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PSAI9 IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS TREATED WITH FILGOTINIB VS PLACEBO: RESULTS FROM EQUATOR, A RANDOMIZED, PHASE 2 STUDY

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Background: Filgotinib (FIL) is an oral, selective Janus kinase 1 inhibitor that, compared with placebo (PBO), significantly improved patient-reported outcomes in active psoriatic arthritis (PsA) in the phase 2 EQUATOR randomized controlled trial (RCT; NCT03101670) [1]. PsA Impact of Disease (PsAID) is a validated, PsA-specific questionnaire for measurement of health-related quality of life (HRQoL) [2]. PsAID is less complex than generic HRQoL tools, such as the 36-Item Short Form Survey (SF–36). To our knowledge, this is the first RCT reporting efficacy results using PsAID9.

Objectives: To determine the effect of FIL vs PBO on PsAID9 in participants of EQUATOR.

Methods: EQUATOR was a multicenter, double-blind study in which patients were randomized 1:1 to FIL 200 mg or PBO once daily for 16 weeks [1]. HRQoL was assessed at weeks 4 and 16 with PsAID9 (total and individual domain scores [each scored 0–10]) and, for comparison, with the Physical Component Summary (PCS) and Mental Component Summary (MCS) of SF–36. Higher PsAID scores correspond to greater impact of PsA [2]. Analysis of covariance was used to compare outcomes between groups.

Results: There were 131 participants in EQUATOR (FIL: n=65; PBO: n=66). Mean (standard deviation [SD]) age was 49 (12.2) and 50 (10.9) years and mean (SD) baseline PsAID9 scores were 5.8 (1.6) and 5.7 (2.0) for FIL and PBO, respectively. Effects of FIL on PsAID9 and SF–36 scores were observed as early as week 4. FIL significantly improved PsAID9 total scores vs PBO; at week 16, PsAID9 total scores were 3.5 (2.0) for FIL and 4.9 (2.2) for PBO. Mean change (SD) from baseline at week 16 was −2.3 (1.8) vs −0.8 (2.2), respectively (Figure 1a); least-squares (LS) mean of group difference (95% confidence interval) was −1.48 (−2.12, −0.84), p<0.0001. At week 16, significant improvements were observed in all nine individual domains.

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PsAI2D domains for FIL vs PBO, including pain (p=0.0001; Figure 1b). A significant improvement in SF–36 PCS, but not in MCS, with FIL vs PBO was observed. The mean change (SD) from baseline in PCS at week 16 was 7.4 (6.6) vs 2.4 (6.6) for FIL vs PBO, respectively (LS mean of group difference 4.67 [2.58, 6.76], p<0.0001).

Conclusion: Compared with PBO, FIL significantly improved disease impact in patients with active PsA, as measured by the PsA-specific PsAI2D total score and individual domain scores. Significant improvement in SF–36 PCS score was also seen with FIL.

REFERENCE


Disclosure of Interests: An evaluation of a randomized double-blind placebo-controlled trial of secukinumab plus MTX in PsA patients with active dactylitis. Secukinumab, a fully human interleukin 17 (IL-17A) monoclonal antibody, has demonstrated efficacy in psoriatic arthritis (PsA) in clinical trials. To assess the efficacy of secukinumab plus MTX in PsA patients with active dactylitis, we conducted a randomized controlled trial (RCT) in patients with active dactylitis who were MTX naïve. Objectives: To assess the efficacy of secukinumab plus MTX in PsA patients, in a phase 3b trial. Methods: GO-DACT was a proof-of-concept multicentric, investigator-initiated, randomized, double-blind, placebo-controlled, parallel-design trial, conducted in 13 Portuguese Rheumatology Centers. PsA patients, naïve for MTX and biologic disease modifying anti-rheumatic drugs (bDMARDs), with active dactylitis, were randomly allocated to either golimumab in combination with MTX or MTX monotherapy. The primary endpoint was the change from baseline in the dactylitis severity score (DSS) assessed at week 24. Key secondary endpoints included DSS response and the magnetic resonance imaging (MRI) dactylitis score, as well as composite indexes of PsA activity.

Results: 44 patients were centrally randomized, 21 to golimumab plus MTX and 23 to placebo plus MTX, for 24 weeks, and 1 patient from each arm dropped out. Due to favorable results on a planned interim analysis recruitment was halted. The median DSS dose in the golimumab plus MTX group was 15mg/week and in the MTX monotherapy group 20mg/week. The median baseline DSS was 6 in each arm. Patients treated with golimumab plus MTX experienced significantly greater improvements in the DSS at week 24 (median change of 5) as compared to the MTX group (median change of 2) (p=0.026). At week 24, 12 (60.0%) patients treated with golimumab plus MTX and 4 (18.2%) with MTX achieved the DSS70 response (p<0.05). Significant differences were also observed in the median changes from baseline to week 24 in MRI dactylitis score Disease Activity Score 28 (DAS28) Disease Activity Index for PsA (DAPA), PsA Disease Activity Score (PASDAS) and Target Nail Psoriasis Severity Index (T-NAPSI), favoring the golimumab and MTX association arm. Likewise, higher proportions of patients treated with golimumab plus MTX achieved DSS50 responses and the American College of Rheumatology 20/50 responses, at week 24. There were no new safety issues for golimumab during this trial.

Conclusion: GO-DACT suggests additional benefits from the combination of golimumab and MTX as first-line bDMARD therapy versus MTX monotherapy, in the treatment algorithm of PsA active dactylitis.