

PHASE III TRIAL OF ANTIEPILEPTIC DRUG PERAMPANEL AS ADJUNCTIVE THERAPY IN PATIENTS WITH REFRACTORY PARTIAL-ONSET SEIZURES CONDUCTED IN ASIA INCLUDING JAPAN AND CHINA MEETS PRIMARY ENDPOINT

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that a Phase III clinical trial (Study 335) of its in-house-discovered antiepileptic drug (AED) perampanel (generic name, U.S. and Europe brand name: Fycompa[®]) in patients with refractory partial-onset seizures conducted in Asia (including Japan and China) has met its primary endpoint.

Study 335 was a multicenter, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of adjunctive perampanel therapy in 710 patients aged 12 years and older with refractory partial-onset seizures conducted in Asia.

The primary endpoint of the study was change in seizure frequency (percent change in seizure frequency per 28 days during treatment relative to baseline). Preliminary analysis of the study confirmed that perampanel statistically significantly reduced seizure frequency at doses of 8 mg/day and 12 mg/day, which demonstrated a greater improvement in seizure frequency when compared to placebo. Furthermore, the most common adverse events (>15% in the perampanel arms and greater than placebo) were dizziness and somnolence. The adverse event profile observed in the study was similar to that observed in other perampanel studies.

Perampanel is a first-in-class AED discovered and developed by Eisai. With epileptic seizures being primarily 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 postsynaptic AMPA receptors. Perampanel is approved as an adjunctive treatment for partial-onset seizures (with or without secondary generalized seizures) in patients with epilepsy aged 12 years and older in more than 40 countries primarily in Europe and North America, and has been launched in over 15 countries.

Furthermore, regarding the adjunctive treatment of primary generalized tonic-clonic (PGTC) seizures, one of the most severe forms of generalized seizures, applications for indication expansion based on a global Phase III study (Study 332) have been submitted in Europe and the United States. In Japan, Eisai has already submitted a part of the submission package, including data from the clinical studies conducted in Europe and the United States, to the Pharmaceutical and Medical Devices Agency based on the prior assessment consultation system* with the aim of shortening application review time. With the submission of additional data from Study 335 and Study 332, Eisai plans to submit a new drug application covering refractory partial-onset seizures as well as PGTC seizures in Japan during the first half of fiscal 2015.

Eisai considers neurology as a therapeutic area of focus and is committed to the development of treatments such as perampanel, through which it seeks to make further contributions to addressing the diverse needs of, as well as increasing the benefits provided to, epilepsy patients and their families.

*The prior assessment consultation system is conducted at the development stage before new drug application submission based on available quality, non-clinical and clinical data. By identifying and resolving any potential issues prior to submission, the aim is to shorten application review time as a result.

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[Notes to editors]

1. About perampanel (generic name, U.S. and Europe brand name: Fycompa)

Perampanel, a novel chemical entity discovered and developed by Eisai, is a noncompetitive AMPA-type glutamate receptor antagonist. Perampanel is an antiepileptic drug (AED) that reduces neuronal hyperexcitation associated with seizures by targeting glutamate activity at postsynaptic AMPA receptors. The agent is approved as an adjunctive treatment (once-daily oral dose) of partial-onset seizures in more than 40 countries and territories, including in Europe and the United States, and has been launched in over 15 countries. Regarding the adjunctive treatment of primary generalized tonic-clonic (PGTC) seizures, which are one of the most severe forms of generalized seizures, a Phase III study (Study 332) conducted across Europe, the United States, Japan and Asia, met its primary endpoints, and applications for an indication expansion have already been filed in Europe and the United States. In Japan, Eisai has already submitted a part of the submission package, including data from the clinical studies conducted in Europe and the United States, to the Pharmaceutical and Medical Devices Agency based on the prior assessment consultation system with the aim of shortening application review time. With the submission of additional data from Study 335 and Study 332, Eisai plans to submit a new drug application covering partial-onset seizures as well as PGTC seizures in Japan during the first half of fiscal 2015.

2. About Study 335

Study population:	710 patients aged 12 years and older who have a diagnosis of epilepsy with partial-onset seizures with or without secondarily generalized seizures receiving treatment with 1-3 AEDs.
Primary objective:	To confirm the efficacy and safety of perampanel compared to placebo given as an adjunctive therapy in patients with refractory partial-onset seizures
Treatment administered:	Perampanel oral tablets, 4 mg/day, 8 mg/day and 12 mg/day, once daily before bedtime Perampanel-matched placebo oral tablets, once daily before bedtime
Duration of treatment:	Prerandomization Phase: 6 weeks Randomization Phase (treatment): 19 weeks (Titration Period, 6 weeks; Maintenance Period, 13 weeks) Extension Phase: over 10 weeks
Study locations:	Japan, China, South Korea, Australia, Thailand, Malaysia, Taiwan
Primary endpoint:	Percent change in seizure frequency per 28 days during treatment relative to baseline