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Eisai Co., Ltd.

## **FDA ACCEPTS BANZEL® (RUFINAMIDE) ORAL SUSPENSION NDA FOR REVIEW**

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito) announced today that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) submitted by its U.S. subsidiary Eisai Inc. for a new oral suspension (40 mg/mL) formulation of the Eisai's antiepileptic agent BANZEL® (generic name: rufinamide). The proposed indication is for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in children four years and older and adults.

The new oral suspension formulation was developed to provide a new treatment option for children four years and older and adults who have trouble swallowing tablets.

The application is based on data from a study designed to demonstrate the bioequivalence of the oral suspension formulation to the currently marketed BANZEL® tablet formulation (400 mg). Acceptance of the NDA indicates that the FDA has found the company's submission to be sufficiently complete to review. The NDA was submitted to the FDA on April 30, 2010.

LGS is a rare form of epilepsy that affects 1 to 4 percent of all U.S. children with epilepsy. Children and adults living with LGS experience frequent seizures of multiple types that are difficult to control and they can be developmentally delayed.

BANZEL® is a triazole derivative that is structurally unrelated to currently marketed antiepileptic drugs (AEDs). It is believed to exert its effect by regulating the activity of sodium channels in the brain which carry excessive electrical charges that may cause seizures. BANZEL® tablets (200 mg and 400 mg) were approved in the United States by the FDA in November 2008 and are currently prescribed for the adjunctive treatment of seizures associated with LGS in children four years and older and adults.

By providing the easy-to-administer oral suspension formulation as a new treatment option, Eisai will make further contributions to addressing the diversified needs and improving the quality of life (QOL) of U.S. patients and families affected by LGS.

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