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Eisai is a Human Health Care Corporation striving for innovative solutions in prevention, cure and care for the health and well-being of people worldwide. We combine our talents to understand and meet the needs of patients and their families to enhance the quality of life.

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Eisai Co., Ltd.

FDA Approves BANZEL™ (rufinamide) as Adjunctive Treatment for Lennox-Gastaut Syndrome

Eisai Corporation of North America (Headquarters: New Jersey, the United States, Chairman & CEO: Hajime Shimizu), a U.S. subsidiary of Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito), announced on November 14th (EST) 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. 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 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.

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.

LGS is one of the most severe forms of childhood epilepsy and characterized by multiple and frequent seizures. Children usually experience the onset of LGS between the ages of 1 and 5 years old. 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. It is reported that about 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 AEDs in attempts to control the seizures. The multiple types and frequency of seizures can lead to developmental delays, as well as behavioral disorders.

LGS is a disease that is devastating to the lives of patients and caregivers. Eisai will remain committed to make further contributions in addressing the needs of and improving benefits to patients and their families, by bringing new treatment options to the people who need them most.

[Please refer to the following notes for product, clinical study data and the disease]

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<Notes to Editors>

About BANZEL™

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. 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.

Product information

- Brand Name: BANZEL™
- Generic Name: rufinamide
- Formulation: film-coated tablet (200mg, 400mg)
- Approved Indication: adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in children 4 years and older and adults

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 1 to 3 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 the ongoing therapy during the 12 week Double-blind Phase. The Double-blind Phase consisted of 2 periods: the Titration Period (1 to 2 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 7 days with the remaining patients achieving the target dose within 14 days.

< Primary Efficacy variables>

- 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 >

- 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 2 treatment groups in favor of BANZEL ($p<0.005$).

About Lennox-Gastaut Syndrome

LGS is a severe form of generalized epilepsy. The seizures usually begin in pre-school aged children. Many of the children who develop LGS have pre-existing organic brain disorder or injury. The relative risk of occurrence of LGS tends to be higher in boys than in girls.

LGS is characterized by multiple types of seizures other than developmental delays and behavioral disorders. The most common seizure types that can be seen in most of the patients with LGS are tonic (muscle stiffening), atonic (loss of muscle tone/drop attacks) and absence (brief loss of consciousness) seizures. Tonic-clonic (grand mal), myoclonic (sudden muscle jerks) and other seizure types can also occur. Atonic seizures lead to the sudden falls seen in LGS patients known as “drop attacks,” a primary cause of injury. Patients with LGS sometimes wear helmet with face guard to protect against the injury.

Use of AEDs is the mainstay of the treatment of the patients with LGS. However, a surgical treatment may be employed in case the symptoms are too difficult to control by medical therapy.

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