# Bimekizumab Efficacy and Safety in Biologic DMARD-Naïve Patients with Psoriatic Arthritis was Consistent With or Without Methotrexate: 52-Week Results from the Phase 3 Active Reference Study BE OPTIMAL 

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## Objective

To report the efficacy and safety of bimekizumab (BKZ) to Week 52 from the phase 3 study BE OPTIMAL in biologic disease-modifying antirheumatic drug-naive patients with psoriatic arthritis (PsA), with or without concomitant methotrexate.

## Background

Given the chronic nature of PsA, understanding long-term efficacy and safety of biologic monotherapy or therapy in combination with ongoing methotrexate ( mecrosis is interest. Studies have shown that tumor necrosis factor inhibitors may have lower efficacy without MTX ( - MTX) than with MTX ( + MTX). ${ }^{1}$
Bimekizumab, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has shown efficacy and tolerability to 52 weeks in patients with PsA who are biologic disease-modifying antirheumatic drug (bDMARD)-naïve.?

## Methods

- BE OPTIMAL (NCT03895203) comprised a 16-week double-blind, placebo (PBO)-controlled period and a 36 -week active treatment-blind period.
Patients were randomized 3:2:1 to subcutaneous BKZ 160 mg every 4 weeks (Q4W), placebo (with switch to BKZ 160 mg Q4W at Week 16) or reference arm (adalimumab [ADA] 40 mg Q2W): the study was not powered for statistical comparisons of ADA to BKZ or PBO.
Patients generally could not adjust their background medication, including MTX usage, during the 16 -week PBO-controlled period. Efficacy and safety were
Missing data were imputed using non-responder
imputation (discrete) or multiple imputation
Results
Baseline patient demographics and disease characteristics
- 770/852 (90.4\%) patients completed Week 52 (+ MTX 458/497 [92.2\%]; - MTX: 312/355 [87.9\%]), including 9 not on randomized treatment (+ MTX: 4; - MTX: 5) Baseline characteristics were generally similar for +/- MTX patient subgroups (Table 1).


## Efficacy to Week 52

To Week 52, the proportions of BKZ-randomized patients who achieved $\geq 50 \%$ improvement in American
College of Rheumatology response criteria (ACR50). College of Rheumatology response criteria (ACR50), Area and Severity (ndex) and minimal disease activity (MDA) were similar regardless of baseline MTX use.

- Fewer patients receiving ADA - MTX achieved ACR50 or MDA at Week 52 compared with the ADA + MTX group (Figure 1).
Other Week 52 efficacy responses on BKZ were generally of a similar magnitude +/- MTX (Table 2)
Safety to Week 52
To Week 52, the proportion of patients with $\geq 1$ treatment-emergent adverse event (TEAE) was similar for BKZ regardless of +/-MTX. More patients receiving ADA - MTX had $\geq 1$ TEAE compared with the ADA + MTX subgroup.
To Week 52, rates of the most frequent TEAEs were similar between $+/-$ MTX on BKZ, and BKZ was well tolerated regardless of MTX (Table 3).


## Conclusions

Bimekizumab treatment demonstrated consistent clinical efficacy across disease manifestations to Week 52 in bDMARD-naïve patients with PsA, irrespective of concomitant MTX. Bimekizumab was well tolerated in patients with PsA with or without MTX.

## Summary

 ACR50
$\square$

+ MTX $\mathbb{Q}$
- MTX $\qquad$

*The study was sot powered for statistical comparisons of ADA to BKZ or PBOA A
+ MT and- MTX subbroups.
Bimekizumab was well tolerated in patients with active PSA with or without MTX

Table 1 Baseline characteristics +/- MTX


## Age, years, mean (ss


















Table 2 Week 52 efficacy endpoints for patients +/- MTX (NRI and MI)

| Endpoint | PBO/BKZ 160 mgQ4W$\mathrm{N}=281$ |  | $\underset{N=431}{\substack{\text { BKZ } \\ 1600 \\ \text { mg Qaw }}}$ |  | $\begin{gathered} \text { Reference Arm } \\ \text { (ADA } 40 \mathrm{mg} \text { Q2W) } \\ \mathrm{N}=140 \end{gathered}$ |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | $\begin{gathered} \substack{\text { MTX } \\ n=163} \end{gathered}$ | $\begin{gathered} - \text { MTX } \\ n=118 \end{gathered}$ | $\begin{aligned} & \substack{n T X \\ n=252} \end{aligned}$ | $\begin{aligned} & -m T x \\ & n=179 \end{aligned}$ | $\begin{gathered} \substack{\text { MTX } \\ n=82} \end{gathered}$ | MTX |
| ACR20 INRI, n | 113 (69.3) | 78 (66.1) | $18473.0)$ | 123 (68.7) | 65 (79.3) |  |
| R50 INRI]. n (\%) | 87 (53.4) | 62 (52.5) | 137 (54.4) | 98 (54.7) | 46 (56.1) |  |
| ACR70 (NRII, n (\%) | 60 (36.8) | 41 (34.7) | 96 (38.1) | 73 (40.8) | $36(43.9)$ |  |
| PASI75 ${ }^{\text {a }}$ NII, n \% | 185. | 884.21 | 10583.3 | 7279 | 23 (62.2) |  |
| S190 ${ }^{\circ} \mathrm{NR1} . \mathrm{n}$ (\%) | (80) | $39(68.4)$ | 89 (70.6) | 66 (72.5) | 20 (54.1) |  |
| PASI100* (NR1], n (\%) | 62 (74.7) | 29 (50.9) | 77 (61.1) | 55 (60.4) | 15 (40.5) |  |
| Mda INRII, n (\%) | 87 (53.4) | $64(54.2)$ | 1388 (54.8) | $99(55.3)$ | 48 (58.5) |  |
| RII, | 35 (21.5) | 27 (22.91 | 72 (28.6) | 53 (29.6) | 25 (30.5) |  |
| ACR50+PASI100 ${ }^{\text {a }}$ | 43 (51.8) | (388) | $61(48.4)$ | 41 (45.1) | $12(32.4)$ |  |
| Enthesitis resolution ${ }^{\text {b }}$ [NRI], $\mathrm{n}(\%)$ | 24 (66.7) | 20 (56.8) | $53(64.6)$ | $34(55.7)$ | 11 (61.1) |  |
| Dactylitis resolution ${ }^{\text {c }}$ | 18 (81.8) | 11 (100.0) | 5.0) | 24 (85.7) | $4(80.0)$ | 66.7 |
| HAQ-DI CfB (MII), mean (SE) | $\begin{gathered} -0.37 \\ (0.04) \end{gathered}$ | $\begin{gathered} -0.38 \\ (0.058 \end{gathered}$ | $\begin{gathered} -0.30 \\ (0.03) \end{gathered}$ | $\begin{gathered} -0.38 \\ (0.04) \end{gathered}$ | $\begin{gathered} -0.49 \\ (0.06) \end{gathered}$ | $\begin{gathered} -0.30 \\ (0.08) \end{gathered}$ |
|  | 68 (73.9) | 43 (67.2) | 100 (68.5) | 60 (61.2) |  |  |






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