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Eisai Co., Ltd.

ANTIEPILEPTIC DRUG FYCOMPA® INJECTION FORMULATION LAUNCHED IN JAPAN

ADDRESSING MEDICAL NEEDS FOR PATIENTS WHO CANNOT TAKE THE MEDICATION ORALLY

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that the injection formulation of its in-house discovered antiepileptic drug (AED) Fycompa® (perampanel hydrate) for intravenous (IV) infusion has been launched in Japan. The injection formulation of Fycompa received manufacturing and marketing approval on January 18, 2024 and was included in the Japan's National Health Insurance (NHI) Drug Price List today.

Fycompa is a first-in-class AED discovered at Eisai's Tsukuba Research Laboratories. The agent is a selective, noncompetitive AMPA receptor antagonist that is postulated to reduce neuronal hyper-excitation associated with seizures by targeting glutamate activity at AMPA receptors on postsynaptic membranes. Two oral formulations of Fycompa are available in Japan: a tablet and a fine granule formulation. Due to concern about the risks of seizures associated with interruption of administration when the drug cannot be taken orally temporarily, such as during surgery, it is suggested that epilepsy patients should continue treatment via routes other than oral administration.
Since Fycompa is the only AMPA receptor antagonist-based AED, Eisai developed this injection formulation to meet the needs of patients who are unable to use oral administration, and leading to the launch today.

Eisai considers neurology, including epilepsy, a therapeutic area of focus. As a *human health care* company, Eisai pursues its mission to provide "seizure freedom" to a greater number of patients with epilepsy. Eisai remains committed to further addressing the diverse needs of, and increasing the benefits provided to, patients with epilepsy and their families.

Media Inquiries:
Public Relations Department,
Eisai Co., Ltd.
+81-(0)3-3817-5120

[Notes to editors]

1. Product Outline in Japan

Product name: Fycompa® Intravenous Infusion 2 mg

Generic name: Perampanel hydrate

Indication for use: Alternative therapy to oral perampanel for treatment of the following patients where the drug cannot be taken orally temporarily

- Partial-onset seizures (including secondarily generalized seizures)
- Adjunctive therapy with antiepileptic drugs for tonic-clonic seizures below in patients with epilepsy showing inadequate response to other antiepileptic drugs

Dosage and administration:

When switching from oral perampanel:

<For use in the treatment of partial-onset seizures (including secondarily generalized seizures)>

［**Monotherapy**］［**Adjunctive therapy**］

The usual dose for adults and children ≥4 years old is the same as the oral dose of perampanel, administered intravenously over 30 minutes once daily.

The administration for children ≥ 4 and <12 years old should be 90 minutes.

<For use in the treatment of tonic-clonic seizures>

［**Adjunctive therapy**］

The usual dose for adults and children ≥12 years old is the same as the oral dose of perampanel, administered intravenously over 30 minutes once daily.

When administered prior to oral perampanel:

<For use in the treatment of partial-onset seizures (including secondarily generalized seizures)>

［**Monotherapy**］

The usual starting dose for adults and children ≥4 years old is 2 mg of perampanel once daily, which may then be increased by 2 mg at intervals of 2 weeks or longer, with a maintenance dose of 4-8 mg once daily, administered intravenously over 30 minutes.

The administration for children ≥ 4 and <12 years old should be 90 minutes.

［**Adjunctive therapy**］

The usual starting dose for adults and children ≥12 years old is 2 mg of perampanel once daily, which may then be increased by 2 mg at intervals of 1 week or longer, with a maintenance dose of 4-8 mg once daily without concomitant use of antiepileptic drugs that accelerate metabolism of the drug, or 8-12 mg once daily with concomitant antiepileptic drug that accelerate metabolism of the drug, administered intravenously over 30 minutes.

The usual starting dose or children ≥ 4 and <12 years old is 2 mg of perampanel once daily, which may then be increased by 2 mg at intervals of 2 weeks or longer, with a maintenance dose of 4-8 mg once daily without concomitant use of antiepileptic drugs that accelerate metabolism of the drug, or 8-12 mg once daily with concomitant antiepileptic drug that accelerate metabolism of the drug, administered intravenously over 90 minutes.

<For use in the treatment of tonic-clonic seizures>

［**Adjunctive therapy**］

The usual starting dose for adults and children ≥12 years old is 2 mg of perampanel once daily, which may then be increased by 2 mg at intervals of 1 week or longer, with a maintenance dose of 8 mg once daily without concomitant use of antiepileptic drugs that accelerate metabolism of the drug, or 8-12 mg once daily

with concomitant antiepileptic drug that accelerate metabolism of the drug, administered intravenously over 30 minutes.

When switching from oral perampanel to intravenous and when administered prior to oral perampanel, the maximum daily dosage and the method of dosage increase or decrease should be as follows

<For use in the treatment of partial-onset seizures (including secondarily generalized seizures)>

［**Monotherapy**］

For adults and children ≥4 years old, dosage may be increased or decreased as necessary by 2 mg or less at intervals of 2 weeks or longer, but the maximum daily dose should not be over 8 mg.

［**Adjunctive therapy**］

For adults and children ≥12 years old, dosage may be increased or decreased as necessary by 2 mg or less at intervals of 1 weeks or longer, but the maximum daily dose should not be over 12 mg.

For children ≥ 4 and <12 years old, dosage may be increased or decreased as necessary by 2 mg or less at intervals of 2 weeks or longer, but the maximum daily dose should not be over 12 mg.

<For use in the treatment of tonic-clonic seizures>

［**Adjunctive therapy**］

For adults and children ≥12 years old, dosage may be increased or decreased as necessary by 2 mg or less at intervals of 1 weeks or longer, but the maximum daily dose should not be over 12 mg.

National Health Insurance (NHI) Drug Price: Fycompa Intravenous Infusion 2 mg　1,962 JPY per vial
Packaging: Fycompa Intravenous Infusion 2 mg　6 Vials

2. About Fycompa (generic name: perampanel hydrate)

Fycompa is a first-in-class anti-epileptic agent (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 AMPA receptors on postsynaptic membranes. Fycompa is currently approved in more than 75 countries and territories, including Japan, China, and other countries in Europe and in Asia as an adjunctive treatment for partial-onset seizures (with or without secondarily generalized seizures) in patients with epilepsy 12 years of age and older. In addition, Fycompa has been approved in more than 70 countries, including Japan, in Europe and in Asia for treatment as an adjunctive therapy for primary generalized tonic-clonic seizures in patients with epilepsy 12 years of age and older. In Japan and China, Fycompa is approved 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. In Europe, the approved age range is 4 years of age and older for the adjunctive treatment of partial-onset seizures (with or without secondarily generalized seizures) and 7 years of age and older for the treatment as an adjunctive therapy for primary generalized tonic-clonic seizure. A tablet, fine granule formulation and injection formulation have been approved in Japan. An oral suspension formulation and tablet have been approved in Europe and China. In January 2023, the commercial rights in the United States were transferred to Catalyst Pharmaceuticals, Inc.

3. About Epilepsy

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 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.

Epilepsy affects approximately 1 million people in Japan, 6 million people in Europe, 9 million people in China, and approximately 60 million people worldwide. As 30-40% of patients with epilepsy are unable to control their seizures with currently available AEDs,* this is a disease with significant unmet medical needs. Although onset occurs at any age, onset is most common in people aged 18 and younger and the elderly. As causes and clinical symptoms of pediatric epilepsy are not uniform, and prognoses can range from very positive cases to obstinate cases, special consideration for each patient is required of treatments.

*"The Epilepsies and Seizures: Hope Through Research. What are the epilepsies?" National Institute of Neurological Disorders and Stroke, accessed September 2018, https://catalog.ninds.nih.gov/sites/default/files/publications/epilepsies-seizures-hope-through-research.pdf