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Eisai receives positive opinion on epilepsy treatments in Europe

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Eisai's UK subsidiary, Eisai Europe, has received a positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) for the use of Fycompa (perampanel) for the adjunctive treatment of partial-onset seizures, with or without secondarily generalized seizures, in patients with epilepsy aged 12 years and older.

Perampanel, a novel chemical entity discovered and in development by Eisai, is a highly selective, non-competitive AMPA-type glutamate receptor antagonist. If approved, perampanel will be the first

product in this new class of anti-epileptic drugs to gain regulatory approval.

The CHMP based its decision on clinical data from 3 pivotal phase III, global, randomized, double-blind, placebo-controlled, dose-escalation studies in 1,480 epilepsy patients. Each of the studies showed consistency with the preferable results in seizure control as adjunctive therapy across all partial onset seizure types, including secondary generalization. The most commonly reported adverse events were dizziness, headache, somnolence, irritability, fatigue, falls, and ataxia.

According to the CHMP positive opinion, perampanel is expected to contribute to epilepsy patients who are aged 12 years or older. Additionally, perampanel delivers the benefit of once-daily dosing, thereby facilitating adherence to treatment. Based on CHMP's recommendation, EU approval of the new therapy is anticipated within three months.

Eisai defines epilepsy as a therapeutic area of focus, and seeks to address the diversified needs of epilepsy patients and their families by providing them with multiple treatment options as part of its abundant epilepsy franchise product portfolio.

Eisai Europe has also received a positive opinion from the CHMP for extending the use of once-daily Zonegran (zonisamide) as monotherapy for the treatment of partial seizures (with or without secondary generalization) in adults with newly diagnosed epilepsy.

Zonegran, originally discovered by Dainippon Sumitomo Pharma (formerly Dainippon Pharmaceutical), was approved in Europe in March 2005 as an adjunctive therapy for the treatment of partial seizures (with or without secondary generalization) in adults with epilepsy, and marketed by Eisai' subsidiaries in Europe.

The CHMP based its decision on clinical data from a double blind, randomized, multi-center study designed to compare once-daily Zonegran with twice-daily controlled release carbamazepine as
monotherapy in 583 adults with newly diagnosed partial-onset epilepsy. The study's primary endpoint was the proportion of seizure-free patients at six months. The results of the study showed that Zonegran was effective and well tolerated in newly diagnosed epilepsy patients when used as monotherapy. The
statistical comparison between Zonegran and carbamazepine met the criterion of non-inferiority as
recommended by treatment guidelines set out by the International League Against Epilepsy.