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Eisai Co., Ltd.

# EISAI TO RECEIVE JAPAN MARKETING AUTHORIZATION HOLDER LICENSE FROM NOBELPHARMA FOR ANTINEOPLASTIC AGENT GLIADEL® 7.7 mg IMPLANT

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that it will receive the Marketing Authorization Holder (MAH) license for the antineoplastic agent Gliadel® 7.7 mg Implant (carmustine, "Gliadel") in Japan from Nobelpharma Co., Ltd. (Headquarters: Tokyo, President & CEO: Jin Shiomura, "Nobelpharma"), effective December 2.

In Japan, marketing authorization for Gliadel was first received in September 2012 by Nobelpharma after it conducted clinical trials of the agent. Eisai is responsible for domestic sales and distribution of Gliadel under an existing agreement with Nobelpharma and is also co-promoting the agent based on this collaboration, but has decided to act on a licensing option provided in the same agreement that allows Eisai to receive the current Japan MAH license for Gliadel from Nobelpharma. Following the transfer, both companies will continue to promote Gliadel domestically, but with Eisai also responsible for the marketing of the agent in Japan, including responding to the needs of healthcare professionals and ensuring and providing information on the proper use of Gliadel.

Gliadel was launched in Japan on January 9, 2013, and is the only sustained-release formulation to be approved for intracranial implantation in that country. Each wafer contains the nitrosourea alkylating agent carmustine distributed in a biodegradable polymer matrix. Implanting the agent into the brain following surgical removal of malignant glioma allows for direct delivery of chemotherapy to the tumor site, allowing Gliadel to be used prior to initiating radiation, chemotherapy and other standard therapies.

Eisai is committed to providing new treatment options for patients with cancer in order to further contribute to addressing unmet medical needs that exist in the treatment of cancer and increase the benefits provided to patients and their families.

**[Please refer to the following notes for further information on Gliadel 7.7 mg Implant, glioma and Nobelpharma Co., Ltd.]**

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**[Notes to editors]**

**1. About Gliadel® 7.7 mg Implant**

Gliadel 7.7 mg Implant is the only sustained-release formulation approved for intracranial implantation in Japan. Each wafer contains the nitrosourea alkylating agent carmustine distributed in a biodegradable polymer matrix. Implanting the agent into the brain following surgical removal of malignant glioma allows for direct delivery of chemotherapy to the tumor site, allowing the agent to be used prior to initiating radiation, chemotherapy and other standard therapies. In Japan, Nobelpharma Co., Ltd. received marketing authorization for Gliadel 7.7 mg Implant in September 2012 after conducting related clinical trials, with Eisai subsequently responsible for domestic sales and distribution for the agent after entering into an agreement with Nobelpharma in January 2013.

**2. About Glioma**

Glioma is the general term for primary brain tumors originating from the glial cells that exist in parenchymal brain tissue. They are mostly malignant with poor prognosis. Gliomas account for approximately 30% of all primary brain tumors and in many cases are difficult to completely remove as they characteristically spread and develop (infiltrate) in the brain or spinal cord without a distinct tumor boundary, with normal brain tissue and tumor cells both being present in surrounding areas. In these cases, the tumor has a poor survival prognosis of 25% or less within the first five years.

Surgical removal (craniotomy) of the tumor is usually performed as standard treatment for glioma and in the majority of cases radiation and/or chemotherapy is administered adjunctively post-surgery. However, the active ingredients in chemotherapeutic agents administered during systemic chemotherapy regimens are often unable to be sufficiently delivered to the brain tumor site at the required dose because of the blood-brain barrier and the actual dose required also cannot be sufficiently administered without systemic adverse events. These difficulties are another reason for poor prognosis in patients with malignant glioma.

**3. About Nobelpharma Co., Ltd.**

Since its establishment in 2003, Nobelpharma has strived to fulfill its corporate mission of developing medicines that satisfy high unmet medical needs and ensuring that they are made accessible to the patients who require them.

Nobelpharma's contribution to health care centers on its dedicated research and development of specific pharmaceutical products such as orphan drugs and pediatric medicines as well as potential indication expansions for existing on-label treatments, so as to satisfy high unmet medical needs in various therapeutic areas. To date, the company has already received manufacturing and marketing approval for eight new medicines and is working to ensure that they are provided as a treatment option to eligible patients. All eight of these medicines continue to be used today to treat diseases for which existing treatments have been unsatisfactory.

For more information on Nobelpharma, please visit: http://www.nobelpharma.co.jp/en/works/company.html.