Filgotinib, an oral, potent, selective Janus kinase (JAK) 1 inhibitor, provided statistically significant and clinically meaningful improvement in rheumatoid arthritis (RA) signs and symptoms compared with placebo (PBO) in two phase 3 trials. In the filgotinib 200 mg (FIL 200 mg) study, a statistically significant improvement in RA signs and symptoms was observed in patients receiving filgotinib compared with placebo at week 12. In this analysis, we assessed the long-term safety of filgotinib using integrated data from three Phase 3 trials (FIL 1, FIL 2, and FIL 3), two Phase 2 trials (DARWIN 1, 2), and long-term extension studies (LTE) for patients with RA in clinical trials.

Methods

A total of 17,941 subjects received filgotinib or placebo (PBO) in these trials. The primary analysis population was defined as all subjects who received at least one dose of filgotinib or PBO and had at least one post-baseline safety assessment. The safety analysis set included all subjects who received at least one dose of filgotinib or PBO and had at least one post-baseline safety assessment. The safety analysis set was updated for the LTE studies to include all subjects who received at least one dose of filgotinib or PBO and had at least one post-baseline safety assessment.

Results

In the placebo-controlled safety analysis set, the raw incidence rates of herpes zoster with filgotinib were similar for both 200 mg and 100 mg doses and placebo. The overall raw incidence rates of TEAEs, TEAEs Grade ≥3, treatment-emergent serious AEs (TE SAEs), TEAEs leading to discontinuation, and deaths were similar between filgotinib and placebo.

In the placebo-controlled safety analysis set, the overall incidence rates of MACE and VTE were similar between filgotinib and placebo. There were no significant differences in the incidence rates of MACE and VTE between filgotinib and placebo.

Discussion

Filgotinib, at an oral, potent, selective Janus kinase (JAK) 1 inhibitor, provided statistically significant and clinically meaningful improvement in rheumatoid arthritis (RA) signs and symptoms compared with placebo (PBO) in two phase 3 trials. In this analysis, we assessed the long-term safety of filgotinib using integrated data from three Phase 3 trials (FIL 1, FIL 2, and FIL 3), two Phase 2 trials (DARWIN 1, 2), and long-term extension studies (LTE) for patients with RA in clinical trials.

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