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Eisai Co., Ltd.

FYCOMPA® NEWLY APPROVED BY U.S. FDA AS TREATMENT FOR PARTIAL-ONSET SEIZURES IN PEDIATRIC PATIENTS WITH EPILEPSY

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that its U.S. subsidiary Eisai Inc. received approval from the U.S. Food and Drug Administration (FDA) for an indication expansion for Eisai's antiepileptic drug (AED) Fycompa (perampanel) to cover partial-onset seizures in pediatric patients with epilepsy 4 years of age and older. Fycompa was designated for Priority Review by the FDA, and was approved approximately six months after submission.

Through this latest approval, Fycompa is indicated 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. This approval was based on the interim results of a Phase III clinical study (Study 311) as well as the results from a Phase II clinical study (Study 232) in pediatric patients with epilepsy. Both studies confirmed the safety and efficacy of Fycompa were similar between adult and pediatric patients.

Fycompa has been approved in countries around the world including the United States as an adjunctive treatment for partial-onset seizures (with or without secondarily generalized seizures) as well as primary generalized tonic-clonic (PGTC) seizures in patients with epilepsy 12 years of age and older. In the United States, Fycompa is also available as monotherapy for the treatment of partial-onset seizures (with or without secondarily generalized seizures) in patients with epilepsy 12 years of age and older. Through this approval, Fycompa is now available in the United States as a new treatment option, including monotherapy, for pediatric patients with epilepsy 4 to 11 years of age for the treatment of partial-onset seizures (with or without secondarily generalized seizures) as well.

Epilepsy affects approximately 3.4 million people (approximately 470,000 children and 3 million adults) in the United States, accounting for 1.2% of the overall population.[1] While epilepsy affects people of all ages, incidence is particularly high among children and the elderly. As approximately 30% of patients with epilepsy are unable to control their seizures with currently available AEDs,[2] this is a disease with significant unmet medical need.

Discovered at Eisai's Tsukuba Research Laboratories, Fycompa is a first-in-class AED available in tablet form to be taken orally once daily. In addition, an oral suspension formulation has also been approved and is available in the United States. Fycompa is a highly selective, noncompetitive AMPA receptor antagonist that reduces neuronal hyperexcitation associated with seizures by targeting glutamate activity at postsynaptic AMPA receptors. Fycompa was initially approved for adjunctive use in partial-onset seizures in 2012 and has been used to treat more than 200,000 patients worldwide in more than 55 countries across all approved indications.

Eisai considers neurology including epilepsy, a therapeutic area of focus, and strives to deliver Fycompa throughout the world in 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 postsynaptic AMPA receptors. Fycompa is available in tablet form to be taken once daily orally at bedtime. In addition, a new oral suspension formulation has been approved and is being marketed 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. 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 PGTC seizures in patients with epilepsy 12 years of age and older.

For further information on Fycompa in the United States, including Important Safety Information, please visit the Fycompa product website (https://fycompa.com).

2. About Study 311

Study 311 was a global (United States, Europe, Japan, Asia) multicenter, open-label, single-arm trial with an extension phase to evaluate the safety, tolerability and exposure-efficacy relationship of Fycompa oral suspension when administered as an adjunctive therapy in approximately 160 pediatric patients (ages 4 to less than 12 years) with inadequately controlled partial-onset seizures or PGTC seizures.

Following the 23-week treatment phase in which patients were titrated to receive 2 to 16 mg of Fycompa orally once-daily, long term safety was assessed during an extension phase. In Japan, pediatric patients with partial-onset seizures were titrated to receive 2 to 12 mg of Fycompa orally once-daily. The most common adverse events (≥10% in the perampanel arms) observed in Study 311 at the time of interim analysis were somnolence, nasopharyngitis, dizziness, and irritability.

3. About Study 232

Study 232 was a global (United States, Europe), multicenter, open-label, long-term administration clinical study in approximately 50 pediatric patients with epilepsy (ages 2 to less than 12). The study evaluated the pharmacokinetics, safety, tolerability and efficacy of Fycompa oral suspension taken at the same time as other AEDs. Administration of once-daily Fycompa was titrated from 0.015 mg/kg to 0.18 mg/kg, and long-term safety was confirmed after 11 weeks of treatment and an extension phase (41 weeks). The most common adverse events (≥10% in the perampanel arms) observed in Study 232 were pyrexia, fatigue, vomiting, irritability, somnolence, dizziness, and upper respiratory tract infection.

4. 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,[2] 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] Matthew M, et al. “National and State Estimates of the Numbers of Adults and Children with Active Epilepsy – United States, 2015” *MMWR Morb Mortal Wkly Rep* 2017; 66: 821-825

[2] “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