

December 6, 2017

EA Pharma Co., Ltd.

Kissei Pharmaceutical Co., Ltd.  
(Code 4547, Tokyo Stock Exchange 1<sup>st</sup> Section)

## **Ulcerative Colitis Treatment “RECTABUL<sup>®</sup> 2 mg Rectal Foam 14 Doses” Launches in Japan**

EA Pharma Co., Ltd.(President & CEO, Yuji Matsue; Headquarters, Tokyo, Japan)(hereinafter “EA Pharma”), a subsidiary of Eisai Co., Ltd. for the gastrointestinal disease area, and Kissei Pharmaceutical Co., Ltd. (Chairman & CEO, Mutsuo Kanzawa; Headquarters, Nagano Prefecture, Japan)(hereinafter “Kissei”) announced today that EA Pharma and Kissei will launch “RECTABUL<sup>®</sup> 2 mg Rectal Foam 14 Doses”, an ulcerative colitis treatment agent, (Development code: AJG511) on December 7, 2017 in Japan.

RECTABUL<sup>®</sup>, 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 and manufacturing 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. In addition, this product is a locally active steroid and, thus, is expected to reduce steroid-related systemic side effects.

Outside Japan, this product was developed by Dr. Falk Pharma and approved for marketing in 2006 in the UK “indicated for the treatment of active ulcerative colitis that is limited to the rectum and the sigmoid colon”. Later in 2014, this product was approved in the US “indicated for the induction of remission in patients with active, mild to moderate distal ulcerative colitis extending up to 40 cm from the anal verge”. As of March 2017, this product is approved for marketing in 36 countries worldwide.

During the development of RECTABUL<sup>®</sup> in Japan, “The IBD Patients Association Requesting the Immediate Approval of Budesonide in Japan”, a patients association consisting of 27 IBD patient groups in Japan, made a request for accelerating the development of this product to the “Evaluation Committee on Unapproved or Off-Labeled Drugs with High Medical Needs”<sup>\*1</sup>. In the PIII double-blind placebo-controlled clinical study in patients with active ulcerative colitis conducted in Japan with the primary endpoint of mucosal healing rates<sup>\*2</sup> measured by endoscopy at 6 weeks of rectal administration of this product twice-daily, the superiority of this product to placebo was confirmed.

Ulcerative colitis is a kind of inflammatory bowel disease. In ulcerative colitis, ulcers develop in the colonic mucosa, with the symptoms including abdominal pain, diarrhea and hemorrhagic stool, leading to a marked decline in QOL (quality of life). In Japan, ulcerative colitis is designated an intractable disease by the Ministry of Health, Labour and Welfare, and it is estimated that at least 170,000 people suffer from the disease in this country.

EA Pharma and Kissei will respectively distribute RECTABUL<sup>®</sup> under the same brand name in Japan. With RECTABUL<sup>®</sup>, the two companies will strive to make further contributions to increasing the QOL of patients and respond to the need for easy-to-use and safe locally-active treatment of ulcerative colitis.

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\*1 The Evaluation Committee on Unapproved or Off-Labeled Drugs with High Medical Needs:

This committee was organized in the Ministry of Health, Labour and Welfare to evaluate the medical needs of the drugs and indications that are not approved in Japan (“unapproved or off-labeled drugs”) and the appropriateness of filing the public knowledge-based application and requirement of additional studies for filing the marketing and manufacturing application to promote development of unapproved or off-labeled drugs by pharmaceutical companies.

\*2 Mucosal healing rates:

The rates of patients in whom the colonic mucosa became normal or the disease was observed to be clinically inactive.

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## More Information

### ■ “RECTABUL<sup>®</sup> 2 mg Rectal Foam 14 Doses” Product Outline

Brand Name	RECTABUL <sup>®</sup> 2mg Rectal Foam 14 Doses
Non-proprietary name	Budesonide
Date of Marketing Approval	September 27, 2017
Date of Inclusion in the National Health Insurance (NHI) Drug Price List	November 22, 2017
NHI Drug Price	RECTABUL <sup>®</sup> 2mg Rectal Foam 14 Doses ¥6,940.60 per bottle of 48mg 30.8g
Date of Launch	December 7, 2017
Manufacturer and Distributor	EA Pharma Co., Ltd.
Distributor	Kissei Pharmaceutical Co., Ltd.
Indication	Ulcerative colitis (except severe cases)
Dosage and Administration	The normal adult dose is one push (2 mg of budesonide) per dose, twice-daily, by rectal enema.

### 【Product Picture】



“RECTABUL<sup>®</sup> 2 mg Rectal Foam 14 Doses”  
The bottle with the applicator mounted