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FDA approves Eisai's gastro reflux drug

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FDA approves Eisai's drugs for Gastroesophageal Reflux Disease



Singapore: US FDA approved Eisai's Aciphex Sprinkle delayed-release capsules 5mg and 10mg for the treatment of gastroesophageal reflux disease (GERD) in children aged from one-to-11 years of age for up to 12 weeks.

Mr Lonnel Coats, president and CEO, Eisai, US, said that, "We are proud to offer a new treatment option for young children who suffer from GERD. Eisai is committed to keeping the medical needs of patients and their families at the forefront of all that we do, as part of our human health care (hhc) corporate misson."

The approval of Aciphex Sprinkle is based on the results of a clinical trial of pediatric patients. The clinical trial was a multicenter, double-blind, parallel-group study conducted in 127 pediatric patients with endoscopically-proven GERD that consisted of a 12-week treatment and a 24-week extension period of two dose levels of rabeprazole.

Overall, 81 percent of patients achieved healing during the 12-week treatment period and 90 percent retained healing during the ensuing 24-week extension period. The absence of a placebo group does not allow assessment of sustained efficacy through 36 weeks.