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:

[Notes to editors]

1. About Lennox-Gastaut Syndrome (LGS)