EISAI RECEIVES POSITIVE CHMP OPINION ON INDICATION EXPANSION FOR ANTIEPILEPTIC AGENT FYCOMPA® (PERAMPANEL) AS ADJUNCTIVE TREATMENT OF PRIMARY GENERALIZED TONIC-CLONIC SEIZURES

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, “Eisai”) announced today that its U.K. subsidiary Eisai Europe Ltd. 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 primary generalized tonic-clonic (PGTC) seizures in adult and adolescent patients from 12 years of age with idiopathic generalized epilepsy.

PGTC seizures are one of the most common and most severe forms of generalized seizures, accounting for approximately 60% of generalized epilepsy and approximately 20% of all epilepsy cases.[1] The CHMP based its opinion on a multicenter, double-blind, randomized, placebo-controlled, parallel-group study (Study 332) to evaluate the efficacy and safety of adjunctive Fycompa therapy in 164 patients aged 12 years and older with PGTC seizures52th PGTin the Fycompa group, which was statistically

on of 38.4% for placebo (p<0.0001). Furthermore, 30.9% of
e of PGTC seizures (12.3% for placebo) during the 13 week
adverse events for Fycompa and placebo were, respectively,
and irritability.

red and developed by Eisai. The agent is a highly selective,
that reduces neuronal hyperexcitation associated with seizures
ptic AMPA receptors.

le in Europe (G5). Fycompa was launched in Europe as an
ures (with or without secondary generalized seizures) in patients
in September 2012. Currently the agent is approved for this
een launched in over 25 countries.

area of focus and by providing multiple treatment options in
sive epilepsy product portfolio, Eisai seeks to make continued
s of, as well

[Notes to editors]

1. About Fycompa (perampanel)

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.

The agent is currently approved in more than 45 countries and territories, including Europe and the United States, as an adjunctive treatment (once-daily oral dose) of partial-onset seizures and has been launched in over 25 countries.

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. Applications are also under review in Switzerland and Russia.

A Phase III study of Fycompa in partial-onset seizures (Study 335) conducted in Asia, including Japan, met its primary endpoint. The company plans to submit a regulatory application covering both PGTC seizures and partial-onset seizures based on St

Adverse events:	The most common adverse events (>10% in the Fycompa arm and greater than