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## FOR IMMEDIATE RELEASE

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### **FDA Approves ACIPHEX<sup>®</sup> (rabeprazole sodium) 20 mg for Short-Term Treatment of GERD in Adolescents**

**Woodcliff Lake, NJ, June 30, 2008** – Eisai Corporation of North America, a wholly-owned subsidiary of Tokyo-based Eisai Co., Ltd., announced today that the Food and Drug Administration (FDA) has approved ACIPHEX (rabeprazole sodium) 20 mg for the short-term (up to eight weeks) treatment of gastroesophageal reflux disease (GERD) in adolescents ages 12 and above.

Included in the submission was a 12-week, multi-center, open-label, randomized, parallel-group study of 111 adolescent GERD patients. In this study, ACIPHEX was well tolerated in adolescent subjects, with a safety profile similar to that of adults. The adverse events reported without regard to relationship to ACIPHEX that occurred in  $\geq 2$  percent of 111 patients were headache (9.9 percent), diarrhea (4.5 percent), nausea (4.5 percent), vomiting (3.6 percent) and abdominal pain (3.6 percent). Efficacy results demonstrated that once-daily treatment with ACIPHEX 20 mg for eight weeks reduced the severity and frequency of GERD symptoms compared to symptoms prior to treatment.

ACIPHEX was discovered and developed by Eisai and is copromoted in the United States with PriCara<sup>®</sup>, a Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.

#### **About ACIPHEX<sup>®</sup> (rabeprazole sodium)**

ACIPHEX<sup>®</sup> is a prescription medication. ACIPHEX 20 mg tablet once daily is approved for use in adults:

- for the short-term (4 to 8 weeks) treatment in the healing and symptom relief of damaging (erosive) Gastroesophageal Reflux Disease (GERD).
- to maintain healing of damage (erosions) and relief of heartburn symptoms with GERD. ACIPHEX has not been studied for treatment lasting longer than 12 months (1 year).
- for the treatment of day-time and night-time heartburn and other symptoms that happen with GERD.

(more)

ACIPHEX 20 mg once daily is now also indicated for adolescents ages 12 and above for the short-term treatment (up to 8 weeks) for heartburn and other GERD symptoms. The safety and effectiveness of ACIPHEX has not been established for children under the age of 12.

### **Important Safety Information**

ACIPHEX has a well-established safety profile. The most common side effect possibly related to ACIPHEX is headache. Symptom relief does not rule out other serious stomach conditions. Patients on warfarin (such as Coumadin<sup>®</sup>) may need to be monitored more closely by their doctor. To learn more, talk to your doctor and see the full product information at [www.aciphex.com](http://www.aciphex.com).

### **About Eisai Corporation of North America**

Eisai Corporation of North America is a wholly-owned subsidiary of Eisai Co., Ltd., a research-based *human health care (hhc)* company that discovers, develops and markets products throughout the world. Eisai focuses its efforts in three therapeutic areas: neurology, gastrointestinal disorders and oncology/critical care.

Eisai Corporation of North America supports the activities of its operating companies in North America. These operating companies include: Eisai Research Institute of Boston, Inc., a discovery operation with strong organic chemistry capabilities; Morphotek, Inc., a biopharmaceutical company specializing in the development of therapeutic monoclonal antibodies; Eisai Medical Research Inc., a clinical development group; Eisai Inc., a commercial operation with manufacturing and marketing/sales functions; MGI PHARMA, INC., an R&D and commercial operation with manufacturing and marketing/sales functions; and Eisai Machinery U.S.A., which markets and maintains pharmaceutical manufacturing machinery.

For more information about Eisai, please visit [www.eisai.com](http://www.eisai.com).

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ACIPHEX is a registered trademark of Eisai Co., Ltd.

Coumadin is a registered trademark of Bristol-Myers Squibb Pharma Company.