No.12-33

May 31, 2012
Eisai Co., Ltd.

EISAI SEEKS APPROVAL TO MARKET PARIET® TRIPLE FORMULATION PACK IN JAPAN FOR *HELICOBACTER PYLORI* ERADICATION

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that it has submitted a marketing authorization application to Japan's Ministry of Health, Labour and Welfare seeking approval for two types of new triple formulation packs (combination packs) for *Helicobacter Pylori* eradication that include the company's proton pump inhibitor Pariet® (rabeprazole sodium) as well as amoxicillin hydrate (generic name) and either clarithromycin (generic name) for primary eradication or metronidazole (generic name) for secondary eradication.

Pariet was approved in Japan in January 2007 for adjunctive use with amoxicillin hydrate and clarithromycin in the eradication (primary eradication) of *Helicobacter Pylori* infections associated with gastric and duodenal ulcers. In August of the same year, the agent was also approved for secondary eradication, in combination with amoxicillin and metronidazole, in patients for whom primary eradication therapy has been unsuccessful. Additionally, the eradication therapy indication for Pariet was expanded in June 2010 to include gastric MALT lymphoma, idiopathic thrombocytopenic purpura, and the stomach after endoscopic resection of early stage gastric cancer.

During eradication therapy consisting of Pariet and two antimicrobial agents, the success of therapy depends on whether or not patients properly adhere to the prescribed treatment regimen. If patients take the wrong medication or forget to take their medication altogether, this leads not only to a reduction in eradication rates but can also result in problems such as bacterial resistance and an increase in side effects. Eisai has developed the new triple formulation pack for primary and secondary eradication that includes three separate formulations in a single package in order to help ensure that eradication therapy will be carried out more appropriately and with greater certainty, improve patient drug compliance and offer increased levels of convenience in the medical setting.

Eisai firmly believes that the newly developed triple formulation pack will help facilitate the proper use of drugs during *Helicobacter pylori* eradication and will thereby further contribute to increasing patient benefits.

[Please refer to the following notes for further information on Pariet/Aciphex, currently approved dosage and administration for Pariet as an adjunctive therapy for *Helicobacter Pylori* eradication, and an outline of the triple formulation pack]

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

[Notes to editors]

1. About Pariet®/Aciphex®

Pariet/Aciphex, discovered and developed by Eisai, was launched in Japan in 1997 and is currently approved in more than 90 countries worldwide. It is one of few branded drugs still under patent coverage in Europe and the United States. In Japan, Pariet is approved for various indications, including the treatment of gastric ulcers, duodenal ulcers and reflux esophagitis, and as an adjunctive therapy for use in *Helicobacter Pylori* eradication. The agent is available in both 10 mg and 20 mg tablet formulations based on evidence collected in Japanese patients. Eisai has also received approval for an alternative twice daily dosing regimen for both these formulations to treat reflux esophagitis patients who have been unable to obtain satisfactory relief with conventional proton pump inhibitor treatment. Eisai is committed to making contributions to increase the benefits provided to many patients by addressing the unique needs of the Japanese market such as obtaining approval to use Pariet as an adjuvant in secondary eradication of *Helicobacter Pylori* infection.

2. Currently Approved Dosage and Administration for Pariet as an Adjunctive Therapy for *Helicobacter Pylori* Eradication

1) Primary Eradication

For adults, the following three-drug regimen should be administered orally at the same time twice daily for seven days: 10 mg/dose of sodium rabeprazole, 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) Secondary Eradication

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 sodium rabeprazole, 750 mg (potency)/dose as amoxicillin hydrate, and 250 mg/dose as metronidazole.

3. Outline of New Triple Formulation Pack

The new triple formulation pack for which Eisai has submitted marketing authorization applications for consists of daily-dose (two doses per day) packs that include the following formulations:

1) Primary Eradication (includes 400 mg of clarithromycin)

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 200 (clarithromycin)	2 tablets (1 tablet x 2 doses)

2) Primary Eradication (includes 800 mg of clarithromycin)

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

3) Secondary Eradication

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)