No.10-25

June 3, 2010
Eisai Co., Ltd.

FDA ACCEPTS FOR REVIEW EISAI'S NDA FOR PROTON PUMP INHIBITOR ACIPHEX® EXTENDED-RELEASE 50 mg FORMULATION

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) submitted by its U.S. subsidiary Eisai Inc. for the proton pump inhibitor ("PPI") AcipHex® (brand name in Japan: Pariet®) Extended-Release 50 mg Formulation.

It is estimated that GastroEsophageal Reflux Disease (GERD) affects approximately 39 million adults in the United States. With about one third of these patients using PPIs in combination with H_2 blockers to treat symptoms, GERD still remains an area with high unmet medical needs. Eisai has been pursuing the development of the new long-acting formulation with the aim of creating a best-in-class PPI that, due to its continuous acid suppression effects, has the longest pH holding time of PPIs, and which has the potential to be highly effective in treating acid control symptoms experienced by GERD patients. The new long-acting extended-release formulation expresses highly potent acid secretion effects with convenient once daily administration by maintaining effective blood plasma concentration over longer period of time when compared to existing PPI formulations.

While AcipHex® is currently available by prescription in 20mg regular tablets in the United States, the extended-release 50 mg capsules is a new formulation which combines two different kinds of drug releasing mechanisms in one capsule. This submission was made based on data from six Phase III studies that evaluated its efficacy in treating mild to moderate GERD, moderate to severe GERD, symptomatic GERD, and maintaining healing of GERD. Eisai has also submitted a Marketing Authorization Application for the new formulation to the health authorities in Europe.

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 first in Japan in 1997, followed by Europe in 1998, and the United States in 1999, and is currently approved in more than 90 countries around the world. In the United States, AcipHex® is co-promoted by Eisai and Pricara®, a division of Ortho-McNeil-Janssen Pharmaceuticals, Inc., and is indicated for the treatment of gastric ulcers, duodenal ulcers, GERD, and as an adjunctive treatment for *Helicobacter pylori* eradication in gastric or duodenal ulcers.

With this application, Eisai hopes to enhance the clinical value of AcipHex® and make further contributions to improving the quality of life (QOL) of patients and families affected by acid related diseases.

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