No.24-29

May 13, 2024
Eisai Co., Ltd.

ANTIEPILEPTIC DRUG FYCOMPA® APPROVED IN CHINA FOR ADJUNCTIVE TREATMENT OF PRIMARY GENERALIZED TONIC-CLONIC SEIZURES

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that it has received approval in China for the additional indication of its in-house discovered antiepileptic drug (AED) Fycompa® (generic name: perampanel hydrate) for adjunctive treatment of primary generalized tonic-clonic seizures in patients with epilepsy aged 12 years and older.

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.

In China, Fycompa was approved for the adjunctive treatment of partial-onset seizures (with or without secondarily generalized seizures) in patients with epilepsy aged 12 years and older in September 2019. Since its launch in January 2020, it has received approval in July 2021 for the additional indications for monotherapy and adjunctive use in the treatment of partial-onset seizures in patients with epilepsy aged 4 years and older, thereby expanding its contribution to epilepsy patients in China.

In China, it is estimated that there are approximately 9 million patients with epilepsy.[1] As 30%-40% of patients with epilepsy are unable to control their seizures with currently available AEDs.[2] As one of the most severe forms of epileptic seizures, primary generalized tonic-clonic seizures can cause significant injury to patients and are one of the leading risk factors associated with sudden unexpected death in epilepsy (SUDEP). Through this indication expansion, Fycompa can now be used in China as an adjunctive treatment for primary generalized tonic-clonic seizures.

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.

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[Notes to editors]

1. **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 75 countries, including Japan, China, 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.

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 50 million people worldwide.[3] As 30-40% of patients with epilepsy are unable to control their seizures with currently available AEDs,[2] 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.

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