

FDA approves FYCOMPA for partial-onset seizures

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Singapore: The US FDA has approved Eisai's FYCOMPA (perampanel) as an adjunctive treatment for partial-onset seizures with or without secondarily generalized seizures in patients aged 12 and older who have epilepsy. FYCOMPA is the first FDA-approved non-competitive AMPA glutamate receptor antagonist.

"The FDA approval of FYCOMPA is an important development for the treatment of patients who continue to have seizures despite being on other prescription medications for epilepsy," said Dr Lonnel Coats, president and CEO, Eisai. "As a non-competitive AMPA glutamate receptor antagonist, FYCOMPA offers doctors and their patients a new approach towards seizure control."

FYCOMPA's approval was primarily based on three phase III studies, which were multi-center, randomized, double-blind, placebo-controlled, dose-escalation, parallel group studies to evaluate the efficacy and safety of perampanel compared to placebo given as adjunctive therapy in patients aged 12 and older with partial-onset seizures. The studies demonstrated that FYCOMPA significantly reduced seizure frequency in patients with partial-onset seizures with or without secondarily generalized seizures.

FDA has recommended that FYCOMPA be classified by the US drug enforcement administration (DEA) as a scheduled drug. The DEA will review the FDA's recommendation and determine the final scheduling designation. Once the DEA has provided the final scheduling designation, Eisai will announce when FYCOMPA will be available to patients and physicians in the US.