

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that its U.S. subsidiary Eisai Inc. has received approval from the U.S. Food and Drug Administration (FDA) for the AMPA receptor antagonist Fycompa<sup>TM</sup> (perampanel) as an adjunctive treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy age 12 years and older.

Discovered and developed by Eisai, Fycompa is a non-competitive AMPA-type glutamate receptor antagonist. As an AMPA receptor antagonist, Fycompa reduces neuronal hyperexcitation associated with seizures by inhibiting glutamate activity at post-synaptic AMPA receptors. This is the first antiepileptic agent approved by the U.S. FDA to work in this manner.

The approval decision was based primarily on clinical data from three pivotal Phase III, global, randomized, double-blind, placebo-controlled, dose-escalation studies that examined 1,480 patients with partial-onset seizures. These studies demonstrated that Fycompa, as an adjunctive therapy, significantly reduced seizure frequency in patients with partial-onset seizures with or without secondary generalized seizures. The most commonly reported adverse events were dizziness, somnolence, fatigue, irritability, falls, nausea, ataxia, balance disorder, gait disturbance, vertigo and weight gain. Serious or life-threatening psychiatric (mental) problems were al

There are an estimated 2.2 million people living with epilepsy in the United States,

and more than 50

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million people living with epilepsy worldwide. Eisai defines epilepsy as a therapeutic area of focus, with its currently marketed U.S. epilepsy portfolio comprising Zonegran<sup>®</sup> (under license from the originator, Dainippon Sumitomo Pharma Co., Ltd.) as an adjunctive treatment for adult epilepsy patients with partial-onset seizures, and Banzel<sup>®</sup> (under license from the originator, Novartis AG) for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome, a severe form of early childhood-onset epilepsy. By providing multiple treatment options as part of an abundant product portfolio in the field of antiepileptic drugs, Eisai seeks to make further

## [Notes to editors]

## 1. About epilepsy

Epilepsy is a medical condition that produces seizures, affecting a variety of mental and physical functions. A

## Falls

Taking Fycompa may increase a patient's chance of falling. These falls can cause serious injuries. A patient's risk of falling may be higher if they are elderly.

Withdrawal of AEDs

license from the originator Dainippon Sumitomo Pharma Co., Ltd. and marketed in Europe, the United States and Asia) and Zebinix<sup>®</sup> (voltage-dependent sodium channel-blocking antiepileptic agent under license from the