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Eisai gets approval of anti-epileptic drug in Japan

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Japanese firm Eisai Co., Ltd. has obtained the approvals of supplementary new drug applications in Japan for its in-house developed antiepileptic drug (AED) Fycompa (perampanel) for an additional indication for monotherapy of partial-onset seizures and an additional indication for partial-onset seizures in pediatric patients aged 4 years and older, as well as a new fine granule formulation.

The approval for monotherapy for partial-onset seizures is based on the results of a Phase III clinical study(FREEDOM/Study 342) conducted in Japan and South Korea. The outcome achieved the primary endpoint, with the rate of complete seizures-free exceeding the initially established efficacy criteria in monotherapy for untreated epilepsy patients aged 12 to 74 years with partial-onset seizures.

The additional approval covering partial-onset seizures in pediatric epileptic patients 4 years of age and older is based on the results of a Phase III clinical study (Study 311) of Fycompa, as adjunctive therapy in pediatric patients, conducted in Japan, the United States and Europe. This study showed that the safety and efficacy of Fycompa combination therapy in pediatric epilepsy patients with poorly controlled partial seizures (ages 4 to less than 12 years) were similar to those in patients aged 12 years and older.

The additional approval for the fine granule formulation is based on the results of a bioequivalence study of fine granules and tablets conducted in Japan. Eisai developed this formulation to make it easier to administer Fycompa to children and patients who have difficulty taking tablets. The study confirmed the bioequivalence of fine granules and tablets.

Fycompa is a first-in-class AED and a once-daily oral drug discovered at Eisai's Tsukuba Research Laboratories. 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 has been approved in many countries around the worldwide as an adjunctive treatment for partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy 12 years of age and older and as an adjunctive

treatment for primary generalized tonic-clonic seizures in patients with epilepsy 12 years of age and older. In the United States, Fycompa is also indicated 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.