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Eisai Co., Ltd.

EISAI ENTERS INTO COMMERCIALIZATION AND DISTRIBUTION AGREEMENT WITH GILEAD FOR JAK INHIBITOR FILGOTINIB IN ASIA

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, “Eisai”) today announced it has entered into an agreement with Gilead Sciences, Inc. (Headquarters: Foster City, California, “Gilead”) for the commercialization and distribution of filgotinib (generic name, product name: Jyseleca®), an oral, JAK1 preferential inhibitor for indications of rheumatoid arthritis (RA), ulcerative colitis, and Crohn's disease in Asia (South Korea, Taiwan, Hong Kong and Singapore). In December 2019, Eisai signed a partnership agreement with Gilead Sciences K.K. (Headquarters: Tokyo), a Japanese subsidiary of Gilead, for the distribution and co-promotion of filgotinib in Japan.

Under the terms of the new agreement, Eisai will obtain an exclusive marketing right for filgotinib in South Korea, Taiwan, Hong Kong and Singapore from Gilead. Gilead has received approval for the treatment of RA in Taiwan and has applied for approval of filgotinib for the treatment of RA in South Korea. Following approvals, Eisai will take over the manufacturing and marketing licenses for filgotinib from Gilead in South Korea and Taiwan. In Hong Kong and Singapore, Eisai will apply for approval for filgotinib. With this agreement, Eisai will pay Gilead a contractual up-front payment, as well as regulatory milestones and sales milestones.

Filgotinib is a once-daily, oral, JAK1 preferential inhibitor. In Japan, filgotinib has been approved for the treatment of rheumatoid arthritis (including prevention of structural joint damage) in patients who have had an inadequate response to conventional therapies. In April 2021, Gilead Sciences K.K. applied for an additional indication of filgotinib as a treatment for patients with moderate to severe active ulcerative colitis.

Eisai will leverage its strong business foundation throughout Asia, provide new treatment options for patients with rheumatoid arthritis and inflammatory bowel disease, and contribute further to addressing the diverse needs of, and increasing the benefits provided to, patients their families, and healthcare providers.

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[Notes to editors]

1. About filgotinib

Filgotinib is a once-daily, oral, JAK1 preferential inhibitor. In Japan, filgotinib has been approved for the treatment of RA (including prevention of structural joint damage) in patients who have had an inadequate response to conventional therapies. In April 2021, Gilead Sciences K.K. applied for an additional indication of filgotinib as a treatment for patients with moderate to severe active ulcerative colitis.

In addition, filgotinib has been approved in the European Union and Great Britain for the treatment of adults with moderate to severe active rheumatoid arthritis who have responded inadequately or are intolerant to one or more disease modifying anti-rheumatic drugs (DMARDs). Filgotinib has also been approved in the European Union for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic agent. Applications have been submitted to the UK's Medicines and Healthcare products Regulatory Agency (MHRA) for the treatment of adults with moderately to severely active ulcerative colitis and are currently under review.

2. About the market for biological products South Korea, Taiwan, Hong Kong and Singapore

The market of biological products in 2020 in South Korea, Taiwan, Hong Kong and Singapore is approximately US $ 400 million, accounting for approximately more than 80% of the total market for biological products in Asia (Hong Kong, India, Indonesia, South Korea, Malaysia, Philippines, Singapore, Taiwan, Thailand and Vietnam).[1] Many of biological products are adapted in the treatments for rheumatoid arthritis and inflammatory bowel disease.

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