CONTACTS:

Gilead
Ken Takashima, Media, Japan
+81 (0) 70 2492 5176

Eisai
Public Relations Dept
+81 (0) 3 3817 5120

GILEAD SCIENCES SUBMITS NEW DRUG APPLICATION IN JAPAN FOR FILGOTINIB FOR THE TREATMENT OF ULCERATIVE COLITIS WITH AN INADEQUATE RESPONSE TO CONVENTIONAL THERAPIES

-- Application is Based on Phase 2b/3 SELECTION Study Data with Patients with Moderately to Severely Active Ulcerative Colitis --

Tokyo, April 23, 2021 – 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 Gilead submitted an application to Japan's Pharmaceuticals and Medical Devices Agency (PMDA) for approval of filgotinib for an additional indication to treat patients with moderately to severely active ulcerative colitis. Filgotinib is a new oral Janus kinase (JAK) inhibitor approved in Japan in September 2020 for the treatment of rheumatoid arthritis.

This latest regulatory submission is based on data from the randomized, double-blind, placebo-controlled Phase 2b/3 SELECTION study evaluating the efficacy and safety of filgotinib for the induction and maintenance of remission in patients with moderately to severely active ulcerative colitis who are biologic-naïve or who have used a biologic. This study showed the efficacy and tolerability of filgotinib 200 mg once daily, and no new safety risks were identified.

Ulcerative colitis is a chronic disease characterized by inflammation of the lining of the mucosa of the colon and rectum. The prevalence of ulcerative colitis has been increasing in recent years, and it has a significant impact on the quality of life of more than 2 million people around the world. Even with treatment, defecation urgency, incontinence, recurrent bloody diarrhea, frequent bowel movements, abdominal pain, insomnia and fatigue are common. Ulcerative colitis is one of the intractable diseases designated by the Ministry of Health, Labour and Welfare in Japan. According to a nationwide survey, the estimated number of patients with ulcerative colitis in Japan in 2014 is 219,685, and the annual prevalence is reported to be 100,000 vs. 172.9 (192.3 men, 154.5 women).*

*Murakami Y, Nishiwaki Y, Oba MS, Asakura K, Ohfuji S, Fukushima W, et al. Estimated prevalence of ulcerative colitis and Crohn's disease in Japan in 2014: an analysis of a nationwide survey. J Gastroenterol 2019;54 (12):1070-7

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About Filgotinib

Filgotinib is approved in Japan is for the treatment of rheumatoid arthritis, including prevention of structural joint damage, in patients who have had an inadequate response to conventional therapies. Filgotinib is approved in the Europe Union and Great Britain for the treatment of adults with moderately to severely active rheumatoid arthritis who have responded inadequately or are intolerant to one or more disease modifying anti-rheumatic drugs (DMARDs). Applications have been submitted to the European Medicines Agency (EMA) and the Medicines and Healthcare products Regulatory Agency (MHRA) for an additional indication for the treatment of adults 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 and are currently under review. Filgotinib is not approved in any other countries.

About Gilead Sciences

Gilead Sciences, Inc. is a biopharmaceutical company that has pursued and achieved breakthroughs in medicine for more than three decades, with the goal of creating a healthier world for all people. The company is committed to advancing innovative medicines to prevent and treat life-threatening diseases, including HIV, viral hepatitis and cancer. Gilead operates in more than 35 countries worldwide, with headquarters in Foster City, California.

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.co.jp.

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, including Gilead's ability to initiate, progress or complete clinical trials within currently anticipated timelines or at all, including those involving filgotinib; the risk that safety and efficacy data from clinical studies may not warrant further development of Gilead's product candidates, including filgotinib, or the product candidates of Gilead's strategic partners; Gilead's ability to receive regulatory approvals in a timely manner or at all, including PMDA approval of filgotinib for treatment of patients with ulcerative colitis, and the risk that any such approvals may be subject to significant limitations on use; and the risk that filgotinib may not be successfully commercialized for the treatment of ulcerative colitis in Japan. These and other risks, uncertainties and other factors are described in detail in Gilead's Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the U.S. Securities and Exchange Commission. These risks, uncertainties and other factors, could cause actual results to differ materially from those referred to in the forward-looking statements. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The reader is cautioned not to rely on any such forward-looking statements. 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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