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EISAI RECEIVES APPROVAL FOR TWICE-DAILY DOSING OF PROTON PUMP INHIBITOR PARIET® FOR TREATMENT OF REFLUX ESOPHAGITIS

Offers New Option to Patients Unable to Obtain
Satisfactory Relief with Conventional Proton Pump Inhibitor Treatment

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that it has received approval in Japan for additional twice-daily 10 mg and twice-daily 20 mg dosage and administration of its proton pump inhibitor Pariet[®] (generic name: rabeprazole sodium) for the treatment of reflux esophagitis patients who are unable to obtain satisfactory relief with conventional proton pump inhibitor treatment.

Reflux esophagitis is a condition which causes erosion and ulceration of the mucosal lining of the esophagus due to the back flow of stomach acid. It also causes frequent and persistent symptoms such as heartburn, discomfort in the throat, belching, heaviness in the stomach, and bloating, which although may improve, often reoccur. Reflux esophagitis is commonly treated with proton pump inhibitors, however, some patients do not achieve satisfactory therapeutic effects with existing approved dosing regimens, and it remains a condition with significant unmet medical needs. Eisai submitted an application to the Japanese Ministry of Health, Labour and Welfare on April 28, 2010 seeking approval of additional twice-daily dosage and administration of Pariet[®] in order to broaden the range of treatment options available to patients with refractory reflux esophagitis.

In a double-blind controlled study designed to compare once-daily and twice-daily dosing regimen healing rates as confirmed on endoscopy at week eight in reflux esophagitis patients resistant to once-daily proton pump inhibitor treatment, patients that received a twice-daily dose of Pariet[®] Tablets 10 mg or Pariet[®] Tablets 20 mg demonstrated significantly higher healing rates as compared to those patients treated with a once-daily dose of Pariet[®] Tablets 20 mg. In regards to safety, the study also confirmed that both Pariet[®]10 mg and 20 mg dosed twice-daily demonstrate favorable tolerability comparable to a once-daily 20 mg dose.

Pariet[®] was launched first in Japan in 1997, followed by Europe in 1998, and the United States in 1999, where it is marketed under the brand name AcipHex[®]. It is currently approved in 100 countries around the world. In Japan, the drug is indicated for the treatment of stomach ulcers, duodenal ulcers, reflux esophagitis, and as an adjunctive treatment for *helicobacter pylori* eradication in gastric and duodenal ulcers.

By offering an alternative treatment option to reflux esophagitis patients who have been unable to obtain satisfactory relief with existing approved proton pump inhibitor dosing regimens, Eisai seeks to make further contributions to addressing the diversified needs of and increasing the benefits provided to patients with acid related diseases and their families as well as healthcare providers.

[Please refer to the following notes for further information the newly approved dosage and administration]

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[Notes to editors]

1. Reflux Esophagitis Additional Dosage and Administration

1) Product Name

Pariet ® Tablets 10 mg, Pariet ® Tablets 20 mg

2) Approved Additional Dosage and Administration

(Underlined wording indicates newly approved dosage and administration)

<Reflux Esophagitis>

The usual adult dose for oral use is 10 mg of rabeprazole sodium administered once daily. However, the dosage may be increased up to 20 mg orally once daily depending on the severity of symptoms. The usual administration should be restricted to up to 8 weeks. For patients who have not healed after 8 weeks of proton pump inhibitor treatment, a 10 mg or 20 mg dose of rabeprazole sodium may be administered orally twice daily for an additional 8 weeks. However, a twice daily 20 mg dose should only be administered to patients with severe mucosal break.

For the maintenance therapy of reflux esophagitis showing repeated recurrence and recrudescence, the dose for oral use is 10 mg once daily.