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Japan approves Jyseleca for rheumatoid arthritis treatment

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The companies will jointly commercialize the medicine to make it available to physicians and patients across Japan

Gilead Sciences, Inc. and Eisai Co., Ltd. have announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) has granted Gilead K.K. (Tokyo, Japan) regulatory approval of Jyseleca® (filgotinib 200 mg and 100 mg tablets), a once-daily, oral, JAK1 preferential inhibitor for the treatment of rheumatoid arthritis (RA) in patients who have had an inadequate response to conventional therapies, including the prevention of structural joint damage.

Gilead Japan will hold the marketing authorization of Jyseleca in Japan and will be responsible for product supply of Jyseleca in Japan, while Eisai will be responsible for product distribution of Jyseleca in Japan in RA.

The companies will jointly commercialize the medicine to make it available to physicians and patients across Japan.

Gilead is developing Jyseleca in collaboration with Galapagos NV (Mechelen, Belgium). The two companies are conducting global studies investigating the potential role of Jyseleca in a variety of diseases, including the previously reported Phase 3 SELECTION trial in ulcerative colitis.

“Despite progress in the treatment of RA, existing therapies have not enabled many patients to reach the treatment goals recommended in clinical guidelines. There continues to be a need for effective and well-tolerated new treatment options,” said Tsutomu Takeuchi, MD, Professor of Internal Medicine and Chief of Rheumatology at the School of Medicine, Keio University. “Jyseleca is a new JAK inhibitor that, in clinical trials, has demonstrated clinical improvement, low disease activity and clinical remission in a broad patient population, including patients with inadequate response to biologics.”