

Eisai launches implantable anti-tumor agent

11 January 2013 | News | By BioSpectrum Bureau



Singapore: Nobelpharma and Eisai launched Gliadel 7.7 mg Implant (carmustine), an antineoplastic agent, in Japan on January 9. Nobelpharma has been conducting clinical studies of the agent and acquired manufacturing and marketing authorization in Japan on September 28, 2012, and National Health Insurance (NHI) Drug Price List registration on November 22, 2012. Gliadel 7.7 mg Implant will be marketed domestically by Eisai and co-promoted by both companies.

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

In phase III clinical studies, conducted outside Japan, Gliadel was shown to significantly extend overall survival in patients with newly diagnosed malignant glioma versus placebo as well as significantly increase the overall survival rate after six months in patients with recurrent glioblastoma.

Furthermore, clinical studies conducted in Japan have demonstrated that the agent possesses excellent antitumor efficacy and a favorable safety profile in patients with newly diagnosed malignant glioma and recurrent glioblastoma. Gliadel is currently approved in 30 countries worldwide, including the US and in Europe and South East Asia.

Glioma is a tumor of the brain that accounts for approximately 30 percent of all primary brain tumors, of which malignant glioma prevalence in Japan is estimated to be about 2,000-to-2,500 cases per year. Gliadel was designated as being of high medical need by the Investigational Committee for Usage of Unapproved Drugs in Japan in September 2008 and designated as an orphan drug in June 2009.

