



EISAI TO INITIATE TWO PHASE III CLINICAL STUDIES FOR ANTIEPILEPTIC DRUG

Together with the worldwide provision of Fycompa, Eisai is striving to continuously create new medicines for the field of epilepsy. In addition, Eisai is promoting initiatives such as provision of the EMILY epilepsy

3. About Study 338

Study 338 is a global (United States, Europe, Japan, Asia) double-blind, randomized, placebo-controlled trial with an open-label extension to demonstrate that perampanel, when given as adjunctive antiepileptic treatment, is superior to placebo in approximately 140 participants at least 2 years of age with inadequately-controlled seizures associated with LGS.

Patients will be titrated to receive up to 8 mg of perampanel orally once-daily. The study will compare the efficacy of perampanel and placebo in reducing incidence of seizures primarily associated with LGS (myoclonic, tonic, atonic seizures) during the treatment period of 18 weeks.

4. About Epilepsy

Epilepsy affects approximately 1 million people in Japan, 2.9 million people in the United States, 6 million people in Europe, and approximately 60 million people worldwide. As approximately 30% of patients with epilepsy are unable to control their seizures with currently available AEDs,¹ this is a disease with significant unmet medical need.

Epilepsy is broadly categorized by seizure type, with partial-onset seizures accounting for approximately 60% of epilepsy cases and generalized seizures accounting for approximately 40%. In a partial-onset seizure, an abnormal electrical disturbance occurs in a limited area of the brain, and sometimes may subsequently spread throughout the brain, becoming a generalized seizure (known as a secondarily generalized seizure). In a generalized seizure, abnormal electrical disturbances occur throughout the brain, and can be followed by a loss of consciousness or physical symptoms manifested throughout the whole body.

Accounting for approximately 60% of generalized epilepsy and approximately 20% of all epilepsy cases,² generalized tonic-clonic seizures are one of the most common and most severe forms of epileptic seizures as they can cause significant injury to patients from falling down suddenly, and the frequency of these seizures is the most important risk factor associated with sudden unexpected death in epilepsy (SUDEP).³

For the majority of patients, a generalized tonic-clonic seizure begins with a loss of consciousness without any prior warning symptoms and a sudden contraction of the tonic muscles, causing the patient to fall down (tonic phase). This is followed by violent convulsions (clonic phase) until the muscles finally relax, and the patient is left with a disturbance of consciousness. As this is a serious event, it is seen as a major hindrance on daily life. While the seizure generally only lasts a few minutes, the patient will often feel confused, groggy or drowsy for a short period of time before returning to normal.

5. About Lennox-Gastaut Syndrome

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 [(A)1isdi