U.S. FDA APPROVES EISAI'S ANTIEPILEPTIC AGENT FYCOMPA® AS ADJUNCTIVE TREATMENT FOR PRIMARY GENERALIZED TONIC-CLONIC SEIZURES

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that its U.S. subsidiary Eisai Inc. has received approval from the U.S. Food and Drug Administration (FDA) for an indication expansion regarding the use of its in-house developed antiepileptic agent Fycompa® (perampanel hydrate) as an adjunctive treatment of primary generalized tonic-clonic (PGTC) seizures in patients with epilepsy 12 years of age and older.

The FDA's decision to approve the indication expansion was based on a placebo-controlled clinical phase III study (Study 332) of Fycompa in 164 patients aged 12 years and older with PGTC seizures. In the study, a statistically significant reduction in PGTC seizure frequency was observed in the Fycompa group compared with placebo (Fycompa: -76.5%, placebo: -38.4%, $p<0.0001$). Additionally, the responder rate for Fycompa was 64.2%, which was a statistically significant improvement over the responder rate for placebo of 39.5% ($p=0.0019$). Furthermore, 30.9% of patients treated with Fycompa were free of PGTC seizures (12.3% for placebo) during the 13 week maintenance period. The most common adverse events for Fycompa were dizziness, fatigue, headache, somnolence and irritability.

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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 primarily 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 as an adjunctive treatment (once-daily oral dose) of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy 12 years of age and older, and has been launched in over 25 countries.

Applications seeking an additional indication for the adjuncti

3. About Generalized Tonic-Clonic Seizures

Epilepsy affects approximately 2.9 million people in the United States, 2.4 million people in Europe (G5: United Kingdom, France, Germany, Italy and Spain), 1 million people in Japan, and more than 50 million people worldwide. Generalized tonic-clonic seizures can cause significant injury to patients from falling down suddenly and is the most important risk factor associated with sudden unexpected death in epilepsy (SUDEP) [1], making them one of the most severe forms of epileptic seizures.

For the majority of patients, a generalized tonic-clonic seizure begins with a loss of consciousness without any prior warning symptoms and a sudden contraction of the tonic muscles, causing the patient to fall down (tonic phase). This is followed by violent convulsions (clonic phase) until the muscles finally relax, and the patient is left with a disturbance of consciousness. As this is a serious event, it is seen as a major hindrance on daily life. While the seizure generally only lasts a few minutes, the patient will often feel confused, groggy or drowsy for a short period of time before returning to normal.