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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.

Proton Pump Inhibitor ACIPHEX® 20 mg Receives Approval for Short-Term Treatment of GERD in Adolescents in United States

On June 30 (the U.S. Eastern Time), Eisai Corporation of North America (Headquarters: New Jersey, United States, Chairman & CEO: Hajime Shimizu), an U.S. subsidiary of Eisai Co., Ltd. (Headquarters: Tokyo, President and CEO: Haruo Naito), announced that the Food and Drug Administration (FDA) has approved ACIPHEX® 20 mg (product name in Japan: PARIET®) 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 >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® 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 approved 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 this approval, Eisai aims to make ACIPHEX® available to more patients in the United States who are suffering from acid-related disorders.

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