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Eisai receives FDA approval for antiepileptic drug

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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.

Eisai Co., Ltd. has announced 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.