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Eisai Co., Ltd.

## **EISAI DISCONTINUES DEVELOPMENT OF PARIET<sup>®</sup>/ACIPHEX<sup>®</sup> EXTENDED-RELEASE CAPSULES, 50 MG**

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito) announced today that the company has decided to terminate development of its investigational proton pump inhibitor (PPI), Pariet<sup>®</sup>/AcipHex<sup>®</sup> (rabeprazole sodium) extended-release capsules, 50 mg.

On February 1, 2011, Eisai received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) concerning the New Drug Application (NDA) it submitted for the agent. After full consideration of the discussions with the FDA regarding the CRL, it was determined that an additional study would be required to support approval. Given that the time necessary to complete the additional study will have an impact on its innovativeness in enhancing patient value, the company has decided to terminate the development of the agent.

Pariet<sup>®</sup>/AcipHex<sup>®</sup> is a proton pump inhibitor discovered and developed by Eisai. Launched first in Japan in 1997, followed by Europe in 1998, and the United States in 1999, it is currently approved in more than 90 countries around the world as a treatment of various acid related gastrointestinal diseases including healing of erosive or ulcerative gastroesophageal reflux disease (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. Furthermore, Eisai is currently conducting Pediatric GERD clinical studies with Pariet<sup>®</sup>/AcipHex<sup>®</sup> in infants and children with Johnson & Johnson Pharmaceutical Research & Development, L.L.C (Janssen Pharmaceuticals, Inc. is a co-promotion partner in the U.S.) as part of a clinical development program that aims at address the lack of treatments approved for use in pediatric patients with such conditions.

Eisai remains committed to seeking new ways to address the diversified needs of, and increase the benefits provided to, patients with acid related diseases.

**[Please refer to the following notes for further information on Pariet<sup>®</sup>/AcipHex<sup>®</sup>]**

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**[Notes to editors]**

**About Pariet® /AcipHex®**

Pariet®/AcipHex® is one of few patented brand proton pump inhibitors available in Europe and the United States (the patent is effective until November 2012 in the United Kingdom/Germany, and May 2013 in the United States, respectively). In Japan, Eisai currently markets a 10 mg tablet formulation of the drug in addition to the globally marketed 20 mg formulation based on evidence from clinical trials conducted in Japanese patients. Eisai has obtained approval to market the drug for secondary eradication of *Helicobacter pylori* in response to the needs of Japanese patients, thereby providing benefits to a great number of patients. As Pariet® is the top PPI brand in the country, Eisai currently conducts various life cycle management programs in Japan to further address the unmet needs of patients including a Phase II/III study for prevention of recurrence of gastric and duodenal ulcers during treatment with low-dosage aspirin and a Phase II study for functional dyspepsia.