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Eisai Co., Ltd.

U.S. FDA ACCEPTS sNDA FOR ANTIEPILEPTIC AGENT FYCOMPA® AS ADJUNCTIVE TREATMENT OF PRIMARY GENERALIZED TONIC-CLONIC SEIZURES

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that the U.S. Food and Drug Administration (FDA) has accepted for review the company's supplemental New Drug Application (sNDA) for its in-house developed antiepileptic drug Fycompa® (generic name: perampanel) for the treatment of primary generalized tonic-clonic seizures (PGTC), a severe form of seizures, in patients 12 years or older.

Acceptance of the application indicates that the FDA has found the company's submission to be sufficiently complete to review. This sNDA was submitted to the FDA by Eisai's U.S. subsidiary Eisai Inc. on August 19, 2014. Furthermore, an application seeking approval of this additional indication for the EU was also submitted on the same day to the regulatory authority in Europe.

Fycompa is a first-in-class antiepileptic drug 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 40 countries primarily in Europe and North America as an adjunctive treatment for partial-onset seizures (with or without secondary generalized seizures) in patients with epilepsy aged 12 years and older, and was launched in the United States in January 2014.

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 antiepileptic drug that reduces neuronal hyperexcitation associated with seizures by targeting glutamate activity at postsynaptic AMPA receptors. The agent is currently approved in more than 40 countries and territories, including Europe and the United States, as an adjunctive treatment (once-daily oral dose) of partial-onset seizures and is also being evaluated in a Phase III study (Study 335) in Asia, including Japan.

A Phase III study (Study 332) of the agent as an adjunctive therapy for the treatment of primary generalized tonic-clonic seizures (PGTC) conducted in the United States, Europe and Asia, including Japan, met its primary endpoint, and the regulatory applications for an indication expansion of the agent are under review in the United States and Europe. The company plans to submit a regulatory application covering both study 332 and study 335 in Japan in fiscal 2015. Furthermore, Eisai is conducting Phase II studies in Europe and the United States for partial-onset epilepsy in pediatric patients.

2. About Study 332

The supplemental New Drug Application (sNDA) for the treatment of primary generalized tonic-clonic seizures (PGTC), Study 332, was based on a multicenter, randomized, double-blind, placebo-controlled, parallel-group clinical study 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 antiepileptic drugs. Analysis of the study demonstrates that Fycompa significantly reduced PGTC seizure frequency (primary analysis for the United States) 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.

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 United States, 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