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Eisai Co., Ltd.

## **EISAI RECEIVES SIX-MONTH PEDIATRIC EXCLUSIVITY FOR PROTON-PUMP INHIBITOR ACIPHEX® IN THE U.S.**

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that pediatric clinical data on proton-pump inhibitor AcipHex® (generic name: rabeprazole sodium, product name in Japan: Pariet®) submitted to the U.S. Food and Drug Administration (FDA) by U.S. subsidiary Eisai Inc. has met the FDA's Written Request requirements for pediatric exclusivity, with Eisai gaining an additional six months of U.S. market exclusivity for AcipHex, which expires on November 8, 2013.

AcipHex/ Pariet is classified as a proton-pump inhibitor that effectively suppresses gastric acid secretion while inhibiting enzyme activity during the last phase of stomach acid secretion. It was launched in the United States in 1999, following its launch in Japan in 1997 and in Europe in 1998, and is currently approved in more than 90 countries worldwide. In the United States, the drug is currently approved for the healing and maintenance of healing of erosive and ulcerative GERD, treatment of symptomatic GERD, healing of duodenal ulcers, and *Helicobacter pylori* eradication to reduce the risk of duodenal ulcer recurrence.

The drug is also indicated in the United States for adolescent patients ages 12 and older for the short-term treatment of symptomatic GERD. Furthermore, an additional indication has been submitted to the FDA for the healing and maintenance of healing of GERD and symptom improvement of GERD in children ages 1 to 11.

By enhancing the clinical value of AcipHex/Pariet, Eisai aims to make further contributions to improve the quality of life of patients with acid-related diseases and their families.

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