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Eisai Co., Ltd.

NEW FINE GRANULE FORMULATION OF ANTI-EPILEPTIC DRUG FYCOMPA® LAUNCHED IN JAPAN

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that it has launched a new fine granule formulation of its in-house-discovered antiepileptic drug (AED) Fycompa® (perampanel hydrate) in Japan on July 6, 2020. Eisai received marketing and manufacturing approval for this formulation on January 23, 2020, and the fine granule formulation was added to Japan's National Health Insurance drug price list on April 23 of the same year.

In Japan, it is estimated that there are approximately 1 million patients with epilepsy. While epilepsy is a disease that may occur regardless of age, it is said that incidence is particularly high in children and the elderly. This newly launched fine granule formula was developed so that even patients who have difficulty taking tablets such as children or those who have difficulties in taking tablets due to reduced swallowing ability may take this drug. Additionally, greater ability to adjust dosage to match patients' symptoms becomes possible.

Fycompa is a first-in-class AED discovered at Eisai's Tsukuba Research Laboratories and was developed in-house. It is a highly selective, noncompetitive AMPA receptor antagonist that reduces neuronal hyperexcitation associated with seizures by targeting glutamate activity at postsynaptic AMPA receptors. In Japan, Fycompa is currently 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, as well as adjunctive treatment for primary generalized tonic-clonic seizures in patients with epilepsy 12 years of age and older.

With the launch of this fine granule formulation in Japan, Eisai will continue to prioritize the provision of safety information. Furthermore, Eisai will pursue its mission of delivering "seizure freedom" to as many patients as possible, and seek 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. Product Information

1) **Product name**
   Fycompa® Fine Granules 1%
2) **Generic name**
   perampanel hydrate
3) **Indications**
   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
4) **Price**
   Fycompa Fine Granules 1%: 1,068.90 yen per 1g containing 1% (package price: 106,890 yen)
5) **Packaging**
   Bottles of 100 g
6) **Product image**

2. 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 AMPA receptors on postsynaptic membranes. Fycompa is available in drug form to be taken once daily orally at bedtime. An oral suspension formulation and tablet have been approved in the United States and Europe.

Fycompa is currently approved in more than 65 countries and territories, including Japan, the United States, China, and other countries in Europe and in Asia as 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 60 countries, including the United States, 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 the United States, 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, an application has been submitted seeking the additional approval of Fycompa for adjunctive use in the treatment of partial-onset seizures (with or without secondarily generalized seizures) or primarily generalized tonic-clonic seizures in pediatric patients with epilepsy. To date, Fycompa has been used to treat more than 300,000 patients worldwide across all indications.

Eisai is conducting a global Phase III clinical study (Study 338) for the agent in patients with seizures associated with Lennox-Gastaut syndrome. In addition, Eisai is conducting development of an injection formulation.

3. About Epilepsy

Epilepsy affects approximately 1 million people in Japan, 3.4 million people in the United States, 6 million people in Europe, 9 million people in China, and approximately 60 million people worldwide. As approximately 30% of patients with epilepsy are unable to control their seizures with currently available AEDs[1], this is a disease with significant unmet medical need.

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.

[1] "The Epilepsies and Seizures: Hope Through Research. What are the epilepsies?" National Institute of Neurological Disorders and Stroke, accessed May 24, 2016, http://www.ninds.nih.gov/disorders/epilepsy/detail_epilepsy.htm#230253109 .