

**EA Pharma Co., Ltd. and Mochida Pharmaceutical Co., Ltd. announce the results of phase 3 study of AJG533 for chronic constipation conducted in Japan  
– Primary endpoint was met in patients with chronic constipation**

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September 30, 2016

EA Pharma Co., Ltd.

Mochida Pharmaceutical Co., Ltd.

EA Pharma Co., Ltd. (President, Hajime Shimizu; Headquarters, Tokyo, Japan) and Mochida Pharmaceutical Co., Ltd. (President, Naoyuki Mochida; Headquarters, Tokyo, Japan) announced that the achievement of primary endpoint was met in Phase 3 clinical study of AJG533 (nonproprietary name: Elobixibat Hydrate), which the two companies have developed for treatment of chronic constipation in Japan.

Constipation is a very common disease, and the prevalence is particularly high in women and the elderly. In constipation, symptoms such as sensation of incomplete evacuation and hard stools appear in addition to reduction of bowel movement frequency. When such symptoms become chronic, many patients suffer from decline of QOL (quality of life). AJG533, which was in-licensed from Albireo (Sweden), is an orally available constipation treatment having a novel action mechanism. AJG533 inhibits the bile acid transporter that regulates reabsorption of bile acids and thereby increases spontaneous colonic motility.

The present phase 3 study is a double blind comparative study in Japan. Patients were randomized to receive AJG533 or placebo orally once daily for 14 days for investigation of efficacy and safety. The study results demonstrated a statistically significant improvement in the AJG533 group as compared to the placebo group in the primary endpoint of spontaneous bowel movement<sup>1)</sup> frequency change and also in the efficacy secondary endpoints including complete spontaneous bowel movement<sup>2)</sup> frequency change and stool consistency. There were no serious adverse events in the study.

A long term study of AJG533 for investigation of safety and efficacy in long term use is now being conducted.

EA Pharma Co., Ltd. and Mochida Pharmaceutical Co., Ltd. are advancing the development of AJG533 with the aim of filing a new drug application in FY2016. By providing AJG533, the two companies are striving to make a further contribution to increasing treatment options and improvement of QOL for patients with chronic constipation.

1) defecation without use of laxative, enema or manual disimpaction

2) spontaneous defecation without sensation of incomplete evacuation

[More information](#)

### **1. 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.

### **2. 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.