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FDA approves Eisai's Fycompa

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Singapore:Ã?Â Eisai announced that its U.S. subsidiary has received approval from the U.S. Food and Drug Administration (FDA) for the AMPA receptor antagonist FycompaÃ?Â® (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 also seen more frequently in patients treated with Fycompa. These reactions are described in the boxed warning bolded below.

The FDA has recommended that Fycompa be classified by the U.S. Drug Enforcement Administration (DEA) as a scheduled drug under the country's Controlled Substances Act. Once the DEA has provided the final scheduling designation, Eisai will

announce when Fycompa will be available to patients and physicians in the United States.

There are an estimated 2.2 million people living with epilepsy in the United States, and more than 50 million people living with epilepsy worldwide. Eisai defines epilepsy as a therapeutic area of focus, with its currently marketed U.S. epilepsy portfolio comprising ZonegranÃ?Â® (under license from the originator, Dainippon Sumitomo Pharma Co., Ltd.) as an adjunctive treatment for adult epilepsy patients with partial-onset seizures, and BanzelÃ?Â® (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 contributions to address the diversified needs of, and increase the benefits provided to, epilepsy patients and their families.