Bimekizumab-Treated Patients With Psoriatic Arthritis Showed Sustained Improvements in HRQoL and Work Productivity Up To 2 Years

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Objective

To assess the evolution of health-related quality of life (HRQoL) and work productivity with bimekizumab (BKZ) treatment up to 2 years in patients with active psoriatic arthritis (PsA) who were biologic disease-modifying antirheumatic drug (bDMARD)-naïve or had prior inadequate response or intolerance to tumor necrosis factor inhibitors (TNFi-IR).

Background

- BKZ, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, demonstrated clinically relevant improvements in HRQoL and work productivity to 1 year in patients with PsA.[1,2]
- PsA has a substantial negative impact on patient HRQoL, including physical health and functional ability, contributing to reduced work productivity.[3,4]

Methods

- BE OPTIMAL (NCT03895203) and BE COMPLETE (NCT03896581) assessed subcutaneous BKZ 160 mg every 4 weeks (Q4W) in bDMARD-naïve and TNFi-IR patients with active PsA, respectively (**Figure 1**). BKZ-treated patients could enter BE VITAL (NCT04009499) after Week 16 of BE COMPLETE or Week 52 of BE OPTIMAL. Patients in the reference arm of BE OPTIMAL switched from adalimumab (ADA) 40 mg Q2W to BKZ 160 mg Q4W (ADA/BKZ) at Week 52.
- Change from baseline (CfB) in Short-Form 36-Item Health Survey Physical Component Summary (SF-36 PCS) is reported. Responder rates were assessed for PsA Impact of Disease 12-Item (PsAID-12) questionnaire total score (decrease from baseline ≥3) and Health Assessment Questionnaire-Disability Index (HAQ-DI; minimal clinically important difference [MCID]: decrease from baseline ≥0.35).
- Mean Work Productivity and Activity Impairment Questionnaire: Specific Health Problem v2.0 (WPAI:SHP) adapted for PsA[5,6] CfB is reported for work time missed (absenteeism), impairment while working (presenteeism), overall work impairment and activity impairment.
- Outcomes were collected to Week 104 of BE OPTIMAL, and to Week 100 (HAQ-DI) or Week 88 (PsAID-12, SF-36, WPAI) of BE COMPLETE.
- Data are reported as observed case (OC) and using multiple imputation (MI; continuous) or non-responder imputation (NRI; binary).

Results

- 710/852 (83.3%) and 322/400 (80.5%) patients had completed Week 104/100 of BE OPTIMAL and BE COMPLETE, respectively. Baseline characteristics have been reported previously.[7,8]
- Improvements in HRQoL achieved by Week 52/40, including disease impact and physical function, were sustained up to 2 years in BKZ-randomized and PBO/BKZ patients (**Figures 2–4**).
- ADA/BKZ patients generally demonstrated sustained improvements from Week 52 to 104 after patients switched to BKZ.
- Improvements in work productivity observed at 1 year were sustained up to 2 years in BKZ-randomized and PBO/BKZ patients in both studies (**Figure 5**). Work productivity improvements at Week 52 were sustained to Week 104 following the ADA/BKZ switch in BE OPTIMAL.

Conclusions

Clinically meaningful improvements in measures of HRQoL, including disease impact and physical function, as well as work productivity, including presenteeism, overall work impairment, and activity impairment, were sustained up to 2 years with bimekizumab treatment irrespective of prior bDMARD use. Patients who switched from adalimumab to bimekizumab at Week 52 showed sustained improvements up to 2 years.

Summary

The impact of bimekizumab treatment on **patient health-related quality of life (HRQoL)** and **work productivity up to 2 years** was assessed in patients with **active PsA** who were biologic disease-modifying antirheumatic drug **(bDMARD)-naive (BE OPTIMAL)** or had prior inadequate response or intolerance to tumor necrosis factor inhibitors **(TNFi-IR) (BE COMPLETE)**.

HRQoL improvements achieved by **bimekizumab-randomized patients** at 2 years:

Disease impact: **PsAID-12 responders** (decrease from BL ≥3) achieved by **44.9%** bDMARD-naive patients at Week 104 **52.0%** TNFi-IR patients at Week 88

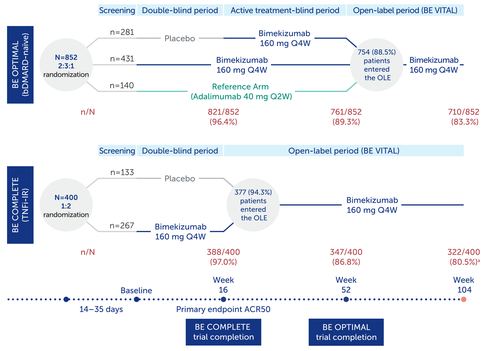
Physical function: **HAQ-DI MCID** (decrease from BL ≥0.35) achieved **52.5%** bDMARD-naive patients at Week 104 **52.4%** TNFi-IR patients at Week 100

HRQoL: **SF-36 PCS** score increased from BL by **8.4** in bDMARD-naive patients at Week 104 **8.9** in TNFi-IR patients at Week 88

Work productivity: **WPAI overall work impairment** decreased from BL by **21.7** in bDMARD-naive patients at Week 104 **18.8** in TNFi-IR patients at Week 88

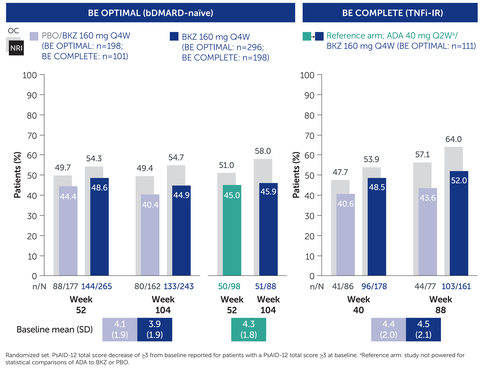
Bimekizumab treatment demonstrated **clinically meaningful improvements** in measures of **HRQoL**, **physical function** and **work productivity**, which were **sustained up to 2 years** in patients with PsA irrespective of prior bDMARD treatment.

Figure 1 BE OPTIMAL and BE COMPLETE study designs



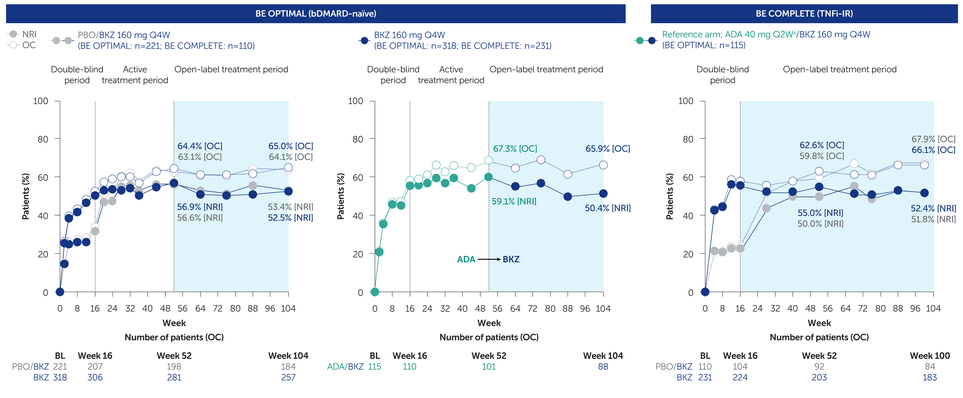
In both studies, PBO-randomized patients switched to BKZ 160 mg Q4W at Week 16 (PBO/BKZ). The ADA 40 mg Q2W treatment arm served as an active reference. There was no washout period for patients who switched from ADA to BKZ (ADA/BKZ) at Week 52 of BE OPTIMAL. The BE OPTIMAL study was not powered for statistical comparisons of ADA to BKZ or PBO. [a]Patients who completed to Week 100 of BE COMPLETE (not including 2 ongoing patients). No patients were ongoing in BE OPTIMAL at Week 104.

Figure 2 Proportion of patients achieving PsAID-12 clinically meaningful within-patient improvement (total score decrease from baseline ≥3) (NRI, OC)



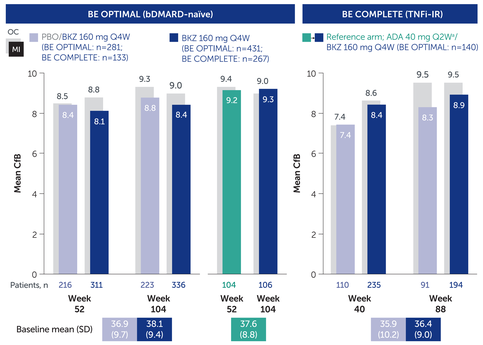
Randomized set. PsAID-12 total score decrease of ≥3 from baseline reported for patients with a PsAID-12 total score ≥3 at baseline. [a]Reference arm: study not powered for statistical comparisons of ADA to BKZ or PBO.

Figure 3 HAQ-DI MCID responders to Week 104/100 (NRI, OC)



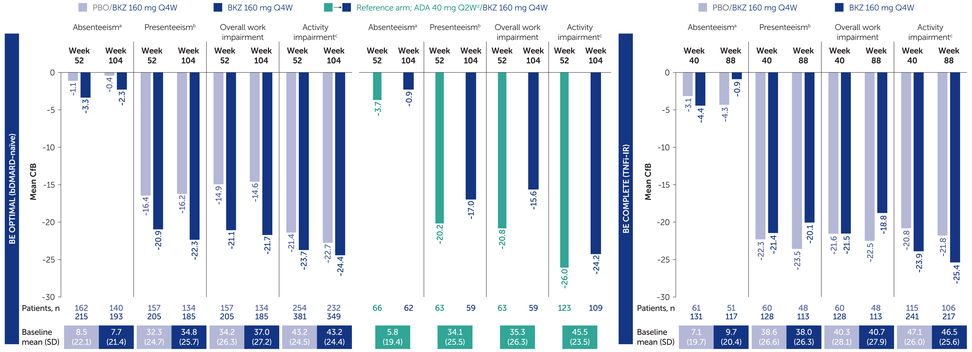
Randomized set. HAQ-DI MCID represents a decrease from baseline of ≥0.35, reported in patients with HAQ-DI score ≥0.35 at baseline. [a]Reference arm: study not powered for statistical comparisons of ADA to BKZ or PBO.

Figure 4 Mean SF-36 PCS CfB at Week 52/40 and Week 104/88 (MI, OC)



Randomized set. [a]Reference arm: study not powered for statistical comparisons of ADA to BKZ or PBO.

Figure 5 Mean CfB in work productivity at Week 52/40 and Week 104/88 (OC)



Randomized set. A negative change from baseline score indicates a reduction in the score and therefore an improvement for the patient. [a]Work time missed due to PsA; [b]Impairment while working due to PsA; [c]Ability to undertake regular, non-work-related activities (e.g., childcare).[a,b]Reference arm; study not powered for statistical comparisons of ADA to BKZ or PBO.

ADA: adalimumab; **bDMARD:** biologic disease-modifying antirheumatic drug; **BKZ:** bimekizumab; **BL:** baseline; **CfB:** change from baseline; **HAQ-DI:** Health Assessment Questionnaire-Disability Index; **HRQoL:** health-related quality of life; **IL:** interleukin; **MCID:** minimal clinically important difference; **MI:** multiple imputation; **NRI:** non-responder imputation; **OC:** observed case; **PBO:** placebo; **PsA:** psoriatic arthritis; **PsAID-12:** Psoriatic Arthritis Impact of Disease 12-Item; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks; **SD:** standard deviation; **SE:** standard error; **SF-36 PCS:** Short-Form 36-Item Health Survey Physical Component Summary; **TNFi-IR:** tumor necrosis factor inhibitor inadequate response or intolerance; **WPAI:SHP:** Work Productivity and Activity Impairment Questionnaire: Specific Health Problem.

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