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US FDA to grant priority review to Eisai's AcipHex

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Singapore: The US Food and Drug Administration (FDA) has accepted for review Eisai's new drug application (NDA) for a new sprinkle capsule formulation (5mg and 10mg) of the proton-pump inhibitor AcipHex (rabeprazole sodium). The formulation is meant for the healing and maintenance of healing of gastroesophageal reflux disease (GERD) and symptom improvement of GERD in children of ages 1 year to 11 years.

The FDA has also indicated that this NDA will receive a priority review, which provides for a six-month review period, with a Prescription Drugs User Fee Act (PDUFA) action date of March 27, 2013.

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 US 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 US, the drug is currently approved for the healing and maintenance of healing of erosive and ulcerative GERD, treatment of symptomatic GERD, healing of duodenal ulcers, and Helicobacter pylori eradication to reduce the risk of duodenal ulcer recurrence. It is also indicated for adolescent patients ages 12 and older for the short-term treatment of symptomatic GERD.

Through the successful filing of this NDA in the US, Eisai aims to enhance the clinical value of AcipHex/Pariet and make further contributions to improve the quality of life of patients with acid-related diseases and their families.