

Licensed for Gliadel[®] Wafer in Japan

April 6, 2009
Nobelpharma Co., Ltd.

Nobelpharma Co., Ltd. (Nobelpharma, Headquarters: Tokyo, President: Jin Shiomura) has entered a licensing agreement with Eisai Co., Ltd. (Eisai, Headquarters: Tokyo, President: Haruo Naito) for Gliadel[®] Wafer (polifeprosan 20 with carmustine implant) in Japan. This license gives Nobelpharma exclusive rights for development and sales of the drug in Japan. However, after Nobelpharma completes application for approval, Eisai has the right to acquire exclusive sales rights in Japan.

Gliadel[®] Wafer is the only chemotherapy implant (effective ingredient: carmustine) approved by the U.S. Food and Drug Administration (FDA) for use during surgery, and it is used during surgery for malignant glioma. So far it has been approved for use in 18 countries, principally in the U.S., Europe and Southeast Asia. Furthermore, the U.S. National Comprehensive Cancer Network (NCCN) includes the use of carmustine wafer in its Central Nervous System Cancers Practice Guidelines as one treatment strategy for malignant glioma.

Glioma is a cancer that develops in the brain, and it accounts for 30% of primary brain tumors. It is estimated that around 2,000 to 2,500 people develop malignant glioma in Japan each year. A request has been submitted for early approval, and it was taken up in 2008 in the Investigational Committee for Usage of Unapproved Drugs of the Ministry of Health, Labour and Welfare.

Malignant glioma is currently a difficult disease to treat. Nobelpharma has made positive efforts to develop drugs with high unmet medical needs in response to strong requests from patient groups and society, and received approval to manufacture and sell three new drugs in succession in 2008. Utilizing that experience, every member of Nobelpharma will make even further effort to bring this drug to market as soon as possible, and to provide a new treatment option to patients who suffer from malignant glioma.

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Notes:

Gliadel[®] Wafer (Overseas):

Gliadel[®] Wafer has been approved by the U.S. FDA as indicated in “newly-diagnosed high-grade malignant glioma patients as an adjunct to surgery and radiation,” and in “recurrent glioblastoma multiforme patients as an adjunct to surgery.” It has been used on approximately 20,000 patients in the U.S. since sales began in 1997.

The preparation is a wafer about the size of a U.S. dime (1mm thick, 14.5mm in diameter) and each wafer contains 7.7mg of carmustine. Up to a maximum of eight wafers are inserted into the cavity left after a tumor is removed in surgery, and the carmustine is released as a form of chemotherapy treatment.

Glioma:

Glioma is a tumor in the glia cells existing in the brain, and most are malignant with an unfavorable prognosis. Glioma accounts for approximately 30% of primary brain tumors, and is classified in a number of types based on the form of the cells composing the tumor. The most common is astrocytoma, and the malignancy is classified in 4 grades (grades I to IV). Grade IV in particular is called glioblastoma, and it has the highest level of malignancy, and the tumor has an extremely unfavorable prognosis. The standard treatment for glioma is normally surgery (craniotomy), but it is difficult to remove the entire tumor in surgery, and in most cases radiation or chemotherapy are performed after surgery.

Nobelpharma Co., Ltd.:

Nobelpharma Co., Ltd. develops drugs for high-unmet needs, and was founded in 2003 with the mission to make those pharmaceuticals available to the patients who need them.

Nobelpharma contributes to ensuring the availability of medicines where they are needed through zealous efforts to research and develop drugs with high-unmet needs such as orphan drugs and pediatric drugs. Nobelpharma obtained approval for the manufacture and sales of three drugs in succession in 2008, including Nobelzin[®] capsule (treatment of Wilson’s Disease), Lunabell[®] compound tablet (treatment of Dysmenorrhea with Endometriosis), and Intravenous Nobelbar[®] (treatment of neonatal seizures, status epilepticus).

Please visit Nobelpharma’s web site at <http://www.nobelpharma.co.jp> for more detailed information.

Outline of Nobelpharma Co., Ltd. (as of December 30, 2008)

1	Name	Nobelpharma Co., Ltd.
2	Business fields	Import, manufacture and sales of pharmaceuticals
3	Date established	June 6, 2003
4	Headquarters	12-10 Nihonbashi-kobunacho, Chuo-ku, Tokyo
5	Representative	Representative Director and CEO, Jin Shiomura
6	Capital	¥161 million
7	Shareholder equity	¥256 million
8	Total assets	¥2.712 billion
9	Sales	¥3.055 billion (in the year to December 2008)
10	Employees	54 employees
11	Major products	Lunabell [®] compound tablet, Nobelzin [®] capsule, Intravenous Nobelbar [®]