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Eisai Co., Ltd.

EISAI TO INITIATE JAPAN CLINICAL TRIAL OF ANTIEPILEPTIC AGENT RUFINAMIDE IN PATIENTS WITH LENNOX-GASTAUT SYNDROME

Eisai Co., Ltd. (Headquarters: Tokyo, President and CEO: Haruo Naito) announced today that it plans to commence a clinical trial in Japan with the antiepileptic agent rufinamide in patients with a rare disorder known as Lennox-Gastaut syndrome (LGS).

Eisai has been preparing to develop rufinamide in Japan ever since the Japanese Ministry of Health, Labour and Welfare's "Study Group on Unapproved Drugs," the predecessor of the "Study Group on Unapproved and Off-label Drugs of High Medical Need," recommended that the Company begin clinical development of the drug as a treatment for LGS as early as possible.

LGS is one of the most severe and intractable forms of epilepsy and is estimated to affect less than 1000 patients in Japan. Characterized by multiple seizures, the disorder is extremely difficult to manage and affects the quality of life of both patients and their families. Eisai will commence a phase III trial in Japan in order to ensure the timely delivery of rufinamide to patients as it continues its mission as a human health care (hhc) company to fulfill the medical needs of patients with orphan diseases.

Rufinamide is a triazole derivative that is structurally unrelated to currently marketed antiepileptic drugs (AEDs). It is believed to exert its antiepileptic effects by regulating the activity of sodium channels in the brain which carry excessive electrical charges that may cause seizures so as to prolong their inactive state. The drug 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.

By moving forward with clinical trials of rufinamide as a treatment for LGS, Eisai will make further contributions to addressing the diversified needs of and increasing the benefits to patients and their families.

[Please see the following notes for further information on LGS and rufinamide]

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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 is also 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 (brief loss of consciousness) 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 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. LGS is estimated to affect less than 1000 patients in Japan.

2. About Rufinamide (generic name)

Rufinamide 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 so as to prolong their inactive state.

Eisai acquired an exclusive worldwide license to develop, use, manufacture and market rufinamide for any human therapeutic use with the exception of bipolar mood disorder, anxiety disorders and ophthalmologic disorders from Novartis Pharma AG in 2004. The drug 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.