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Eisai Co., Ltd.

SUPPLEMENTARY NEW DRUG APPLICATION SUBMITTED IN JAPAN FOR ANTIEPILEPTIC DRUG FYCOMPA® INJECTION FORMULATION AS A NEW ROUTE OF ADMINISTRATION

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, “Eisai”) announced today that it has filed a supplementary new drug application in Japan for its in-house discovered antiepileptic drug (AED) Fycompa® (perampanel) seeking approval for an injection formulation as a new route of administration.

Fycompa is a first-in-class AED discovered at Eisai’s Tsukuba Research Laboratories. The agent is a highly selective, noncompetitive AMPA receptor antagonist that is postulated to reduce neuronal hyper-excitation associated with seizures by targeting glutamate activity at AMPA receptors on postsynaptic membranes. Two oral formulations of Fycompa are available in Japan: a tablet and a fine granule formulation. Due to concern about the risks associated with interruption of administration when the drug cannot be taken orally temporarily, such as during surgery, it is suggested that epilepsy patients should continue treatment other than via oral administration. The injection formulation was developed as a non-oral administration route to meet such medical needs, and its bioequivalence to the tablet formulation, as well as the confirmation of the safety and tolerability of the injection formulation when administered as an alternative therapy to the tablet, lead to this application. The addition of an injection formulation of Fycompa, the only AMPA receptor antagonist-based AED, to the product lineup is expected to provide a new treatment option for a broader range of patients.

It is estimated that there are approximately 1 million patients with epilepsy in Japan, and although onset occurs at any age, it is most common in people aged 18 and younger, and the elderly.

Eisai considers neurology, including epilepsy, a therapeutic area of focus and is 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 (generic name: perampanel)

Fycompa is a first-in-class anti-epileptic agent (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 currently approved in more than 70 countries and territories, including Japan, the United States, China, and other countries in Europe and in Asia as an 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 70 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, the United States and China, 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 the approved age range is 4 years of age and older for the adjunctive treatment of partial-onset seizures (with or without secondarily generalized seizures) and 7 years of age and older for the treatment as an adjunctive therapy for primary generalized tonic-clonic seizure. Fycompa is available in drug form to be taken once daily orally at bedtime. A tablet and fine granule formulation have been approved in Japan. An oral suspension formulation and tablet have been approved in the United States and Europe. To date, Fycompa has been used to treat more than 500,000 patients worldwide across all indications.

2. About Epilepsy

Epilepsy affects approximately1 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 needs.

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