

## **EISAI RESUBMITS ANTIEPILEPTIC DRUG FYCOMPA® TO GERMAN FEDERAL JOINT COMMITTEE FOR ADDITIONAL BENEFIT ASSESSMENT**

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that its German sales company Eisai GmbH (Location: Frankfurt) has resubmitted its first-in-class anti-epilepsy drug (AED) Fycompa® (AMPA receptor antagonist, generic name: perampanel) to the German Federal Joint Committee (G-BA) for additional benefit assessment. The new decision is expected to be published within 6 months.

In Germany approximately 3,000 and 4,000 people with epilepsy have been treated with Fycompa since its launch in September 2012. Eisai temporarily suspended Fycompa from 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, while the G-BA considers the resubmission.

In Germany, approximately one in every 200 people has epilepsy, which equates to an estimated 400,000 people in the country who live with the condition. The successful treatment of partial-onset seizures remains a challenge as over 30% of patients do not achieve adequate seizure control despite appropriate therapy with existing AEDs, and there continues to be a pressing need for innovative new treatments. Fycompa was approved in over 35 countries in Europe, North America and Asia as an adjunctive treatment for partial-onset seizures (including secondarily generalized seizures) in patients with epilepsy aged 12 years and older.

Eisai believes that through this reassessment of additional benefit, Fycompa will be recognized appropriately for its benefits as well as being an innovative new treatment, and that sales of the drug will be resumed in Germany, ensuring delivery to patients with partial-onset seizures.

**[Please refer to the following notes for further information on Fycompa and a glossary of terms.]**

Media Inquiries:  
Public Relations Department,  
Eisai Co., Ltd.  
+81-(0)3-3817-5120

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**[Notes to editors]**

**1. About Fycompa® (Perampanel)**

Fycompa (perampanel), a novel chemical entity discovered and developed by Eisai, is a noncompetitive AMPA-type glutamate receptor antagonist. Fycompa is the first AED to reduce neuronal hyperexcitation associated with seizures by targeting glutamate activity at postsynaptic AMPA receptors and has demonstrated its antiseizure effects in Phase II and III studies. The agent is currently approved in more than 35 countries and territories, including in Europe and the United States, as a treatment (once-daily oral dose) of partial-onset seizures and is also being evaluated in a Phase III study in Asia, including in Japan. Furthermore, Eisai is conducting a global Phase III perampanel study for