

November 27, 2017

EA Pharma Co., Ltd.

Mochida Pharmaceutical Co., Ltd.

## **Application for Marketing and Manufacturing Approval of Chronic Constipation Treatment AJG555 Was Filed in Japan**

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 EA Pharma has filed an application for marketing and manufacturing approval of chronic constipation treatment AJG555 (polyethylene glycol preparation), which EA Pharma and Mochida have developed 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 and in other markets, under the brand name *MOVICOL*, and widely used for treatment of chronic constipation in pediatric and adult patients. The guidelines of NICE (National Institute for Health and Care Excellence) UK endorse the use of polyethylene glycol preparations for treatment of pediatric chronic constipation, and so do the guidelines of World Gastroenterology Organisation for treatment in adults.

Constipation is a very common disease. The prevalence is particularly high in women and in the elderly, and the 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).

Once EA Pharma has obtained the marketing and manufacturing approval of AJG555, EA Pharma and Mochida will distribute the product in Japan respectively under a same brand name. The two companies have jointly developed another chronic constipation treatment AJG533 of a different action mechanism from that of AJG555 (AJG533 is now being reviewed by the regulatory authorities for marketing and manufacturing approval). By providing AJG555 and AJG533, EA Pharma and Mochida desire to add treatment options for patients suffering from chronic constipation with different disease histories to make a contribution to fulfillment of various needs and increase of benefits of patients with chronic constipation, their families and medical practitioners.

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## More Information

### 1. About AJG555 (polyethylene glycol preparation)

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\* in April 2015. Upon request from the Ministry of Health, Labour and Welfare, Ajinomoto Pharmaceuticals Co., Ltd. (now EA Pharma) has developed AJG555 for treatment of chronic constipation in pediatric and adult patients in Japan. As of September 29, 2017, EA Pharma and Mochida signed a joint development and marketing agreement for AJG555.

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

This committee was organized in the Ministry of Health, Labour and Welfare to evaluate the medical needs of the drugs and indications that are not approved in Japan (“unapproved or off-labeled drugs”) and the appropriateness of filing the public knowledge-based application and requirement of additional studies for filing the marketing and manufacturing application to promote development of unapproved or off-labeled drugs by pharmaceutical companies.

### 2. About AJG533 (nonproprietary name: elobixibat hydrate)

AJG533, which EA Pharma in-licensed from Albireo AB (Headquarters, Sweden), is an orally available chronic constipation treatment having a novel mechanism of action. AJG533 inhibits the bile acid transporter that regulates reabsorption of bile acids thereby increasing the flow of bile acids to the colon, which is expected to enhance colonic motility. EA Pharma and Mochida have a joint development and marketing agreement for AJG533. EA Pharma filed the application for marketing and manufacturing approval as of February 1, 2017. Once EA Pharma has obtained the approval, the two companies will distribute AJG533 respectively under a same brand name in Japan.

### **3. About EA Pharma Co., Ltd.**

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 at least 60 years history of the Eisai Group and the gastrointestinal business unit of the Ajinomoto Group having amino acid as its business core. EA Pharma is a gastrointestinal specialty pharma with a full value chain covering R&D, logistics and sales & marketing.

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

### **4. 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.

For more information on Mochida Pharmaceutical Co., Ltd., please see <http://www.mochida.co.jp/english/>