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FOR IMMEDIATE RELEASE from the FDA
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FDA Approves Drug for Treatment of Aggressive Brain Cancer

The U.S. Food and Drug Administration recently approved Avastin (bevacizumab) to treat patients with glioblastoma multiforme (GBM) when this form of brain cancer continues to progress following standard therapy.

GBM is a rapidly progressing cancer that invades brain tissue and can impact physical activities and mental abilities. It affects about 6,700 persons in the United States every year. Following initial treatment with surgery, radiation, and/or chemotherapy, the cancer nearly always returns.

"This type of cancer is very resistant to therapy and thus challenging to treat," said Richard Pazdur, M.D., director of the Office of Oncology Drug Products in the FDA's Center for Drug Evaluation and Research. "Avastin provides a therapy for patients with progressive GBM who have not responded to other medications."

Avastin is a laboratory-produced molecule known as a monoclonal antibody that mimics the antibodies produced by the body's immune system to defend against harmful substances. The medication inhibits the action of vascular endothelial growth factor that helps form new blood vessels. These vessels can feed a tumor, helping it to grow and can also provide a pathway for cancer cells to circulate in the body. The drug was first approved in 2004 to treat metastatic cancer of the colon or rectum and has since been approved for treatment of non-squamous, non-small cell lung cancer and metastatic breast cancer.

In two clinical trials, about 25 percent of patients with GBM responded to Avastin with an average duration of response of about four months.

The most serious side effects associated with Avastin, in some cases resulting in death, are gastrointestinal perforation, wound healing complications, hemorrhage, and blood clots. Other serious side effects of Avastin are severe high blood pressure, nervous system and vision disturbances, decreased white blood cell counts, infection, stroke, myocardial infarction, and kidney problems.

The most common adverse reactions were nose bleeds, headache, high blood pressure, runny nose, excess proteins in the urine, taste alteration, dry skin, rectal bleeding, excessive tearing, and skin peeling.

Avastin is manufactured by Genentech Inc. of San Francisco.