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Eisai Co., Ltd.

EUROPEAN COMMISSION APPROVES INDICATION EXPANSION OF EISAI'S ANTIEPILEPTIC AGENT FYCOMPA® FOR ADJUNCTIVE TREATMENT OF PRIMARY GENERALIZED TONIC-CLONIC SEIZURES

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that its U.K. subsidiary Eisai Europe Ltd. has received approval from the European Commission (EC) for an indication expansion regarding the use of its in-house developed antiepileptic agent Fycompa® (perampanel hydrate) for the adjunctive treatment of primary generalized tonic-clonic (PGTC) seizures in adult and adolescent patients from 12 years of age with idiopathic generalized epilepsy.

PGTC seizures are one of the most severe forms of generalized seizures, accounting for approximately

was 64.2%, which was a statistically significant improvement over th
(p=0.0019). Additionally, a reduction in PGTC seizure frequency of
group, which was statistically significant when compared to a reduc
Furthermore, 30.9% of patients treated with Fycompa were free o
during the 13 week maintenance period. The most common
respectively, dizziness, fatigue, headache, somnolence and irritabili

Fycompa was launched in Europe as an adjunctive treatment for
secondarily generalized seizures) in adult and adolescent patients
September 2012. Through this indication expansion, Fycompa
treatment for primary, in addition to, secondarily generalized
tonic-clonic seizures can cause significant injury to patients from fa
important risk factor associated with sudden unexpected death in

[3] making them one

the most severe forms of epileptic seizures.

Epilepsy affects nearly 6 million people in Europe. As approximately 30% of patients with epilepsy are unable to control their seizures with currently available AEDs,[4] this is a disease with significant unmet medical needs. 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 hydrate)

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.

The agent is currently approved in more than 45 countries and territories, including Europe and the United States, as an adjunctive treatment (once-daily oral dose) of partial-onset seizures (with or without secondarily generalized seizures) in adult and adolescent patients from 12 years of age with epilepsy, and has been launched in over 25 countries.

Applications seeking an additional indication for the adjunctive treatment of primary generalized tonic-clonic (PGTC) seizures in adult and adolescent patients from 12 years of age with generalized epilepsy were filed with regulatory authorities in Europe and the United States in August 2014. Approval for the United States was received on June 19, 2015, and now approval for Europe has been received as well.

Adverse events:	The most common adverse events