



For Immediate Release

November 18, 2020
Gilead Sciences K.K.
Eisai Co., Ltd.

JYSELECA® (FILGOTINIB) FOR RHEUMATOID ARTHRITIS LAUNCHES IN JAPAN

-- A once-daily, oral, JAK inhibitor for the treatment of rheumatoid arthritis in patients who have had an inadequate response to conventional therapies --

Tokyo, November 18, 2020 – Gilead Sciences K.K. (Head office: Chiyoda-ku, Tokyo; President and Representative Director: Luc Hermans; “Gilead”) and Eisai Co., Ltd. (Head office: Bunkyo-ku, Tokyo, CEO: Haruo Naito; “Eisai”) today announced that Jyseleca® (filgotinib maleate 200 mg and 100 mg tablets), a new once-daily, oral, JAK (Janus kinase) inhibitor that preferentially inhibits JAK1, will be 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. Jyseleca is indicated for RA (including prevention of structural joint damage) in patients who have had an inadequate response to conventional therapies. The therapy has received approval in Japan and Europe.

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.

“It is estimated that approximately 600,000 to 1 million people¹ are living with RA across Japan,” said Luc Hermans, MD, President and Representative Director, Gilead Sciences, K.K. “While RA treatment is advancing, many patients still do not experience sufficient disease remission, and many unmet medical needs remain. Gilead and Eisai are committed to delivering the new treatment option Jyseleca and supporting RA patients in Japan.”

“Eisai has extensive clinical development and commercialization experience in RA and has established a solid RA franchise in Japan,” said Hidenori Yabune, President of Eisai Japan, Senior Vice President, Eisai. “With the launch of Jyseleca, we will make further contributions to meet the diverse needs of RA patients and improve their QOL (quality of life).”

Multiple clinical trials are being conducted to investigate the potential role of filgotinib in a variety of diseases, including the Phase 3 SELECTION program in ulcerative colitis and the Phase 3 DIVERSITY program in Crohn’s disease. The safety and efficacy of filgotinib has not been demonstrated for these uses.

1) Committee on Rheumatology and Other Diseases, Committee on Disease Control, Health Science Council, "Current status of rheumatology from the perspective of internal medicine", March 26, 2018.

Overview of Jyseleca®

Brand name	Jyseleca®
Generic name	filgotinib maleate
Indications	Rheumatoid arthritis (including prevention of structural joint damage) in patients who have had inadequate response to conventional therapies
Composition	Light brown film-coated tablet
Dosage and Administration	The recommended dosage for adults is filgotinib 200 mg once-daily, which can be adjusted to filgotinib 100 mg once-daily, depending on the condition of the patient
Date of regulatory approval	September 25, 2020
Date of listing on drug price list (Japanese National Health Insurance)	November 18, 2020
Date of launch	November 18, 2020
Manufacturer	Gilead Sciences K.K.
Drug price (Japan)	Jyseleca® 100 mg tablet: 2,550.90 yen Jyseleca® 200 mg tablet: 4,972.80 yen

Jyseleca® is a registered trademark of Gilead Sciences, Inc. and its associated companies.



About Gilead Sciences

Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. The company strives to transform and simplify care for people with life-threatening illnesses around the world. Gilead has operations in more than 35 countries worldwide, with headquarters in Foster City, California.

For more information on Gilead Sciences, please visit the company's website at www.gilead.com.

For more information on Gilead Sciences K.K., please visit the company's website at <https://www.gilead.co.jp/>.

About Eisai

Eisai Co., Ltd. is a leading global research and development-based pharmaceutical company headquartered in Japan. We define our corporate mission as "giving first thought to patients and their families and to increasing the benefits health care provides," which we call our *human health care (hhc)* philosophy. With approximately 10,000 employees working across our global network of R&D facilities, manufacturing sites and marketing subsidiaries, we strive to realize our *hhc* philosophy by delivering innovative products to address unmet medical needs, with a particular focus in our strategic areas of Neurology and Oncology. As a global pharmaceutical company, our mission extends to patients around the world through our investment and participation in partnership-based initiatives to improve access to medicines in developing and emerging countries.

For more information about Eisai Co., Ltd., please visit <https://www.eisai.com>.

Gilead Forward-Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors. There is also the possibility of unfavorable results from ongoing and additional clinical trials involving Jyseleca and the risk that other regulatory authorities may not approve Jyseleca for the treatment of rheumatoid arthritis and other indications, and any marketing approvals, if granted, may have significant limitations on its use. Further, it is possible that Gilead may make a strategic decision to discontinue development and commercialization of Jyseleca, and as a result, Jyseleca may never be successfully commercialized. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in Gilead's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements.

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