



# ***NEWS RELEASE***

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## **FDA APPROVES AVASTIN FOR THE MOST COMMON TYPE OF KIDNEY CANCER**

**South San Francisco, Calif. – August 2, 2009** – Genentech, Inc., a wholly-owned member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY), today announced that the U.S. Food and Drug Administration (FDA) approved Avastin<sup>®</sup> (bevacizumab) plus interferon-alfa for people with metastatic renal cell carcinoma, the most common type of kidney cancer. According to the American Cancer Society, kidney cancer is the eighth most commonly diagnosed cancer in the United States. In 2009, approximately 13,000 Americans will die from the disease.

“During the last five years, Avastin has been approved by the FDA to treat five different types of cancer,” said Hal Barron, M.D., executive vice president, Global Development and chief medical officer, Genentech. “We aim to help more people facing difficult-to-treat cancers and will continue studying Avastin in more than 30 other tumor types.”

Avastin is designed to block the vascular endothelial growth factor (VEGF) protein to address a key underlying cause of cancer growth. Avastin works differently than other

approved medicines for renal cell carcinoma because it specifically binds to the VEGF protein, which is produced in elevated amounts in most kidney cancers.

“We hope that researchers someday find a cure for kidney cancer,” said William P. Bro, chief executive officer of the Kidney Cancer Association. “Until then, each new medicine, like Avastin, offers patients an opportunity to find a treatment best suited for them.”

Kidney cancer is the uncontrolled growth of cancerous cells that originate in the kidneys without a known cause. Nine out of ten people with kidney cancer have renal cell carcinoma.

### **Avastin in Metastatic Kidney Cancer**

This FDA approval is based on data from a global, randomized, double-blind, placebo-controlled Phase III study (AVOREN) of 649 patients with previously untreated metastatic renal cell carcinoma. The study showed patients who received Avastin plus interferon-alfa had a 67 percent increase in the time patients lived without their disease worsening (progression-free survival or PFS), compared to those who received interferon-alfa alone (hazard ratio=0.60, 95 percent CI=0.49, 0.72). In AVOREN, median PFS was 10.2 months for patients who received Avastin plus interferon-alfa compared to 5.4 months for patients who received interferon-alfa alone, corresponding to an 89 percent improvement in median PFS.

The study was originally designed to measure an improvement in overall survival (OS). However, in prior consultation with the FDA and European regulatory authorities, the

primary analysis endpoint was revised to assess improvement in PFS.

Secondary analysis endpoints included objective response rate and OS. In this study, tumor size decreased in 30 percent of patients in the Avastin plus interferon-alfa group, compared to 12 percent of patients who received interferon-alfa alone. There was no improvement in OS based on the final analysis after 444 deaths, with a median OS of 23 months in the Avastin plus interferon-alfa arm and 21 months in the interferon-alfa plus placebo arm (hazard ratio=0.86, 95 percent CI=0.72, 1.04).

Adverse events in this study were consistent with those previously reported for Avastin or interferon-alfa. The most common severe (Grade 3 to 5) adverse events that occurred at a rate of at least 2 percent more often in patients who received Avastin plus interferon-alfa versus interferon-alfa plus placebo included fatigue (13 percent vs. 8 percent), weakness (10 percent vs. 7 percent), protein in the urine (7 percent vs. 0 percent), hypertension (6 percent vs. 1 percent) and bleeding (3 percent vs. 0.3 percent).

### **About Avastin**

Avastin is a biologic antibody designed to specifically bind to a protein called vascular endothelial growth factor (VEGF) that plays an important role throughout the lifecycle of the tumor to develop and maintain blood vessels, a process known as angiogenesis. Avastin is designed to interfere with the blood supply to a tumor by directly binding to the VEGF protein to prevent interactions with receptors on blood vessel cells. Avastin does not bind to receptors on normal or cancer cells. The tumor blood supply is thought to be critical to a tumor's ability to grow and spread in the body (metastasize). For more information about angiogenesis, visit <http://www.gene.com>.

Avastin was the first anti-angiogenesis therapy approved by the FDA. In addition to metastatic renal cell carcinoma, Avastin is indicated for the first- or second-line treatment of metastatic colorectal cancer plus intravenous 5-FU based chemotherapy and for the first-line treatment of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer plus carboplatin and paclitaxel.

### **About Genentech Access Solutions**

Genentech is committed to people having access to our medicines. Genentech Access Solutions is a team of 350 Genentech employees who help those who need Genentech medicines. This team works with patients and doctors to resolve reimbursement and insurance issues and provides assistance to eligible patients in the United States who do not have insurance coverage or who cannot afford their out-of-pocket co-pay costs.

Since its first medicine was approved in 1985, Genentech has donated approximately \$1.3 billion in free Genentech medicines to the uninsured through the Genentech<sup>®</sup> Access to Care Foundation (GATCF) and other product donation programs. The household income limit to receive free medicine through GATCF is \$100,000 per year. Since 2005, Genentech has also donated approximately \$250 million to various independent, non-profit organizations that provide financial assistance to those who cannot access needed medical treatment due to co-pay costs.

### **BOXED WARNINGS and Additional Important Safety Information**

Patients treated with Avastin may experience side effects. In clinical trials, some patients treated with Avastin experienced serious side effects, including:

**Gastrointestinal (GI) perforation:** Treatment with Avastin can result in the development of

a serious side effect called GI perforation, which is the development of a hole in the stomach, small intestine or large intestine. In clinical trials, this side effect occurred in 0.3 to 2.4 percent of patients and in some cases resulted in fatality. Avastin therapy should be permanently stopped in people with GI perforation.

**Surgery and wound healing problems:** Treatment with Avastin can lead to slow or incomplete wound healing (for example, when a surgical incision has trouble healing or staying closed). In some cases this event resulted in fatality. In a clinical trial, 15 percent of patients with metastatic colorectal cancer who had surgery while receiving Avastin treatment had serious and fatal complications. Avastin should not be initiated for at least 28 days following surgery and until the surgical wound is fully healed. Avastin therapy should be permanently stopped in patients with wound healing problems that require medical treatment. The appropriate waiting time between stopping treatment with Avastin and having surgery has not been determined.

**Severe bleeding:** Severe or fatal bleeding, including hemoptysis (coughing up of blood), GI bleeding, hematemesis (bloody vomit), central nervous system (CNS) hemorrhage (bleeding in the brain), epistaxis (nose bleed), and vaginal bleeding occurred up to five-fold more frequently in patients receiving Avastin. Grade 3 or higher (severe or fatal) bleeding events have occurred in 1.2 to 4.6 percent of patients receiving Avastin.

In patients with previously treated glioblastoma, intracranial hemorrhage (bleeding within the brain) occurred in eight of 163 patients and two people had Grade 3 to 4 (severe) bleeding. Some people receiving Avastin with chemotherapy for lung cancer experienced hemoptysis. In some cases, this event resulted in fatality. People with serious bleeding or recent hemoptysis should not receive Avastin.

In clinical trials, additional serious side effects seen across different cancer types, in some cases resulting in fatality, included the following: formation of an abnormal passage from parts of the body to another part (non-GI fistula formation – less than or equal to 0.3 percent); stroke or heart problems (arterial thromboembolic events – 2.4 percent); high blood pressure (5 to 18 percent); nervous system and vision disturbances known as RPLS (reversible posterior leukoencephalopathy syndrome – less than 0.1 percent); severe infusion reactions (0.2 percent), and too much protein in the urine, which may be a sign of kidney problems, were increased.

The most common adverse reactions observed in Avastin patients at a rate of more than 10 percent and at least twice the control arm rate, were nose bleeds, headache, high blood pressure, irritation of the nose (rhinitis), protein in the urine, taste alteration, dry skin, rectal bleeding, tear production disorder (lacrimation), back pain and inflammation of the skin (exfoliative dermatitis).

Avastin may cause problems getting pregnant. People who are pregnant or thinking of becoming pregnant should talk with their doctor about the potential risk of loss of pregnancy or the potential risk of Avastin to the fetus. Nursing mothers should not breast-feed while receiving Avastin or for a short period of time after treatment is finished.

For Avastin full prescribing information, including Boxed WARNINGS and additional important safety information, please visit <http://www.avastin.com>.

### **About Genentech**

Founded more than 30 years ago, Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes medicines to treat patients with

serious or life-threatening medical conditions. The company, a wholly-owned member of the Roche Group, has headquarters in South San Francisco, Calif. For additional information about the company, please visit <http://www.gene.com>.

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