Bimekizumab Impact on Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) Core Domains for Patients with Psoriatic Arthritis: Results up to 2 Years of Treatment Duration

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Objective

To report the long-term efficacy of bimekizumab (BKZ) across the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) core domains up to 2 years from phase 3 trials in psoriatic arthritis (PsA) and axial spondyloarthritis (axSpA).

Background

- The GRAPPA domain-based treatment recommendations for PsA focus on six key domains: peripheral arthritis, axial disease, enthesitis, dactylitis, skin psoriasis, and nail psoriasis, and two PsA-related conditions: uveitis and inflammatory bowel disease (IBD).[1]
- BKZ, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated clinical efficacy up to 1 year in phase 3 clinical trials of patients with PsA, and in phase 3 clinical trials of patients with psoriasis and axSpA.[2–7]

Methods

- Included patients were randomized to receive subcutaneous BKZ 160 mg or placebo (PBO) every 4 weeks (Q4W) in BE OPTIMAL (NCT03895203; biologic disease-modifying antirheumatic drug [bDMARD]-naïve patients with PsA), BE COMPLETE (NCT03896581; patients with PsA who had prior inadequate response or intolerance to tumor necrosis factor inhibitors [TNFi-IR]), BE MOBILE 1 (NCT03928704; non-radiographic axSpA), and BE MOBILE 2 (NCT03928743; radiographic axSpA, i.e., ankylosing spondylitis).[2,3,7]
- From Week 16, all PBO-randomized patients received BKZ 160 mg Q4W. BE OPTIMAL Week 52 and BE COMPLETE Week 16 completers could enter BE VITAL (open-label extension [OLE]; NCT04009499); BE MOBILE 1 and 2 Week 52 completers could enter BE MOVING (OLE; NCT04436640).
- Outcomes are reported by GRAPPA domain to Week 104 (BE OPTIMAL) and Week 100 (BE COMPLETE) in PsA; uveitis and IBD are reported to Week 104 for BKZ 160 mg Q4W Total patients, including patients randomized to PBO up to Week 16, in all studies (uveitis events identified using the preferred terms 'autoimmune uveitis', 'iridocyclitis', 'iritis', and 'uveitis').
- Axial domain outcomes are reported to Week 104 (BE MOBILE 1 and 2) in axSpA, in accordance with GRAPPA recommendations.[1]
- Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) outcomes are reported in patients with baseline BASDAI ≥4 in BE OPTIMAL and BE COMPLETE and in all patients in BE MOBILE 1 and 2.
- Change from baseline data are reported for BKZ 160 mg Q4W Total patients, including patients randomized to PBO up to Week 16; change from baseline values compared to feeder study baseline values.
- Missing data were imputed using non-responder imputation (NRI; binary) and multiple imputation (MI; continuous), or reported using observed case (OC).

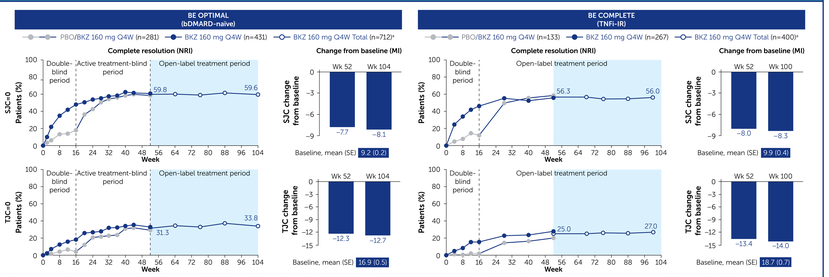
Results

- Week 104/100 completion rate was similar across all four trials (BE OPTIMAL: 598/712 [84.0%], BE COMPLETE: 322/400 [80.5%], BE MOBILE 1: 189/254 [74.4%], BE MOBILE 2: 267/332 [80.4%]).
- Baseline demographics and disease characteristics have been previously reported.[2,3,7]
- For all GRAPPA domains, 1-year improvements were sustained to 2 years across all studies.
- Individual domain responses were generally consistent between bDMARD-naïve and TNFi-IR patients.
- Improvements in axial domain outcomes were sustained to 2 years in BE MOBILE 1 and 2 and are suggestive of BKZ efficacy for axial disease in PsA.[1]
- To Week 104, overall incidence of uveitis was low and few patients had definite or probable adjudicated IBD.

Conclusions

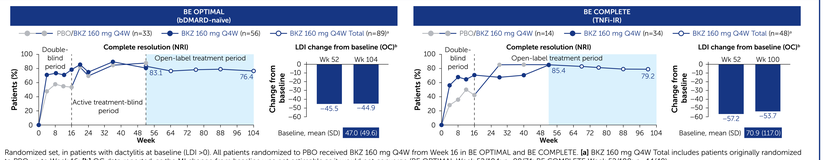
Bimekizumab treatment resulted in sustained improvements across GRAPPA domains up to 2 years in both bDMARD-naïve and TNFi-IR patients with PsA, with low rates of IBD and uveitis reported. Results from studies in patients across the full disease spectrum of axSpA further support the efficacy of bimekizumab in the axial domain.

Improvements in **peripheral arthritis** responses were sustained from Week 52 to Week 104/100; **56.0%–59.6%** had **SJC=0** and **27.0%–33.8%** had **TJC=0** at Week 104/100



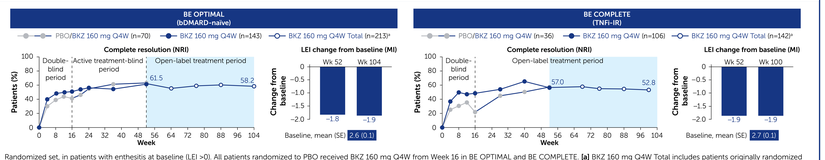
Randomized set. All patients randomized to PBO received BKZ 160 mg Q4W from Week 16 in BE OPTIMAL and BE COMPLETE. **[a]** BKZ 160 mg Q4W Total includes patients originally randomized to PBO up to Week 16.

76.4%–79.2% had complete resolution of **dactylitis** (**LDI=0**) at Week 104/100

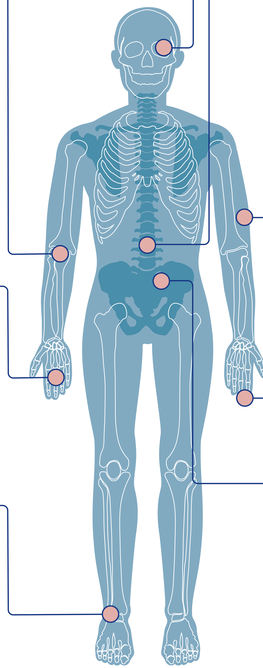


Randomized set, in patients with dactylitis at baseline (LDI >0). All patients randomized to PBO received BKZ 160 mg Q4W from Week 16 in BE OPTIMAL and BE COMPLETE. **[a]** BKZ 160 mg Q4W Total includes patients originally randomized to PBO up to Week 16; **[b]** OC data reported, as the MI change from baseline was not estimable as it would not converge (BE OPTIMAL Week 52/104: n=80/74; BE COMPLETE Week 52/100: n=44/40).

52.8%–58.2% had complete resolution of **enthesitis** (**LEI=0**) at Week 104/100



Randomized set, in patients with enthesitis at baseline (LEI >0). All patients randomized to PBO received BKZ 160 mg Q4W from Week 16 in BE OPTIMAL and BE COMPLETE. **[a]** BKZ 160 mg Q4W Total includes patients originally randomized to PBO up to Week 16.

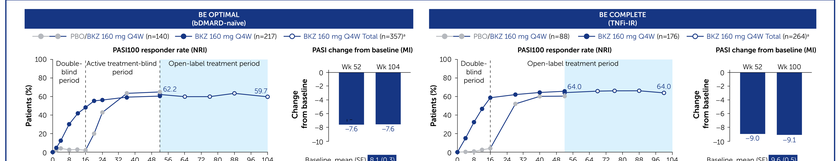


Few instances of **uveitis** reported up to Week 104 (n [EAIR/100 PY]: BE OPTIMAL: 1 [0.08] iridocyclitis; BE MOBILE 1: 3 [0.52] uveitis, 2 [0.35] iridocyclitis, 2 [0.35] iritis; BE MOBILE 2: 9 [1.07] uveitis, 6 [0.71] iridocyclitis, 4 [0.47] iritis)[a]

Few patients had definite or probable adjudicated **IBD** up to Week 104 (n [EAIR/100 PY]: BE OPTIMAL: 4 [0.33]; BE MOBILE 1: 3 [0.52]; BE MOBILE 2: 5 [0.59])[a]

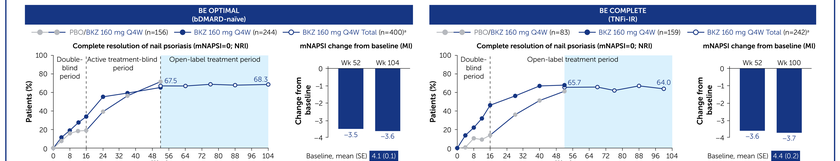
[a] No cases of uveitis or IBD reported in BE COMPLETE

59.7%–64.0% had complete resolution of **skin psoriasis** at Week 104/100



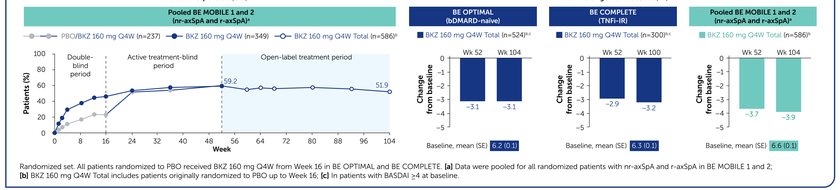
Randomized set, in patients with ≥3% body surface area affected by psoriasis at baseline. All patients randomized to PBO received BKZ 160 mg Q4W from Week 16 in BE OPTIMAL and BE COMPLETE. **[a]** BKZ 160 mg Q4W Total includes patients originally randomized to PBO up to Week 16.

64.0%–68.3% had complete resolution of **nail psoriasis** at Week 104/100



Randomized set, in patients with nail psoriasis at baseline (mNAPSI >0). All patients randomized to PBO received BKZ 160 mg Q4W from Week 16 in BE OPTIMAL and BE COMPLETE. **[a]** BKZ 160 mg Q4W Total includes patients originally randomized to PBO up to Week 16.

Improvements in **axial disease** were sustained from Week 52 to Week 104/100



Randomized set. All patients randomized to PBO received BKZ 160 mg Q4W from Week 16 in BE OPTIMAL and BE COMPLETE. **[a]** Data were pooled for all randomized patients with nr-axSpA and r-axSpA in BE MOBILE 1 and 2; **[b]** BKZ 160 mg Q4W Total includes patients originally randomized to PBO up to Week 16; **[c]** In patients with BASDAI ≥4 at baseline.

ASAS40: Assessment in Spondyloarthritis international Society 40% improvement; **axSpA:** axial spondyloarthritis; **BASDAI:** Bath Ankylosing Spondylitis Disease Activity Index; **bDMARD:** biologic disease-modifying antirheumatic drug; **BKZ:** bimekizumab; **EAIR:** exposure-adjusted incidence rate; **GRAPPA:** Group for Research and Assessment of Psoriasis and Psoriatic Arthritis; **LDI:** Leeds Dactylitis Index; **LEI:** Leeds Enthesitis Index; **MI:** multiple imputation; **mNAPSI:** modified nail psoriasis severity index; **nr-axSpA:** non-radiographic axSpA; **NRI:** non-responder imputation; **OC:** observed case; **PASI:** Psoriasis Area and Severity Index; **PASI100:** 100% improvement from baseline in PASI; **PBO:** placebo; **PY:** patient-year; **Q4W:** every 4 weeks; **r-axSpA:** radiographic axSpA; **SD:** standard deviation; **SE:** standard error; **SJC:** swollen joint count; **TJC:** tender joint count; **TNFi-IR:** prior inadequate response or intolerance to tumor necrosis factor inhibitors.

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