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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 H₂ 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.