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Eisai Limited

## **BRAIN TUMOUR TREATMENT NOW AVAILABLE IN CANADA – FIRST TO DELIVER CHEMOTHERAPY DIRECTLY TO THE AFFECTED SITE**

*Gliadel<sup>®</sup> Wafer approved by Health Canada for patients with Glioblastoma Multiforme*

**Mississauga, ON (November 3, 2011)** – Eisai Limited, a wholly-owned Canadian subsidiary of Eisai Inc., announced today the Health Canada approval and availability of Gliadel<sup>®</sup> Wafer (carmustine implant in polifeprosan 20) indicated in recurrent Glioblastoma Multiforme (GBM) patients for whom surgical resection is indicated as an adjunct to surgery.

There are more than 120 types of brain tumours<sup>i</sup>, causing a diagnostic and treatment challenge for physicians. GBM is one of the most progressive and fatal types. An estimated 55,000 Canadians<sup>ii</sup> are currently dealing with some form of brain tumour, highlighting a need for new options to treat these aggressive cells.

“Eisai is pleased to continue our patient-focused corporate mission in Canada with the approval of Gliadel<sup>®</sup>, a dime-sized wafer that delivers chemotherapy directly into the affected area of the brain,” says Takihito Hirasawa, President, Eisai Limited. “We are proud to offer an additional treatment option for patients who suffer from brain tumours.”

The approval of Gliadel<sup>®</sup> was based on a pivotal trial in patients with recurrent glioblastoma multiforme treated with Gliadel<sup>®</sup> who experienced an increased six-month survival rate when compared to treatment with placebo (56% with Gliadel<sup>®</sup> compared to 36% with placebo). Both Gliadel<sup>®</sup> and placebo were used as an adjunct to surgery.

Brain tumours are often classified by cell origin and how the cells behave, from the least aggressive (non-malignant) to the most aggressive (malignant) and assigned a grade, ranging from Grade I (least malignant) to Grade IV (most malignant), which signifies the rate of growth. The classification and grade of a tumour helps to predict its likely behavior.

“A brain tumour diagnosis can be utterly devastating for a patient and it is important to reinforce that there are treatment options that can help to stop or slow the growth of cells and prolong survival,” says, Dr. Warren Mason, Neurooncologist, Gerry and Nancy Pencer Brain Tumour Centre, Princess Margaret Hospital. “The approval of Gliadel<sup>®</sup>, which improved six-month survival rates, is another option and the only chemotherapeutic implant approved by Health Canada to treat malignant tumours.”

Gliadel<sup>®</sup> Wafer, a novel approach to the treatment of recurrent GBM, is a biodegradable wafer, implanted at the time of surgery that delivers chemotherapy directly to the tumor site, minimizing drug exposure to other areas of the body. Gliadel<sup>®</sup> Wafer complements other standard therapies for

brain cancer, such as surgery, radiation and chemotherapy.

“Brain Tumour Foundation of Canada is committed to providing people with support, education and information as they navigate their journey with a brain tumour”, said Susan Marshall, Executive Director, Brain Tumour Foundation of Canada. “An additional part of our mandate is to support research in Canada. Every bit of information helps give hope to thousands of Canadian families. We encourage brain tumour patients and families to discuss all treatment options with their health care professional.”

### **About Gliadel<sup>®</sup>**

Gliadel<sup>®</sup> has been approved and implanted in more than 15 countries including the United States, Spain, Greece, U.K., France, Germany, Italy, Australia and South East Asia. Since 1997, over 20,000 procedures have been performed with Gliadel<sup>®</sup>.

Gliadel<sup>®</sup> Wafer is a small, dime-sized wafer that is designed to deliver a type of chemotherapy, carmustine, directly into the cavity created when a brain tumour is removed during surgery. Up to eight wafers are implanted along the walls and floor of the cavity where the tumour was previously located. Gliadel<sup>®</sup> slowly dissolves and delivers carmustine.

Gliadel<sup>®</sup> Wafer is the only Health Canada approved chemotherapeutic implant for use during surgical resection.

### **Gliadel<sup>®</sup> Important Safety Information**

Gliadel<sup>®</sup> should not be given to individuals who have demonstrated a previous hypersensitivity to carmustine or any of the components of Gliadel<sup>®</sup>.

Patients undergoing craniotomy for malignant glioma and implantation of Gliadel<sup>®</sup> should be monitored closely for known complications of craniotomy, including seizures, intracranial infections, abnormal wound healing and brain edema.

### **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. 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. For more information about Eisai, please visit [www.eisai.com/us](http://www.eisai.com/us).

Eisai established Eisai Limited Canada 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.

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**REFERENCES**

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<sup>i</sup> <http://www.btfc.org/2494/brain-tumour-facts>

<sup>ii</sup> <http://www.btfc.org/2494/brain-tumour-facts>