

SAFETY OF FILGOTINIB IN CROHN'S DISEASE COMPARED WITH ULCERATIVE COLITIS: DATA FROM THE PHASE 3 DIVERSITY1 AND PHASE 2B/3 SELECTION STUDIES

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Filgotinib, an oral JAK1-preferential inhibitor, demonstrated a well-tolerated safety profile in moderately to severely active Crohn's disease that was generally consistent with its established profile in ulcerative colitis, with no new safety signals identified.

KEY POINTS

- The phase 3 DIVERSITY1 trial randomized 1,372 adults with moderately to severely active Crohn's disease to filgotinib 200 mg, filgotinib 100 mg, or placebo for 10-week induction, followed by rerandomization to maintenance through week 58 for responders.
- Treatment-emergent adverse event rates were balanced across filgotinib and placebo groups in Crohn's disease and comparable to those observed in the ulcerative colitis SELECTION trial.
- Gastrointestinal perforations reported in Crohn's disease were adjudicated by an external expert committee as related to underlying disease progression, not study treatment.
- Events of special interest were infrequent: serious infections occurred in 1.9% of Crohn's disease maintenance patients, malignancies (excluding non-melanoma skin cancer) in one Crohn's disease maintenance patient, venous thromboembolism in one Crohn's disease maintenance patient, and major adverse cardiovascular events in one Crohn's disease patient overall.
- No deaths occurred in the Crohn's disease trial; two deaths in the ulcerative colitis trial were not considered treatment-related by investigators.

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