

No.14-09

February 13, 2014
Eisai Co., Ltd.

EISAI ANNOUNCES LAUNCH OF PARIET® TRIPLE FORMULATION COMBINATION PACKS RABECURE® 400 AND 800 AND RABEFINE®, FOR PRIMARY AND SECONDARY *H. PYLORI* ERADICATION RESPECTIVELY, IN JAPAN

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that it will launch two types of triple formulation combination packs that contain its proton pump inhibitor Pariet® (rabeprazole sodium) in Japan on February 14 for use in *Helicobacter pylori* eradication.

The launch will feature three products: Rabecure® Pack 400 and Rabecure Pack 800, which package together individual blister sheets each containing a daily triple formulation dose of Pariet, amoxicillin hydrate and clarithromycin for use in primary *H. pylori* eradication, and Rabefine® Pack, which similarly packages together individual blister sheets containing a daily triple formulation dose of Pariet, amoxicillin hydrate and metronidazole for use in secondary *H. pylori* eradication. Eisai received approval to manufacture and market both combination types in Japan from the country's Ministry of Health, Labour and Welfare in August 2013, with all three products added to Japan's National Health Insurance drug price list on December 13 of the same year.

In *H. pylori* eradication triple therapy with Pariet and two antimicrobial agents, successful eradication significantly depends on whether the patient properly adheres to the prescribed treatment regimen. Taking the incorrect dose or missing doses altogether can lead not only to reduced eradication rates but also to bacterial resistance. With daily-dose blister sheets adopted for both the primary and secondary eradication combinations of Eisai's new triple formulation packs, the launch is expected to help ensure that *H. pylori* eradication therapy is administered more appropriately and with greater certainty, while also improving patient drug compliance and offering increased convenience in a medical setting.

Eisai believes that the launch of its Rabecure and Rabefine combination packs will further promote the appropriate use of therapeutic agents in *H. pylori* eradication therapy and contribute to a wider range of treatment options available for gastric cancer eradication and other treatments for diseases associated with *H. pylori*.

**[Please refer to the following notes for product outlines,
further information on Pariet, and product photographs.]**

Media Inquiries:
Public Relations Department,
Eisai Co., Ltd.
+81-(0)3-3817-5120

<Notes to editors>

1. Product Outlines

1) Rabecure[®] Pack 400 and Pack 800 triple formulation packs for primary *Helicobacter pylori* eradication

(1) Principal Agents (per blister sheet, equivalent to daily dose)

Rabecure Pack 400

Pariet[®] Tablets 10 mg (rabeprazole sodium) 2 tablets (1 tablet x 2 doses)

Sawacillin[®] Tablets 250 (amoxicillin hydrate) 6 tablets (3 tablets x 2 doses)

Clarith[®] Tablets 200 (clarithromycin) 2 tablets (1 tablet x 2 doses)

Rabecure Pack 800

Pariet Tablets 10 mg (rabeprazole sodium) 2 tablets (1 tablet x 2 doses)

Sawacillin Tablets 250 (amoxicillin hydrate) 6 tablets (3 tablets x 2 doses)

Clarith Tablets 200 (clarithromycin) 4 tablets (2 tablets x 2 doses)

(2) Indications

[Micro-organisms]

H. pylori strains susceptible to amoxicillin and clarithromycin

[Conditions]

H. pylori infections:

Gastric ulcer, duodenal ulcer, gastric MALT lymphoma, idiopathic thrombocytopenic purpura, the stomach after endoscopic resection of early-stage gastric cancer, and *H. pylori* gastritis

(3) Dosage and Administration

For adults, the following triple formulation regimen should be administered orally at the same time twice daily for seven days: 10 mg/dose of rabeprazole sodium, 750 mg (potency)/dose of amoxicillin hydrate, and 200 mg (potency)/dose of clarithromycin. The dose of clarithromycin may be increased appropriately depending on the patients' needs. However, dosage should not exceed 400 mg (potency)/dose twice daily.

(4) Price (per blister sheet, equivalent to daily dose)

Rabecure Pack 400 544.20 yen

Rabecure Pack 800 721.40 yen

(5) Packaging

Rabecure Pack 400 7 blister sheets

Rabecure Pack 800 7 blister sheets

2) Rabefine[®] Pack triple formulation pack for secondary *H. pylori* eradication

(1) Principal Agents (per blister sheet, equivalent to daily dose)

Pariet Tablets 10 mg (rabeprazole sodium) 2 tablets (1 tablet x 2 doses)

Sawacillin Tablets 250 (amoxicillin hydrate) 6 tablets (3 tablets x 2 doses)

Flagyl[®] Oral Tablets 250 mg (metronidazole) 2 tablets (1 tablet x 2 doses)

(2) Indications

[Micro-organisms]

H. pylori strains susceptible to amoxicillin and metronidazole

[Conditions]

H. pylori infections:

Gastric ulcer, duodenal ulcer, gastric MALT lymphoma, idiopathic thrombocytopenic purpura, the stomach after endoscopic resection of early-stage gastric cancer, and *H. pylori* gastritis

(3) Dosage and Administration

If *Helicobacter pylori* eradication with a three-drug regimen comprising a proton pump inhibitor, amoxicillin hydrate and clarithromycin has been unsuccessful, as an alternative treatment, adults should be administered the following three drugs orally at the same time twice daily for seven days: 10 mg/dose of rabeprazole sodium, 750 mg (potency)/dose of amoxicillin hydrate, and 250 mg/dose of metronidazole.

(4) Price (per blister sheet, equivalent to daily dose)

Rabefine Pack	438.60 yen
---------------	------------

(5) Packaging

Rabefine Pack	7 blister sheets
---------------	------------------

2. About Pariet®

Pariet is a proton pump inhibitor discovered and developed by Eisai. First launched in Japan in 1997, the drug is today approved in more than 100 countries and territories worldwide. In Japan, Pariet is indicated for multiple uses, including for the treatment of gastric ulcer, duodenal ulcer, reflux esophagitis, non-erosive gastroesophageal reflux disease, and as an adjunctive therapy in various types of *H. pylori* eradication, including in patients with gastric ulcer, duodenal ulcer, and *H. pylori* gastritis, and is available in both 10 mg and 20 mg tablet formulations based on evidence collected in Japanese patients. In addition, in December 2010, Eisai received approval in Japan for additional twice-daily 10 mg and twice-daily 20 mg dosage and administration of Pariet for treatment of patients with reflux esophagitis who are unable to obtain satisfactory relief with conventional proton pump inhibitor treatment.

In November 2013, Eisai submitted an application for Pariet in Japan seeking a further indication expansion for use in the prevention of recurrence of gastric and duodenal ulcers during treatment with low-dose aspirin and the approval of a new 5 mg tablet formulation. Eisai is currently also conducting a Phase III study in Japan of Pariet as a maintenance therapy for patients with reflux esophagitis resistant to once-daily proton pump inhibitor treatment.

<Product photographs>



[Rabecure® Pack 400]



[Rabecure® Pack 800]



[Rabefine® Pack]