EISAI SUBMITS APPLICATIONS FOR ANTIEPILEPSY AGENT FYCOMPA® SIMULTANEOUSLY IN EUROPE AND U.S. SEEKING INDICATION EXPANSION AS ADJUNCTIVE TREATMENT OF PRIMARY GENERALIZED TONIC-CLONIC SEIZURES

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, “Eisai”) announced today that it has submitted applications to regulatory authorities in the U.S. and Europe (the FDA and EMA respectively) for the indication expansion of its in-house developed antiepileptic drug Fycompa® (generic name: perampanel) as an adjunctive treatment of primary generalized tonic-clonic seizures (PGTC).

PGTC is one of the most severe forms of generalized seizures, accounting for approximately 60% of generalized epilepsy and approximately 20% of all epilepsy cases.[1] This application was based on a double-blind, randomized, placebo-controlled, multicenter, parallel-group clinical study (Study 332) to evaluate the efficacy and safety of adjunctive Fy

[Notes to editors]

1. About Fycompa® (perampanel)

Fycompa, a novel chemical entity discovered and developed by Eisai, is a noncompetitive AMPA-type glutamate receptor antagonist. Fycompa is an AED that reduces neuronal hyperexcitation associated with seizures by targeting glutamate activity at postsynaptic AMPA receptors. The agent is currently approved in more than 35 countries and territories, including Europe and the U.S., as a treatment (once-daily oral dose) of partial-onset seizures and is also being evaluated in a Phase III study in Asia, including Japan. Furthermore, Eisai is conducting Phase II studies in Europe and the U.S. for partial-onset epilepsy in pediatric patients, as it seeks to expand the drug's range of approved indications.

2. About Study 332

Study population:	164 patients aged 12 years and older with PGTC seizures receiving one to a maximum of three anti-epileptic drugs
Primary objective:	To demonstrate the efficacy of adjunctive perampanel therapy, compared to placebo on PGTC seizures