Bimekizumab Impact on Health-Related Quality of Life and Physical Function in Patients with Active Psoriatic Arthritis who were Biologic DMARD-Naïve or had Inadequate Response or Intolerance to TNF-α Inhibitors: 1-Year Results from Two Phase 3, Randomized Studies

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Objective

To report the impact of bimekizumab (BKZ) treatment up to 1 year on health-related quality of life (HRQoL) and physical function in patients with active psoriatic arthritis (PsA) who were biologic DMARD (bDMARD)-naïve or had inadequate response or intolerance to TNF-α inhibitors (TNFi-IR).

Background

- PsA imparts a substantial burden on patient HRQoL.[1]
- Maximizing HRQoL through controlling symptoms, preventing structural damage, and normalizing physical and social function is a key treatment goal.[2]
- BKZ, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated improvements in efficacy outcomes and HRQoL measures in patients with PsA in phase 3 studies up to 16 weeks.[3,4]

Methods

- BE OPTIMAL (NCT03895203) and BE COMPLETE (NCT03896581) are phase 3 studies assessing BKZ 160 mg every 4 weeks (Q4W) in patients with active PsA who were bDMARD-naïve or had inadequate response or intolerance to TNFi, respectively (**Figure 1**).
- Both trials had a 16-week double-blind, placebo (PBO)-controlled phase. PBO-receiving patients switched to BKZ at Week 16 (PBO/BKZ).
- Patients completing BE OPTIMAL at Week 52 or BE COMPLETE at Week 16 were eligible to enter BE VITAL (open-label extension; NCT04009499); BE COMPLETE plus BE VITAL is referred to as 'BE COMPLETE' hereafter (**Figure 1**). Data are reported here up to 52 weeks of therapy.
- We present individual study data for HRQoL, physical function, and health status outcomes up to 1 year. Psoriatic Arthritis Impact of Disease 12-item (PsAID-12) Questionnaire data were also collected; results reported on poster 2249.[5]
- Some BE COMPLETE outcomes were only collected to Week 40, as indicated in **Figures 2–3**.
- Non-responder and multiple imputation (NRI, MI) were used for missing binary and continuous variables.

Results

- Overall, 770/852 (90.4%) and 347/400 (86.8%) patients completed Week 52 of BE OPTIMAL and BE COMPLETE.*
- Baseline (BL) characteristics were generally comparable between treatment groups within trials, with some differences in some BL characteristics between trials (**Table 1**).
- Across both trials, Week 16 improvements in HRQoL, health status, and physical function were sustained to Week 52/40 in BKZ-treated patients (**Figure 2**).
- Patients who switched to BKZ achieved comparable improvements across HRQoL and physical outcomes to BKZ-randomized patients by Week 52/40 (**Figure 2**).
- PsAQoL individual item scores were sustained to Week 52 in BKZ-randomized patients and improved in PBO/BKZ-treated patients compared to Week 16 in BE OPTIMAL (**Figure 3**).
- Improvements in SF-36 individual domain scores at Week 16 were sustained to Week 52/40 on BKZ treatment. SF-36 physical functioning, role physical, and bodily pain scores showed most improvement over the other individual domains (**Figure 4**).

Conclusions

Treatment with bimekizumab resulted in sustained improvements in patient-reported measures of HRQoL, physical function, and health status from Week 16 up to 1 year in patients with active PsA, irrespective of prior bDMARD use.

Summary

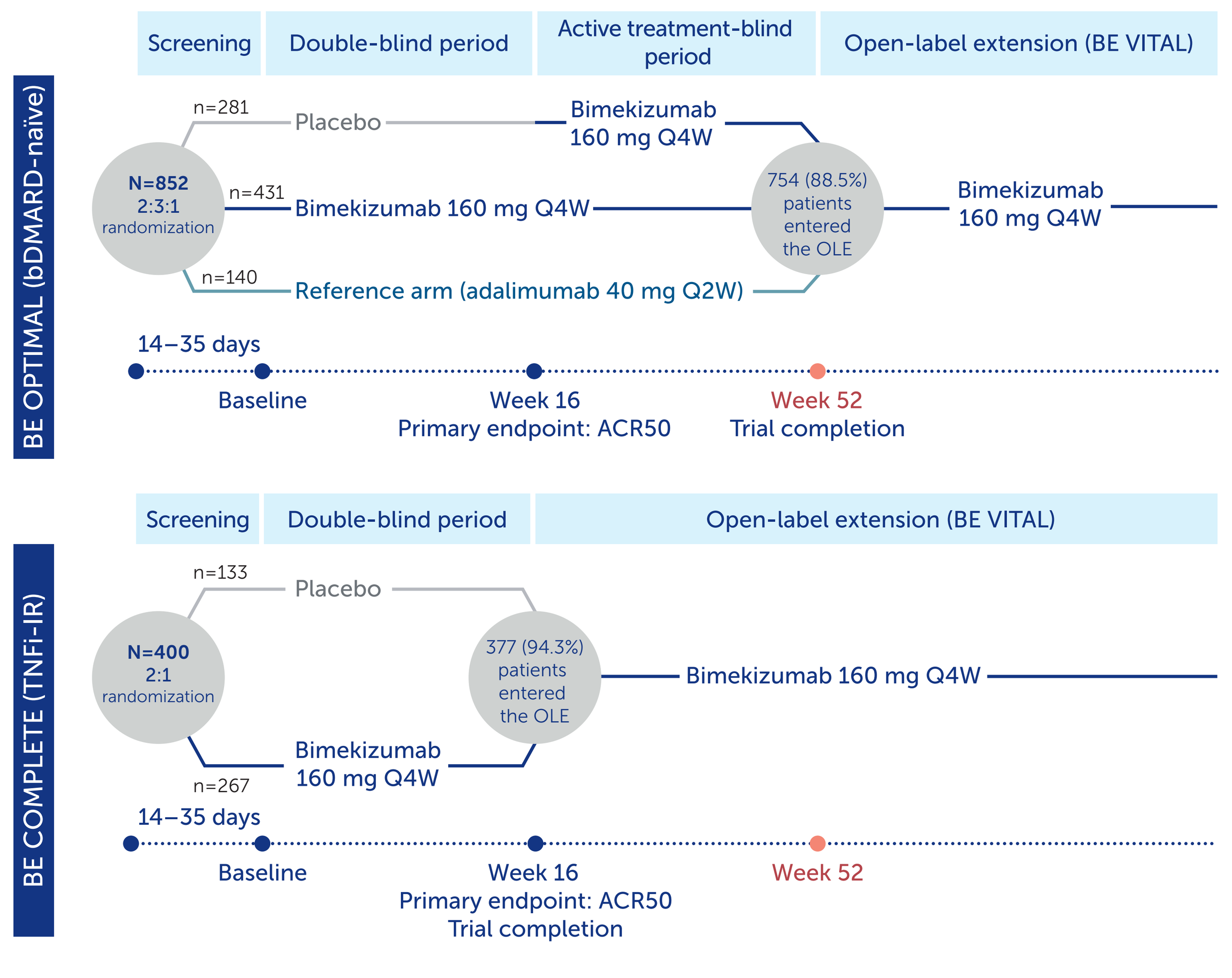
PsA imparts a substantial burden on HRQoL and physical function

The impact of up to 1 year of bimekizumab treatment on **HRQoL**, **physical function**, and **health status** was evaluated in two phase 3 clinical trials by changes from baseline in:

- PsA Quality of Life (PsAQoL); Short-Form 36-Item Health Survey (SF-36)
- Health Assessment Questionnaire-Disability Index (HAQ-DI)
- EQ-5D-3L Visual Analog Scale (VAS)

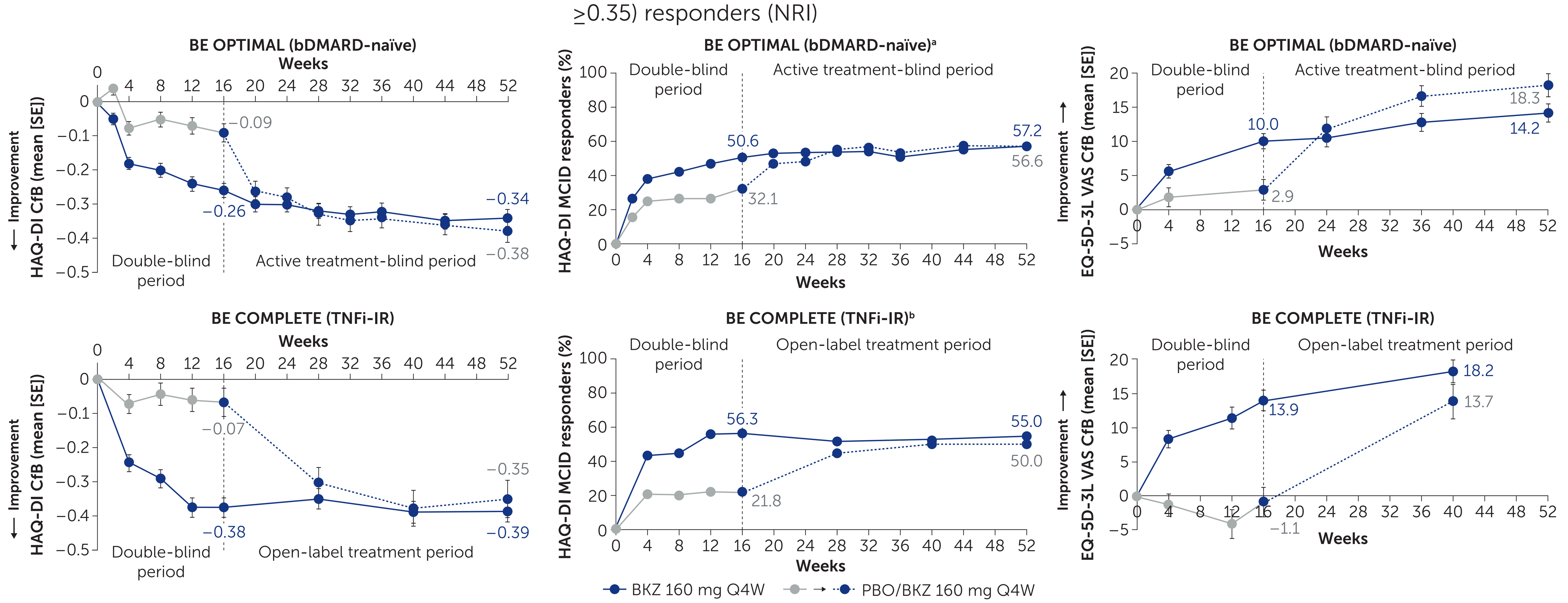
Patients receiving bimekizumab demonstrated clinically meaningful improvements in **HRQoL**, **physical function**, and **health status** scores up to 1 year; results were consistent between studies.

Figure 1 BE OPTIMAL and BE COMPLETE/BE VITAL study designs



BE VITAL includes patients from the BE OPTIMAL or BE COMPLETE studies; results are only presented for patients from BE COMPLETE.

Figure 2 Change from baseline in HAQ-DI score (A), HAQ-DI MCID responders (B), and change from baseline in EQ-5D-3L VAS (C) to 1 year



Randomized set. HAQ-DI MCID defined as decrease from baseline ≥0.35 in patients with HAQ-DI ≥0.35 at baseline. [a] PBO/BKZ 160 mg Q4W n=221, BKZ 160 mg Q4W n=318; [b] PBO/BKZ 160 mg Q4W n=110, BKZ 160 mg Q4W n=231.

Figure 3 PsAQoL heatmaps by individual item scores at baseline, Week 16, and Week 52

PsAQoL Items, %	BE OPTIMAL (bDMARD-naïve) PBO		PBO/BKZ	BKZ			BE COMPLETE (TNFi-IR)[a] PBO		PBO/BKZ	BKZ		
Week	0	16	52	0	16	52	0	16	52	0	16	52
I can't do the things I want to do	60.5	55.5	33.1	53.0	35.1	27.2	55.6	52.8	Not assessed	58.1	36.9	Not assessed
It takes me a long time get going in AM	59.4	50.2	34.6	58.1	34.6	25.9	64.7	67.2	Not assessed	68.2	36.9	Not assessed
I keep stopping what I'm doing to rest	57.7	49.8	35.0	49.3	40.4	31.7	58.6	56.0	Not assessed	60.3	36.1	Not assessed
I feel older than my years	48.0	44.2	28.7	36.3	26.7	19.1	36.1	42.4	Not assessed	44.6	27.0	Not assessed
It limits the places I go	47.0	48.3	26.0	46.3	28.6	22.0	53.4	49.6	Not assessed	53.2	35.7	Not assessed
I feel tired whatever I do	43.4	39.2	21.3	38.8	24.0	17.0	39.1	40.8	Not assessed	43.1	27.4	Not assessed
I have to push myself to do things	34.9	31.7	19.7	28.1	22.4	17.0	29.3	28.8	Not assessed	36.3	25.1	Not assessed
I'm unable to join activities with friends	32.0	24.2	15.0	21.4	15.4	11.0	27.8	29.6	Not assessed	30.3	12.5	Not assessed
I can't do things on the spur of moment	28.5	28.3	18.5	25.1	18.8	13.4	30.1	29.6	Not assessed	31.1	23.6	Not assessed
I often get angry with myself	23.8	22.6	15.7	20.2	14.4	10.2	17.3	16.8	Not assessed	21.3	14.1	Not assessed
I feel I am losing my independence	21.0	19.6	10.6	17.4	10.6	7.3	23.3	24.8	Not assessed	22.1	9.9	Not assessed
I find it difficult to have a good wash	19.9	21.5	11.0	19.8	11.5	8.4	28.6	28.0	Not assessed	27.0	12.5	Not assessed
I am easily irritated by other people	19.9	20.8	13.4	18.8	15.9	11.3	16.5	17.6	Not assessed	22.1	15.6	Not assessed
I feel dependent on others	19.6	22.6	11.4	15.1	12.3	8.4	25.6	21.6	Not assessed	21.3	13.7	Not assessed
It's too much effort to go out see people	19.2	20.0	11.4	13.0	9.9	7.1	21.1	20.0	Not assessed	18.7	10.6	Not assessed
I take it out on people close to me	14.9	12.5	7.9	10.5	10.1	6.5	15.8	14.4	Not assessed	15.0	8.0	Not assessed
I feel there's no enjoyment in my life	12.8	12.8	8.7	10.2	5.8	6.3	14.3	12.0	Not assessed	11.6	5.3	Not assessed
I feel like a prisoner in my own home	7.5	7.2	3.9	4.7	3.6	3.4	10.5	8.8	Not assessed	7.9	3.8	Not assessed

>60–≤70 | >50–≤60 | >40–≤50 | >30–≤40 | >20–≤30 | >10–≤20 | 0–≤10

[a] PsAQoL data collected to Week 16 in BE COMPLETE; not collected in BE VITAL.

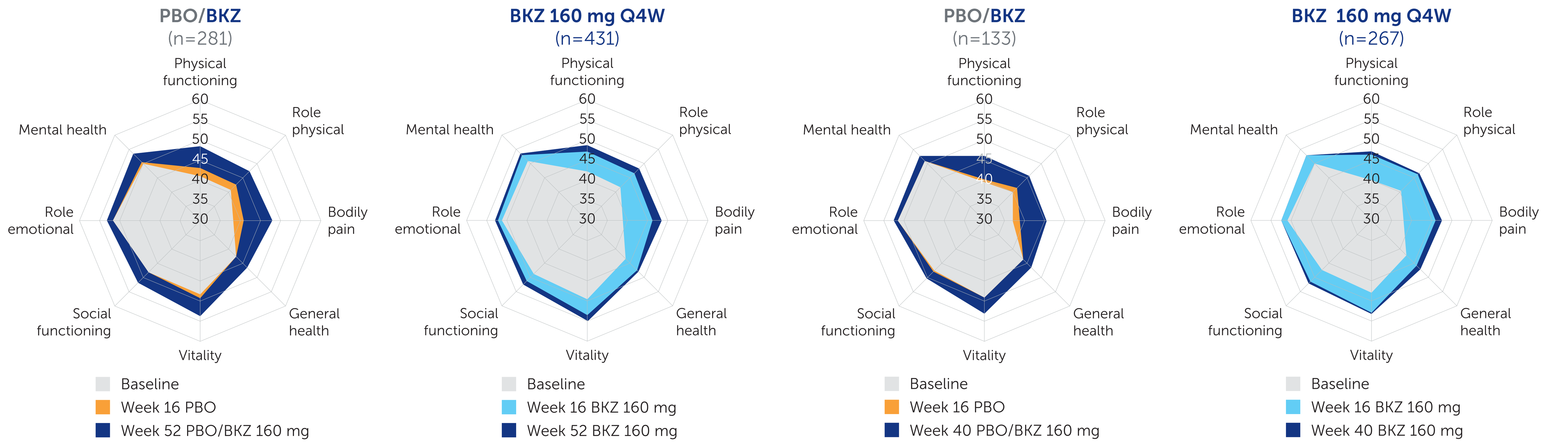
Table 1 Patient demographics and baseline characteristics

	BE OPTIMAL (bDMARD-naïve) PBO (n=281)	BE OPTIMAL (bDMARD-naïve) BKZ 160 mg Q4W (n=431)	BE COMPLETE (TNFi-IR) PBO (n=133)	BE COMPLETE (TNFi-IR) BKZ 160 mg Q4W (n=267)
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)
BMI, kg/m^2, mean (SD)	29.6 (6.1)	29.2 (6.8)	29.0 (5.4)	30.1 (6.5)
Time since first PsA diagnosis,[a] years, mean (SD)	5.6 (6.5)	6.0 (7.3)	9.2 (8.1)	9.6 (9.9)
BSA affected by psoriasis ≥3%, n (%)	140 (49.8)	217 (50.3)	88 (66.2)	176 (65.9)
PASI score,[b] 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)
Enthesitis (LEI >0),[c] n (%)	70 (24.9)	143 (33.2)	36 (27.1)	106 (39.7)
LEI score[d]	2.9 (1.5)	2.5 (1.5)	2.9 (1.6)	2.6 (1.5)
Dactylitis (LDI >0),[e] n (%)	33 (11.7)	56 (13.0)	14 (10.5)	34 (12.7)
Dactylitic sites[f]	1.5 (0.6)	1.4 (0.8)	1.9 (2.4)	2.0 (1.8)
LDI score[f]	47.3 (41.1)	46.7 (54.3)	66.4 (127.6)	72.7 (114.4)
hs-CRP ≥6 mg/L, n (%)	121 (43.1)	158 (36.7)	59 (44.4)	118 (44.2)
HAQ-DI, mean (SD)	0.89 (0.61)	0.82 (0.59)	1.04 (0.69)	0.97 (0.59)
EQ-5D-3L VAS,[g] mean (SD)	54.1 (20.2)	58.1 (19.7)	54.5 (20.8)	54.3 (20.3)
SF-36 PCS,[g] mean (SD)	36.9 (9.7)	38.1 (9.4)	35.9 (10.2)	36.4 (9.0)
SF-36 MCS,[g] mean (SD)	54.3 (8.8)	54.7 (8.8)	55.3 (10.1)	54.0 (9.3)
PsAQoL,[g] mean (SD)	6.4 (5.1)	5.5 (4.6)	6.4 (5.1)	6.7 (5.2)

Randomized set. [a] Data missing for 2 PBO and 8 BKZ patients in BE OPTIMAL, and 1 PBO and 1 BKZ patient in BE COMPLETE; [b] In patients with psoriasis involving at least 3% of BSA at baseline; [c] Data missing for 6 BKZ patients in BE OPTIMAL, and 1 PBO patient in BE COMPLETE; [d] In patients with enthesitis at baseline (LEI >0); Data missing for 6 BKZ patients in BE OPTIMAL, and 1 PBO patient in BE COMPLETE; [e] Data missing for 1 PBO and 7 BKZ patients in BE OPTIMAL, and 1 PBO patient in BE COMPLETE; [f] In patients with dactylitis at baseline (LDI >0); Data missing for 1 PBO and 7 BKZ patients in BE OPTIMAL, and 1 PBO patient in BE COMPLETE; [g] Data missing for 1 BKZ patient in BE OPTIMAL.

Figure 4 SF-36 individual domain scores at baseline, Week 16, and Week 52/40 (MI)

Higher score indicates improvement in health status



Randomized set. SF-36 scores range from 0–100; increase in SF-36 individual domain scores indicates improvement in health status. Domain scores are standardized, with a mean of 50 and standard deviation of 10. Scores below 47 are indicative of impaired functioning.

*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; **BL:** baseline; **BMI:** body mass index; **BSA:** body surface area; **CfB:** change from baseline; **HAQ-DI:** Health Assessment Questionnaire-Disability Index; **HRQoL:** health-related quality of life; **hs-CRP:** high-sensitivity C-reactive protein; **LDI:** Leeds Dactylitis Index; **LEI:** Leeds Enthesitis Index; **IL:** interleukin; **MCID:** minimal clinically important difference; **MCS:** Mental Component Summary; **MI:** multiple imputation; **NRI:** non-responder imputation; **OLE:** open-label extension; **PASI:** Psoriasis Area and Severity Index; **PBO:** placebo; **PCS:** Physical Component Summary; **PsA:** psoriatic arthritis; **PsAID-12:** Psoriatic Arthritis Impact of Disease 12-item; **PsAQoL:** Psoriatic Arthritis Quality of Life; **PtAAP:** Patient's Assessment of Arthritis Pain; **Q2W:** every two weeks; **Q4W:** every four weeks; **SD:** standard deviation; **SE:** standard error; **SF-36:** Short-Form 36-item Health Survey; **SJC:** swollen joint count; **TJC:** tender joint count; **TNFi:** tumor necrosis factor inhibitor; **TNFi-IR:** intolerance or inadequate response to 1–2 tumor necrosis factor inhibitors; **VAS:** visual analog scale.

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