

# News Release

December 19, 2018

EA Pharma Co., Ltd.

## **EA Pharma Signs License Agreement with Synmosa for Chronic Constipation Treatment AJG533**

EA Pharma Co., Ltd. (President, Yuji Matsue; Headquarters, Tokyo, Japan) (hereinafter “EA Pharma”), announced today that EA Pharma signed a license agreement with Synmosa Biopharma Corporation (President, Peter Lin; Headquarters, Taipei, Taiwan) (hereinafter “Synmosa”) to grant Synmosa the exclusive rights to develop and market the chronic constipation treatment, AJG533 (nonproprietary name, elobixibat hydrate; brand name in Japan, GOOFICE<sup>®</sup>) in Taiwan.

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.

The prevalence of constipation is high in young women and both men and women in the elderly in Japan. The symptoms of constipation include reduced bowel movement, feeling of incomplete evacuation and hard stools. When the symptoms become chronic, many patients suffer from a decline of QOL (Quality of Life).

In Taiwan, it is said that treatment needs for gastrointestinal diseases have been increasing against the backdrop of the aging society and the lifestyle change. According to the National Health Insurance Statistical Annual Reports of the Ministry of Health and Welfare of Taiwan, 1.4 million people are prescribed with chronic constipation drugs every year.

The above sublicense granted to Synmosa will contribute to addressing the diverse needs of chronic constipation patients in Taiwan with various disease histories, as well as their families and healthcare providers, and also contribute to increasing the benefits of treatment, like in Japan.

EA Pharma aims to create new values in healthcare to make a contribution to patients, their families and medical practitioners in the world through development of pharmaceuticals focusing on the gastrointestinal disease area.

\*Excluding structural disease-induced constipation

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## More Information

### 1. About EA Pharma Co., Ltd.

EA Pharma, 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 see <http://www.eapharma.co.jp/en/>

### 2. About Synmosa Biopharma Corporation

Established in 1980, Synmosa focuses on the multi-faceted development in the medical industry. Synmosa specializes in R&D, manufacturing, distribution, sales and marketing of new drugs, generics, OTC, and healthcare products. Synmosa is strong in respiratory, cardiovascular, sex hormones, urology, oncology oriented therapeutic products. Digestive system therapeutic area will be the next focus area.

For more information on Synmosa Biopharma Corporation, Please see <http://www.synmosa.com.tw/EN/>

### 3. About AJG533 (Nonproprietary name, elobixibat hydrate; brand name in Japan, GOOFICE®)

AJG533, which EA Pharma in-licensed from Albireo AB (Headquarters, Sweden), is an orally available chronic constipation (excluding structural disease-induced 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. AJG533 is the world's first pharmaceutical product approved for marketing with the above action mechanism. The dual action of moisture secretion and bowel movement promotion by bile acids can facilitate defecation. The results from phase III clinical trials (a 2-week double-blind placebo-controlled phase III trial and an open-label single-arm 52-week long-term phase III trial) for AJG533 have been published in The Lancet Gastroenterology & Hepatology, a journal of The Lancet, which is one of the world's most influential medical journals.

EA Pharma signed a joint development and marketing agreement for AJG533 with Mochida Pharmaceutical Co., Ltd., and the two companies started distribution of "GOOFICE® 5 mg Tablet" respectively under the same brand name on April 19, 2018 in Japan. EA Pharma also has a co-promotion agreement with Eisai Co., Ltd. EA Pharma and Eisai Co., Ltd. jointly provide proper use information of "GOOFICE® 5 mg Tablet" in Japan.