EISAI RECEIVES HEALTH CANADA APPROVAL FOR ANTI-EPILEPTIC AGENT FYCOMPA® AS ADJUNCTIVE TREATMENT FOR PATIENTS WITH PRIMARY GENERALIZED TONIC-CLONIC SEIZURES

MISSISSAUGA, ON, December 2, 2015 – Eisai Limited announced today that it has received approval from Health Canada for a new indication regarding the use of its antiepileptic agent FYCOMPA® (perampanel) as an adjunctive treatment for adults with primary generalized tonic-clonic (PGTC) seizures.

"New treatment options are important for people living with this type of seizure, which can be disabling and cause injuries and even death (SUDEP)," says Dr. Jean-Francois Clément, Hôpital Charles-Lemoyne, Neuro Rive-Sud clinic, Université de Sherbrooke. "For clinicians dealing with PGTC, treatment options could rapidly be exhausted. Since approved in Canada three years ago, Fycompa has demonstrated good seizure control in patients with partial onset seizures and this new indication provides hope for patients with uncontrolled PGTC seizures. For people living with epilepsy, seizure freedom is vital to help people lead a more normal life."

The indication expansion was based on a placebo-controlled clinical phase III study (Study 332) of FYCOMPA in 164 patients with PGTC seizures. In the study, a statistically significant reduction in PGTC seizure frequency was observed in the FYCOMPA group compared with placebo (FYCOMPA: -76.5%, placebo: -38.4%, p<0.0001). Additionally, the responder rate for Fycompa was 64.2%, which was a statistically significant improvement over the responder rate for placebo of 39.5% (p=0.0019). The most common adverse events for FYCOMPA were dizziness, fatigue, headache, somnolence and irritability.

Generalized tonic-clonic seizures can cause significant injury to patients from falling down suddenly and are the most important risk factor associated with sudden unexpected death in epilepsy (SUDEP)¹, making them one the most severe forms of epileptic seizures. Through this indication expansion, FYCOMPA can now be used as an adjunctive treatment for primary, in addition to, secondarily generalized tonic-clonic seizures.

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"The expanded indication of FYCOMPA is positive news for the epilepsy community, specifically for people living with Primarily Generalized Tonic-clonic seizures in Canada. Patients now have a new treatment option that is proven to significantly reduce seizure frequency," says Deirdre Floyd, President, Canadian Epilepsy Alliance.

FYCOMPA is an oral medication taken once-daily and is a first-in-class antiepileptic drug (AED) discovered and developed by Eisai. 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 in 2013 as an adjunctive treatment for partial-onset seizures (this type of seizure may be associated with secondarily generalized seizures) in patients with epilepsy 18 years of age and older in Canada.

"Eisai is committed to epilepsy and addressing the unmet medical need of patients, and their families," says Daniel Asch, General Manager, Eisai Limited. Our human health care mission, a commitment to innovative solutions in disease prevention, cure and care for the health and well-being of people worldwide, is at the forefront of everything we do."

For more information on FYCOMPA, please refer to the Product Monograph.

**About Epilepsy**
In Canada, 300,000 Canadians currently live with epilepsy, and an estimated 15,500 are diagnosed each year. Despite the high epilepsy incidence, there still remains a relatively low understanding and awareness of this neurological disorder. As approximately 30% of patients with epilepsy are unable to control their seizures with currently available AEDs, this is a disease with significant unmet medical need.

Eisai seeks to make continued contributions to address the diverse needs of, as well as increasing the benefits provided to, patients with epilepsy and their families.

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About Eisai Limited
Eisai established the Canadian pharmaceutical company Eisai Limited in 2010. As a wholly-owned subsidiary of Eisai Inc., Eisai Limited is based in Mississauga, Ontario, one of the largest biopharmaceutical clusters in North America. For more information about Eisai in Canada, please visit www.eisai.ca.

About Eisai Inc.
At Eisai Inc., human health care is our goal. We give our first thoughts to patients and their families. As the U.S. pharmaceutical subsidiary of Tokyo-based Eisai Co., Ltd., we have a passionate commitment to patient care that is the driving force behind our efforts to help address unmet medical needs. We are a fully integrated pharmaceutical business with discovery, clinical, manufacturing and marketing capabilities. To learn more about Eisai Inc., please visit us at www.eisai.com/US.

Eisai’s global areas of R&D focus include neuroscience; oncology; metabolic disorders; vascular, inflammatory and immunological reactions; and antibody-based programs.

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