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Eisai Co., Ltd.

EISAI SUBMITS APPLICATION IN JAPAN FOR TWICE-DAILY DOSING OF ITS PROTON PUMP INHIBITOR PARIET® FOR THE TREATMENT OF REFLUX ESOPHAGITIS

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito) announced today that the Company has submitted applications to the health authorities in Japan seeking approval of 10mg twice-daily dosing and 20mg twice-daily dosing of its proton pump inhibitor Pariet® (generic name: rabeprazole sodium) for the treatment of reflux esophagitis.

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, as well as frequent and persistent symptoms, including heartburn, discomfort in the throat, belching, heaviness in the stomach, and bloating. While symptoms may improve, they often reoccur, and it is necessary for patients to continue appropriate treatment even after their symptoms disappear completely.

While reflux esophagitis is commonly treated with proton pump inhibitors, some patients do not achieve satisfactory therapeutic effects with the currently approved once-daily dosing, and it remains a condition with significant unmet medical needs. Eisai has been developing twice-daily dosing of Pariet® in order to broaden the range of treatment options available to patients with refractory reflux esophagitis.

The application was made based on a double blind controlled study which evaluated the efficacy and safety of twice-daily dosing of Pariet® 10mg Tablets or Pariet® 20mg Tablets against once-daily dosing of Pariet 20mg Tablets in patients with refractory reflux esophagitis. With the new twice-daily dosing schedule, Eisai expects that to be able to offer yet another treatment option for refractory reflux esophagitis.

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 99 countries around the world. In Japan, it 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.

With this application for additional dosing, Eisai hopes to enhance the clinical value of Pariet® and make further contributions to the treatment of patients with acid related diseases.

[Please refer to the following notes for currently approved Pariet® dosage and administration]

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

[Notes to editors]

Current Pariet® Dosage and Administration for 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 the maintenance therapy of reflux esophagitis showing repeated recurrence and recrudescence, the dose for oral use is 10 mg once daily.