## **IN EPILEPSY**

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that results of a Phase III study in epilepsy patients with refractory partial seizures demonstrate the clinical benefits of the novel investigational compound E2007 (generic name: perampanel). Discovered and developed by Eisai, perampanel is a first-in-class drug with a unique mechanism that selectively and non-competitively antagonizes AMPA-type glutamate receptors.

The global study (Study 306), conducted primarily in Europe and Asia, was a multi-center, randomized, double-blind, placebo-controlled, dose escalation, parallel-group study. The study consisted of 706 patients from 25 countries who were randomized to placebo or one of three perampanel doses (2 mg, 4 mg or 8 mg). Patients randomized to receive perampanel started on 2 mg doses, then remained on 2 mg or increased dosage weekly in 2 mg increments to their randomized doses of 4 mg or 8 mg.

Findings demonstrated that perampanel was effective in reducing median seizure frequency, and increasing responder rates (the percentage of patients who experienced a 50% or greater reduction in seizure frequency), the study's two primary outcome measures, with high statistical significance in 4 mg and 8 mg doses compared to placebo. A linear trend for dose response was also highly statistically significant. The most frequently observed adverse events were dizziness, somnolence and headache, and the study confirmed that perampanel was well-tolerated.

Study 306 is the first in a series of Phase III clinical trials being conducted as part of Eisai's global development program for perampanel and two more Phase III studies are currently underway. Final results of all threeist[Feeist] EMC P MCID 17 BDC BT/TTO 1 Tf0 Tc 0 Tw 10.02 0 0 10.02 65.22 263.1217 Tm() Tjl

## Notes to editors

## 1. About E2007 (Perampanel)

Discovered and developed by Eisai, perampanel (generic name) is a novel investigational agent currently under development as a potential treatment for epilepsy, neuropathic pain, multiple sclerosis and migraine prevention. The compound selectively antagonizes the AMPA receptor, a type of receptor to which the neurotransmitter glutamate binds, and by preventing the excessive influx of calcium into brain cells, it suppresses the overactivity of excitatory nerves, thereby correcting excitatory-inhibitory nerve imbalance and inhibiting neuronal cell death.

## 2. About Study 306

Global Placebo-controlled Phase III Study

Indication: Epilepsy patients with refractory partial-onset seizures

Objective: To evaluate the efficacy, safety and tolerability of three doses of perampanel (2 mg, 4 mg

and 8 mg doses) in comparison to placebo as an adjunctive treatment in epilepsy patients

with refractory partial seizures

Treatment groups: E2007 2 mg, 4 mg, 8mg, placebo

Dosing duration: 19 weeks
Conducted in: 25 countries

Primary endpoint: Percent change in seizure frequency\* per 28 days cycle in the maintenance period relative

to the pre-randomization phase

\* United States: Median seizure frequency

European Union: Responder rate (percentage of patients who experienced a 50% or

more reduction in seizure frequency)