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Health Canada Approves BANZEL™ (rufinamide) as Adjunctive Treatment for Severe Epilepsy Disorder

New Hope For Epilepsy Patients

Mississauga, ON (September 22, 2011) – Eisai Limited, a wholly-owned Canadian subsidiary of Eisai Inc., announced today the Health Canada approval and availability of Banzel™ (rufinamide) for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in children 4 years of age and older and adults. One of the most severe forms of childhood epilepsy, LGS is characterized by frequent seizures and multiple types.

A double-blind, randomized study of LGS patients treated with Banzel as adjunctive therapy showed a significant reduction in total seizures, seizure severity and a 42.5 per cent median reduction in the frequency of drop attacks (tonic-atonic seizures). Drop attacks are a primary cause of injury in LGS patients.

“Patients living with LGS are in need of treatment options,” says Dr. Jong Rho, Head of Neurology, Alberta Children’s Hospital. “Now available in Canada, Banzel was well tolerated by children with LGS who were unable to control their seizures with other antiepileptic medications. The approval of Banzel is great news for Canadians and provides patients with more options to help control their seizures.”

LGS affects between one and four per cent of all Canadian children diagnosed with epilepsy. The frequent seizures and multiple types associated with LGS are extremely difficult to control and impact the quality of life for both patients and their families.

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 one and five years old; approximately three to seven per cent of LGS patients die within 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.

“The Canadian approval of Banzel supports the Eisai *human health care (hhc)* mission to bring medicines to the people who need them the most,” says Takihiro Hirasawa, President, Eisai Canada. “We are pleased to offer this new treatment option to patients living with LGS in Canada.”

Banzel is a triazole derivative that is structurally unrelated to antiepileptic drugs (AEDs) that are currently available. 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.

“The Canadian epilepsy community welcomes the approval of Banzel, another important option for those dealing with the multiple and frequent seizures associated with LGS,” says Gail Dempsey, President, Canadian Epilepsy Alliance.

About Lennox – Gastaut Syndrome (LGS)

One of the most rare and severe forms of epilepsy, LGS usually develops in preschool-aged children, many of whom have some kind of pre-existing organic brain disorder such as encephalopathy.

LGS is not only characterized by frequent seizures and multiple types, it may be accompanied by delayed intellectual development and personality disorders. The most frequently occurring seizure types seen in the majority of patients with LGS are tonic (muscle stiffening), atonic (sudden loss of muscle tone) and absence (staring) seizures. Tonic-clonic (grand mal), myoclonic (sudden muscle jerks) and other types of seizures may also occur. Tonic-atonic seizures lead to the sudden falls seen in LGS patients known as “drop attacks”, a primary cause of injury.

Patients with LGS often have to wear protective helmets with face guards to protect against head injury from these attacks. Although LGS is most commonly treated with antiepileptic drugs, patients whose seizures are difficult to manage with pharmacotherapy may have to undergo surgical treatment.

About Banzel™

Banzel contains the medicinal ingredient rufinamide, which is an antiepileptic drug.

Banzel is indicated for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in children 4 years and older and adults.

The Health Canada approval was based on quality, non-clinical, and clinical evidence submitted. The efficacy of Banzel as adjunctive treatment for the seizures associated with LGS was established in a multicentre, double-blind, placebo-controlled, randomized, parallel-group study. A total of 138 male and female patients (between 4 and 37 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 antiepileptic drugs. Compared to placebo, Banzel-treated patients demonstrated significant improvements in the number of total seizures, drop attacks, and seizure severity. Overall, Banzel was generally well-tolerated.

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 ($p<0.005$).

Banzel™ Important Safety Information

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 for patients with Familial Short QT syndrome, family history of short QT syndrome, presence, or history of short QT interval; and patients who are hypersensitive to rufinamide, triazole derivatives or any of the excipients.

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.

About Eisai Corporation of North America

Eisai Inc. was established in 1995 and is ranked among the top-20 U.S. pharmaceutical companies (based on retail sales). The company began marketing its first product in the United States in 1997 and has rapidly grown to become a fully integrated pharmaceutical business. Eisai's areas of commercial focus include neurology, gastrointestinal disorders and oncology/critical care. The company serves as the U.S. pharmaceutical operation of Eisai Co., Ltd., a research-based *human health care* (*hhc*) company that discovers, develops and markets products throughout the world.

Eisai has a global product creation organization that includes U.S. - based R&D facilities in Massachusetts, New Jersey, North Carolina and Pennsylvania as well as manufacturing facilities in Maryland and North Carolina. The company's areas of R&D focus include neuroscience, oncology, vascular, inflammatory and immunological reaction, and antibody-based programs.

Eisai established Eisai Limited Canada in 2010. As a wholly-owned subsidiary of Eisai Inc., Eisai Limited is based in Mississauga, Ontario, one of the largest biopharmaceutical clusters and medical communities in North America.

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.

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