No.24-07

January 18, 2024
Eisai Co., Ltd.

ANTIEPILEPTIC DRUG FYCOMPA® INJECTION FORMULATION APPROVED IN JAPAN

ADDRESSING MEDICAL NEEDS FOR TREATMENT THROUGH A NON-ORAL ADMINISTRATION ROUTE

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that it has obtained marketing authorization approval from the Japanese Ministry of Health, Labour and Welfare for the injection formulation of its in-house discovered antiepileptic drug (AED) Fycompa® (perampanel) in Japan as an alternative therapy when oral administration is temporarily not possible.

Fycompa is a first-in-class AED discovered at Eisai's Tsukuba Research Laboratories. The agent is a highly 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 filed a supplementary new drug application as a new route of administration in August 2022, leading to this approval.

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. **About perampanel (product name: Fycompa)**

Perampanel 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. Perampanel 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, perampanel 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, perampanel 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.

2. **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, 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 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