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OP0109

EFFICACY OF FILGOTINIB VS PLACEBO IN ACTIVE PSORIATIC ARTHRITIS: PATIENT-LEVEL DATA FROM EQUATOR, A RANDOMIZED, PHASE 2 STUDY

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Background: Filgotinib (FIL) is an oral, selective Janus kinase 1 inhibitor in development for the treatment of several inflammatory diseases. In the phase 2 EQUATOR 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 EQUATOR by evaluating patient-level response over time.

Methods: EQUATOR 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.

REFERENCE:

[1] Mease P, et al. Lancet 2018;392:2367–77.

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OP0110

IXEKIZUMAB IMPROVES SIGNS AND SYMPTOMS OF PSORIATIC ARTHRITIS IN PATIENTS WHO HAVE HAD INADEQUATE RESPONSE TO 1 OR 2 TUMOR NECROSIS FACTOR INHIBITORS

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Background: Psoriatic arthritis (PsA) is a progressive, chronic inflammatory disease often treated with tumor necrosis factor inhibitors (TNFi) when conventional treatments fail. Patients with inadequate response to TNFi represent a more difficult-to-treat population.

Objectives: To report the efficacy of ixekizumab (IXE), a monoclonal antibody that selectively targets interleukin-17A, in patients with inadequate response to 1 TNFi or 2 TNFi.

Methods: In a Phase 3 study (SPIRIT-P2; NCT02349295), patients who had an inadequate response or intolerance to 1 or 2 TNFi were randomized to receive subcutaneous IXE 80 mg every 2 weeks (IXEQ2W; N=123) or every 4 weeks (IXEQ4W; N=122), after a 160-mg starting dose, or placebo (PBO; N=118) for up to 24 weeks. At Week 16, patients not meeting predefined criteria (<20% improvement in tender joint count [TJC] and swollen joint count [SJC]) received rescue therapy and were imputed as nonresponders at Weeks 20 and 24. At Week 24, PBO patients were rerandomized to IXEQ2W or IXEQ4W through Week 52 and excluded from the 52-week analysis. At Week 32 or any subsequent visit, patients were discontinued if they did not reach ≥20% improvement from baseline in both TJC and SJC. These ad-hoc data were derived from patients in the intent-to-treat population with prior inadequate response to TNFi; intolerant patients were excluded from the analysis. Efficacy was measured by percentage of patients who attained ≥50% improvement in American College of Rheumatology response criteria (ACR50), an improvement in Health Assessment Questionnaire-Disability Index (HAQ-DI) ≥0.35, minimal disease activity (MDA), Disease Activity Score 28 – C-reactive protein (DAS28-CRP) EULAR Good Response criteria, and Disease Activity in Psoriatic Arthritis (DAPSA) ≤14.

Results: At baseline, 1-TNFi inadequate responders were, on average, 52 years of age with a PsA diagnosis for 10 years; 40% were using MTX, and HAQ-DI was 1.2. 2-TNFi inadequate responders were 52 years of age with a PsA diagnosis for 11 years; 42% were using MTX, and HAQ-DI was 1.3. Regardless of inadequate response to 1 or 2 TNFi, at Week 24 significantly more patients receiving Q4W or