

**APPROVAL OF ANTIEPILEPTIC DRUG FYCOMPA® IN JAPAN FOR MONOTHERAPY
AND PEDIATRIC INDICATIONS FOR PARTIAL-ONSET SEIZURES,
AS WELL AS A NEW FORMULATION**

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that it has obtained the approvals of supplementary new drug applications in Japan for its in-house developed antiepileptic drug (AED) Fycompa® (peramppanel) for an additional indication for monotherapy of partial-onset seizures and an additional indication for partial-onset seizures in pediatric patients aged 4 years and older, as well as a new fine granule formulation.

The approval for monotherapy for partial-onset seizures is based on the results of a Phase III clinical study (FREEDOM/Study 342) conducted in Japan and South Korea. The outcome achieved the primary endpoint, with the rate of complete seizures-free exceeding the initially established efficacy criteria* in monotherapy for untreated epilepsy patients aged 12 to 74 years with partial-onset seizures. The most common adverse events (incidence of 10% or higher) observed in this study were dizziness, somnolence, nasopharyngitis and headache, which were consistent with the safety profile of Fycompa to date.

The additional approval covering partial-onset seizures in pediatric epileptic patients 4 years of age and older is based on the results of a Phase III clinical study (Study 311) of Fycompa, as adjunctive therapy in pediatric patients, conducted in Japan, the United States and Europe. This study showed that the safety and efficacy of Fycompa combination therapy in pediatric epilepsy patients with poorly controlled partial seizures (ages 4 to less than 12 years) were similar to those in patients aged 12 years and older.

The additional approval for the fine granule formulation is based on the results of a bioequivalence study of fine granules and tablets conducted in Japan. Eisai developed this formulation to make it easier to administer Fycompa to children and patients who have difficulty taking tablets. The study confirmed the bioequivalence of fine granules and tablets.

Fycompa is a first-in-class AED and a once-daily oral drug discovered at Eisai's Tsukuba Research Laboratories. The agent is a highly selective, noncompetitive AMPA receptor antagonist that reduces neuronal hyperexcitation associated with seizures by targeting glutamate activity at AMPA receptors on postsynaptic membranes. Fycompa has been approved in many countries around the worldwide as an adjunctive treatment for partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy 12 years of age and older and as an adjunctive treatment for primary generalized tonic-clonic seizures in patients with epilepsy 12 years of age and older. In the United States, Fycompa is also indicated for monotherapy and adjunctive use in the treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy 4 years of age and older.

The number of epilepsy patients in Japan is estimated to be approximately 1 million, and it is possible that the disease may occur regardless of age group, but it is said that the incidence is particularly high in children and the elderly. Eisai considers neurology including epilepsy as a priority disease area, and provides information on appropriate use of Fycompa, aiming to satisfy the diverse needs of patients and their families and offer improved benefits. With the approval for monotherapy, pediatric indication aged 4 years and older and fine granule formulation, Eisai will continue to prioritize the provision of safety information. Furthermore, Eisai will pursue its mission of delivering "seizure freedom" to as many patients as possible.

* The criteria for efficacy in this study with 73 patients for evaluation of efficacy required a 52.1% or higher proportion of patients to have achieved seizure freedom, which was set primarily in consideration of the results from other AED monotherapy studies.

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

[Notes to editors]

1. About Fycompa (perampanel)

Fycompa is a first-in-class AED discovered and developed by Eisai. With epileptic seizures being mediated by the neurotransmitter glutamate, the agent is a highly selective, noncompetitive AMPA receptor antagonist that reduces neuronal hyperexcitation associated with seizures by targeting glutamate activity at AMPA receptors on postsynaptic membranes. Fycompa is available in drug form to be taken once daily orally at bedtime. An oral suspension formulation and tablet have been approved in the United States and Europe. Based on the new additional use approval, in Japan, tablet and fine granule formulation have been approved. Furthermore, the indications in Japan are treatment of partial-onset seizures (including secondarily generalized seizures) in patients with epilepsy and adjunctive therapy with antiepileptic drugs for tonic-clonic seizures in patients with epilepsy showing inadequate response to other antiepileptic drugs.

Fycompa is currently approved in more than 65 countries and territories, including Japan, the United States, China, and other countries in Europe and in Asia as adjunctive treatment for partial-onset seizures (with or without secondarily generalized seizures) in patients with epilepsy 12 years of age and older. In addition, Fycompa has been approved in more than 60 countries, including the United States, Japan, in Europe and in Asia for treatment as an adjunctive therapy for primary generalized tonic-clonic seizures in patients with epilepsy 12 years of age and older. In Japan and the United States, Fycompa is approved for monotherapy and adjunctive use in the treatment of partial-onset seizures (with or without secondarily generalized seizures) in patients with epilepsy 4 years of age and older. In Europe, an application has been submitted seeking the additional approval of Fycompa for adjunctive use in the treatment of partial-onset seizures (with or without secondarily generalized seizures) or primarily generalized tonic-clonic seizures in pediatric patients with epilepsy.

To date, Fycompa has been used to treat more than 270,000 patients worldwide across all indications.

Eisai is conducting a global Phase III clinical study (Study 338) for the agent in patients with seizures associated with Lennox-Gastaut syndrome.

2. About Study 342 (FREEDOM)

Study title:	An Uncontrolled, Open-label Study for Verification of Efficacy and Safety for Perampanel Monotherapy in Untreated Patients with Partial Onset Seizures (Including Secondarily Generalized Seizures)
Study population:	89 untreated patients aged 12 to 74 with partial-onset seizures with or without secondarily generalized seizures
Treatment administered:	Up to 4 mg of perampanel administered orally once daily before bedtime (may be titrated up to 8 mg if seizures occur)
Duration of treatment:	Treatment Phase (Titration Period: 6 weeks, Maintenance Period: 26 weeks (if titrated up from 4 mg to 8 mg, titration period is 4 weeks and treatment period is 26 weeks)) Extension Phase
Study locations:	Japan, South Korea
Primary endpoint:	Seizure-free rate during 26-week Maintenance Period for participants with partial onset seizures
Results:	89 patients were administered Fycompa as monotherapy, and the proportion of 73 patients for evaluation receiving 4 mg who were seizure-free during the treatment period exceeded the efficacy criteria*, and the primary endpoint was met. In addition, the interim results demonstrated that the 4 mg and 8 mg patients combined also exceeded the efficacy criteria. The most common adverse events (incidence of 10% or higher) observed in this study were dizziness, somnolence, nasopharyngitis and headache, which is consistent with the safety profile of Fycompa to date

*The criteria for efficacy in this study with 73 patients for evaluation of efficacy required a 52.1% or higher proportion of patients to have achieved seizure freedom, which was set primarily in consideration of the results from other AED monotherapy studies.

3. About Study 311

Study title:	An Open-Label Study to Evaluate the Safety, Tolerability, and Exposure-Efficacy Relationship of Perampanel Oral Suspension When Administered as an Adjunctive Therapy in Pediatric Subjects With Inadequately Controlled Partial-Onset Seizures or Primary Generalized Tonic Clonic Seizures
Study population:	180 patients aged 4 to 12 with inadequately controlled partial-onset seizures or primarily generalized tonic-clonic seizures.
Treatment administered:	2 - 16 mg of perampanel administered orally once daily before bedtime
Duration of treatment:	Treatment Phase (Titration Period: up to 11 weeks, Maintenance Period: up to 12 weeks) Extension Phase
Study locations:	Global (United States, Europe, Japan, Asia)
Primary endpoint:	Safety and tolerability
Results:	In the 180 patients who were administered Fycompa, efficacy was similar to that observed in patients 12 years of age and older. The most common adverse events (incidence of 10% or higher) observed in this study were somnolence, nasopharyngitis, pyrexia, vomiting, dizziness, influenza, and irritability, which were consistent with the safety profile of Fycompa to date.

4. About Epilepsy

Epilepsy affects approximately 1 million people in Japan, 3.4 million people in the United States, 6 million people in Europe, 9 million people in China, 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 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.

¹ "The Epilepsies and Seizures: Hope Through Research. What are the epilepsies?" National Institute of Neurological Disorders and Stroke, accessed May 24, 2016, http://www.ninds.nih.gov/disorders/epilepsy/detail_epilepsy.htm#230253109