

May 30, 2022

EA Pharma Co., Ltd.
Kissei Pharmaceutical Co., Ltd.
(Code 4547, Tokyo Stock Exchange Prime Market)

**“CAROGRA[®] Tablets”, Launched in Japan for Treatment of Ulcerative Colitis
- The World-First Orally Available α 4 Integrin Antagonist Come onto the Market -**

EA Pharma Co., Ltd. (Head Office: Chuo-ku, Tokyo, Japan; President: Hidenori Yabune; “EA Pharma”) and Kissei Pharmaceutical Co., Ltd. (Head Office: Matsumoto, Nagano; Chairman and CEO: Mutsuo Kanzawa; “Kissei”) announced that “CAROGRA[®] Tablets” (nonproprietary name, carotegrast methyl; “CAROGRA[®]”), was launched today for treatment of ulcerative colitis in Japan, following the inclusion in the National Health Insurance Drug Price List as of May 25.

CAROGRA[®] is a small molecule compound that was originated by EA Pharma (formerly known as Ajinomoto Pharmaceuticals Co., Ltd.) and is the first α 4 integrin antagonist drug launched as an orally available dosage form in the world. CAROGRA[®] acts on both α 4 β 1 and α 4 β 7 integrins expressed on the surface of inflammatory cells to exert anti-inflammatory effects by suppressing excessive aggregation and invasion of inflammatory cells into the inflamed site of colonic mucosa in ulcerative colitis.

EA Pharma and Kissei have jointly developed CAROGRA[®] since 2015. As of March 28, 2022, EA Pharma obtained the manufacturing and marketing approval in Japan. CAROGRA[®] will be distributed by Kissei with co-promotion by EA Pharma in Japan.

EA Pharma and Kissei strive to increase treatment options for ulcerative colitis and contribute to QOL (Quality of Life) of patients and their families by providing CAROGRA[®] for clinical practice quickly.

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《More Information》

1. CAROGRA® Tablets Product Outline

Brand Name	CAROGRA® Tablets
Nonproprietary Name	Carotegrast Methyl
Color, Formulation	White or yellowish white to yellowish greenish white film coated tablets
National Health Insurance (NHI) Drug Price	¥200.00/tablet (¥4,800.00/day)
Date of Manufacturing and Marketing Approval	March 28, 2022
Date of Inclusion in the NHI Drug Price List	May 25, 2022
Date of Launch	May 30, 2022
Manufacturer and Marketing Authorization Holder	EA Pharma Co., Ltd.
Distributor	Kissei Pharmaceutical Co., Ltd.
Indication	Moderate ulcerative colitis (limited to those patients who had inadequate response to 5-aminosalicylic acid)
Dose and Administration	Normally in adults, 960 mg of carotegrast methyl per dose should be taken orally after a meal 3 times a day.



2. 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/>

3. 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/>

4. 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 repeatedly 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