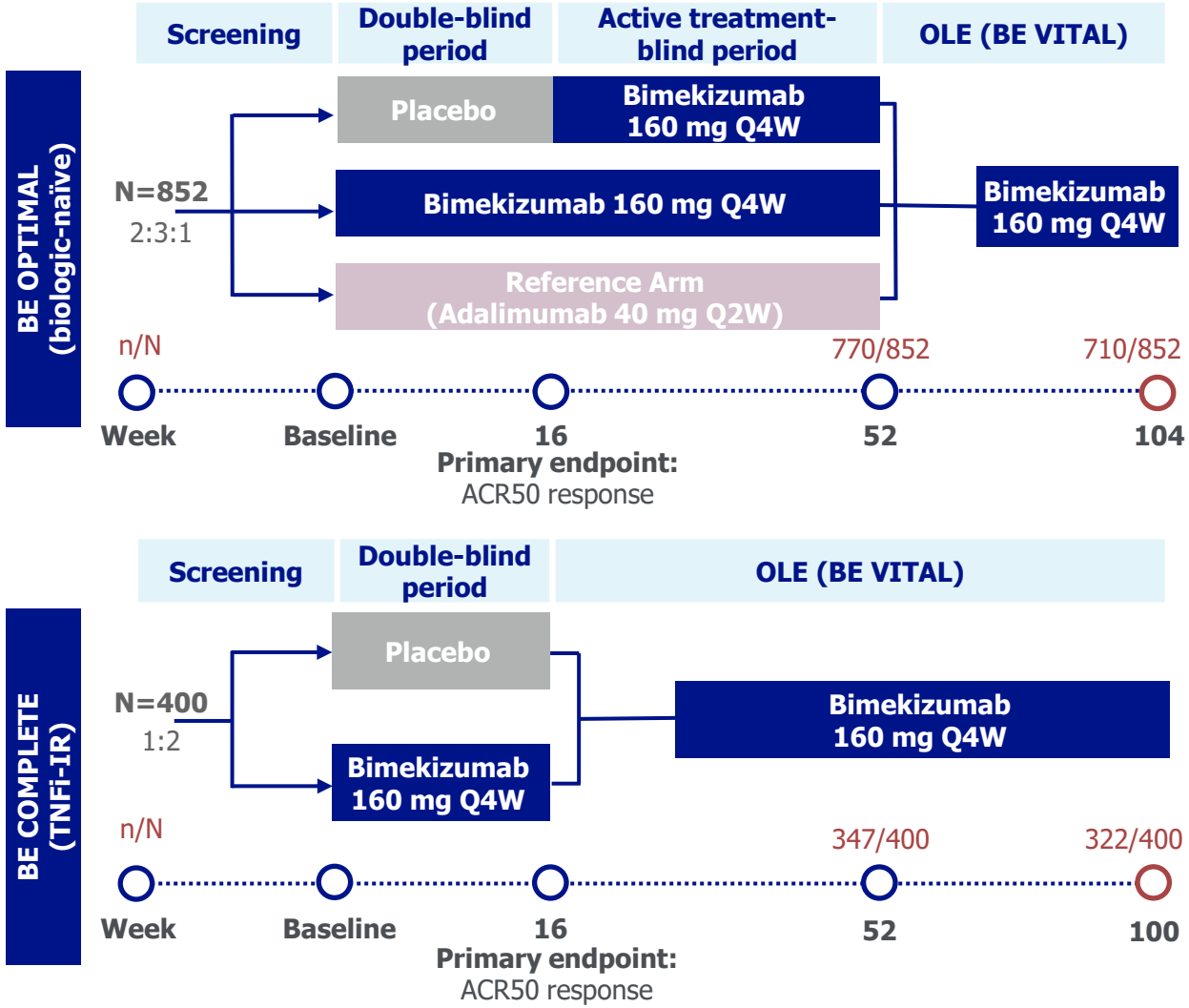


OBJECTIVE: To assess the long-term efficacy and safety of bimekizumab in patients with PsA, stratified by baseline psoriasis severity,[a] to 2 years.

[a] Baseline psoriasis severity definitions: no/minimal psoriasis (BSA <3%), mild psoriasis (BSA ≥3% [including those with BSA ≥10% and either IGA <3 or PASI <12]) or moderate/severe psoriasis (BSA ≥10%, IGA ≥3 and PASI ≥12). **1.** Mease PJ. Rheumatol Ther 2024;11:1363–82; **2.** Thaçi D. EADV 2023; Abstract:2959; **3.** Glatt S. Ann Rheum Dis 2018;77:523–32. BSA: body surface area; IGA: Investigator's Global Assessment; IL: interleukin; PASI: Psoriasis Area and Severity Index; PsA: psoriatic arthritis; R: receptor.

Methods

Bimekizumab PsA Study Designs[a]



- Efficacy data reported to Week 104 in biologic disease-modifying antirheumatic drug (biologic)-naïve patients (BE OPTIMAL) and Week 100 in tumour necrosis factor inhibitor inadequate response/intolerance (TNFi-IR) patients (BE COMPLETE).[b]
- Upon completion in both studies, patients were eligible to enrol in the open-label extension, BE VITAL.
- Patients were stratified by baseline psoriasis severity as having either no/minimal to mild psoriasis or moderate/severe psoriasis.

Results

- At baseline, 650 (76.3%) biologic-naïve and 344 (86.0%) TNFi-IR patients had no/minimal to mild psoriasis; 62 (7.3%) biologic-naïve and 56 (14.0%) TNFi-IR patients had moderate/severe psoriasis.

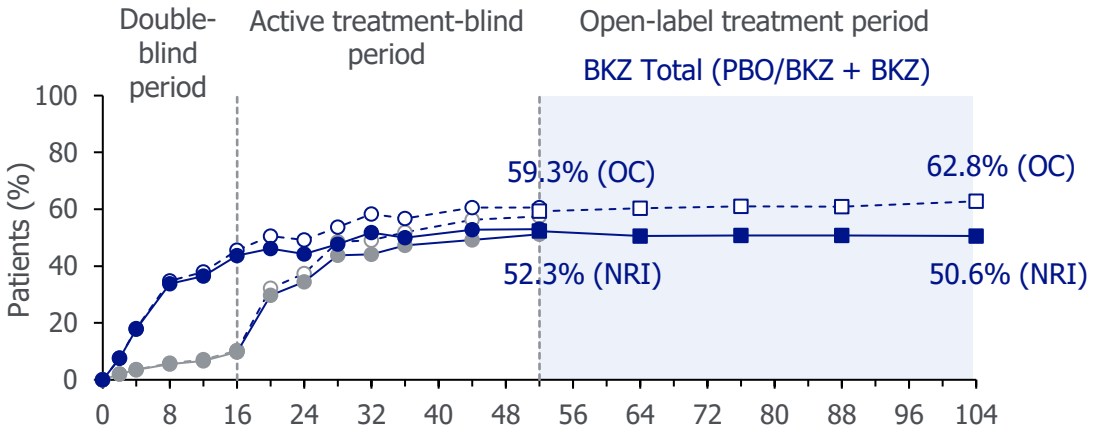
Study design: BE OPTIMAL (NCT03895203) and BE COMPLETE (NCT03896581) assessed bimekizumab 160 mg Q4W in patients with PsA. Patients completing BE OPTIMAL Week 52 or BE COMPLETE Week 16 could enter BE VITAL (OLE; NCT04009499). The adalimumab 40 mg Q2W treatment arm served as an active reference. BE OPTIMAL was not powered for statistical comparisons of adalimumab to bimekizumab or placebo. Completion rates include patients that completed to Week 52/104 in BE OPTIMAL and Week 52/100 in BE COMPLETE not on randomised treatment. **[a]** Disposition data are presented for the overall population. ACR50: ≥50% improvement from baseline in American College of Rheumatology response criteria; **[b]** Efficacy outcomes and safety data are reported in patients randomised to placebo or bimekizumab at baseline; biologic: biologic disease-modifying antirheumatic drug; OLE: open-label extension; Q2W: every 2 weeks; Q4W: every 4 weeks; TNFi-IR: inadequate response or intolerance to tumour necrosis factor inhibitors.

ACR50 responses (NRI, OC)

Sustained to Week 104/100 in patients with no/minimal to mild psoriasis and moderate/severe psoriasis at baseline

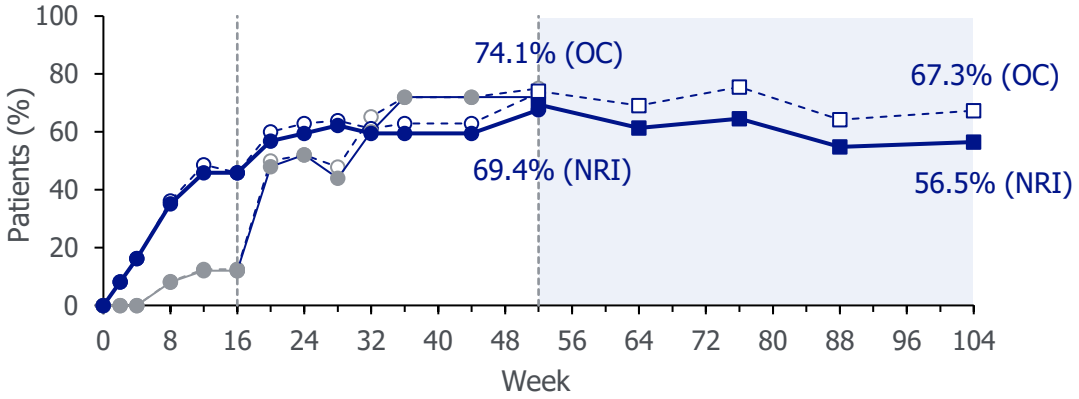
BE OPTIMAL (biologic-naïve)

No/minimal to mild psoriasis



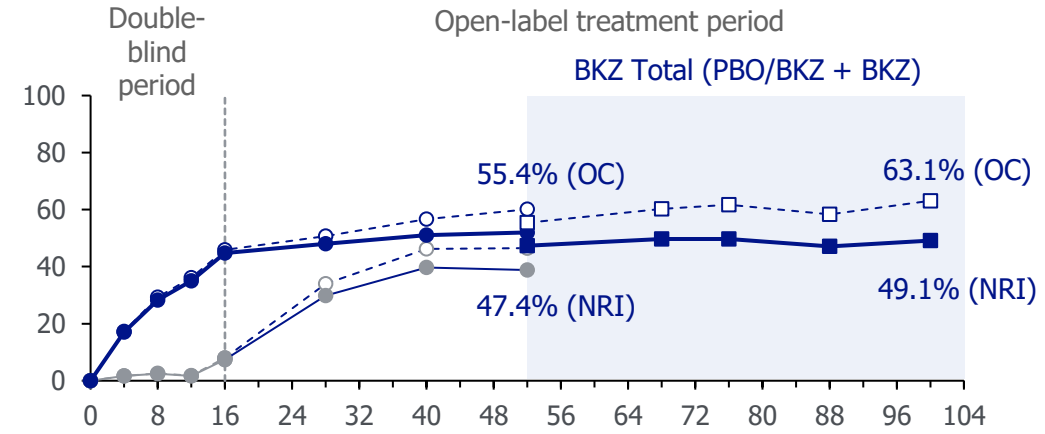
Number of patients (n/N); OC	Year 1	Year 2
BKZ Total	340/573	329/524

Moderate/ severe psoriasis

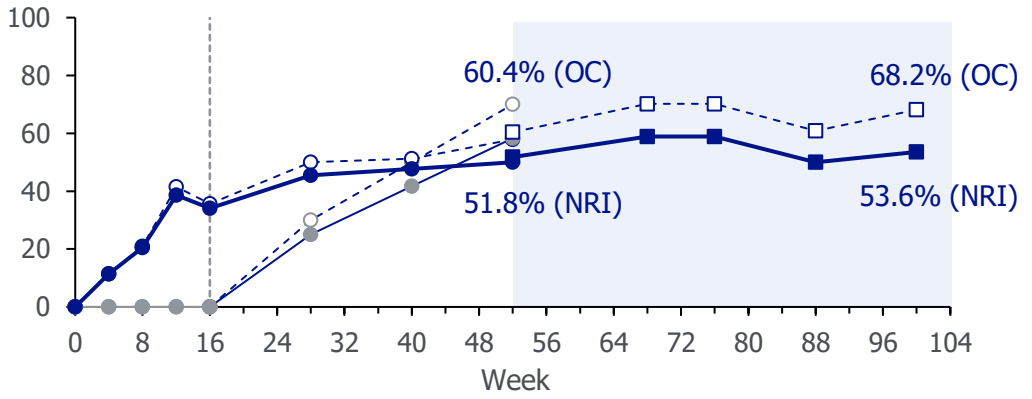


Number of patients (n/N); OC	Year 1	Year 2
BKZ Total	43/58	35/52

BE COMPLETE (TNFi-IR)



	Year 1	Year 2
BKZ Total	163/294	169/268



	Year 1	Year 2
BKZ Total	29/48	30/44

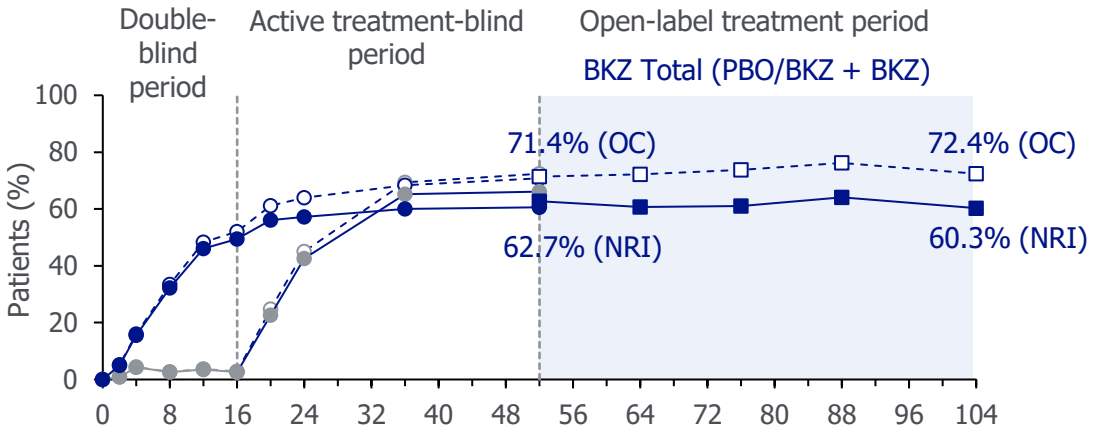
PBO/BKZ 160 mg Q4W[a] — BKZ 160 mg Q4W[b] — BKZ Total 160 mg Q4W (PBO/BKZ + BKZ)[c] — OC — NRI

Randomised set. BKZ Total includes patients who switched from PBO to BKZ at Week 16. Baseline psoriasis severity definitions: no/minimal psoriasis (BSA <3%), mild psoriasis (BSA ≥3% [including those with BSA ≥10% and either IGA <3 or PASI <12]) or moderate/severe psoriasis (BSA ≥10%, IGA ≥3 and PASI ≥12). Data reported to Year 1 (Week 52 in BE OPTIMAL/BE COMPLETE) and Year 2 (Week 104 in BE OPTIMAL and Week 100 in BE COMPLETE). **[a]** BE OPTIMAL (no/minimal to mild psoriasis n=256; moderate/severe psoriasis n=25); BE COMPLETE (no/minimal to mild psoriasis n=121; moderate/severe psoriasis n=12); **[b]** BE OPTIMAL (no/minimal to mild psoriasis n=394; moderate/severe psoriasis n=37); BE COMPLETE (no/minimal to mild psoriasis n=223; moderate/severe psoriasis n=44); **[c]** BE OPTIMAL (no/minimal to mild psoriasis n=650; moderate/severe psoriasis n=62); BE COMPLETE (no/minimal to mild psoriasis n=344; moderate/severe psoriasis n=56). BKZ: bimekizumab; NRI: non-responder imputation; OC: observed case; PBO: placebo.

PASI100 responses (NRI, OC)

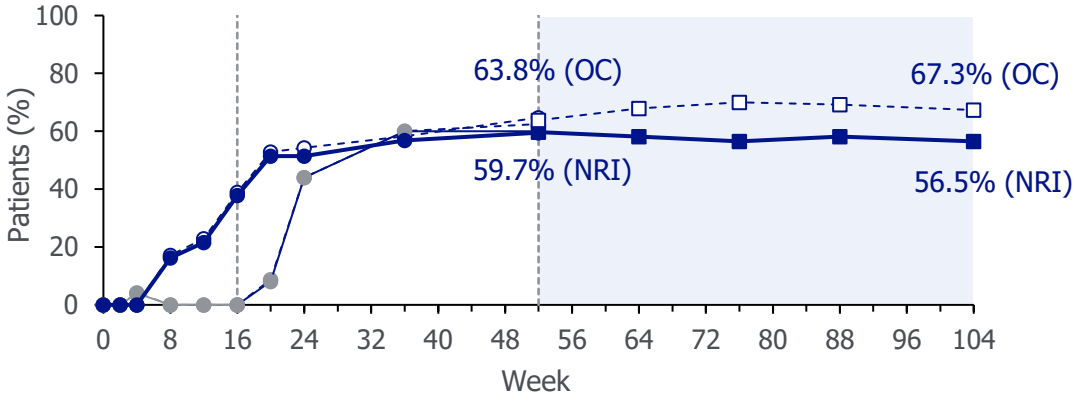
Sustained to Week 104/100 in patients with mild psoriasis and moderate/severe psoriasis at baseline

BE OPTIMAL (biologic-naïve)



Mild psoriasis

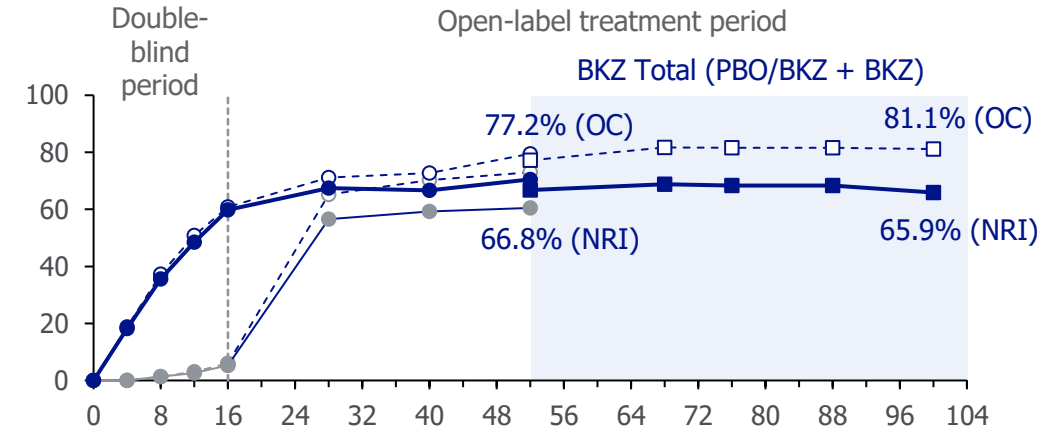
Number of patients (n/N); OC	Year 1	Year 2
BKZ Total	185/259	178/246



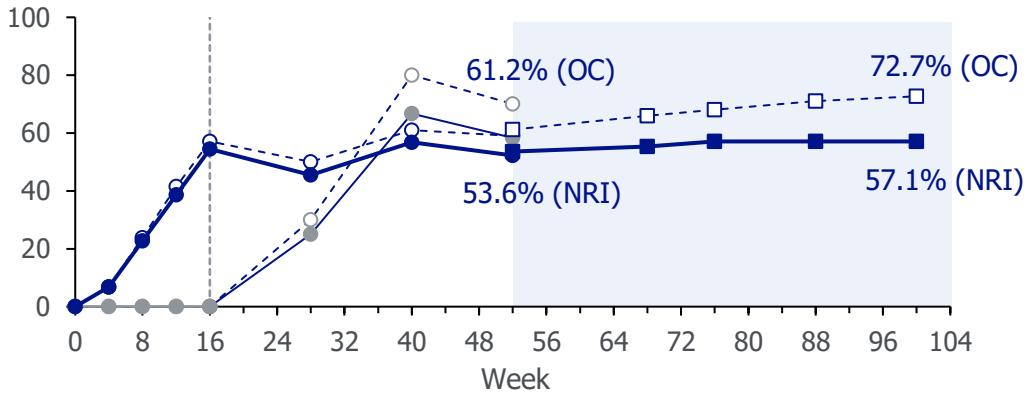
Moderate/ severe psoriasis

Number of patients (n/N); OC	Year 1	Year 2
BKZ Total	37/58	35/52

BE COMPLETE (TNFi-IR)



	Year 1	Year 2
BKZ Total	139/180	137/169



	Year 1	Year 2
BKZ Total	30/49	32/44

PBO/BKZ 160 mg Q4W[a] — BKZ 160 mg Q4W[b] — BKZ Total 160 mg Q4W (PBO/BKZ + BKZ)[c] — OC — NRI

Randomised set. In patients with psoriasis affecting ≥3% of BSA at baseline (mild or moderate/severe psoriasis). BKZ Total includes patients who switched from PBO to BKZ at Week 16. Baseline psoriasis severity definitions: mild psoriasis (BSA ≥3% [including those with BSA ≥10% and either IGA <3 or PASI <12]) or moderate/severe psoriasis (BSA ≥10%, IGA ≥3 and PASI ≥12). Data reported to Year 1 (Week 52 in BE OPTIMAL/BE COMPLETE) and Year 2 (Week 104 in BE OPTIMAL and Week 100 in BE COMPLETE). **[a]** BE OPTIMAL (mild psoriasis n=115; moderate/severe psoriasis n=25); BE COMPLETE (mild psoriasis n=76; moderate/severe psoriasis n=12); **[b]** BE OPTIMAL (mild psoriasis n=180; moderate/severe psoriasis n=37); BE COMPLETE (mild psoriasis n=132; moderate/severe psoriasis n=44); **[c]** BE OPTIMAL (mild psoriasis n=295; moderate/severe psoriasis n=62); BE COMPLETE (mild psoriasis n=208; moderate/severe psoriasis n=56). PASI100: 100% improvement from baseline in PASI.

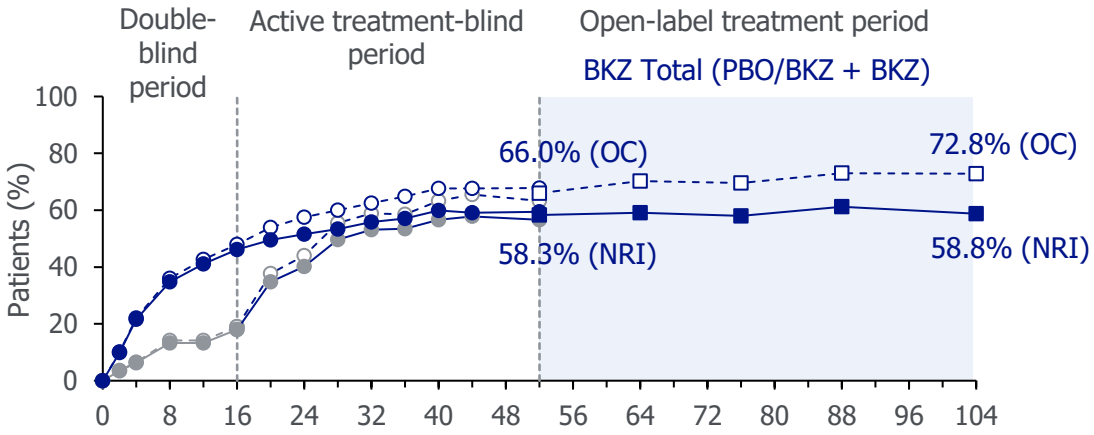
Resolution of swollen joint count (SJC=0) responses (NRI, OC)

Sustained to Week 104/100 in patients with no/minimal to mild psoriasis and moderate/severe psoriasis at baseline

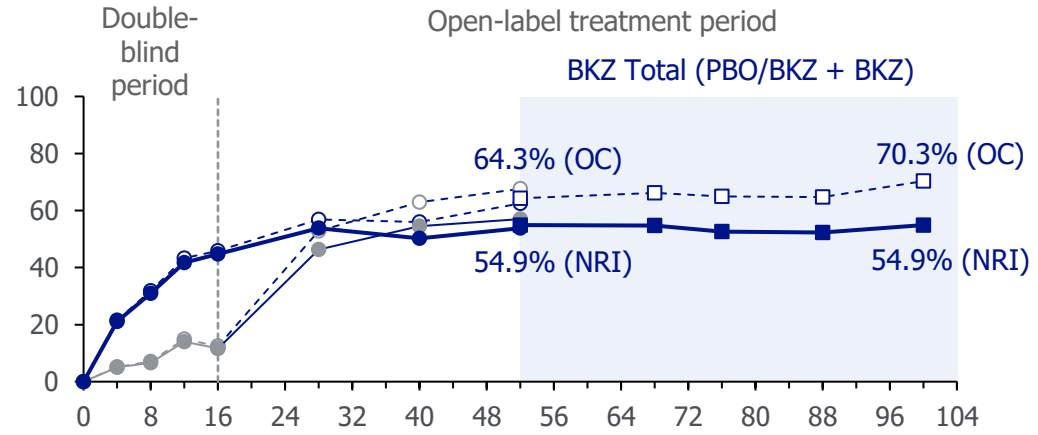
BE OPTIMAL (biologic-naïve)

BE COMPLETE (TNFi-IR)

No/minimal to mild psoriasis

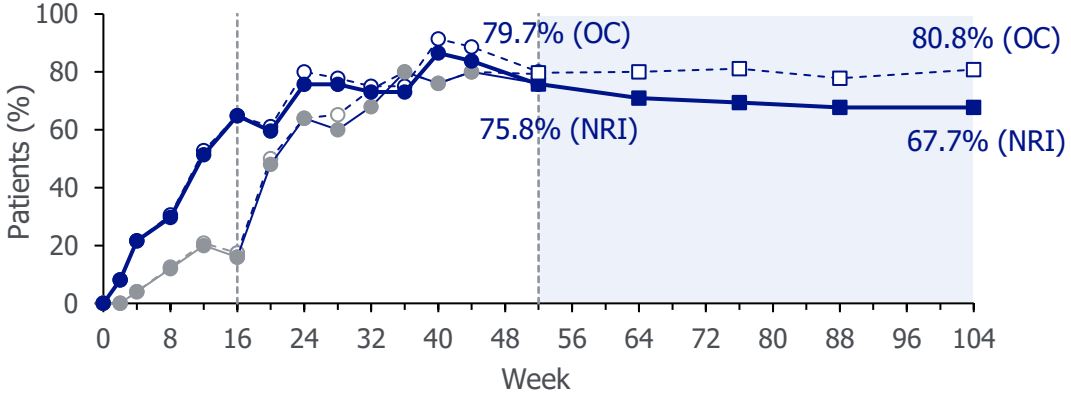


Number of patients (n/N); OC	Year 1	Year 2
BKZ Total	379/574	382/525

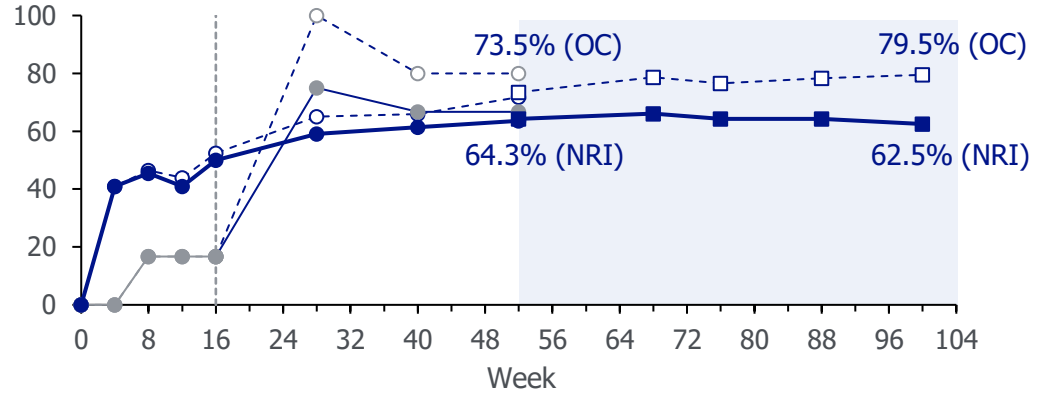


	Year 1	Year 2
BKZ Total	189/294	189/269

Moderate/ severe psoriasis



Number of patients (n/N); OC	Year 1	Year 2
BKZ Total	47/59	42/52



	Year 1	Year 2
BKZ Total	36/49	35/44

PBO/BKZ 160 mg Q4W[a] — BKZ 160 mg Q4W[b] — BKZ Total 160 mg Q4W (PBO/BKZ + BKZ)[c] — OC — NRI

Randomised set. BKZ Total includes patients who switched from PBO to BKZ at Week 16. Baseline psoriasis severity definitions: no/minimal psoriasis (BSA <3%), mild psoriasis (BSA ≥3% [including those with BSA ≥10% and either IGA <3 or PASI <12]) or moderate/severe psoriasis (BSA ≥10%, IGA ≥3 and PASI ≥12). Data reported to Year 1 (Week 52 in BE OPTIMAL/BE COMPLETE) and Year 2 (Week 104 in BE OPTIMAL and Week 100 in BE COMPLETE). **[a]** BE OPTIMAL (no/minimal to mild psoriasis n=256; moderate/severe psoriasis n=25); BE COMPLETE (no/minimal to mild psoriasis n=121; moderate/severe psoriasis n=12); **[b]** BE OPTIMAL (no/minimal to mild psoriasis n=394; moderate/severe psoriasis n=37); BE COMPLETE (no/minimal to mild psoriasis n=223; moderate/severe psoriasis n=44); **[c]** BE OPTIMAL (no/minimal to mild psoriasis n=650; moderate/severe psoriasis n=62); BE COMPLETE (no/minimal to mild psoriasis n=344; moderate/severe psoriasis n=56). SJC: swollen joint count.

Improvements in additional outcomes

Similar, sustained improvements were observed for additional efficacy outcomes to 2 years (NRI)[a]

	BE OPTIMAL (biologic-naïve)		BE COMPLETE (TNFi-IR)	
	BKZ Total 160 mg Q4W		BKZ Total 160 mg Q4W	
n (%) [95% CI]	No/minimal to mild psoriasis (n=650)	Moderate/ severe psoriasis (n=62)	No/minimal to mild psoriasis (n=344)	Moderate/ severe psoriasis (n=56)
	Week 104		Week 100	
MDA responders[b]	332 (51.1) [47.2, 54.9]	34 (54.8) [42.5, 67.2]	158 (45.9) [40.7, 51.2]	24 (42.9) [29.9, 55.8]
Pain50 responders[c,d]	342 (52.6) [48.8, 56.5]	34 (54.8) [42.5, 67.2]	185 (53.8) [48.5, 59.0]	30 (53.6) [40.5, 66.6]
mNAPSI=0[e]	242 (68.6) [63.7, 73.4] n=353	31 (66.0) [52.4, 79.5] n=47	132 (65.3) [58.8, 71.9] n=202	23 (57.5) [42.2, 72.8] n=40
	Week 104		Week 88	
FACIT-Fatigue MCID[f]	285 (48.7) [44.7, 52.8] n=585	34 (58.6) [45.9, 71.3] n=58	161 (50.5) [45.0, 56.0] n=319	25 (48.1) [34.5, 61.7] n=52

Safety data

Bimekizumab was well tolerated and the safety profile was consistent across baseline psoriasis severities

- To Week 104, for ≥1 treatment emergent adverse event (TEAE) with bimekizumab:

	BE OPTIMAL (biologic-naïve)		BE COMPLETE (TNFi-IR)	
	BKZ Total 160 mg Q4W[g]		BKZ Total 160 mg Q4W[g]	
n (%) [EAIR/100 PY]	No/minimal to mild psoriasis n=640 1108.8 PY	Moderate/severe psoriasis n=62 110.9 PY	No/minimal to mild psoriasis n=333 580.2	Moderate/severe psoriasis n=55 96.8 PY
TEAEs	564 (88.1) [185.9]	55 (88.7) [153.7]	254 (76.3) [99.1]	43 (78.2) [108.0]
Serious TEAEs	80 (12.5) [7.7]	8 (12.9) [7.5]	33 (9.9) [6.0]	3 (5.5) [3.2]
Study discontinuation due to TEAEs	39 (6.1) [3.6]	4 (6.5) [3.7]	19 (5.7) [3.3]	4 (7.3) [4.2]
Drug-related TEAEs	270 (42.2) [35.0]	20 (32.3) [23.3]	100 (30.0) [21.8]	15 (27.3) [18.7]
Severe TEAEs	38 (5.9) [3.5]	8 (12.9) [7.5]	18 (5.4) [3.2]	5 (9.1) [5.4]
Deaths, n (%)	1 (0.2)[h]	0	0	1 (1.8)[i]

- **Most frequent TEAEs by preferred term were Corona virus infection, nasopharyngitis, upper respiratory tract infection, oral candidiasis and urinary tract infection.[j]**
- No cases of active tuberculosis or uveitis were reported.
- Most *Candida* infections were oral candidiasis; the majority of oral candidiasis cases were mild/moderate and none were serious or systemic.

[a] Randomised set; **[b]** MDA response defined as achievement of ≥5/7 of the following: TJC ≤1, SJC ≤1, PASI ≤1 or BSA ≤3%, patient pain VAS ≤15, PGA-PsA VAS ≤20, HAQ-DI ≤0.5, and tender entheseal points (LEI) ≤1; **[c]** Arthritis pain assessed using Patient's Assessment of Arthritis Pain Visual Analogue Scale (Pain VAS; 0 [no pain] to 100 [most severe pain]); **[d]** ≥50% improvement from baseline in Pain VAS (Pain50) represents a substantial improvement in patient-reported pain;[1] **[e]** In patients with mNAPSI >0 at baseline; **[f]** FACIT-Fatigue MCID defined as ≥4-point increase from baseline in patients with FACIT-Fatigue ≤48 at baseline; **[g]** Safety set. Safety events reported whilst receiving BKZ in BKZ Total group patients only. BKZ Total includes PBO/BKZ Week 16 switchers, includes events after switch only; **[h]** One death due to a motorcycle accident; **[i]** One sudden death, deemed unrelated to treatment; **[j]** Five most common TEAEs in any BKZ Total group in patients with no/minimal to mild psoriasis at Week 104 data cut. **1.** Dworkin RH. J Pain 2008;9:105–21. CI: confidence interval; FACIT-Fatigue: Functional Assessment of Chronic Illness; Therapy-Fatigue; HAQ-DI: Health Assessment Questionnaire-Disability Index; LEI: Leeds Enthesitis Index; MCID minimal clinically important difference; MDA: minimal disease activity; mNAPSI: modified Nail Psoriasis Severity Index; Pain50: ≥50% improvement from baseline in patient-reported pain; PGA: Patient's Global Assessment; TJC: tender joint count; VAS: visual analogue scale.

Conclusions

Treatment with bimekizumab resulted in **consistent** and **sustained improvements** to **2 years** in patients with either no/minimal to mild psoriasis or moderate/severe psoriasis at baseline.

Improvements with bimekizumab were similar in **biologic-naïve** and **TNFi-IR** patients with active PsA.

The **safety** profile of bimekizumab was **consistent** across baseline psoriasis severities and with **previous reports.**[1]

To access the presentation, scan the QR code

Link expiration: 19 September 2025

1. Mease PJ. Rheumatol Ther 2024;11:1363–82. ACR50: ≥50% improvement from baseline in American College of Rheumatology response criteria; ALT: alanine aminotransferase; AST: aspartate aminotransferase; biologic: biologic disease-modifying antirheumatic drug; BKZ: bimekizumab; BSA: body surface area; CI: confidence interval; 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; IGA: Investigator's Global Assessment; IL: interleukin; LEI: Leeds Enthesitis Index; MACE: major adverse cardiac event; MCID: minimal clinically important difference; MDA: minimal disease activity; MI: multiple imputation; mNAPSI: modified Nail Psoriasis Severity Index; NRI: non-responder imputation; OC: observed case; OLE: open-label extension; Pain50: ≥50% improvement from baseline in Pain VAS; PASI: Psoriasis Area and Severity Index; PASI100: 100% improvement from baseline in Psoriasis Area and Severity Index; PBO: placebo; PGA: Patient's Global Assessment; PsA: psoriatic arthritis; PY: patient-years; Q2W: every 2 weeks; Q4W: every 4 weeks; R: receptor; 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.