EISAI SUBMITS APPLICATION FOR PROTON PUMP INHIBITOR PARIET® IN JAPAN SEEKING INDICATION EXPANSION FOR PREVENTION OF RECURRENT GASTRIC OR DUODENAL ULCER CAUSED BY LOW-DOSE ASPIRIN THERAPY AND APPROVAL OF NEW FORMULATION

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that it has submitted an application for the proton pump inhibitor Pariet® (rabeprazole sodium, "rabeprazole") in Japan seeking a further indication expansion for use in the prevention of recurrent gastric or duodenal ulcer 2emememmemer 2e.ulce-d0 1216 -1.,sE In recent years, Japan's aging population has led to an increasing number of patients requiring long-term low-dose aspirin therapy to prevent recurrent thrombotic events in the heart or brain. At the same time, however, low-dose aspirin administration is also associated with the development of mucosal injuries in the upper gastrointestinal tract. As it is often difficult to discontinue low-dose aspirin administration in patients, it is therefore important from a clinical standpoint to work to prevent mucosal injuries from developing in the upper gastrointestinal tract while continuing to administer treatment to prevent against cardiovascular and cerebrovascular events.

The data used in the application was from a double-blind comparative Phase II/III study in 472 patients who required long-term administration of low-dose aspirin and who were confirmed to also have a history of gastric or duodenal ulcer. The resultwere consistent with the known safety profile of rabeprazole and no new AEs occurred.

Currently approved in more than 100 countries and territories worldwide, Pariet was first launched in Japan in 1997, where it is indicated for multiple uses, including for the treatment of gastric ulcer, duodenal ulcer, reflux esophagitis, non-erosive gastroesophageal reflux disease, and as an adjunct therapy in various types of *Helicobacter pylori* (*H. pylori*) eradication, including in patients with gastric ulcer, duodenal ulcer, or *H. pylori* gastritis.

By expanding current indications for Pariet and receiving approval for the new 5 mg tablet formulation, Eisai aims to increase the clinical value of the drug so as to further contribute to the range of treatment options available to patients with acid-related diseases.

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

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[Notes to editors]

1. About Pariet®

Pariet is a proton pump inhibitor (PPI) that was discovered and developed by Eisai. First launched in Japan in 1997, it is 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 *Helicobacter pylori* (*H. pylori*) eradication, including in patients with gastric ulcer, duodenal ulcer, or *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 was granted domestic approval 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 PPI treatment. Most recently, Eisai received marketing authorization in Japan in August 2013 for two types of triple formulation packs (combination packs) for *H. pylori* eradication, both of which contain Pariet. Among the most commonly reported adverse reactions are rash, urticaria, itching sensation, diarrhea, and loose stool.

Eisai is also conducting a Phase III study in Japan on Pariet as a maintenance therapy for patients with reflux esophagitis resistant to once-daily PPI treatment.