July 1, 2021

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

Phase III Clinical Study Data of AJM300 (Nonproprietary Name: Carotegrast Methyl) Conducted in Japan for Treatment of Ulcerative Colitis (AJM300/CT3 Study) will be presented in the 16th Congress of European Crohn's and Colitis Organisation (ECCO'21)

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 results of Phase III clinical study (AJM300/CT3) conducted in Japan for AJM300 (nonproprietary name: carotegrast methyl), which the two companies develop for treatment of ulcerative colitis, will be presented in an oral presentation in the 16th Congress of ECCO'21 to be virtually held July 2, 3 and 8-10, 2021.

<Study Data to be Presented>

Abstract No.	Title	e-Presentation Schedule, e-Presentation Style
OP34	AJM300, an Oral Antagonist of α4-Integrin, as induction therapy for patients with Moderately Active Ulcerative Colitis: A Phase 3, randomized, double-blind, placebo-controlled induction study	July 10, 2021 10:50-11:00 (Central European Summer Time) 17:50-18:00 (Japan Time) Online Oral Presentation

The study was a randomized, double-blind, placebo-controlled study in 203 patients with moderate active ulcerative colitis who had inadequate response or intolerance 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 placebo and received oral administration 3 times daily for 8 weeks to investigate the efficacy and safety of AJM300. As a result of the study, in clinical response rate by Mayo score at 8 weeks of administration (the primary endpoint), the superiority of AJM300 group to placebo group was demonstrated. In addition, statistically significant improvements were observed in the secondary endpoints including endoscopic remission rate. The adverse event incidences were similar between AJM300 group and placebo group. The major adverse events observed in AJM300 group were nasopharyngitis, headache and nausea.

AJM300 is a small molecule that was originated by EA Pharma (formerly known as Ajinomoto Pharmaceuticals Co., Ltd.). EA Pharma filed the New Drug Application in Japan on May 27, 2021, aiming to launch the world-first orally available α4-integrin antagonist onto the market. EA Pharma and Kissei 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. 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, nephrology, dialysis, diabetes, gastroenterology and rare diseases.

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

3. AJM300 (nonproprietary name: carotegrast methyl)

AJM300 is an orally available small molecule α4-integrin antagonist that was originated by EA Pharma (formerly known as Ajinomoto Pharmaceuticals Co., Ltd.). AJM300 acts on both α4β1 integrin and α4β7 integrin expressed on the surface of inflammatory cells to exert an anti-inflammatory effect by inhibiting the cell adhesion and suppressing excessive aggregation and invasion of inflammatory cells into the inflamed site in the colonic mucosa in ulcerative colitis. EA Pharma and Kissei have jointly developed AJM300 since 2015, and EA Pharma filed the New Drug Application in Japan on May 27, 2021.

4. 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.

5. Mayo Score

Mayo Score is a disease activity index to rate the activity level of ulcerative colitis most frequently used in clinical study in these years. Mayo Score comprises of 4 sub-scores (stool frequency, rectal bleeding, mucosal appearance at endoscopy and physician's global assessment). Each score ranges between 0 to 3 points, and the disease activity is rated by the total of the points (0-12 points). The disease activity is regarded mild with the points between 3-5, moderate between 6-10 and severe between 11-12.