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March 28, 2022

Gilead Sciences K.K.
Eisai Co., Ltd.
EA Pharma Co., Ltd.

**Announcement about an approval for additional indication of Jyseleca[®],
JAK inhibitor, for the treatment of moderate to severe ulcerative colitis with
inadequate response to conventional therapies**
**—Approval of additional indication based on Phase IIb/III SELECTION data for patients
with active moderate-to-severe ulcerative colitis—**

Gilead Sciences K.K. (Headquarter: Chiyoda-ku, Tokyo, General Manager: Kennet Brysting, "Gilead"), Eisai Co., Ltd. (Headquarter: Bunkyo-ku, Tokyo, CEO: Haruo Naito, "Eisai") and EA Pharma Co., Ltd. (Headquarter: Chuo-ku, Tokyo, Representative Director, President & CEO: Hidenori Yabune, "EA pharma") today announced that Gilead acquired an approval of additional indication of Jyseleca[®] (Generic name: Filgotinib, "Jyseleca"), Janus Kinase (JAK) inhibitor, for the treatment of patients with active moderate-to-severe ulcerative colitis in Japan. In September 2020, Jyseleca was approved for the treatment of patients with rheumatoid arthritis (including prevention of structural joint damage) who had an inadequate response to conventional therapies in Japan.

The approval of the additional indication is based on the data from Phase IIb/III SELECTION trial evaluating the efficacy and safety of Jyseleca in the induction and maintenance treatment of biologic-naïve and biologic-experienced patients with moderately to severely active ulcerative colitis. The trial comprises of two induction studies and one maintenance study. The trial showed the efficacy and safety profile of Jyseleca, and no new safety risks were identified.

Dr. Norifumi Hibi, Director of the Center for Advanced Treatment of Inflammatory Bowel Disease at Kitasato Institute Hospital, commented "Ulcerative colitis is a chronic inflammatory disease with sores and ulcers forms on the lining of the large intestine, and it accompanies by symptoms such as blood in stool, diarrhea and abdominal pain during the active stage. Despite advances in the treatment of ulcerative colitis, there is no curative treatment, and it is important to promptly induce remission and maintain remission to prevent relapse of inflammation. Because of persistent inflammation, there remains unmet medical needs as many patients still suffer from symptoms that affect their daily lives. With the approval for the additional indication, which showed the efficacy and safety in the induction and maintenance of remission, I am pleased that it provides a new treatment option for patients with unmet medical needs".

Dr. Mamoru Watanabe, Vice president of Tokyo Medical and Dental University, commented “Jyseleca is a new JAK inhibitor and in clinical studies, the efficacy and safety profile of Jyseleca for induction and maintenance of remission were demonstrated in patients with moderately to severely active ulcerative colitis who are biologic-naïve and biologic-experienced. With the approval for the additional indication, I expect to see further progress in the treatment of ulcerative colitis”.

Gilead and Eisai co-market Jyseleca for rheumatoid arthritis indication in Japan. Gilead and EA Pharma, which has been commissioned by Eisai, will co-promote the additional indication of ulcerative colitis. Gilead, Eisai and EA Pharma will expand the therapeutic options for ulcerative colitis and strive to further contribute to improving the QOL of patients and their families through Jyseleca.

Reference

About Jyseleca

Jyseleca is a new oral JAK inhibitor (administered once daily). Jyseleca has been approved in Japan for the treatment of rheumatoid arthritis (including prevention of structural damage) who have responded inadequately to conventional therapies. Jyseleca has been approved in the European Union and Great Britain for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response with or intolerance to one or more disease-modifying antirheumatic drugs (i.e. DMARDs) and for the treatment of moderately to severely active ulcerative colitis who have had an inadequate response or lost response with, or are intolerant to conventional therapies or a biologic agent.

Details of additional indication

Indications	Treatment and maintenance therapy for moderately to severely active ulcerative colitis (limited to patients who have had an inadequate response with, lost response to, or were intolerant to conventional therapies)
Dosage and Administration (Exerted that are related to UC only)	Generally, adult dosage is 200mg of filgotinib administered orally once daily. For maintenance therapy, 100mg may be administered once daily depending on the patient's condition.

About Ulcerative colitis

Ulcerative colitis is a chronic disease characterized by inflammation of the lining of the large intestine. In recent years, the prevalence of ulcerative colitis has been increasing and has a significant impact on the quality of life (QOL) of more than two million people worldwide. Even with treatment, patients with ulcerative colitis experience imminent urgency, fecal incontinence, recurrent bloody diarrhea, frequent bowel movements, abdominal pain, insomnia, and fatigue. In Japan, ulcerative colitis is one of the intractable diseases designated by the Ministry of Health, Labour and Welfare. According to a nationwide survey in 2015, the estimated number of patients with ulcerative colitis in Japan was 219,685. The annual prevalence rate per 100,000 was 172.9 (192.3 men, 154.5 women).*

* Murakami Y, Nishiwaki Y, Oba MS, Asakura K, Ohfuji S, Fukushima W, et al. Correction to: Estimated prevalence of ulcerative colitis and Crohn's disease in Japan in 2015: an analysis of a nationwide survey. J Gastroenterol 2020;55:131.

About SELECTION Study

Phase IIb/III SELECTION trial is a multi-center, randomized, double-blinded, placebo-controlled trial evaluating the safety and efficacy of Jyseleca in the induction and maintenance of remission in biologic-naïve and biologic-experienced patients with moderately to severely active ulcerative colitis. The primary endpoint for the induction and maintenance was the percentage of participants who achieved EBS* remission at Week 10. The secondary endpoints included percentage of participants who achieved an endoscopic remission, 6-month corticosteroid free EBS remission and sustained EBS remission.

*EBS: Endoscopy/Bleeding/Stool Frequency

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 increase the benefit 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 particular focus on our strategic area of Neurology and Oncology. For more information about Eisai Co., Ltd., please visit www.eisai.com.

About EA Pharma

EA Pharma Co., Ltd., a subsidiary of Eisai Co., Ltd. for gastrointestinal disease area, was established in April 2016 by integration of the gastrointestinal business unit with more than 60 year's history of the Eisai Group and the gastrointestinal business unit of the Ajinomoto Group having amino acid as its business core. EA Pharma Co., Ltd., is a gastrointestinal specialty pharmaceutical company with a full value chain covering R&D, production & logistics and sales & marketing.

For further information on EA Pharma Co., Ltd., please visit <https://www.eapharma.co.jp/en>

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