

STATEMENT REGARDING THE GERMAN FEDERAL JOINT COMMITTEE'S DECISION ON ANTIEPILEPTIC DRUG FYCOMPA®

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that the German Federal Joint Committee (G-BA) has determined no additional benefit for its in-house developed anti-epilepsy drug (AED) Fycompa® (perampanel) when compared to conventional AEDs in its assessment for insurance reimbursement. It is deeply regrettable that the G-BA's conclusion did not appropriately assess the clinical value brought about by the innovative properties of Fycompa or the needs of patients. Eisai will continue to seek an accurate understanding of the value of Fycompa from the G-BA.

Fycompa is a first-in-class antiepileptic drug 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 was approved for 27 countries in the EU in July 2012 and has already been launched in nine countries in the region. It is approved in more than 40 countries worldwide including the United States 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.

For the G-BA's assessment, Eisai submitted data from three global pivotal Phase III studies conducted on 1,480 patients who have uncontrolled partial-onset seizures despite having been treated with other AEDs. These randomized, double-blind, placebo-controlled and dose-escalated studies showed consistent results in the efficacy and tolerability of Fycompa as an adjunctive therapy in patients with partial-

After Fycompa was launched in Germany in September 2012, Eisai temporarily suspended distribution in Germany following the previous negative G-BA ruling in March 2013 and established a patient access program for continued supply of Fycompa free of charge to German pharmacies through individual import to ensure that people with epilepsy continue to receive treatment with Fycompa. In response to a partial revision to the additional benefit assessment system, Eisai then resubmitted Fycompa to the G-BA for additional benefit reassessment in May 2014.

Eisai remains committed to seeking out an accurate understanding and assessment from the relevant

2. About Adjunctive Treatment of Epilepsy

The goal of treating patients with epilepsy is seizures-free. Once epilepsy is diagnosed, a patient usually begins monotherapy (single-agent) treatment with an antiepileptic drug. In cases where the treatment's efficacy on seizure control is inadequate, the initial treatment can typically be replaced with a different monotherapy. In approximately 30-40% of patients, however, seizure control is not achieved even after undergoing two different monotherapy treatments and in these circumstances the patient can then opt to switch to a treatment that includes an adjunctive therapy. In these cases, adjunctive therapies like Fycompa are used as an "add-on" to the patient's existing treatment. Based on these types of clinical conditions, it has become the standard for placebo to be used as the comparator "add-on" to existing treatments in clinical studies in guidelines on clinical development for the pharmaceutical approval of new refractory epilepsy treatments. Phase III clinical studies of Fycompa were conducted in accordance with such guidelines.

Study Design for Phase III Clinical Studies on Fycompa

3. About Fycompa

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 a