

## Media Inquiries

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## **NEW APPROACH FOR THE TREATMENT OF EPILEPSY AUTHORIZED BY HEALTH CANADA - FYCOMPA™ (PERAMPANEL) IS NOW AVAILABLE AS AN ADJUNCTIVE TREATMENT FOR ADULT PATIENTS**

*First and Only Selective, Non-Competitive AMPA Glutamate Receptor Antagonist*

**MISSISSAUGUA, ON, July 10, 2013** – Eisai Limited is pleased to announce the Health Canada authorization and availability of FYCOMPA (perampanel) indicated as an adjunctive therapy in the management of partial-onset seizures, in adult patients with epilepsy who are not satisfactorily controlled with conventional therapy.

FYCOMPA is a first-in-class treatment authorized by Health Canada that selectively and non-competitively targets post-synaptic AMPA glutamate receptors, representing a new approach to seizure control.

Health Canada's authorization of FYCOMPA was primarily based on three Phase III studies (304, 305 and 306). These multi-centre, randomized, double-blind, placebo-controlled, parallel group studies evaluated the efficacy and safety of FYCOMPA compared to placebo given as an adjunctive therapy in patients with partial-onset seizures. The studies demonstrated that FYCOMPA significantly reduced seizure frequency in patients with partial-onset seizures with or without secondarily generalized seizures.<sup>1</sup>

"FYCOMPA represents an innovative approach in the treatment of epilepsy and a much needed option for Canadian patients and physicians," says Dr. Neelan Pillay, Clinical Professor, Director Adult Epilepsy Program, EEG and Evoked Potentials, Department of Clinical Neurosciences, Foothills Medical Centre. "When added to their current treatment regimen, FYCOMPA is shown to significantly reduce seizures in patients."

In Canada, 300,000 Canadians currently live with epilepsy<sup>2</sup>, and an estimated 15,500 are diagnosed each year<sup>3</sup>. Despite the high epilepsy incidence, there still remains a relatively low understanding and awareness of this neurological disorder.<sup>4</sup>

“Health Canada’s authorization of FYCOMPA marks another important milestone for Canadian epilepsy patients with partial-onset seizures who now have a new option that is proven to control their seizures,” says Oliver Technow, President and General Manager, Eisai Limited. “Eisai’s human healthcare (*hhc*) philosophy centres around improving the health and quality of life for patients and their families and we are committed to improving these lives by providing innovative therapies that can have a positive impact.”

“The epilepsy community celebrates the authorization of FYCOMPA as an additional tool to manage the disorder,” says Gail Dempsey, President, Canadian Epilepsy Alliance. “Access to new options is key - every patient responds differently to a treatment and it is our goal as a community to ensure the tools are available, so that patients can live a fulfilling and rewarding life.”

In the three clinical studies, most adverse events in all treatment groups were considered mild or moderate in severity. The most common adverse events (greater than or equal to 5 per cent) in patients treated with FYCOMPA were dizziness, somnolence, fatigue, irritability, nausea, ataxia and falls.

### **About Epilepsy**

Epilepsy is a medical condition that produces seizures affecting a variety of mental and physical functions. About 70 per cent of people with epilepsy have partial-onset seizures.<sup>5</sup> In about 30 per cent of patients with epilepsy, seizures cannot be controlled with treatment.<sup>6</sup>

### **About FYCOMPA (perampanel)**

FYCOMPA is an oral medication taken once-daily and is the first Health Canada-authorized selective and non-competitive post-synaptic AMPA (alpha-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid) glutamate receptor antagonist. AMPA receptors, widely present in almost all excitatory neurons, transmit signals stimulated by the excitatory neurotransmitter glutamate within the brain. Glutamate is the primary excitatory neurotransmitter in the central nervous system.

Discovered and developed by Eisai, FYCOMPA has been licensed in more than 30 countries including, the U.S., U.K., Germany, Sweden, Norway, Denmark, Austria and Switzerland.

FYCOMPA is supplied as 2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg film-coated tablets.<sup>7</sup>

Epilepsy is a therapeutic area of focus for Eisai. The company continues to make further contributions to help address the diversified needs of epilepsy patients and their families as part of its corporate *human health care (hhc)* mission.

For more information on FYCOMPA, please refer to the product monograph for complete prescribing instructions.

### **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 and medical communities in North America. For more information about Eisai in Canada, please visit [www.eisai.ca](http://www.eisai.ca)

### **About Eisai Inc.**

Eisai Inc. was established in 1995 and is ranked among the top-20 U.S. pharmaceutical companies (based on retail sales). The Company began marketing its first product in the United States in 1997 and has rapidly grown to become a fully integrated pharmaceutical business. With operations now in North and South America, Eisai provides innovative treatments to patients in the US, Canada, Mexico and Brazil. Eisai's areas of commercial focus include neurology, gastrointestinal disorders and oncology/critical care. The Company serves as the U.S. pharmaceutical operating company of Eisai Co., Ltd., a research-based human health care (hhc) company that discovers, develops and markets products throughout the world.

Eisai Inc. has a global product creation organization that includes U.S. - based R&D facilities in Massachusetts, New Jersey, North Carolina and Pennsylvania as well as manufacturing facilities in Maryland and North Carolina. The Company's areas of R&D focus include neuroscience, oncology, vascular, inflammatory and immunological reaction, and antibody-based programs.

### **About Eisai Co., Ltd.**

Eisai Co., Ltd. is one of the world's leading R&D-based pharmaceutical companies that has defined its corporate mission as "giving first thought to patients and their families and to increasing the benefits health care provides," which we call *human health care (hhc)*.

Eisai concentrates its R&D activities in three key areas:

- Neuroscience: Alzheimer's disease, multiple sclerosis, neuropathic pain, epilepsy, depression, etc.
- Oncology: Anticancer therapies; tumour regression, tumour suppression, antibodies, etc. and Supportive cancer therapies; pain relief, nausea, etc.
- Vascular/Immunological Reaction: Acute coronary syndrome, atherothrombotic disease, sepsis, rheumatoid arthritis, psoriasis, Crohn's disease, etc.

With operations in Canada, the U.S., Asia, Europe and its domestic home market of Japan, we employ more than 11,000 people worldwide.

## REFERENCES

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- <sup>1</sup> FYCOMPA Canadian Product Monograph
- <sup>2</sup> Canadian League Against Epilepsy - [http://www.clae.org/html/en/general\\_information.html](http://www.clae.org/html/en/general_information.html). Last accessed on June 4<sup>th</sup>, 2013.
- <sup>3</sup> Canadian League Against Epilepsy - [http://www.clae.org/html/en/general\\_information.html](http://www.clae.org/html/en/general_information.html). Last accessed on June 4<sup>th</sup>, 2013.
- <sup>4</sup> Canadian League Against Epilepsy - [http://www.clae.org/html/en/general\\_information.html](http://www.clae.org/html/en/general_information.html). Last accessed on June 4<sup>th</sup>, 2013.
- <sup>5</sup> Canadian League Against Epilepsy - [http://www.clae.org/html/en/general\\_information.html](http://www.clae.org/html/en/general_information.html). Last accessed on June 4<sup>th</sup>, 2013.
- <sup>6</sup> Canadian League Against Epilepsy - [http://www.clae.org/html/en/general\\_information.html](http://www.clae.org/html/en/general_information.html). Last accessed on June 4<sup>th</sup>, 2013.
- <sup>7</sup> FYCOMPA Canadian Product Monograph