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FDA approves Eisai's ACIPHEX

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Singapore:Ã?Â Eisai announced that the US Food and Drug Administration (FDA) has approved ACIPHEX Sprinkle Ã?Â Delayed-Release Capsules 5mg and 10mg for the treatment of Gastroesophageal Reflux Disease (GERD) in children 1 to 11 years of age for up to 12 weeks.Ã?Â

"We are proud to offer a new treatment option for young children who suffer from GERD," said Mr Lonnel Coats , president and CEO of Eisai. "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 mission."

The approval of ACIPHEX Sprinkle is based on the results of a clinical trial of pediatric patients 1 to 11 years of age. 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.

In the 12-week treatment period, the most commonly reported treatment-emergent adverse events (greater than or equal to 5 percent of subjects) were cough (14 percent), vomiting (14 percent), abdominal pain (12 percent), diarrhea (11 percent), pyrexia (10 percent), headache (9 percent), upper respiratory tract infection (8 percent), oropharyngeal pain (6 percent), and nasopharyngitis (5 percent).

In the 24-week extension period, the most commonly reported treatment emergent adverse events (greater than or equal to 5 percent of subjects) were upper respiratory tract infection (13 percent), vomiting (11 percent), abdominal pain (8 percent), diarrhea (6 percent), pyrexia (5 percent), nasopharyngitis (5 percent), pharyngitis streptococcal (5 percent), and sinusitis (5 percent).

Indication for ACIPHEX Sprinkle

ACIPHEX Sprinkle is indicated for the treatment of GERD in children 1 to 11 years of age for up to 12 weeks.