U.S. FDA ACCEPTS sNDA FOR ANTIEPILEPTIC AGENT FYCOMPA® AS ADJUNCTIVE TREATMENT OF PRIMARY GENERALIZED TONIC-CLONIC SEIZURES

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, “Eisai”) announced today that the U.S. Food and Drug Administration (FDA) has accepted for review the company’s supplemental New Drug Application (sNDA) for its in-house developed antiepileptic drug Fycompa® (generic name: perampanel) for the treatment of primary generalized tonic-clonic seizures (PGTC), a severe form of seizures, in patients 12 years or older.

Acceptance of the application indicates that the FDA has found the company's submission to be sufficiently complete to review. This sNDA

[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 antiepileptic drug that reduces neuronal hyperexcitation associated with seizures by targeting glutamate activity at postsynaptic AMPA receptors. The agent is currently approved in more than 40 countries and territories, including Europe and the United States, as an adjunctive treatment (once-daily oral dose) of partial-onset seizures and is also being evaluated in a Phase III study (Study 335) in Asia, including Japan.

A Phase III study (Study 332) of the agent as an adjunctive therapy for the treatment of