

Eisai is a Human Health Care Corporation striving for innovative solutions in prevention, cure and care for the health and well-being of people worldwide. We combine our talents to understand and meet the needs of patients and their families to enhance the quality of life.

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Eisai Co., Ltd.

FDA Grants Priority Review for ACIPHEX[®] sNDA for Short-Term Treatment of GERD in Adolescents

Eisai Co., Ltd. (Headquarters: Tokyo, President and CEO: Haruo Naito) announced today that on February 29, 2008 (US Eastern Time), the U.S. Food and Drug Administration (FDA) accepted a supplemental New Drug Application (sNDA) submitted by its U.S. subsidiary, Eisai Corporation of North America (Headquarters: New Jersey, United States, Chairman & CEO: Hajime Shimizu), for ACIPHEX[®] (generic name: rabeprazole sodium, product name in Japan: PARIET[®]) for the short-term (up to eight weeks) treatment of gastroesophageal reflux disease (GERD) in patients ages 12-16. Further, FDA has indicated that the sNDA will receive priority review in accordance with the Best Pharmaceuticals for Children Act, which provides for a 180-day review period.

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 United States in 1999, following its launch in Japan in 1997 and in Europe in 1998, and is currently marketed in more than 90 countries worldwide. In the United States, ACIPHEX[®] is co-promoted by Eisai and PriCara[®], a Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.

With the sNDA filing by FDA, Eisai aims to make ACIPHEX[®] available to more patients in the United States who are suffering from acid-related disorders.

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