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Eisai Co., Ltd.

EISAI LAUNCHES NEW ORAL SUSPENSION FORMULATION FOR ANTIEPILEPTIC DRUG FYCOMPA® (PERAMPANEL) IN THE UNITED STATES

As Adjunctive Therapy for the Treatment of Partial-Onset Seizures and Primary Generalized Tonic-Clonic Seizures in Patients with Epilepsy

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that it has launched Fycompa® (perampanel) Oral Suspension, a new formulation of its in-house-discovered antiepileptic drug (AED) Fycompa, in the United States.

Fycompa is a first-in-class AED discovered at Eisai's Tsukuba Research Laboratories. It is a highly selective, noncompetitive AMPA receptor antagonist that reduces neuronal hyperexcitation associated with seizures by targeting glutamate activity at postsynaptic AMPA receptors. It is approved in the United States as an adjunctive therapy for the treatment of partial-onset seizures with or without secondarily generalized seizures, and primary generalized tonic-clonic (PGTC) seizures in patients with epilepsy 12 years of age and older.
The new oral suspension formulation was developed to provide a new option for patients who have difficulty swallowing tablets. The oral suspension formulation was approved by the U.S. Food and Drug Administration on April 29, 2016, based on study data that proves bioequivalence with the tablet formulation of Fycompa currently available.

Epilepsy affects approximately 2.9 million people in the United States. 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%. PGTC seizures are one of the most common and most severe forms of generalized seizures, accounting for approximately 60% of generalized seizures and approximately 20% of all epilepsy cases.[1] The frequency of generalized tonic-clonic seizures is the most important risk factor associated with sudden unexpected death in epilepsy (SUDEP).[2] As approximately 30% of patients with epilepsy are unable to control their seizures with currently available AEDs,[3] this is a disease with significant unmet medical needs.

Fycompa is currently approved in more than 45 countries and territories, including Japan, the United States and in Europe as an adjunctive treatment of partial-onset seizures (with or without secondarily generalized seizures) in adult and adolescent patients with epilepsy 12 years of age and older. Fycompa has also been approved in more than 35 countries, including Japan, the United States, and in Europe for the adjunctive therapy of PGTC seizures in patients with epilepsy 12 years of age and older.

Eisai considers neurology a therapeutic area of focus, and with the launch of Fycompa Oral Suspension in the United States, Eisai continues to make 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 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 as a once-daily oral dose. Fycompa is now available in the United States in an oral suspension formulation, and an application seeking approval of this formulation is under review in Europe.

The agent is currently approved in more than 45 countries and territories, including Japan, the United States and in Europe as an adjunctive treatment of partial-onset seizures (with or without secondarily generalized seizures) in adult and adolescent patients with epilepsy 12 years of age and older.

In addition, Fycompa has been approved in more than 35 countries, including Japan, the United States and in Europe for the adjunctive therapy of primary generalized tonic-clonic (PGTC) seizures in patients with epilepsy 12 years of age and older. More specifically, Eisai has obtained approval for the agent indicated in the United States as an adjunctive treatment of PGTC seizures in patients with epilepsy 12 years of age and older, and in Europe as an adjunctive treatment of PGTC seizures in adult and adolescent patients from 12 years of age with idiopathic generalized epilepsy.

Fycompa is approved in Japan indicated as an adjunctive therapy for partial-onset seizures (including secondarily generalized seizures) or tonic-clonic seizures in patients with epilepsy showing inadequate response to other AEDs.

Furthermore, Eisai is conducting Phase II studies in Europe and the United States for partial-onset epilepsy in pediatric patients.

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

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

[2] Shorvon S, Tomson T. “Sudden unexpected death in epilepsy.” *Lancet*, 2011; 378:2028-2038

3 “The Epilepsies and Seizures: Hope Through Research. What are the epilepsies?” National Institute of Neurological Disorders and Stroke, accessed June 15, 2016, http://www.ninds.nih.gov/disorders/epilepsy/detail_epilepsy.htm#230253109