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Eisai Co., Ltd.

EISAI SUBMITS APPLICATION IN JAPAN FOR ANTIEPILEPTIC AGENT RUFINAMIDE FOR LENNOX-GASTAUT SYNDROME

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that it has submitted a marketing authorization application to Japan's Ministry of Health, Labour and Welfare (MHLW) for rufinamide (generic name), an antiepileptic agent developed by the company in Japan. Eisai is seeking approval to market the agent as an adjunctive therapy in the treatment of a rare disorder known as Lennox-Gastaut syndrome (LGS).

LGS is one of the most severe and intractable forms of childhood-onset epilepsy and is estimated to affect some 3,600 patients in Japan. Characterized by multiple seizure types, the disorder is extremely difficult to control, with patients normally having to take several different antiepileptic drugs (AEDs). The most common seizure types associated with LGS, tonic and atonic seizures, lead to the frequent falls due to sudden loss of consciousness. LGS often causes delayed intellectual development and behavioral disturbances, and therefore has a significant impact on the quality of life of both patients and their families.

In October 2009, rufinamide was designated by the MHLW's "Study Group on Unapproved Drugs," the predecessor to the "Study Group on Unapproved and Off-Label Drugs of High Medical Need," as an unapproved drug for which development support would be provided. In clinical studies conducted in Japan to assess efficacy and safety of the agent in LGS patients, rufinamide statistically significantly reduced the frequency of seizures associated with LGS compared to placebo, demonstrating an efficacy and safety profile consistent with overseas Phase III studies used to support regulatory submissions filed in the European Union and the United States. Rufinamide received approval in the European Union in January 2007 and in the United States in November 2008 as an adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in children 4 years and older and adults. The agent is currently marketed in these regions under the brand names Inovelon® and Banzel®, respectively.

Eisai defines epilepsy as a therapeutic area of focus, and is currently working on expanding its Japan epilepsy portfolio through the domestic development of rufinamide in addition to the AMPA receptor antagonist perampanel, as it seeks to make further contributions to address the diversified needs of, and increase the benefits provided to, patients and families suffering from intractable forms of epilepsy.

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[Please refer to the following notes for further information on Lennox-Gastaut syndrome, rufinamide, overseas clinical studies, and Eisai's commitment to epilepsy]

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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 majority of patients with LGS experience tonic (muscle stiffening), atonic (sudden loss of muscle tone/drop attacks) and absence (brief loss of consciousness/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 wear protective helmets with face guards to protect against head injury from these attacks. Although LGS is most commonly treated with antiepileptic drugs (AEDs), patients whose seizures are difficult to manage with pharmacotherapy may have to undergo surgical treatment.

2. About Rufinamide (generic name)

Rufinamide is a triazole derivative that is structurally unrelated to currently marketed AEDs. The agent is believed to exert its antiepileptic effects by regulating activity of sodium channels in the brain that carry excessive electrical charges thought to cause seizures so as to prolong their inactive state. Eisai entered into a license agreement with Novartis Pharma AG in 2004, under which Novartis granted Eisai the exclusive worldwide rights to develop, use, manufacture and market rufinamide. The agent received approval in the European Union in January 2007 and in the United States in November 2008 as an adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in children 4 years and older and adults. Rufinamide is currently marketed in these regions under the brand names Inovelon® and Banzel®, respectively, in addition to the Asia region. In Japan, rufinamide received orphan drug designation in June 2011.

3. Overseas Clinical Studies

A 12-week double-blind comparative study of rufinamide versus placebo was conducted in 138 LGS patients aged between 4 and 30 years old. During the maintenance period, patients received either placebo or rufinamide at a dose of 1000 mg, 1800 mg, 2400 mg or 3200 mg daily depending on their weight (target dose of approximately 45 mg/kg/day). Results showed that patients administered rufinamide experienced a significant reduction in tonic/atonic seizure frequency (change in seizure frequency; rufinamide arm: -42.5%; placebo arm: 1.4%; p=<0.0001) and overall seizure frequency (change in seizure frequency; rufinamide arm: -37%; placebo arm: -11.7%; p=0.0015).

The most frequently observed adverse events were somnolence, nausea, fever and diarrhea.

4. Eisai’s Commitment to Epilepsy

Eisai defines epilepsy as a therapeutic area of focus. In addition to the Lennox-Gastaut syndrome treatment Inovelon®/Banzel®, Eisai currently markets Zonegran® (under license from the originator Dainippon Sumitomo Pharma Co., Ltd.; sodium/calcium channel blocking antiepileptic agent; marketed in Europe, the United States and Asia) and Zebinix® (under license from the originator BIAL-Portela & Ca S.A.; voltage-dependent sodium channel-blocking antiepileptic agent; marketed in Europe) for the treatment of partial-onset seizures, and the anticonvulsant agent Fostoin® (Co-promotion partner: Nobelpharma Co., Ltd.; water-soluble prodrug of phenytoin; marketed in Japan) for use in the treatment of conditions such as status epilepticus.

Eisai also submitted marketing authorization applications to the regulatory authorities in the European Union and

United States seeking approval to market Fycompa® (perampanel), an AMPA antagonist discovered and developed in-house, as a first-in-class treatment for partial-onset seizures. The application submitted in the European Union was approved in July 2012. Perampanel is currently in Phase III clinical development in Japan for partial-onset seizures. Eisai is currently conducting Phase III clinical studies as part of a global development program of perampanel for generalized epilepsy with the aim to further expand the range of approved indications. By offering multiple treatment options as part of an extensive epilepsy product portfolio, Eisai seeks to make further contributions to address the diversified needs of, and increase the benefits provided to, epilepsy patients and their families.