

# Genentech **FACT SHEET**



Media Contact: Ed Lang (650) 467-2313  
Investor Contact: Kathee Littrell (650) 225-1034  
Advocacy Contact: Kristin Reed (650) 467-9831

## **Commitment to Patient Access**

Genentech is committed to making sure price is not a barrier to access for patients. The vast majority of patients who receive treatment with Genentech medicines have insurance that covers the cost of their treatment. Genentech supports several programs for eligible patients treated in the United States who do not have insurance, cannot afford their out-of-pocket co-pay costs or need assistance with health insurance coverage or reimbursement issues through the Genentech Access Solutions program.

- Since 1985, when our first product was approved, Genentech has donated approximately \$1 billion in free medicine to uninsured patients through the [Genentech® Access to Care Foundation \(GATCF\)](#) and other charitable programs.
- The company recently expanded GATCF to provide free drug to eligible patients who have private insurance and have met or exceeded their lifetime maximum benefits.
- In February 2007, the company announced the expansion of GATCF to help address the needs of financially eligible patients enrolled in a Medicare Part D plan who are prescribed Tarceva® (erlotinib).

### **Avastin Patient Assistance Program**

The Avastin Patient Assistance program provides an opportunity for physicians and eligible patients who are treated for an FDA-approved indication and who reach an annual dosage of 10,000 mg to receive free Avastin from Genentech for the remainder of the 12-month period.

This program is open to all patients receiving Avastin regardless of insurance coverage. To be eligible for the program, patients will need to:

- Receive 10,000 mg of Avastin for a FDA-approved indication in a twelve-month period.
- Earn less than \$100,000 adjusted gross income per year.
- Receive the 10,000 mg of Avastin from a single provider or provider organization.

The price of Avastin was established in February 2004, when it was FDA-approved for the treatment of first-line metastatic colorectal cancer (mCRC) in combination with 5-FU-based chemotherapy. At that time, the monthly price of

Avastin was set below the standard-of-care chemotherapy for mCRC, and the price of Avastin has not changed since then. The Avastin Patient Assistance program is a step toward addressing the cost variability in current FDA-approved indications.

For more information, please call (866) 4 ACCESS or visit [www.GenentechAccessSolutions.com](http://www.GenentechAccessSolutions.com).

### **Co-Pay Assistance**

Since 2005, Genentech has donated more than \$140 million to independent non-profit organizations that provide co-pay assistance. To learn more about these independent, public charities, patients can speak with a specialist from Genentech's Access Solutions group by calling (866) 4 ACCESS or visiting [www.GenentechAccessSolutions.com](http://www.GenentechAccessSolutions.com).

### **Genentech Access Solutions**

Genentech's Access Solutions provides one-stop access to a broad array of coverage, reimbursement and patient assistance services. For more information on potential assistance options, please call (866) 4 ACCESS or visit [www.GenentechAccessSolutions.com](http://www.GenentechAccessSolutions.com).

### **Avastin Indications and Safety Information**

#### ***Indications***

Avastin, in combination with intravenous 5-fluorouracil-based chemotherapy, is indicated for first- or second-line treatment of patients with metastatic carcinoma of the colon or rectum.

Avastin, in combination with carboplatin and paclitaxel, is indicated for first-line treatment of patients with unresectable, locally advanced, recurrent or metastatic non-squamous, non-small cell lung cancer.

Avastin is indicated for the treatment of metastatic renal cell carcinoma in combination with interferon alfa.

Avastin, in combination with paclitaxel is indicated for the treatment of patients who have not received chemotherapy for metastatic HER2-negative breast cancer.

The effectiveness of Avastin in metastatic breast cancer is based on an improvement in progression-free survival. Avastin is not indicated for patients with breast cancer that has progressed following anthracycline and taxane chemotherapy administered for metastatic disease.

Currently, no data are available that demonstrate an improvement in disease-related symptoms or increased survival with Avastin in breast cancer.

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

People receiving Avastin may experience side effects. In clinical trials, some people treated with Avastin experienced serious and sometimes fatal side effects, including:

**Gastrointestinal (GI) perforation:** Treatment with Avastin can result in the development of a potentially 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 event occurred in more people who received Avastin than in the comparison group (0.3% to 2.4%). In some cases, GI perforation resulted in fatality. Avastin therapy should be permanently stopped if GI perforation occurs.

**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. Surgery and wound healing problems occurred more often in people who received Avastin than in the comparison group. Avastin therapy should not be started for at least 28 days after surgery and until the surgical wound is fully healed. The length of time between stopping Avastin and having voluntary surgery without the risk of having surgery and wound healing problems has not been determined. Treatment with Avastin should be stopped at least 28 days before voluntary surgery and in people with surgery and wound healing problems that require medical treatment.

**Severe bleeding:** Treatment with Avastin can result in serious bleeding, including coughing up blood, bleeding in the stomach, vomiting of blood, bleeding in the brain, nosebleeds, and vaginal bleeding. These events occurred up to 5 times more often in people who received Avastin. Across cancer types, 1.2% to 4.6% of people who received Avastin experienced severe to fatal bleeding. People who have recently coughed up blood (greater than or equal to a half teaspoon of red blood) or have serious bleeding should not receive Avastin. Treatment with Avastin should be permanently stopped if serious bleeding occurs (ie, requiring medical attention).

In clinical trials for different cancer types, there were additional serious and sometimes fatal side effects that occurred in more people who received Avastin than in those in the comparison group. The formation of an abnormal passage from parts of the body to another part (non-GI fistula formation) was seen in 0.3% or less of people. Severe to life threatening stroke or heart problems were seen in 2.4% of people. Too much protein in the urine, which led to kidney problems, was seen in less than 1% of people. Additional serious side effects that occurred in more people who received Avastin than those in the comparison group

included severe to life-threatening high blood pressure, which was seen in 5% to 18% of people, and nervous system and vision disturbances (reversible posterior leukoencephalopathy syndrome), which was seen in less than 0.1% of people. Infusion reactions with the first dose of Avastin were uncommon and occurred in less than 3% of people, and severe reactions occurred in 0.2% of people.

Common side effects that occurred in more than 10% of people who received Avastin for different cancer types, and at least twice the rate of the comparison group, were nosebleeds, headache, high blood pressure, inflammation of the nose, too much protein in the urine, taste change, dry skin, rectal bleeding, tear production disorder, back pain, and inflammation of the skin (exfoliative dermatitis). Across all trials, treatment with Avastin was permanently stopped in 8.4% to 21% of people because of side effects.

Avastin may impair fertility. Patients who are pregnant or thinking of becoming pregnant should talk with their doctor about the potential risk of loss of the pregnancy or the potential risk of Avastin to the fetus during and following Avastin therapy, and the need to continue an effective birth control method for at least 6 months following the last dose of Avastin.

### **First-line Metastatic Colorectal Cancer**

In the first-line metastatic colorectal cancer trial, the most common severe to life-threatening side effects that increased by 2% or more in people who received Avastin plus IFL (chemotherapy) vs IFL (chemotherapy) alone were weakness (10% vs 7%), abdominal pain (8% vs 5%), pain (8% vs 5%), high blood pressure (12% vs 2%), blood clots in the veins of the body (9% vs 5%), blood clots inside the abdomen (3% vs 1%), a brief loss of consciousness (3% vs 1%), diarrhea (34% vs 25%), constipation (4% vs 2%), reduced white blood cell counts (37% vs 31%), and reduced white blood cell counts that may increase the chance of infection (21% vs 14%).

### **Second-line Metastatic Colorectal Cancer**

In the second-line metastatic colorectal cancer trial, the most common severe to life-threatening and fatal side effects that increased by 2% or more in people who received Avastin plus FOLFOX4 (chemotherapy) vs FOLFOX4 (chemotherapy) alone were diarrhea (18% vs 13%), nausea (12% vs 5%), vomiting (11% vs 4%), dehydration (10% vs 5%), blockage of the bowel (4% vs 1%), numbness and tingling in fingers and toes (17% vs 9%), nervous system disturbances (5% vs 3%), tiredness (19% vs 13%), abdominal pain (8% vs 5%), headache (3% vs 0%), high blood pressure (9% vs 2%), and severe bleeding (5% vs 1%).

### **Metastatic Kidney Cancer**

In the metastatic kidney cancer trial, the most common severe to fatal side effects that increased by 2% or more in people who received Avastin vs those in the comparison group included tiredness (13% vs 8%), weakness (10% vs 7%),

too much protein in the urine (7% vs 0%), high blood pressure (6% vs 1%), and severe bleeding (3% vs 0.3%).

### **Non-small Cell Lung Cancer**

In the non-small cell lung cancer trial, the most common life-threatening to fatal side effects that increased by 2% or more in people who received Avastin vs those in the comparison group were reduced white blood cell counts (27% vs 17%), tiredness (16% vs 13%), high blood pressure (8% vs 0.7%), infection without reduced white blood cell counts (7% vs 3%), blood clots in the veins of the body (5% vs 3%), fever with reduced white blood cell counts (5% vs 2%), inflammation of the lungs (5% vs 3%), infection with severe or life-threatening reduced white blood cell counts (4% vs 2%), low sodium levels in the blood that could lead to seizure or coma.

### **Metastatic Breast Cancer**

In the metastatic breast cancer trial, there was a 20.5% increase in severe to life-threatening and fatal side effects for Avastin plus paclitaxel (chemotherapy) vs paclitaxel (chemotherapy) alone. Because mild side effects of Avastin plus paclitaxel (chemotherapy) were not studied, they are not known. The most common severe to life-threatening and fatal side effects that increased by 5% or more in people who received Avastin plus paclitaxel (chemotherapy) vs paclitaxel (chemotherapy) alone included numbness and tingling in fingers and toes (24% vs 18%), high blood pressure (16% vs 1%), and tiredness (11% vs 5%). Congestive heart failure was seen in more people who received Avastin plus paclitaxel (chemotherapy) vs paclitaxel (chemotherapy) alone (2.2% vs 0.3%). Among people receiving anthracyclines, congestive heart failure was more common in people who received Avastin plus paclitaxel (chemotherapy) vs paclitaxel (chemotherapy) alone (3.8% vs 0.6%). Deaths due to side effects were seen in 1.7% (6 of 363) of people who received Avastin plus paclitaxel (chemotherapy). Causes of death were the development of a hole in the stomach, small intestine, or large intestine (2), heart attack (2), and diarrhea/abdominal pain/weakness/low blood pressure (2).

For Full Prescribing Information and Boxed WARNINGS on Avastin, please visit <http://www.avastin.com>.