

November 15, 2021

EA Pharma Co., Ltd.
Kissei Pharmaceutical Co., Ltd.
(Code 4547, Tokyo Stock Exchange 1st Section)

**Change of Marketing Scheme for "RECTABUL® 2 mg Rectal Foam 14 Doses" and
AJM300 (Nonproprietary Name: Carotegrast Methyl), Both for Treatment of
Ulcerative Colitis – Agreement Concluded**

EA Pharma Co., Ltd. (President, Hidenori Yabune; Headquarters, Chuo-ku, Tokyo, Japan; "EA Pharma") and Kissei Pharmaceutical Co., Ltd. (Head Office: Matsumoto, Nagano; Chairman and CEO: Mutsuo Kanzawa; "Kissei") announced that the two companies signed an agreement to change the marketing scheme for their anti-ulcerative colitis products "RECTABUL® 2 mg Rectal Foam 14 Doses" and AJM300 (nonproprietary name: carotegrast methyl), the latter is under marketing approval examination.

For RECTABUL®, EA Pharma and Kissei concluded a joint development and marketing agreement in March 2015. While EA Pharma holds the ownership to marketing approval of RECTABUL®, both EA Pharma and Kissei have distributed the product since December 2017. For AJM300 also, the two companies concluded an agreement likewise in March 2015, under which the two companies jointly developed the product to file the application for marketing approval under EA Pharma's name in May 2021. Both EA Pharma and Kissei were to distribute AJM300 after obtainment of the approval. According to the new agreement, however, one company undertakes distribution of one product, and the other undertakes the copromotion, and vice versa.

Under the new agreement, RECTABUL® will be distributed by EA Pharma with copromotion by Kissei from April 1, 2022. AJM300, once the marketing approval is obtained, will be distributed by Kissei with copromotion by EA Pharma. EA Pharma continues to hold the ownership of the marketing approvals of the two products.

After change of the marketing scheme, EA Pharma and Kissei continue to strive to increase treatment options for ulcerative colitis to contribute to QOL (Quality of Life) of patients and their families.

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《More Information》

1. 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 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. About 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, nephrology, dialysis, diabetes, gastroenterology and rare diseases.

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

3. About 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. 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. About RECTABUL[®]

RECTABUL[®], an in-licensed product of EA Pharma from Dr. Falk Pharma (Germany), is the first foam product for rectal enema (rectal foam) in Japan. EA Pharma and Kissei have jointly developed this product for the Japanese market, and EA Pharma obtained the marketing approval. Since the dosage form is a foam, the drug stays in the rectum and the sigmoid colon after reaching them, and leakage after administration is avoided.

5. About AJM300 (nonproprietary name: carotegrast methyl)

In ulcerative colitis, lymphocytes and other inflammatory cells excessively aggregate and invade into the inflamed site in the colonic mucosa. AJM300 can antagonize both $\alpha 4\beta 1$ and $\alpha 4\beta 7$ integrins expressed on the surface of inflammatory and inhibit the cell adhesion mediated by binding to adhesion molecules excessively expressed on the vascular endothelial cells in the colonic mucosa, which suppresses invasion of lymphocytes into the inflamed site to exert anti-inflammation effects.