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Eisai Co., Ltd.

EISAI SUBMITS APPLICATIONS FOR ANTIEPILEPSY AGENT FYCOMPA® SIMULTANEOUSLY IN EUROPE AND U.S. SEEKING INDICATION EXPANSION AS ADJUNCTIVE TREATMENT OF PRIMARY GENERALIZED TONIC-CLONIC SEIZURES

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that it has submitted applications to regulatory authorities in the U.S. and Europe (the FDA and EMA respectively) for the indication expansion of its in-house developed antiepileptic drug Fycompa® (generic name: perampanel) as an adjunctive treatment of primary generalized tonic-clonic seizures (PGTC).

PGTC is one of the most severe forms of generalized seizures, accounting for approximately 60% of generalized epilepsy and approximately 20% of all epilepsy cases.[1] This application was based on a double-blind, randomized, placebo-controlled, multicenter, parallel-group clinical study (Study 332) to evaluate the efficacy and safety of adjunctive Fycompa therapy in 164 patients aged 12 years and older with uncontrolled PGTC seizures receiving one to a maximum of three anti-epileptic drugs (AED). Analysis of the study demonstrates that Fycompa significantly reduced PGTC seizure frequency (primary analysis for the U.S.) and improved responder rates (the percentage of patients who experienced a 50% or greater reduction in PGTC seizure frequency, primary analysis for the EU), the study's two primary outcome measures, when compared to placebo. In this study, the most common adverse events (≥10% in the Fycompa arm and greater than placebo) were dizziness, fatigue, headache, irritability and somnolence. The adverse event profile observed in the study was similar to that observed in other Fycompa studies.

Fycompa 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. Fycompa is approved in more than 35 countries primarily in Europe and North America, and has been launched in the U.S., Europe and Canada as an adjunctive treatment for partial-onset seizures (with or without secondary generalized seizures) in patients with epilepsy aged 12 years and older. Furthermore, a clinical study on patients with partial-onset seizures (Study 335) is currently underway in Asia including Japan, and Eisai plans to submit a regulatory application covering both study 332 and study 335 in Japan in fiscal 2015.

Eisai considers epilepsy a therapeutic area of focus and by providing multiple treatment options in addition to Fycompa as part of an extensive epilepsy product portfolio, Eisai seeks to make continued contributions 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, a novel chemical entity discovered and developed by Eisai, is a noncompetitive AMPA-type glutamate receptor antagonist. Fycompa is an AED that reduces neuronal hyperexcitation associated with seizures by targeting glutamate activity at postsynaptic AMPA receptors. The agent is currently approved in more than 35 countries and territories, including Europe and the U.S., as a treatment (once-daily oral dose) of partial-onset seizures and is also being evaluated in a Phase III study in Asia, including Japan. Furthermore, Eisai is conducting Phase II studies in Europe and the U.S. for partial-onset epilepsy in pediatric patients, as it seeks to expand the drug's range of approved indications.

2. About Study 332

Study population:	164 patients aged 12 years and older with PGTC seizures receiving one to a maximum of three anti-epileptic drugs
Primary objective:	To demonstrate the efficacy of adjunctive perampanel therapy, compared to placebo on PGTC seizures
Treatment administered:	(Placebo-controlled) Perampanel oral tablets, once daily, up to 8 mg/day (Titration Period), randomized dose 8 mg/day (Maintenance Period)
Duration of treatment:	Prerandomization Phase (Screening and Baseline Periods): up to 12 weeks Randomization Phase (treatment): 17 weeks (Titration Period, 4 weeks; Maintenance Period, 13 weeks) Extension Phase: over 38 weeks
Study locations:	U.S., Europe, Japan, Asia
Primary endpoints:	-Percent change in PGTC seizure frequency (U.S.): Percent change from baseline in PGTC seizure frequency per 28 days during treatment -Responder rate (EU): Percentage of patients who experience a 50% or greater reduction in PGTC seizure frequency per 28 days in the maintenance period relative to baseline

3. About Primary Generalized Tonic-Clonic Seizures

Epilepsy affects nearly 1 million people in Japan, 2.4 million people in Europe (G5), 2.2 million people in the U.S., and more than 50 million people worldwide. 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%. Primary generalized tonic-clonic (PGTC) seizures are one of the most common and most severe forms of generalized seizures, accounting for approximately 60% of generalized epilepsy and approximately 20% of all epilepsy cases.[1] For the majority of patients, a PGTC 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.

[1] Hauser WA, et al. Epilepsia, 34(3):453-468,1993