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**FDA Approves BANZEL™ (rufinamide) as Adjunctive
Treatment for Severe Epilepsy Disorder**

New Treatment Option for Seizures Associated with Lennox-Gastaut Syndrome

Woodcliff Lake, NJ – November 14, 2008 – Eisai Corporation of North America announced today that the U.S. Food and Drug Administration (FDA) approved BANZEL™ (rufinamide) for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in children 4 years and older and adults. One of the most severe forms of childhood epilepsy, LGS is characterized by multiple and frequent seizures. LGS accounts for 1 to 4 percent of all childhood epilepsy cases; approximately 300,000 children under the age of 14 in the U.S. have epilepsy. Eisai received a complete response letter for BANZEL as an adjunctive treatment for partial-onset seizures with and without secondary generalization in adults and adolescents 12 years of age and older. BANZEL for LGS will be available to the public in January 2009.

A double-blind, placebo-controlled pivotal study of LGS patients treated with BANZEL as adjunctive therapy showed a 42.5 percent median reduction in frequency of drop attacks, seizures that cause a person to lose consciousness and fall to the ground, compared with a 1.4 percent median increase for placebo-treated patients. Drop attacks are a primary cause of injury in LGS patients.

“People living with LGS need more treatment options,” said Tracy Glauser, MD, Director, Comprehensive Epilepsy Program, Cincinnati Children's Hospital Medical Center, Ohio, and lead investigator in a clinical trial for BANZEL. “What’s exciting about this study is that BANZEL was effective and generally well tolerated in children with LGS whose seizures were previously uncontrolled on other multiple antiepileptic medications.”

LGS is a disease that is devastating to the lives of patients and caregivers. Children usually experience the onset of LGS between the ages of 1 and 5 years old; approximately 3 to 7 percent of LGS patients die within a mean follow-up period of less than 10 years. The condition is difficult to treat, with patients often taking multiple antiepileptic drugs (AEDs) in attempts to control the seizures. The multiple types and frequency of seizures can lead to

developmental delays, as well as behavioral disorders. Symptoms of LGS include a variety of seizure types, with tonic (muscle stiffening), atonic (loss of muscle tone/drop attacks) and absence (staring) seizures being the most common. Atonic seizures lead to the sudden falls seen in LGS patients known as “drop attacks,” a primary cause of injury. Tonic-clonic (grand mal), myoclonic (sudden muscle jerks) and other seizure types can also occur.

“We’ve seen how BANZEL benefitted participants in our clinical trials and I’m so pleased that Eisai can offer this much needed new treatment option,” said Lonnel Coats, President and Chief Operating Officer of Eisai Corporation of North America. “The approval of BANZEL further exemplifies our *human health care (hhc)* mission to bring treatments to the people who need them most.”

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.

About the BANZEL™ Clinical Study

The effectiveness of BANZEL as adjunctive treatment for the seizures associated with Lennox-Gastaut syndrome was established in a single multicenter, double-blind, placebo-controlled, randomized, parallel-group study (n=138). Male and female patients (between 4 and 30 years of age) were included if they had a diagnosis of inadequately controlled seizures associated with LGS (including both atypical absence seizures and drop attacks) and were being treated with one to three concomitant stable dose AEDs. Each patient must have had at least 90 seizures in the month prior to study entry. After completing a 4-week baseline phase on stable therapy, patients were randomized to have BANZEL or placebo added to their ongoing therapy during the 12-week double-blind phase. The double-blind phase consisted of two periods: the titration period (one to two weeks) and the maintenance period (10 weeks). During the titration period, the dose was increased to a target dosage of approximately 45 mg/kg/day (3200 mg in adults of > 70kg), given on a b.i.d. schedule. Dosage reductions were permitted during titration if problems in tolerability were encountered. Final doses at titration were to remain stable during the maintenance period. Target dosage was achieved in 88% of the BANZEL-treated patients. The majority of these patients reached the target dose within seven days, with the remaining patients achieving the target dose within 14 days.

The primary efficacy variables were:

- The percent change in total seizure frequency per 28 days;
- The percent change in tonic-atonic (drop attacks) seizure frequency per 28 days;
- Seizure severity from the Parent/Guardian Global Evaluation of the patient’s condition.

Results of the primary efficacy variable analyses were as follows:

- BANZEL-treated patients had a 32.7% median reduction and placebo-treated patients had an 11.7% median reduction in total seizure frequency per 28 days in the double-blind phase relative to the baseline phase (p<0.002).

- BANZEL-treated patients had a 42.5% median reduction and placebo-treated patients had a 1.4% median increase in tonic-atonic (“drop attacks”) seizure frequency per 28 days in the double-blind phase relative to the baseline phase ($p < 0.0001$).
- An improvement in seizure severity was observed in 53.4% of the BANZEL-treated patients compared to 30.6% of the placebo-treated patients in the Seizure Severity Rating from the Global Evaluation of the patient's condition (documented by the parent/guardian). There was a significant difference between the two treatment groups in favor of BANZEL ($p < 0.005$).

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BANZEL™ Important Safety Information

Antiepileptic drugs (AEDs) increase the risk of suicidal thoughts or behavior in patients taking these drugs. Patients should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, or any unusual changes in mood or behavior.

Use of BANZEL (rufinamide) has been associated with central nervous system-related adverse reactions, such as somnolence or fatigue, coordination abnormalities, dizziness, gait disturbances, and ataxia.

BANZEL is contraindicated in patients with Familial Short QT syndrome. These patients should not be treated with BANZEL. Caution should be used when administering BANZEL with other drugs that shorten the QT interval.

As with all AEDs, BANZEL should be gradually withdrawn to minimize the risk of increased seizure frequency. Multi-organ hypersensitivity syndrome has been reported in association with BANZEL therapy. In clinical trials, hypersensitivity reactions occurred mostly in the pediatric population and usually within four weeks of starting BANZEL therapy. If this reaction is suspected, BANZEL should be discontinued and alternative treatment started. All patients who develop a rash while taking BANZEL must be closely supervised.

In all patients with epilepsy treated with BANZEL in double-blind, adjunctive therapy studies, the most commonly observed adverse reactions were headache, dizziness, fatigue, somnolence, and nausea.

For full prescribing information or more information about BANZEL, go to <http://www.eisai.com/product.asp?ID=268>.

Eisai acquired an exclusive worldwide license to develop, use, manufacture and market BANZEL for any human therapeutic use with the exception of bipolar mood disorder, anxiety disorders and ophthalmologic disorders from Novartis Pharma AG in 2004. BANZEL™ is a trademark of Novartis Pharma AG, used under license.

About Eisai Corporation of North America

Eisai Corporation of North America is a wholly-owned subsidiary of Eisai Co., Ltd. and supports the activities of its operating companies in North America. These operating companies include: Eisai Research Institute of Boston, Inc., a discovery operation with strong organic chemistry capabilities; Morphotek, Inc., a biopharmaceutical company specializing in the development of therapeutic monoclonal antibodies; Eisai Medical Research Inc., a clinical development group; Eisai Inc., a commercial operation with manufacturing and marketing/sales functions; and Eisai Machinery U.S.A., which markets and maintains pharmaceutical manufacturing machinery.

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