

ANTIEMETIC AGENT ALOXI® APPROVED FOR CHILDREN BY THE U.S. FDA
U.S. MARKET EXCLUSIVITY EXTENDED BY SIX MONTHS TO OCTOBER 13, 2015

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that the antiemetic agent ALOXI® (generic name: palonosetron HCl) has been approved in the U.S. for an additional indication regarding the prevention of acute nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including highly emetogenic cancer chemotherapy, in children aged 1 month to up to 17 years by the U.S. Food and Drug Administration (FDA). Despite peak cancer incidence among children occurring within the first year of life, this is the first product for chemotherapy-induced nausea and vomiting (CINV) prevention approved in patients aged between 1 and 6 months after birth. Eisai's U.S subsidiary Eisai Inc. markets this product based on having received exclusive marketing rights from Helsinn Healthcare S.A. (Headquarters: Lugano, Switzerland) for the U.S.

This approval was based on a randomized, double-blind, non-inferiority pivotal trial comparing ALOXI with ondansetron in pediatric patients, which was conducted in response to a Written Request by the FDA. The primary endpoint of Complete Response, defined as no vomiting, no retching and no antiemesis rescue medication required within the first 24 hours after chemotherapy, was achieved in 59.4% of patients who received ALOXI (20 mcg/kg, single-dose IV) versus 58.6% of patients who received the ondansetron regimen. Treatment-emergent adverse events (TEAEs) were comparable across both arms, with the most frequently reported TEAE in the ALOXI group being headaches. While this study demonstrated that pediatric patients require a higher palonosetron dose based on weight than adults to prevent CINV, the safety profile for ALOXI was confirmed as being consistent with the established profile in adults.