No.11-21

March 4, 2011
Eisai Co., Ltd.

U.S. FDA APPROVES ANTI-EPILEPTIC AGENT BANZEL® (RUFINAMIDE) ORAL SUSPENSION, 40MG/ML

Indicated for Adjunctive Treatment of Seizures Associated With Lennox-Gastaut Syndrome in Children 4 Years and Older and Adults

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") and its U.S. subsidiary Eisai Inc. announced today that the United States Food and Drug Administration (FDA) approved the company's anti-epileptic agent BANZEL® (rufinamide) Oral Suspension, 40 mg/ml on March 3 (U.S. local time) for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in children 4 years and older and adults. The oral suspension formulation is bioequivalent to the currently marketed BANZEL® tablet formulation on a milligram per milligram basis and will be available in the United States for prescription use by late March 2011.

LGS is a rare form of epilepsy that affects 1-4% of children with epilepsy in the United States. The age of onset is between 1 and 8 years, with a peak of 3 to 5 years. LGS affects an estimated 1 in 50,000 to 1 in 100,000 children, and is characterized by a clinical triad of a slow spike-and-wave pattern on an EEG, impairment of cognitive function and multiple types of seizures, including tonic (muscle stiffening), atypical absence (staring) and atonic (loss of muscle tone) seizures.

In studies, the most commonly observed (≥10%) side effects with BANZEL® vs. placebo, respectively, were headache (25% vs. 20%), dizziness (17% vs. 10%), feeling tired (15% vs. 9%), sleepiness (13% vs. 9%), and nausea (11% vs. 7%). Most of these side effects were mild to moderate in severity and typically went away in a short amount of time.

BANZEL® Oral Suspension provides another option for patients who may prefer a liquid or find it difficult to take a medication in tablet form, and its development exemplifies Eisai's *human health care (hhc)* mission of keeping patients' needs at the forefront of all that it does. Eisai defines neuroscience as a therapeutic area of focus and remains committed to making further contributions to addressing the diversified needs of and increasing the benefits provided to patients and their families through BANZEL®.

[Please refer to the following notes for further information on BANZEL®]

Media Inquiries:
Public Relations Department,
Eisai Co., Ltd.
+81-(0)3-3817-5120

[Notes to editors]

About BANZEL®

BANZEL® is an antiepileptic-drug indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in children 4 years and older and adults. BANZEL® is a triazole derivative that is structurally unrelated to currently marketed antiepileptic drugs (AEDs). It is believed to exert its effect by regulating the activity of sodium channels in the brain which carry excessive electrical charges that may cause seizures. BANZEL® was approved by the FDA in November 2008 and is currently available in 200 mg and 400 mg tablets.