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Eisai Co., Ltd.

EISAI RECEIVES APPROVAL TO MARKET PARIET® TRIPLE FORMULATION 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 has received marketing authorization from Japan's Ministry of Health, Labour and Welfare for two types of triple formulation packs (combination packs) that contain its proton pump inhibitor Pariet® (rabeprazole sodium) for *Helicobacter pylori* eradication.

The authorization approves 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 primary *H. pylori* eradication, and Rabefine® Pack, which similarly packages together individual blister sheets each containing a daily triple formulation dose of Pariet, amoxicillin hydrate and metronidazole for secondary *H. pylori* eradication.

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 not only lead to reduced eradication rates but also to bacterial resistance and increased side effects. Both the primary and secondary eradication combination packs contain daily triple formulation doses of Pariet and two antimicrobial agents packaged in individual blister sheets and as such are expected to help ensure that *H. pylori* eradication therapy is carried out more appropriately and with greater certainty, improve patient drug compliance, and offer increased convenience in a medical setting.

Eisai believes that its Rabecure and Rabefine combination packs will further promote the proper use of agents used in *H. pylori* eradication and further contribute to increasing the benefits provided to patients with diseases associated with *H. pylori*.

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

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[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 × 2 doses)
Sawacillin Tablets 250 (amoxicillin hydrate)	6 tablets (3 tablets × 2 doses)
Clarith Tablets 200 (clarithromycin)	2 tablets (1 tablet × 2 doses)

Rabecure Pack 800

Pariet Tablets 10 mg (rabeprazole sodium)	2 tablets (1 tablet × 2 doses)
Sawacillin Tablets 250 (amoxicillin hydrate)	6 tablets (3 tablets × 2 doses)
Clarith Tablets 200 (clarithromycin)	4 tablets (2 tablets × 2 doses)

(2) Indications

[Micro-organisms]

Helicobacter pylori strains susceptible to amoxicillin and clarithromycin

[Conditions]

Helicobacter pylori infections:

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

(3) Dosage and Administration

For adults, the following three-drug 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.

2) Rabefine® Pack triple formulation pack for secondary *Helicobacter pylori* eradication

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

Pariet Tablets 10 mg (rabeprazole sodium)	2 tablets (1 tablet × 2 doses)
Sawacillin Tablets 250 (amoxicillin hydrate)	6 tablets (3 tablets × 2 doses)
Flagyl Oral Tablets 250 mg (metronidazole)	2 tablets (1 tablet × 2 doses)

(2) Indications

[Micro-organisms]

Helicobacter pylori strains susceptible to amoxicillin and metronidazole

[Conditions]

Helicobacter pylori infections:

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

(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.

2. About Pariet®

Pariet is a proton pump inhibitor (PPI) that was discovered and developed by Eisai. First launched in Japan in 1997, it is currently approved in more than 90 countries and territories worldwide. In Japan, Pariet is approved for multiple indications, including the treatment of gastric ulcers, duodenal ulcers and reflux esophagitis, and as an adjunctive therapy for use in *H. pylori* eradication. The agent is available in both 10 mg and 20 mg tablet formulations based on evidence collected in patients in Japan. Eisai received marketing approval for an alternative twice-daily dosing regimen for both of these formulations to treat patients with reflux esophagitis who have been unable to obtain satisfactory relief with conventional PPI treatment. Pariet was later also approved as an adjunctive therapy for *H. pylori* eradication, first in January 2007 as a combination therapy with amoxicillin hydrate and clarithromycin for primary eradication in patients with gastric and duodenal ulcers, and subsequently in August 2007 as a combination therapy with amoxicillin hydrate and metronidazole for secondary eradication in patients for whom primary eradication has been unsuccessful. Diseases indicated for the agent were again expanded in June 2010 to include *H. pylori* eradication in gastric MALT lymphoma, idiopathic thrombocytopenic purpura, and the stomach after endoscopic resection of early-stage gastric cancer and again in February 2013 to include *H. pylori* gastritis.

Furthermore, in Japan, Eisai is conducting a Phase II/III study of Pariet for the prevention of recurrence of gastric and duodenal ulcers during treatment with low-dosage aspirin as well as a Phase III study of Pariet as maintenance therapy for PPI-resistant GERD.