News Release

**[Notes to editors]**

1. **Product Outline**
    1) Product name
    Fycompa® Tablets 2 mg, Fycompa® Tablets 4 mg
    2) Generic name
    Perampanel hydrate
    3) Indication for use
    Adjunctive therapy for the types of seizures below in patients with epilepsy showing inadequate response to other antiepileptic drugs (AEDs)
        Partial-onset seizures (including secondarily generalized seizures)
        Primary generalized tonic-clonic seizures
    4) Dosage and administration
    The usual dose for adults and children 12 years of age or older is initially 2 mg once daily as perampanel at bedtime, and the daily dose may then be increased by 2 mg at intervals of 1 week or longer.

## 2. About Fycompa

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.

The agent is currently approved in more than 45 countries and territories, including Europe and the United States, 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 Europe and the United States 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 groups respectively and 5.7% for placebo) and somnolence (15.9%, 17.7%, 17.8% in the perampanel 4 mg, 8 mg, 12 mg groups respectively and 13.1% for placebo).

## 4. About Study 332[2]

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| Study title: | A Multicenter, Double-blind, Randomized, Placebo-controlled, Parallel-group Study to Evaluate the Efficacy and Safety of Adjunctive Perampanel in Refractory PGTC Seizures |
| Study population: | 164 patients aged 12 years and older with PGTC seizures receiving one to a maximum of three anti-epileptic drugs |
| Treatment administered: | (Placebo- |

## 6. About Epilepsy

Epilepsy affects approximately 1 million people in Japan, 2.9 million people in the United States, 6 million people in Europe, and approximately 60 million people worldwide. As approximately 30% of patients with epilepsy are unable to control their seizures with currently available AEDs,[5] this is a disease with significant unmet medical needs.

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 sometimes 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.

Accounting for approximately 60% of generalized epilepsy and approximately 20% of all epilepsy cases,[3] generalized tonic-clonic seizures are one of the most common and most severe forms of epileptic seizures as they can cause significant injury to patients from falling down suddenly, and the frequency of these seizures is the most important risk factor associated with sudden unexpected death in epilepsy (SUDEP).[4]

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.

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[1] Nishida T, et al. “A randomized double-blind, placebo-controlled study to evaluate the efficacy and safety of perampanel as adjunctive therapy in patients with refractory partial-onset seizures from the Asia-Pacific region.” Abstract. *69th American Epilepsy Society (AES) Annual Meeting*, 2015; 3.256

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