

Gilead, Eisai to co-promote drug in Japan for RA treatment

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Agreement Extends to Additional Potential Indications for Filgotinib, Including Ulcerative Colitis, Crohn's Disease and Psoriatic Arthritis



Gilead Sciences, Inc. and Eisai Co., Ltd. have announced that Gilead Sciences K.K. and Eisai have entered into an agreement for the distribution and co-promotion of filgotinib, an investigational, oral, selective JAK1 inhibitor, in Japan, pending regulatory approval for the treatment of rheumatoid arthritis (RA). Through this collaboration, Gilead Japan will retain responsibility for manufacturing and marketing approval of filgotinib, while Eisai will be responsible for product distribution in Japan in RA and other potential future indications. The companies will jointly commercialize the medicine if approved.

Approximately 600,000 to 1 million people are living with RA across Japan, and despite available options, many still do not experience disease remission. In the global Phase 3 FINCH studies, filgotinib demonstrated durable efficacy and safety results across multiple RA patient populations, including in people with prior inadequate response to methotrexate treatment (MTX), those who were intolerant to one or more biologic treatments and those who were MTX treatment-naïve.

"We are very pleased to announce this important new partnership with Eisai, which brings together our complementary expertise and commitment in inflammation, to deliver this important new option to patients living with inflammatory diseases in Japan," said Luc Hermans, M.D., President and Representative Director, Gilead Japan.

"We have extensive clinical development and commercialization experience spanning more than 20 years in RA and have established a solid RA franchise in Japan," said Hidenori Yabune, President of Eisai Japan, Senior Vice President of Eisai. "With this agreement, we look forward to contributing more to patients living with RA by adding filgotinib to our product line-up."

Global studies investigating filgotinib in additional diseases are also underway, including the Phase 3 SELECTION trial in ulcerative colitis, the DIVERSITY Phase 3 trial in Crohn's disease, the Phase 3 PENGUIN trials in psoriatic arthritis, as well as Phase 2 studies in uveitis and in small bowel and fistulizing Crohn's disease.

Gilead and Galapagos NV (Mechelen, Belgium) have entered into a global collaboration for the development and commercialization of filgotinib in inflammatory indications. Filgotinib is an investigational drug whose efficacy and safety have not been established. Filgotinib is pending regulatory approval in Japan, Europe and the United States based on global Phase 3 trials evaluating its efficacy and tolerability.