

EISAI SUBMITS SUPPLEMENTAL APPLICATION FOR PARTIAL LABEL CHANGE FOR ANTIEPILEPTIC DRUG FYCOMPA® AS MONOTHERAPY FOR TREATMENT OF PARTIAL-ONSET SEIZURES BASED ON NEW U.S. FDA POLICY

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that its U.S. subsidiary Eisai Inc. has submitted a supplemental application for its in-house-discovered antiepileptic drug (AED) Fycompa (perampanel) proposing the inclusion in labelling of a description of use as monotherapy for the treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy 12 years of age and older to the U.S Food and Drug Administration (FDA) based on new FDA policy.

The FDA policy has determined that it is acceptable to extrapolate safety and efficacy of AEDs approved as an adjunctive therapy for the treatment of partial-onset seizures to their use as monotherapy for the treatment of partial-onset seizures. Based on the policy, Eisai Inc. has submitted a supplemental application for monotherapy labelling for Fycompa which includes pharmacokinetic information supporting proposed doses to be used in monotherapy.

According to the policy, usage of an AED as monotherapy applies to both adult and pediatric populations where the AED has been previously established as adjunctive therapy for the treatment of partial-onset seizures in the respective age range. Furthermore, this extrapolation applies to partial-onset seizures only, and not to other forms of epilepsy.

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 is 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.

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.¹

Eisai considers neurology a therapeutic area of focus, and strives to maximize the value of Fycompa to further contribute to addressing the diverse needs of, as well as 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 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, Fycompa is now available in the United States in an oral suspension formulation.

The agent is currently approved in more than 45 countries and territories, including Japan, the United States and in Europe as an adjunctive treatment of partial-onset seizures (with or without secondarily generalized seizures) in adult and adolescent patients with epilepsy 12 years of age and older.

In addition, Fycompa has been approved in more than 35 countries, including Japan, the United States and in Europe for the adjunctive therapy of primary generalized tonic-clonic (PGTC) seizures in patients with epilepsy 12 years of age and older. More specifically, Eisai has obtained approval for the agent indicated in the United States as an adjunctive treatment of PGTC seizures in patients with epilepsy 12 years of age and older, and in Europe as an adjunctive treatment of PGTC seizures in adult and adolescent patients from 12 years of age with idiopathic generalized epilepsy.

Fycompa is approved in Japan indicated as an adjunctive therapy for partial-onset seizures (including secondarily generalized seizures) or tonic-clonic seizures in patients with epilepsy showing inadequate response to other AEDs. Furthermore, Eisai is conducting Phase II studies in Europe and the United States for partial-onset epilepsy in pediatric patients.

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

¹ Hauser WA, et al. *Epilepsia*, 34(3):453-468,1993