

on structural outcomes. Third, the effect of filgotinib on dactylitis could not be established here; a phase 3 study is needed to evaluate this outcome. Filgotinib's effect on axial disease is also important and, although not assessed here, was investigated in a phase 2 trial²³ in patients with ankylosing spondylitis. Fourth, although previous exposure to one anti-TNF drug was allowed in this study (following an appropriate washout period), the results might not be generalisable to patients with psoriatic arthritis who have failed multiple biological treatments, in whom the need for new pharmacotherapies is greatest. Confirmation of these results in larger phase 3 trials is awaited and, until then, comparisons with data from other phase 3 trials should be done with caution.

In conclusion, selective JAK1 inhibition by filgotinib significantly improved signs and symptoms of psoriatic arthritis in patients with active disease. The primary, secondary, and exploratory efficacy endpoints showed rapid improvements in multiple domains of psoriatic arthritis disease activity, including enthesitis and patient-reported outcomes. The safety profile of filgotinib after 16 weeks of treatment was similar to previous reports and no new safety signals were identified.

Contributors

PM, CT, LM, PH, and DDG designed the study. MS, ARH, AD, LM, PH, RN, and AVdA collected the data. PSH, CT, LM, RB, and AVdA analysed the data. PM, LCC, PSH, AD, WA-S, CT, LM, PH, RB, NM, JMG, RK, FVdB, and DDG interpreted the data. All authors reviewed and revised drafts of the manuscript and approved the final version.

Declaration of interests

PM reports consultancy fees from Galapagos during the conduct of the study and, outside of the submitted work, reports consultancy fees, research grants, and speaker fees from Abbvie, Amgen, BMS, Eli Lilly, Janssen, Novartis, Pfizer, and UCB; consultancy fees and research grants from SUN; research grants and speaker fees from Celgene; and speaker fees from Genentech. LCC reports personal fees from Galapagos during the conduct of the study and, outside of the submitted work, reports grants and personal fees from Abbvie, Celgene, Eli Lilly, Novartis, and Pfizer, and personal fees from Amgen, Galapagos, Janssen, Prothena, Sun pharma, and UCB. PSH reports advisory fees from Galapagos during the conduct of the study and, outside of the submitted work, reports grants, personal fees, research funding, speaker fees, and nonfinancial support from Abbvie; grants and speaker fees from Amgen and Janssen; grants and research support from Pfizer; grants from UCB and Novartis; and personal fees from Celgene. MS reports fees to conduct this study from Galapagos during the conduct of the study and, outside the submitted work, reports fees for conducting studies from AstraZeneca, Celltrion, Eli Lilly, Galapagos, Genentech, GlaxoSmithKline, Human Genome, MedImmune, Pfizer, Roche, and UCB. ARH reports a national coordinator fee, her institute received a fee to conduct this study from Galapagos during the conduct of the study and, outside the submitted work, her institute received fees from Gilead Sciences for conducting another study. WA-S, CT, LM, and RB are employees of, and have received warrants from, Galapagos during the conduct of the study. PH and AVdA were employees of, and received warrants from, Galapagos during the conduct of the study. NM, JMG, and RK are employees of, and have shares from, Gilead Sciences. FVdB reports consultancy fees from Galapagos during the conduct of the study and, outside of the submitted work, reports speaker and consultancy fees from Abbvie, BMS, Eli Lilly, Janssen, Merck, Novartis, Pfizer, and UCB. DDG reports involvement in trial participation and design for, and has received grants, personal fees, and consultancy fees from Abbvie, Amgen, Celgene, Eli Lilly, Gilead, Janssen, Novartis, Pfizer, and UCB. DDG also reports trial participation and design, personal fees, and consultancy fees from BMS and Galapagos outside the submitted work. AD reports no competing interests.

Data sharing

Data sharing with regard to this study is being managed by Gilead Sciences. The clinical study report synopsis and de-identified patient-level data from clinical trial analysis datasets will be made available from 6 months after approval of the study compound by the US Food and Drug Administration and European Medicines Agency until an indefinite date. Research proposals should be submitted to Gilead at datarequest@gilead.com. Access to these data will be provided in a secured analysis environment to qualified external researchers approved by Gilead, depending on the nature of the request, the merit of the research proposed, availability of the data and the intended use of the data. To gain access, approved requestors will need to sign a data sharing agreement.

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