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Eisai Co., Ltd.

## **EISAI'S ANTIEPILEPTIC AGENT BANZEL™ RECEIVES APPROVAL IN CANADA**

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that its Canadian pharmaceutical subsidiary Eisai Limited ("Eisai Canada") has received approval to market the company's antiepileptic agent Banzel™ (rufinamide) for adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in children 4 years and older and adults. Banzel™ is the first product for which Eisai Canada has received marketing authorization from Health Canada.

Rufinamide is a triazole derivative structurally unrelated to currently marketed antiepileptic drugs. It is believed to exert its antiepileptic effects by regulating the abnormal activity of sodium channels in the brain that cause seizures. The agent received approval in Europe in January 2007 and in the United States in November 2008 for the adjunctive treatment of seizures associated with LGS in children 4 years and older and adults. It is currently marketed in these regions under the brand names Inovelon® and Banzel®, respectively.

LGS is a severe form of epilepsy, affecting 1% to 4% of all Canadian children diagnosed with epilepsy. As children and adults living with LGS experience frequent seizures of multiple types, it is extremely difficult to control and significantly impacts the quality of life of both patients and their families.

Eisai Canada was established in April 2010 as a pharmaceutical base to serve the entire Canadian market. Eisai Canada plans to launch Banzel™ and Gliadel® Wafer in Canada in the middle of the current fiscal year and intends to expand business in the future with products from its oncology and neurology franchises such as Halaven®, an anticancer agent currently marketed in the United States and Europe, and its global pipeline product perampanel (generic name), an AMPA receptor antagonist, pending approval from the Canadian regulatory authorities.

By expanding its capabilities in Canada, the ninth largest pharmaceutical market in the world, Eisai will make further contributions to address the diversified needs of and increase benefits provided to patients and their families as it seeks to fulfill its *human health care (hhc)* mission.

**[Please refer to the following notes for further information on LGS, Banzel®,  
Eisai's Commitment to Epilepsy, and Eisai Canada]**

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## **[Notes to editors]**

### **1) 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 seizure 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/drop attacks) and absence (staring) seizures. Tonic-clonic (grand mal), myoclonic (sudden muscle jerks) and other types of seizures may also occur. Tonic and 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.

### **2) About Banzel™**

Banzel™ is a triazole derivative that is structurally unrelated to currently marketed antiepileptic drugs (AEDs). It is believed to exert its antiepileptic effects by regulating activity of sodium channels in the brain which carry excessive electrical charges that may cause seizures.

Eisai acquired the exclusive worldwide rights to develop, use, manufacture and market rufinamide for any human therapeutic use (excluding bipolar mood disorder, anxiety disorders and ophthalmologic disorders) in a licensing agreement it concluded with Novartis Pharma AG in 2004. Rufinamide received approval in Europe in January 2007 and in the United States in November 2008 for the adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in children 4 years and older and adults. It is currently marketed in these regions under the brand names Inovelon® and Banzel®, respectively, and is also available in a number of countries in Asia.

### **3) Eisai's Commitment to Epilepsy**

Eisai defines epilepsy as a therapeutic area of focus. In addition to Inovelon®/Banzel®, the company also markets Zonegran® (zonisamide) (sodium/calcium channel blocking antiepileptic agent; Europe, the United States, Asia) and Zebinix® (eslicarbazepine acetate) (voltage-dependent sodium channel-blocking antiepileptic agent; Europe) as adjunctive therapies in adults with partial onset seizures.

Eisai has submitted regulatory applications in the European Union (EU) and the United States seeking approval of its AMPA receptor antagonist perampanel as a treatment for patients with partial-onset seizures that offers a completely different mechanistic approach to previous molecules, with the application submitted in the EU already under review. Eisai also plans to conduct further studies for perampanel in primary tonic-clonic seizures, monotherapy in partial-onset seizures, Lennox-Gastaut Syndrome and other forms of epilepsy as it seeks to expand the range of indications for which the drug is approved. By offering multiple treatment options as part of its abundant epilepsy franchise product portfolio, Eisai will continue to make contributions to address the diversified needs of and increase the benefits provided to epilepsy patients and their families.