

World's First Bile Acid Transporter Inhibitor "GOOFICE[®] 5mg Tablet" Launched in Japan

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

April 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 diseases EA Pharma Co., Ltd. (President & CEO: Yuji Matsue; Headquarters: Tokyo, Japan) (hereinafter "EA Pharma") today announced that the bile acid transporter inhibitor "GOOFICE[®] 5mg Tablet" (nonproprietary name: Elobixibat Hydrate; development code: AJG533) (hereinafter "GOOFICE[®] Tablet") was listed in Japan's National Health Insurance Drug Price List as of April 18, 2018, and Mochida and EA Pharma launched the product onto Japan's market today.

GOOFICE[®] Tablet, which EA Pharma in-licensed from Albireo AB (Sweden), is a once-daily, orally available constipation treatment with a novel action mechanism. GOOFICE[®] Tablet inhibits the bile acid transporter that regulates reabsorption of bile acids thereby increasing the flow of bile acids to the colon. The dual action of moisture secretion and bowel movement promotion is expected to enhance natural defecation. GOOFICE[®] Tablet is the first ileal bile acid transporter inhibitor approved anywhere in the world.

Constipation is a very common disease. The prevalence is high in young women and both elderly men and women. In Japan, the number of patients with subjective symptoms of constipation is estimated to be about 4.5 million¹⁾. 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 a decline in QOL (quality of life). In a placebo-controlled, double-blind Phase 3 clinical study conducted in Japan, which was the basis for marketing approval, there were statistically significant improvements observed in changes in spontaneous bowel movement²⁾ (primary endpoint), complete spontaneous bowel movement³⁾ (secondary endpoint), time to first spontaneous bowel movement, stool consistency and other parameters for the GOOFICE[®] Tablet-treated group compared to the placebo group. No serious adverse events were observed.

GOOFICE[®] Tablet was jointly developed by Mochida and EA Pharma. Mochida and EA Pharma will distribute the product under the same brand name, respectively. EA Pharma and Eisai have signed a co-promotion agreement and will jointly provide information for proper use of the product. 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) Estimation based on the Comprehensive Survey of Living Conditions 2016 conducted by Ministry of Health, Labour and Welfare
- 2) Defecation without use of laxative, enema or manual disimpaction
- 3) Spontaneous defecation without sensation of incomplete evacuation

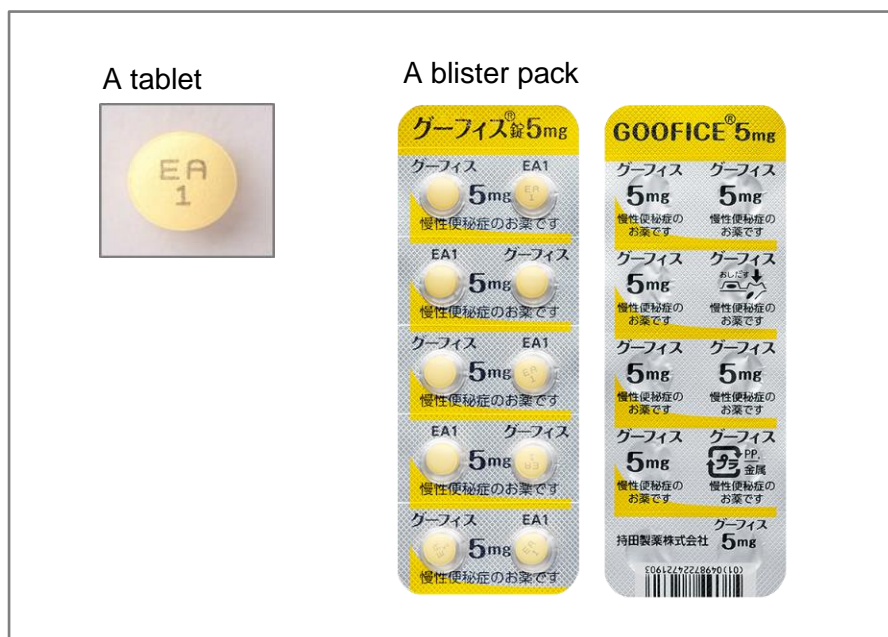
End

More Information

1. "GOOFICE® 5 mg Tablet"

Brand name	GOOFICE® 5 mg Tablet
Nonproprietary name	Elobixibat Hydrate
Dosage form	A film-coated tablet containing 5 mg of elobixibat
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.
Package	100 tablets (blister pack), 500 tablets (blister pack)
National Health Insurance (NHI) Drug Price	¥105.80 per tablet of GOOFICE® 5 mg Tablet
Date of marketing approval	January 19, 2018
Listing in NHI Drug Price List	April 18, 2018
Date of launch	April 19, 2018
Manufacturer and distributor	EA Pharma Co., Ltd.
Promotion alliance with EA Pharma Co., Ltd.	Eisai Co., Ltd.
Distributor	Mochida Pharmaceutical Co., Ltd.

■ Product photos



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, obstetrics and gynecology, dermatology, psychiatry, and gastroenterology, 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 more than 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 <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 <https://www.eisai.com/>