No.17-37

July 27, 2017
Eisai Co., Ltd.

U.S. FDA APPROVES ADDITIONAL USE OF ANTIEPILEPTIC DRUG FYCOMPA® AS MONOTHERAPY FOR PARTIAL-ONSET SEIZURES

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") has announced that on July 26, 2017 (U.S. time), its U.S. subsidiary Eisai Inc. received approval from the U.S. Food and Drug Administration (FDA) for a supplemental New Drug Application (sNDA) for Eisai's antiepileptic drug (AED) Fycompa (perampanel) as monotherapy use for the treatment of partial-onset seizures (with or without secondarily generalized seizures) in patients with epilepsy 12 years of age and older.

The FDA's regulatory pathway for monotherapy use[1], which was communicated in September 2016, states that "it is acceptable to extrapolate the efficacy and safety of drugs approved as adjunctive therapy for the treatment of partial-onset seizures to their use as monotherapy for the treatment of partial-onset seizures." Fycompa is the first AED to be approved as monotherapy for partial-onset seizures in accordance with this regulatory pathway.

Fycompa is a first-in-class AED discovered at Eisai's Tsukuba Research Laboratories. It is a highly selective, noncompetitive AMPA receptor antagonist that reduces neuronal hyperexcitation associated with seizures by targeting glutamate activity at postsynaptic AMPA receptors. It was originally approved in the United States as an adjunctive therapy for the treatment of partial-onset seizures (with or without secondarily generalized seizures) and primary generalized tonic-clonic seizures in patients with epilepsy 12 years of age and older. With the approval of monotherapy for partial-onset seizures, Fycompa can now be prescribed to all patients with partial-onset seizures 12 years of age and older in the United States.

Epilepsy affects approximately 2.9 million people in the United States. Epilepsy is broadly categorized by seizure type, with partial-onset seizures accounting for approximately 60% of epilepsy cases.[2] Eisai considers neurology a therapeutic area of focus, and through the provision of new treatment options such as Fycompa monotherapy for partial-onset seizures in the United States, seeks to further contribute to addressing 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. About Fycompa (perampanel)

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 to be taken once daily orally at bedtime. In addition, a new oral suspension formulation has been approved and is being marketed in the United States.

Fycompa is currently approved in more than 55 countries and territories, including Japan, the United States, and in Europe 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 45 countries, including Japan, the United States, and in Europe as an adjunctive therapy for primary generalized tonic-clonic (PGTC) seizures in patients with epilepsy 12 years of age and older.

Based on the new additional use approval, Fycompa is now indicated in the United States for the treatment of partial-onset seizures (with or without secondarily generalized seizures) and the adjunctive treatment of PGTC in patients with epilepsy aged 12 and older.

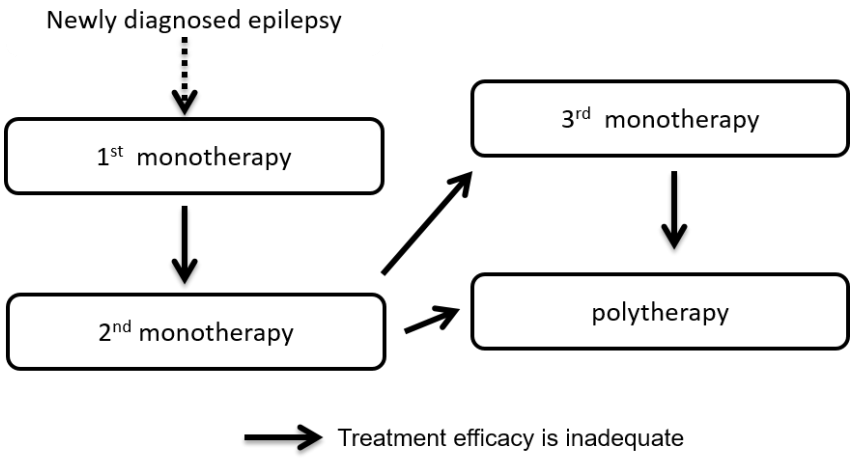
Fycompa is approved in Japan as an adjunctive therapy for partial-onset seizures (with or without secondarily generalized seizures) or PGTC seizures in patients with epilepsy showing inadequate response to other AEDs.

Furthermore, Eisai is conducting respective global Phase III studies for the agent in pediatric patients with partial-onset seizures or PGTC seizures and in patients with seizures associated with Lennox-Gastaut syndrome. Additionally, a Phase III study as monotherapy for partial-onset seizures is being conducted in Japan.

For further information on Fycompa in the United States, including Important Safety Information, please visit the Fycompa product website (https://fycompa.com).

2. About Epilepsy Treatment

The goal of epilepsy treatment is to be seizure free. When diagnosed with epilepsy, patients undergo monotherapy treatment with antiepileptic drugs. In cases where the treatment's efficacy on seizure control is inadequate, the initial treatment can typically be replaced with a different monotherapy or combination therapy.



1 FDA Communication. Reference ID: 3985169. September 13, 2016.

2 Hauser WA, et al. *Epilepsia*, 34(3):453-468,1993