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Eisai Co., Ltd.

EISAI PRESENTS RESULTS FROM PHASE III TRIAL OF ANTIEPILEPTIC DRUG FYCOMPA® AS ADJUNCTIVE THERAPY FOR PRIMARY GENERALIZED TONIC-CLONIC SEIZURES AT 68TH AMERICAN EPILEPSY SOCIETY ANNUAL MEETING

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that it has presented the results from a Phase III clinical study (Study 332) of its in-house developed antiepileptic drug (AED) Fycompa® (perampanel) in patients with primary generalized tonic-clonic (PGTC) seizures, one of the most severe forms of generalized seizures. The data was presented at the 68th American Epilepsy Society (AES) Annual Meeting held from December 5 to 9 in Seattle, Washington in the United States (Abstract No.: 2389). Furthermore, this presentation was selected by the AES for its official program, and was highlighted at a press conference on Sunday, December 7.

Study 332 was a double-blind, randomized, placebo-controlled, multicenter, parallel-group study to evaluate the efficacy and safety of adjunctive Fycompa therapy in 164 patients aged 12 years and older with uncontrolled PGTC seizures. In this study, eligible patients receiving one to a maximum of three AEDs were randomized to receive Fycompa or placebo in a 1:1 ratio.

The primary endpoints of the study were change in PGTC seizure frequency (percent change from Baseline in PGTC seizure frequency per 28 days) and responder rate (percentage of patients who experienced a 50% or greater reduction in PGTC seizure frequency).* A reduction in PGTC seizure frequency of 76.5% was observed in the Fycompa group, which was statistically significant when compared to a reduction of 38.4% for placebo ($p<0.0001$). Additionally, the responder rate for Fycompa was 64.2%, which was a statistically significant improvement over the responder rate for placebo of 39.5% ($p=0.0019$).
In addition, in this study which enrolled patients who had been unable to adequately control PGTC seizures with existing AEDs, 30.9% of patients treated with Fycompa were free of PGTC seizures (12.3% for placebo) during the 13 week Maintenance period.

Furthermore, the most common adverse events (>10% in the Fycompa arm and greater than placebo) for Fycompa and placebo were, respectively, dizziness (32.1% vs 6.1%), fatigue (14.8% vs 6.1%), headache (12.3% vs 9.8%), somnolence (11.1% vs 3.7%) and irritability (11.1% vs 2.4%).

Fycompa is a first-in-class AED discovered and developed by Eisai. With epileptic seizures being primarily mediated by the neurotransmitter glutamate, the agent is a highly selective, noncompetitive AMPA receptor antagonist that reduces neuronal hyperexcitation associated with seizures by targeting glutamate activity at postsynaptic AMPA receptors. Fycompa is approved in more than 40 countries primarily in Europe and North America as an adjunctive treatment for partial-onset seizures (with or without secondary generalized seizures) in patients with epilepsy aged 12 years and older, and has been launched in 15 countries around the world.

Also, applications seeking an additional indication for the adjunctive treatment of PGTC seizures in patients with epilepsy aged 12 years and older based on the results of this study were filed with regulatory authorities in Europe and the United States in August 2014.