EQUATOR was a 16-week, multicenter, double-blind study in which patients with active psoriatic arthritis (PsA), and was well tolerated [1].

Efficacy of Filgotinib vs Placebo in Active Psoriatic Arthritis: Patient-Level Data from EQUIATOR, a Randomized, Phase 2 Study

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Background: Filgotinib (FL) is an oral, selective Janus kinase 1 inhibitor in development for the treatment of several inflammatory diseases. In the phase 2 EQUIATOR trial (NCT03101670), FIL was efficacious vs placebo (PBO) in patients with active psoriatic arthritis (PsA), and was well tolerated [1].

Objectives: To evaluate the onset and maintenance of response to FIL vs PBO in EQUIATOR by evaluating patient–level response over time.

Methods: EQUIATOR was a 16-week, multicenter, double-blind study in which patients with active PsA were randomized 1:1 to FIL 200 mg or PBO once daily [1]. Disease activity was assessed at screening, day 1 and weeks 1, 2, 4, 8, 12, and 16, and the primary efficacy endpoint was the proportion of patients achieving 20% American College of Rheumatology (ACR20) response. The onset of response was assessed by calculating the median time to ACR20 response using the Kaplan-Meier method and compared between FIL and PBO using the log-rank test. Maintenance of response was assessed by analysing ACR20 response patterns over time in the FIL and PBO groups.

Results: Of 131 patients randomized (FIL: n=65; PBO: n=66), 124 (95%) completed the study. Demographics and baseline disease characteristics were similar between groups. The onset of response to FIL was early, with a median (95% confidence interval) time to first ACR20 response of 4.07 weeks (2.29, 4.14) in the FIL group compared with 12.29 weeks (12, not reached) in the PBO group (p<0.0001; Figure 1). ACR20 responses were achieved at week 16 in 80.0% (52/65) and 33.3% (22/66) of patients in the FIL and PBO groups, respectively, using the non-responder imputation method, and 86.7% (52/60) and 34.4% (22/64), respectively, using observed cases. The number of patients who presented with a stable ACR20 response (i.e. the response was maintained once initially achieved regardless of the time point at which the patient first became a responder) among those who were responders at week 16 (i.e. the primary endpoint) was higher in the FIL group than in the PBO group (80.8% [42/52] vs 68.2% [15/22]) (Figure 2).

Similar trends were observed for other efficacy endpoints representing various manifestations of PsA.

Conclusion: In general, patients treated with FIL achieved an ACR20 response earlier than those on PBO and these responses appeared to be more stable. In the PBO group, there were more occurrences of the response being lost over time and fewer cases of regaining a lost response.

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Q2W than PBO attained ACR50, improvement in HAQ-DI ≥ 0.35, MDA, DAS28-CRP, and DAPSA ≤ 14. Improvement persisted on all measures through Week 52.

**Methods**: Patients with active PsA naïve to biologic drugs (no prior MTX for PsA) were randomized to 3 groups for 48 weeks: ETN 50mg/MTX 20mg weekly (Combo; N=283); ETN 50mg/placebo weekly (ETN-mono; N=284); or MTX 20mg/placebo weekly (MTX-mono; N=284). At Week 24, the American College of Rheumatology (ACR20) and Minimal Disease Activity (MDA) responses were the primary and key secondary endpoints, respectively. Other PsA-specific composite measures used for disease activity included the Psoriatic Arthritis Disease Activity Score (PASDAS) and Disease Activity Index for Psoriatic Arthritis (DAPSA).

**Results**: Baseline characteristics were well balanced in the 3 arms. Mean (SD) age was 48.13 (11.1) years and mean/median PsA duration 3.2/0.6 years. ACR20 and MDA responses at week 24 were significantly greater with ETN-mono vs MTX-mono and Combo vs MTX-mono; ETN-mono and Combo had similar results (Table). PASDAS also showed differences between each ETN-containing arm vs MTX-mono and no difference for ETN-mono vs Combo, whereas study arm differences were not seen with DAPSA. PASDAS had a greater effect size and standardized response than DAPSA.

**Conclusion**: In this large randomized, controlled PsA trial, ETN-mono or Combo had greater efficacy than MTX-mono. Combining ETN and MTX did not improve ETN efficacy. Compared with the joint-focused DAPSA, PASDAS captured a wider range of PsA manifestations and performed better in this trial.

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