

Joint Development and Marketing Agreement for Chronic Constipation Treatment AJG555 in Japan Was Signed

This material is an English translation of the press release issued on September 29, 2017 in Japanese, and the Japanese release is given priority regarding content and interpretation.

September 29, 2017

Mochida Pharmaceutical Co., Ltd.
EA Pharma Co., Ltd.

EA Pharma Co., Ltd. (President, Yuji Matsue; Headquarters, Tokyo, Japan) (hereinafter “EA Pharma”), a subsidiary of Eisai Co., Ltd. for the gastrointestinal disease area, and Mochida Pharmaceutical Co., Ltd. (President, Naoyuki Mochida; Headquarters, Tokyo, Japan) (hereinafter “Mochida”) announced today that the two companies have signed a joint development and marketing agreement for chronic constipation treatment AJG555 (polyethylene glycol preparation), which EA Pharma has been developing for the Japanese market.

AJG555 is an oral chronic constipation treatment that EA Pharma in-licensed from Norgine B.V. (Headquarters, the Netherlands). AJG555 controls osmotic pressures in the intestinal tract and promotes bowel movement. This product has been mainly marketed in Europe, under the brand name MOVICOL[®] and is widely used for treatment of chronic constipation in pediatric and adult patients. In Japan, polyethylene glycol preparation for chronic constipation was designated as a drug with high medical needs by the Evaluation Committee on Unapproved or Off-Labeled Drugs with High Medical Needs*¹ in April 2015, and the Ministry of Health, Labour and Welfare requested that Ajinomoto Pharmaceuticals Co., Ltd. (now EA Pharma) develop the product for the Japanese market. At this moment, the PIII clinical study of AJG555 in pediatric and adult patients with chronic constipation is ongoing.

Constipation is a very common disease. The prevalence is particularly high in women and in the elderly, and symptoms can become severe in pediatric patients. The symptoms of constipation are reduced bowel movements, feeling of incomplete evacuation, hard stools and others. When the symptoms become chronic, many patients suffer from a decline of QOL (Quality of Life).

EA Pharma and Mochida have a joint development and marketing agreement for another chronic constipation treatment AJG533*² which has a different action mechanism from that of AJG555. The application for the new drug approval for AJG533 has already been filed and is now under regulatory review. With these two types of chronic constipation treatments, EA Pharma and Mochida desire to add treatment options for patients with chronic constipation to make a contribution to increase patients' QOL, and the two companies' have found a consistency in their portfolio strategy which has led to the execution of above-captioned agreement.

Under this agreement, EA Pharma and Mochida will jointly distribute AJG555 under the same brand name in Japan after EA Pharma has obtained the marketing and manufacturing approval. With AJG533 and AJG555, EA Pharma and Mochida strive together to make a further contribution to increase of QOL of patients with chronic constipation.

*1 The Evaluation Committee on Unapproved or Off-Labeled Drugs with High Medical Needs:

This committee is a ministerial council that was organized in the Ministry of Health, Labour and Welfare with the purpose of evaluating the medical needs of the drugs or indications that have not been approved yet in Japan (hereinafter “unapproved or off-labeled drugs”) and confirming the appropriateness of filing new drug applications for such drugs as well as the adequate additional studies required for filing such applications to accelerate the development of unapproved or off-labeled drugs by pharmaceutical companies.

*2 Chronic constipation treatment AJG533:

AJG533 (nonproprietary name: elobixibat hydrate) has a novel action mechanism which inhibits the transporter that regulates reabsorption of bile acids. It is currently under development.

More information

1. About Mochida Pharmaceutical Co., Ltd.

Mochida Pharmaceutical Co., Ltd. has committed to research and development of innovative pharmaceutical products since its establishment thereby providing distinctive medicines to the medical field. Currently, the core pharmaceutical business focuses resources on the targeted areas of cardiovascular medicine, obstetrics and gynecology, dermatology, emergency medicine and psychiatry, while also providing medicine for intractable disease as well as generics including biosimilars, to meet medical needs. Please see <http://www.mochida.co.jp/> for more information about Mochida Pharmaceutical Co., Ltd.

2. About EA Pharma Co., Ltd.

EA Pharma Co., Ltd. is a gastrointestinal specialty pharma having a full value chain of research and development, production and logistics, sales and marketing, established in April 2016 by integration of the gastrointestinal business unit with more than 60 year-history of the Eisai Group and the Ajinomoto Group’s gastrointestinal business unit with the core in amino acid. Please see <http://www.eapharma.co.jp/> for more information about EA Pharma Co., Ltd.