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Gilead, Eisai launch rheumatoid arthritis drug in Japan

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Oral JAK inhibitor administered once daily to patients with rheumatoid arthritis for whom existing treatments are inadequate

Gilead Sciences K.K. (Head office: Chiyoda-ku, Tokyo; President and Representative Director: Luc Hermans) and Eisai Co., Ltd. (Head office: Bunkyo-ku, Tokyo, CEO: Haruo Naito) have announced that Jyseleca® (filgotinib maleate 200 mg and 100 mg tablets), a new once-daily, oral, JAK (Janus kinase) inhibitor that preferentially inhibits JAK1, has been launched in Japan on November 18 for the treatment of rheumatoid arthritis (RA), with prior regulatory approval by the Japanese Ministry of Health, Labour and Welfare.

Diseleca is a novel oral JAK inhibitor (once daily) that is selective for JAK1. The indication of diseleca is "rheumatoid arthritis (including prevention of structural damage to joints)", which is insufficiently effective with existing treatments. This drug has been approved in Europe in addition to Japan.

Based on a co-promotion agreement entered into by Gilead and Eisai in December 2019, Gilead will hold the marketing authorization of Jyseleca, while Eisai will be responsible for product distribution of Jyseleca in Japan. The companies will collaborate in product information provision activities in Japan.

"The number of patients with rheumatoid arthritis in Japan is estimated to be 600,000 to 1 million," said Luc Hermans, MD, President of Gilead. While treatment progresses, sufficient symptoms There are a certain number of patients who have not been alleviated, and there is an unmet medical need. Gilead and Eisai will continue to contribute to providing new options for patients with rheumatoid arthritis through Jisereka. I will. "

Eisai Japan President Hidenori Hione, Managing Executive Officer of Eisai, said, "We have abundant clinical development and sales experience in the field of rheumatoid arthritis in Japan and are building a leading franchise. With the new launch of Jisereka , We will make further contributions to meet the diverse needs of patients with rheumatoid arthritis and improve their QOL. "

Numerous clinical trials are currently underway for filgotinib, including indications for ulcerative colitis (SELECTION study, phase III) and Crohn's disease (DIVERSITY study, phase III). The safety and efficacy of filgotinib have not been established in these indications.