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FDA Approves First Angiogenesis Inhibitor To Treat Colorectal Cancer

Date: February 27, 2004

Source: U.S. Food And Drug Administration

Summary: The FDA has approved Avastin (bevacizumab) as a first-line treatment for patients with metastatic colorectal cancer -- cancer that has spread to other parts of the body.

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FULL STORY

February 26, 2004 -- The U.S. Food and Drug Administration today approved Avastin (bevacizumab) as a first-line treatment for patients with metastatic colorectal cancer -- cancer that has spread to other parts of the body. Avastin, a monoclonal antibody, is the first product to be approved that works by preventing the formation of new blood vessels, a process known as angiogenesis. Avastin was shown to extend patients' lives by about five months when given intravenously as a combination treatment along with standard chemotherapy drugs for colon cancer (the "Saltz regimen" also known as IFL). IFL treatment includes irinotecan, 5-fluorouracil (5FU) and leucovorin.

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Avastin is a genetically engineered version of a mouse antibody that contains both human and mouse components. (Antibodies are substances produced by the body's immune system to fight foreign substances.) Special technology also allows it to be produced in large quantities in the laboratory.

This new monoclonal antibody is believed to work by targeting and inhibiting the function of a natural protein called "vascular endothelial growth factor" (VEGF) that stimulates new blood vessel formation. When VEGF is targeted and bound to Avastin, it cannot stimulate the growth of blood vessels, thus denying tumors blood, oxygen and other nutrients needed for growth. Angiogenesis inhibitors such as Avastin have been studied, first in the laboratory and then in patients, for three decades with the hope they might prevent the growth of cancer. This is the first such product that has been proven to delay tumor growth and more importantly, significantly extend the lives of patients.

"The approval of Avastin is the result of many years of research and development exploring a promising new approach to fighting cancer, and it is one of a number of recent new treatments for colorectal cancer that taken together, have significantly improved the armamentarium for fighting this disease," said Mark B. McClellan, M.D., Ph.D., FDA Commissioner. "These medical achievements reflect the innovation of drug developers and the hard work of FDA's cancer review teams, and they are proof of the promise offered by biomedical innovation. The dedication of everyone involved in these efforts is making a real difference in the lives of cancer patients."

Colorectal cancer -- cancer of the colon or rectum -- is the third most common cancer affecting men and women in the U.S. and, according to the Centers for Disease Control and Prevention (CDC), is the second leading cause of cancer-related death. Colorectal cancer is also one of the most commonly diagnosed cancers in the U.S.; approximately 147,500 new cases were diagnosed in 2003.

The safety and efficacy of Avastin was primarily shown in a randomized,

double-blind clinical trial of more than 800 patients with metastatic colorectal cancer designed to find out whether Avastin extended the lives of patients. Roughly half the patients received IFL, the standard chemotherapy combination, and the other half received Avastin once every two weeks in addition to IFL. Overall, patients given Avastin in combination with IFL survived about five months longer and the average time before tumors started regrowing or new tumors appeared was four months longer than patients receiving IFL alone. The overall response rate to the treatment was 45% compared to 35% for the control arm of the trial.

Serious, but uncommon, side-effects of Avastin include formation of holes in the colon (gastrointestinal perforation) generally requiring surgery and sometimes leading to intra-abdominal infections, impaired wound healing, and bleeding from the lungs or internally. Other, more common, side-effects are high blood pressure, tiredness, blood clots, diarrhea, decreased white blood cells (lowering immunity to diseases) headache, appetite loss and mouth sores.

Avastin is manufactured by Genentech, Inc., South San Francisco, Calif.

Story Source:

Materials provided by **U.S. Food And Drug Administration**. *Note: Content may be edited for style and length.*

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U.S. Food And Drug Administration. "FDA Approves First Angiogenesis Inhibitor To Treat Colorectal Cancer." ScienceDaily. ScienceDaily, 27 February 2004.
<www.sciencedaily.com/releases/2004/02/040227071334.htm>.

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