

New Drug Application of AJG533 for chronic constipation was filed in Japan.

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

EA Pharma Co., Ltd. (President, Hajime Shimizu; Headquarters, Tokyo, Japan) (hereinafter “EA Pharma”), a subsidiary of Eisai Co., Ltd. for gastrointestinal disease area, and Mochida Pharmaceutical Co., Ltd. (President, Naoyuki Mochida; Headquarters, Tokyo, Japan) (hereinafter “Mochida Pharmaceutical”) announce that EA Pharma today filed an NDA for 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 a once-daily, orally available 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.

The application was mainly made based on the results of double-blind, placebo-controlled Phase III clinical study. As a result of administration of AJG533 or placebo in oral administration once daily for 14 days, statistically significant improvements were observed in the AJG533 group as compared to the placebo group in the primary endpoint of spontaneous bowel movement¹⁾ frequency change and also in the efficacy secondary endpoints including complete spontaneous bowel movement²⁾ frequency change and stool consistency. There were no serious adverse events in the study.

EA Pharma and Mochida Pharmaceutical plan to distribute the product under the same brand name in Japan after having obtained approval of the NDA submitted by EA Pharma. The two companies will strive to make a further contribution to improve QOL of patients by providing AJG533 with novel action mechanism to increase treatment choices.

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

2) spontaneous defecation without sensation of incomplete evacuation

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.