

**Genentech Statement on Counterfeit Drug Labeled
as Avastin[®] (bevacizumab) in the United States**

SOUTH SAN FRANCISCO, Calif. – February 14, 2012 – Roche and Genentech have been informed that a counterfeit product, labeled as Avastin (bevacizumab), has been distributed in the United States.

The counterfeit product is not safe or effective and should not be used. Chemical analyses of the counterfeit vials tested to date have confirmed the product does not contain the active ingredients for Avastin. Further analyses are being conducted to confirm the actual content of the counterfeit vials.

Patient safety is Roche and Genentech's primary concern. We are working with the U.S. Food and Drug Administration (FDA) and law enforcement to aid their evaluations, determine the source of the counterfeit drug, and prevent its further distribution.

Important Information for Healthcare Providers to Identify Suspected Counterfeit Product

If a healthcare provider has any product in their possession that they suspect may be counterfeit, they should immediately contact the FDA's Office of Criminal Investigations (OCI) at 1-800-551-3989 (<http://www.fda.gov/OCI>) or Genentech's Product Quality Assurance department at 1-800-334-0290.

It is believed that some product in the United States labeled as Avastin 400 mg/16 mL with the following lot numbers on either the vials or packaging may be counterfeit:

- B86017
- B6011
- B6010

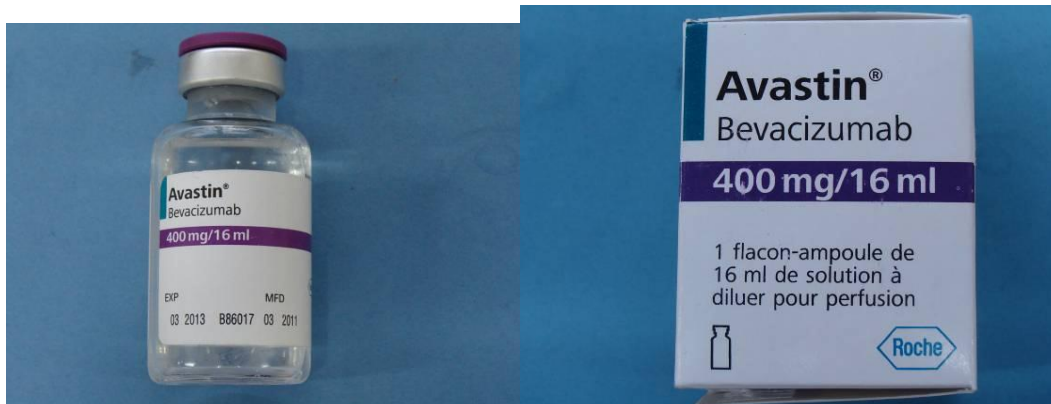
The counterfeit product does not look similar to authentic Avastin that is FDA-approved for the treatment of certain cancers in the United States. The images below show some of the differences. In addition, the following is true for all authentic Avastin that is FDA-approved for use in the United States:

- All cartons and vials approved for use in the United States have "Genentech" or "Genentech, a member of the Roche Group" printed on the labels;
- The lot number on the carton and vial should be 6 digits with no letters;
- The expiry date is formatted as a 3-letter month and 4-digit year, e.g. JUL 2014;
- The date of manufacture is not printed on the carton or vial;
- All the text on the vial labels, cartons and package inserts is English.

Authentic Avastin FDA-Approved for Use in the United States



Counterfeit Product



Implications for Patients

If a healthcare provider suspects a patient may have received counterfeit drug, they should immediately report this by contacting the FDA's Office of Criminal Investigations (1-800-551-3989, <http://www.fda.gov/OCI>) or Genentech's Product Quality Assurance department at 1-800-334-0290.

If a patient taking Avastin is experiencing any side effects, they should contact their healthcare provider immediately. If the patient is experiencing any side effects that the healthcare provider thinks may be related to Avastin or that are different from those commonly associated with Avastin (please see important safety information detailed below), the healthcare provider should immediately call FDA's MedWatch Program (1-800-FDA-1088) or Genentech's Drug Safety Department at 1-888-835-2555.

Roche and Genentech's Anti-Counterfeiting Measures

As the implications for public health and safety are high, we take the issue of counterfeiting extremely seriously. Roche and Genentech have implemented various approaches to combat counterfeiting that include working with relevant stakeholders to secure the distribution system, and implementing special packaging and printing techniques that make counterfeits both more difficult to make and easier to spot. We work closely with health authorities and law enforcement agencies to combat the unsafe distribution of our products through unauthorized sources.

Counterfeit medicines are mostly offered for sale by unlicensed sources. In order to help ensure the integrity of the supply chain for Genentech's medicines in the United States, our medicines are sold directly to a defined number of licensed wholesalers and specialty distributors.

Roche and Genentech take very seriously compliance with relevant national and international standards, guidelines and regulations aimed at combating counterfeit active pharmaceutical ingredients (APIs), medicines and diagnostics. We fully support governmental efforts and are committed to cooperating with the authorities whenever one of our products is concerned. Further, we participate in national and international industry and governmental efforts to develop stronger laws and improve enforcement, educate the public and train local officials.

About Avastin

Avastin is a prescription-only medicine that is a solution for intravenous infusion. It 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 tumor blood supply by directly binding to the VEGF protein to prevent interactions with receptors on blood vessel 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 is approved for the first- and second-line treatment of metastatic colorectal cancer in combination with intravenous 5-FU-based chemotherapy; first-line treatment of unresectable, locally advanced, recurrent or metastatic, non-squamous, non-small cell lung cancer in combination with carboplatin and paclitaxel; metastatic renal cell carcinoma in combination with interferon alfa; glioblastoma, as a single agent for adult patients with progressive disease following prior therapy. The effectiveness of Avastin glioblastoma is based on an improvement in objective response rate. Currently, no data are available from randomized controlled trials demonstrating an improvement in disease-related symptoms or increased survival with Avastin in glioblastoma.

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 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 (2.4 percent to 0.3 percent). 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. In a controlled clinical trial, in patients with metastatic colorectal cancer who had surgery during the course of treatment, the incidence of wound healing complications, including serious and fatal complications, was 15 percent for patients who received Avastin and four percent for patients who did not receive Avastin.

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 wound healing problems following surgery has not been determined. Treatment with Avastin should be stopped at least 28 days before voluntary surgery and in people with wound healing problems following surgery that require medical treatment. Treatment with Avastin should be stopped in patients with slow or incomplete wound healing.

Severe bleeding: Treatment with Avastin can result in serious or fatal 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 five times more often in people who received Avastin compared to patients who received only chemotherapy. Across cancer types, 1.2 percent to 4.6 percent 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.

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 percent or less of people. Severe to life-threatening stroke or heart problems were seen in 2.6 percent of people. Too much protein in the urine that led to kidney problems was seen in less than one percent 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 five percent to 18 percent of people, and nervous system and vision disturbances (reversible posterior leukoencephalopathy syndrome), which was seen in less than 0.1 percent of people. Infusion reactions with the first dose of Avastin were uncommon and occurred in less than three percent of people, and severe reactions occurred in 0.2 percent of people. Avastin can cause fertility issues for women. Avastin could cause a woman's ovaries to stop working and may impair her ability to have children.

Common side effects that occurred in more than 10 percent 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 percent to 21 percent of people because of side effects.

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 six months following the last dose of Avastin.

Women should be advised to discontinue nursing or discontinue treatment with Avastin, taking into account the importance of Avastin to the mother.

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 two percent or more in people who received Avastin plus IFL chemotherapy vs. IFL alone were weakness (10 percent vs. 7 percent), abdominal pain (8 percent vs. 5 percent), pain (8 percent vs. 5 percent), high blood pressure (12 percent vs. 2 percent), blood clots in the veins of the body (9 percent vs. 5 percent), blood clots inside the abdomen (3 percent vs. 1 percent), a brief loss of consciousness (3 percent vs. 1 percent), diarrhea (34 percent vs. 25 percent), constipation (4 percent vs. 2 percent), reduced white blood cell counts (37 percent vs. 31 percent), and reduced white blood cell counts that may increase the chance of infection (21 percent vs. 14 percent).

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 two percent or more in people who received Avastin plus FOLFOX4 chemotherapy vs. FOLFOX4 alone were diarrhea (18 percent vs. 13 percent), nausea (12 percent vs. 5 percent), vomiting (11 percent vs. 4 percent), dehydration (10 percent vs. 5 percent), blockage of the bowel (4 percent vs. 1 percent), numbness and tingling in fingers and toes (17 percent vs. 9 percent), nervous system disturbances (5 percent vs. 3 percent), tiredness (19 percent vs. 13 percent), abdominal pain (8 percent vs. 5 percent), headache (3 percent vs. 0 percent), high blood pressure (9 percent vs. 2 percent), and severe bleeding (5 percent vs. 1 percent).

First-line Advanced Non-Squamous 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 two percent or more in people who received Avastin vs. those in the comparison group were reduced white blood cell counts (27 percent vs. 17 percent), tiredness (16 percent vs. 13 percent), high blood pressure (8 percent vs. 0.7 percent), infection without reduced white blood cell counts (7 percent vs. 3 percent), blood clots in the veins of the body (5 percent vs. 3 percent), fever with reduced white blood cell counts (5 percent vs. 2 percent), inflammation of the lungs (5 percent vs. 3 percent), infection with severe or life-threatening reduced white blood cell counts (4 percent vs. 2 percent), low sodium levels in the blood that could lead to seizure or coma (4 percent vs. 1 percent), headache (3 percent vs. 1 percent), and too much protein in the urine (3 percent vs. 0 percent).

Metastatic Kidney Cancer

In the metastatic kidney cancer trial, the most common severe to fatal side effects that increased by two percent or more in people who received Avastin vs. those in the comparison group included tiredness (13 percent vs. 8 percent), weakness (10 percent vs. 7 percent), too much protein in the urine (7 percent vs. 0 percent), high blood pressure (6 percent vs. 1 percent), and severe bleeding (3 percent vs. 0.3 percent).

Glioblastoma

In the glioblastoma clinical trial, the most common side effects in people who received Avastin alone were infection (occurred in 55 percent of people), tiredness (occurred in 45 percent of people), headache (occurred in 37 percent of people), high blood pressure (occurred in 30 percent of people), nosebleeds (occurred in 19 percent of people), and diarrhea (occurred in 21 percent of people). Some of these common side effects were severe to life-threatening or fatal: infection (occurred in 10 percent of people), tiredness (occurred in 4 percent of people), headache (occurred in 4 percent of people), high blood pressure (occurred in 8 percent of people), and diarrhea (occurred in 1 percent of people). Two fatalities were possibly related to Avastin: one from bleeding in the abdomen, and one from severely reduced white blood cell counts that led to infection.

People who received Avastin alone or Avastin plus irinotecan* (chemotherapy) experienced mild to life-threatening side effects including bleeding (occurred in 40 percent of people), nosebleeds (occurred in 26 percent of people), bleeding in the brain (occurred in 5 percent of people), high blood pressure (occurred in 32 percent of people), blood clots in the veins of the body (occurred in 8 percent of people), stroke or heart problems (occurred in 6 percent of people), surgery and wound healing problems (occurred in 6 percent of people), too much protein in the urine (occurred in 4 percent of people), the development of a hole in the stomach, small intestine, or large intestine (occurred in 2 percent of people), and nervous system and vision disturbances (occurred in 1 percent of people). People who received Avastin alone or Avastin plus irinotecan (chemotherapy) experienced severe to fatal side effects including bleeding (occurred in 2 percent of people), bleeding in the brain (occurred in 1 percent of people), high blood pressure (occurred in 5 percent of people), blood clots in the veins of the body (occurred in 7 percent of people), stroke or heart problems (occurred in 3 percent of people), surgery and wound healing problems (occurred in 3 percent of people), too much protein in the urine (occurred in 1 percent of people), and the development of a hole in the stomach, small intestine, or large intestine (occurred in 2 percent of people). Bleeding within the brain occurred in 8 of 163 people; 2 people had severe to life-threatening bleeding.

** Avastin is not indicated in combination with irinotecan for glioblastoma.*

For full Prescribing Information and Boxed WARNINGS on Avastin 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 member of the Roche Group, has headquarters in South San Francisco, California. For additional information about the company, please visit <http://www.gene.com>.

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