PEDIATRIC NDA FOR PROTON-PUMP INHIBITOR ACIPHEX® GRANTED PRIORITY REVIEW IN THE U.S.

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, “Eisai”) announced today that the U.S. Food and Drug Administration (FDA) has accepted for review Eisai’s New Drug Application (NDA) for a new sprinkle capsule formulation (5mg and 10mg) of the proton-pump inhibitor AcipHex® (generic name: rabeprazole sodium, product name in Japan: Pariet®) for the healing and maintenance of healing of gastroesophageal reflux disease (GERD) and symptom improvement of GERD in children ages 1 to 11. Furthermore, the FDA has indicated that this NDA will receive a priority review, which provides for a six-month review period, with a Prescription Drugs User Fee Act (PDUFA) action date (proposed review deadline) of March 27, 2013.

AcipHex 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. AcipHex was launched in the