May 28, 2021

EA Pharma Co., Ltd.
Kissei Pharmaceutical Co., Ltd.
(Code 4574, Tokyo Stock Exchange 1st Section)

EA Pharma Filed Marketing Approval Application for AJM300 (Nonproprietary Name: Carotegrast Methyl) Indicated for Treatment of Ulcerative Colitis

EA Pharma Co., Ltd. (President, Yuji Matsue; Headquarters, Chuo-ku, Tokyo, Japan; “EA Pharma”) and Kissei Pharmaceutical Co., Ltd. (Head Office: Matsumoto, Nagano; Chairman and CEO: Mutsuo Kanzawa; "Kissei") announced that EA Pharma has filed the marketing approval application in Japan for AJM300 (nonproprietary name: carotegrast methyl), which the two companies have developed for treatment of ulcerative colitis. The application was filed based on the results of Phase III clinical study (AJM300/CT3) and other studies conducted in Japan. Detailed data of AJM300/CT3 will be presented at an upcoming major medical conference this year.

AJM300 is an orally available small molecule α4 integrin antagonist that was originated by EA Pharma (formerly known as Ajinomoto Pharmaceuticals Co., Ltd.). EA Pharma and Kissei have jointly developed AJM300 since 2015, aiming to launch the world-first orally available α4 integrin antagonist onto the market.

In ulcerative colitis, lymphocytes and other inflammatory cells excessively aggregate and invade into the inflamed site in the colonic mucosa. AJM300 can antagonize both α4β1 and α4β7 integrins expressed on the surface of inflammatory cells and inhibit the cell adhesion mediated by binding to adhesion molecules excessively expressed on the vascular endotherial cells in the colonic mucosa, which suppresses invasion of lymphocytes into the inflamed site to exert anti-inflammation effects.

EA Pharma and Kissei strive to quickly provide AJM300 for clinical use to increase treatment options for ulcerative colitis to contribute to QOL of patiens and their families.

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《More information》

1. 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 year's history of the Eisai Group and the gastrointestinal business unit of the Ajinomoto Group having amino acid as its business core. EA Pharma Co., Ltd., is a gastrointestinal specialty pharmaceutical company with a full value chain covering R&D, production & logistics and sales & marketing.

For further information on EA Pharma Co., Ltd., please visit https://www.eapharma.co.jp/en/

2. Kissei Pharmaceutical Co., Ltd.

Under the management philosophy "contribute to society through high-quality, innovative pharmaceutical products" and "serve society through our employees", Kissei Pharmaceutical Co., Ltd. provides unique innovative pharmaceutical products as a drug discovery and R&D-oriented company for patients in the world with a special focus on urology, renal diseases, dialysis, diabetes, gastroenterology and rare diseases.

For more details about Kissei Pharmaceutical Co., Ltd., please visit https://www.kissei.co.jp/

3. Ulcerative Colitis

Ulcerative colitis is an inflammatory disease that causes ulcers and erosions in the colonic mucosa. The major symptoms are abdominal pain, diarrhea, bloody stools and so on. In many cases, the "remission" stage where the symptoms improve and the "relapse" stage where the symptoms deteriorate repeat over time, and patients suffer from the decline of QOL (quality of life). The mechanism of onset is unknown up to the present. In Japan, ulcerative colitis is one of the "designated intractable disease" by Ministry of Health, Labour and Welfare. The registered patient number in Japan was nearly 220,000 in 2019, and the patient number has a tendency to increase in recent years.[1)]

1) "Basic treatment guidance for patients with ulcerative colitis" (revised March 2020), Research group for intractable inflammatory bowel diseases, Research project on rare and intractable diseases, Health and Labour Sciences Research Grants.

4. AJM300/CT3 Study

The study was a randomized, double blind, pracebo controlled study in 203 patients with moderately active ulcerateive colitits who had inadequate response or intorelance to the basic treatment with 5-aminosalicylic acid in 82 medical facilities in Japan. The patients were randomized to the groups treated with AJM300 or pracebo and received oral administration 3 times daily for 8 weeks to investigate the efficacy and safety of AJM300.