

New drug approval of bile acid transporter inhibitor “GOOFICE® 5mg Tablet” for chronic constipation was obtained in Japan

This material is an English translation of the press release issued on January 19, 2018 in Japanese, and the Japanese release is given priority regarding content and interpretation.

January 19, 2018

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

Mochida Pharmaceutical Co., Ltd. (President: Naoyuki Mochida; Headquarters: Tokyo, Japan) (hereinafter “Mochida”) and Eisai Co., Ltd. (CEO: Haruo Naito; Headquarters: Tokyo, Japan) (hereinafter “Eisai”), Eisai’s subsidiary for gastrointestinal disease area EA Pharma Co., Ltd. (President & CEO: Yuji Matsue; Headquarters: Tokyo, Japan) (hereinafter “EA Pharma”) today announced that EA Pharma has obtained new drug approval for bile acid transporter inhibitor “GOOFICE® 5mg Tablet” (nonproprietary name: Elobixibat Hydrate; development code: AJG533) (hereinafter “GOOFICE® Tablet”) for chronic constipation (excluding structural disease-induced constipation) in Japan.

GOOFICE® Tablet was jointly developed by Mochida and EA Pharma. After inclusion in the National Health Insurance drug price list, the two companies will respectively market the product under the same brand name in Japan. EA Pharma and Eisai concluded a co-promotion agreement and jointly provide proper use information of this product.

GOOFICE® Tablet, which EA Pharma in-licensed from Albireo AB (Headquarters: Sweden), is a once-daily, orally available constipation treatment with a novel mechanism of action. GOOFICE® Tablet 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 natural defecation.

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).

The above new drug approval was mainly based on the results of a placebo-controlled, double-blind Phase III clinical study in patients with chronic constipation conducted in Japan. As a result of oral administration of GOOFICE® Tablet or placebo once daily for 14 days, statistically significant improvements were observed in the GOOFICE® Tablet group as compared to the placebo group in the primary endpoint of spontaneous bowel movement¹⁾ frequency change and also in the secondary endpoints including complete spontaneous bowel movement²⁾ frequency change and stool consistency. There were no serious adverse events in the study.

By providing GOOFICE® Tablet with its novel mechanism of action, Mochida, EA Pharma and Eisai strive to broaden treatment options for patients with chronic constipation to make a further contribution to improve patients’ QOL.

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

2) spontaneous defecation without sensation of incomplete evacuation

More information

1. "GOOFICE® 5 mg Tablet" Product outline

Brand name	GOOFICE® 5 mg Tablet
Nonproprietary name	Elobixibat Hydrate
Date of new drug approval	January 19, 2018
Manufacturer and distributor	EA Pharma Co., Ltd.
Promotion alliance with EA Pharma Co., Ltd.	Eisai Co., Ltd.
Distributor	Mochida Pharmaceutical Co., Ltd.
Indication	Chronic constipation (excluding structural disease-induced constipation)
Dosage and administration	The normal adult dose is 10 mg of elobixibat once daily orally before a meal. The dose can be increased or reduced depending on the symptoms. The maximal dose should be 15 mg per day.

2. About Mochida Pharmaceutical Co., Ltd.

Mochida Pharmaceutical Co., Ltd. has been 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/>

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 <http://www.eapharma.co.jp/en/>

4. About Eisai Co., Ltd.

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 increasing the benefits 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 a particular focus in our strategic areas of Neurology and Oncology.

For more information on Eisai Co., Ltd., please see <http://www.eisai.com/>