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Eisai Co., Ltd.

NEW DRUG APPLICATION FOR PEDIATRIC FORMULATION ACIPHEX® SPRINKLE™ APPROVED BY U.S. FDA

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that its U.S. subsidiary Eisai Inc. has received approval from the U.S. Food and Drug Administration (FDA) for its pediatric formulation ACIPHEX® Sprinkle™ (rabeprazole sodium, product name in Japan: PARIET®) Delayed-Release Capsules 5 mg and 10 mg for the treatment of gastroesophageal reflux disease (GERD) in children 1 to 11 years of age for up to 12 weeks. The newly approved formulation has been developed to be administered to pediatric patients by sprinkling granules of the drug, which are contained in the capsules, onto soft foods, milk or baby formula, or fruit juices.

The approval is based on a multicenter, double-blind, parallel-group study conducted in 127 pediatric patients ages 1 to 11 with endoscopically proven GERD. The study consisted of a 12-week treatment and a 24-week extension period of two dose levels of rabeprazole approximating 0.5 mg/kg and 1.0 mg/kg. Overall, 81% of patients achieved healing during the 12-week treatment period and 90% maintained healing during the ensuing 24-week extension period. The absence of a placebo group does not allow assessment of sustained efficacy through 36 weeks. Adverse reactions that occurred in ≥5% of patients included abdominal pain (5%), diarrhea (5%), and headache (5%). Furthermore, the pediatric clinical data submitted along with the application has met the FDA's Written Request requirements for pediatric exclusivity, with Eisai gaining six additional months of U.S. market exclusivity for the drug, which will now expire 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 respective launches 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 in adults, 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 age 12 or older for the short-term treatment of symptomatic GERD.

By enhancing the clinical value of ACIPHEX/PARIET based on this latest approval, Eisai seeks to make further contributions to improve the quality of life of patients with acid-related diseases and their families.

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