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Eisai Co., Ltd.

U.S. FDA ACCEPTS EISAI'S sNDA FOR BANZEL® (RUFINAMIDE) AS ADJUNCTIVE TREATMENT IN PEDIATRIC PATIENTS WITH LENNOX-GASTAUT SYNDROME

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that the U.S. Food and Drug Administration (FDA) has accepted for review the supplemental New Drug Application (sNDA) submitted by its U.S. subsidiary Eisai Inc. for Eisai's antiepileptic agent BANZEL® (generic name: rufinamide), which was approved in November 2008 for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in children four years older and adults. This application seeks an additional indication for pediatric patients from one to three years of age.

The sNDA was submitted to the FDA by Eisai Inc. on August 12, 2014. Acceptance of the sNDA indicates that the FDA has found the company's submission to be sufficiently complete to review. Furthermore, Priority Review designation was assigned to this sNDA because the FDA requested this pediatric data under the Best Pharmaceuticals for Children Act. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) action date (proposed review deadline) of February 12, 2015.

LGS is a severe form of epilepsy that affects 1 to 4 percent of all U.S. children with epilepsy. 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 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.

BANZEL is a triazole derivative that is structurally unrelated to currently marketed AEDs. It is believed to exert its effect by regulating the activity of voltage-gated sodium channels in the brain involved in the overexcitement of neurons that potentially causes seizures. BANZEL has been approved by the U.S. FDA for the adjunctive treatment of seizures associated with LGS in children four years and older and in adults, and is currently marketed in the U.S. in tablet form (200 mg and 400 mg) as well as an oral suspension formulation (40 mg/ml).

Eisai considers epilepsy a therapeutic area of focus and has been marketing rufinamide in over 20 countries such as in Europe, the Americas and Asia as well as Japan. By enhancing its drug development capabilities in the field of epilepsy and providing 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.

Media Inquiries:
Public Relations Department,
Eisai Co., Ltd.
+81-(0)3-3817-5120

[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 preexisting 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 or drop attacks) and absence (brief loss of consciousness or 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 that are 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

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 voltage-gated sodium channels in the brain involved in the overexcitement of neurons that potentially causes seizures, so as to prolong their inactive state. Eisai entered into a license agreement with Novartis Pharma AG in February 2004, under which Novartis granted Eisai 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. The agent was approved as an adjunctive therapy to other AEDs in the treatment of seizures associated with LGS in the European Union in January 2007 as Inovelon® and in the United States in November 2008 as BANZEL®. In Japan, the agent was approved in March 2013 under the brand name Inovelon as an adjunctive therapy to other AEDs in the treatment of tonic and atonic seizures associated with LGS when therapy with other AEDs is considered inadequate, and was launched in May 2013 as Inovelon 100 mg and 200 mg tablets. Rufinamide is currently marketed in more than 20 countries in Europe, the Americas and Asia as well as Japan. Among the most common adverse reactions reported in the study this application was based on are headache, dizziness, fatigue, somnolence, and nausea.