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Eisai Co., Ltd.

PRIMARY ENDPOINT MET IN PHASE III CLINICAL STUDY OF FYCOMPA® AS MONOTHERAPY FOR PARTIAL-ONSET SEIZURES AIMING FOR SUBMISSION IN JAPAN

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that based on topline results, the primary efficacy endpoint was met in a Phase III clinical study (Study 342) conducted for submission in Japan, which evaluated its in-house discovered antiepileptic drug (AED) Fycompa® (perampanel) as monotherapy for partial-onset seizures. Based on the results of this study, Eisai plans to file an application seeking approval of Fycompa as monotherapy for partial onset seizures in Japan during fiscal 2018.

Study 342 is a multicenter, open-label, single-arm Phase III clinical study for verification of efficacy and safety for Fycompa monotherapy in untreated patients from 12 to 74 years of age with partial onset seizures, and compared this efficacy and safety with the results from other AED monotherapy studies. The primary efficacy endpoint of the study is the percentage of patients who achieved seizure-free during the maintenance period (26 weeks of treatment administration) of 4 mg/day of Fycompa. From the results of this study, the percentage of patients who achieved seizure-free exceeded the criteria for efficacy, and the primary endpoint was met.
The most common adverse events (incidence of 10% or higher) observed in Study 342 were dizziness, somnolence, nasopharyngitis and headache, which is consistent with the safety profile of Fycompa to date.
Detailed results of the study will be presented at upcoming academic conferences.

Discovered at Eisai's Tsukuba Research Laboratories, Fycompa is a first-in-class AED available in tablet form to be taken orally once daily. Fycompa is a highly selective, noncompetitive AMPA receptor antagonist that reduces neuronal hyperexcitation by targeting glutamate activity at AMPA receptors on postsynaptic membranes. In Japan, Fycompa is approved as an adjunctive therapy for partial-onset seizures (including secondarily generalized seizures) or primary generalized tonic-clonic seizures in patients with epilepsy showing inadequate response to other AEDs.

Eisai considers neurology including epilepsy, a therapeutic area of focus, and in continued pursuit of our mission to provide "seizure freedom" to a greater number of patients living with epilepsy. Eisai seeks to address the diverse needs of, as well as increasing the benefits provided to, patients with epilepsy and their families.

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[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 tablet form to be taken once daily orally at bedtime. In addition, an oral suspension formulation has been approved in the United States.

Fycompa is currently approved in more than 55 countries and territories, including the United States, Japan, 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. An application seeking approval for use in the adjunctive treatment of partial-onset seizures is under review in China. In addition, Fycompa has been approved in more than 50 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 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.

Furthermore, Eisai is conducting a global Phase III clinical study (Study 338) for the agent in patients with seizures associated with Lennox-Gastaut syndrome. In Japan and Europe, Eisai is conducting a Phase III study in pediatric patients with epilepsy (Study 311).

2. About Study 342

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:	Untreated patients aged 12 to 74 with partial-onset seizures with or without secondarily generalized seizures (73 patients for evaluation)
Treatment administered:	Perampanel oral tablets, 4 mg (may be titrated up to 8 mg if seizures occur) once daily before bedtime
Duration of treatment:	Titration Period: 6 weeks Maintenance Period (treatment): 26 weeks
Study locations:	Japan, South Korea
Primary endpoint:	Seizure-free rate during 26-week Maintenance Period for participants with partial onset seizures

3. About Epilepsy

Epilepsy affects approximately 3.4 million people in the United States, 1 million people in Japan, 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