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Eisai Co., Ltd.

EISAI RECEIVES COMPLETE RESPONSE LETTER FROM U.S. FDA FOR INVESTIGATIONAL PROTON PUMP INHIBITOR ACIPHEX® EXTENDED-RELEASE CAPSULES, 50 MG

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito) announced today that its U.S. subsidiary Eisai Inc. received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) on February 1 (local time) regarding the New Drug Application (NDA) of AcipHex® (Brand name in Japan: Pariet®; generic name: rabeprazole sodium) extended-release capsules, 50 mg, an investigational proton pump inhibitor (PPI) under review for the healing and long-term maintenance of healing and symptom resolution of erosive gastroesophageal reflux disease (GERD), and for the treatment of daytime and nighttime heartburn and other symptoms of non-erosive GERD.

The FDA issues a Complete Response Letter to indicate the review cycle of an application is complete and there are still requirements to be fulfilled. Eisai will work with the FDA to address the requirements of the Complete Response Letter for the approval of AcipHex® extended-release capsules, 50 mg.

AcipHex® extended-release capsules, 50 mg, is a capsule formulation that contains 50 mg of rabeprazole sodium per capsule, and is being evaluated as a new formulation that combines two different drug releasing mechanisms in one capsule to treat patients with GERD. An estimated 19 million Americans have GERD, which is a medical condition characterized by persistent, frequent heartburn and regurgitation due to reflux of stomach acid into the esophagus. Some patients develop erosive GERD, in which there are breaks in the lining of the esophagus.

AcipHex®/Pariet® is a proton pump inhibitor that effectively suppresses the secretion of gastric acid by inhibiting enzyme activity during the last phase of gastric acid secretion. It was launched first in Japan in 1997, followed by Europe in 1998, and the United States in 1999, and is currently approved in more than 90 countries around the world. In the United States, AcipHex® is indicated for the healing of erosive or ulcerative GERD, maintenance of healing of erosive or ulcerative GERD, treatment of symptomatic GERD, healing of duodenal ulcers, helicobacter pylori eradication to reduce the risk of duodenal ulcer recurrence and others.

[Please refer to the following notes for further information on GERD, heartburn and regurgitation]

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[Notes to editors]

About GERD, Heartburn and Regurgitation

GERD is a chronic condition characterized by persistent, frequent heartburn and regurgitation due to the reflux of stomach acid into the esophagus. In the United States, GERD leads to 18.3 million ambulatory care visits and 3.1 million hospitalizations. More than 60 million Americans experience heartburn, a burning feeling that can occur from reflux of stomach acid into the esophagus, at least once a month. Regurgitation is the backflow of stomach contents (food or stomach acid) passing up through the esophagus and into the mouth. The therapeutic goals in the management of erosive GERD include symptom relief and healing of esophagitis.