FDA: Avastin should not be used for breast cancer (Update)

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(AP) -- Federal health authorities are recommending the blockbuster drug Avastin no longer be used to treat breast cancer, saying recent studies failed to show the drug's original promise to help slow the disease.

The Food and Drug Administration's decision is supported by many cancer experts but is sure to draw resistance from cancer patients and some doctors who fiercely defend the drug and say it should remain available.

FDA officials stressed that the recommendation is only a preliminary step toward revoking the drug's approval for breast cancer. Swiss drugmaker Roche has refused to voluntarily withdraw the indication, and under law the company has 15 days to request a public meeting on the issue, according to the FDA.

"Today's decision was a difficult one for the agency but certainly not unique," said Dr. Janet Woodcock, director of FDA's drug center. "The FDA is responsible for assuring that the products we approve for patients are both effective and safe."

The FDA approved Avastin for breast cancer in 2008 based on studies suggesting it halted the spread of breast cancer for more than five months. But follow-up studies showed that the delay lasted no more than three months, and patients suffered dangerous side effects.

"Given the number of serious and life-threatening side effects, the FDA does not believe there is a favorable risk-to-benefit ratio," said Dr. Richard Pazdur, FDA's chief of cancer drug review.

In a separate announcement Thursday, the European Medicines Agency said it would keep the drug available for breast cancer.

If the FDA does revoke Avastin's breast cancer approval, doctors will still be able to prescribe the drug "off-label," though some insurers may not pay for it. For the time being, the FDA said the drug will remain available and patient care will not be affected.

The FDA's decision is a significant setback for the world's best-selling cancer drug and will likely cost drugmaker Roche hundreds of millions of dollars in lost revenue. Avastin is also approved for various types of colon, lung, kidney and brain cancer.

While vigorously opposed by thousands of cancer patients, the FDA's ruling is in line with the guidance of its outside panel of cancer experts, who voted 12-1 in July to rescind the drug's approval for breast cancer.

Cancer specialists said this week that Avastin never lived up to its initial promise.

"The bottom line is that it doesn't work very well," said Dr. Albert Braverman, chief of oncology at State University of New York Downstate Medical Center. "I've seen the occasional patient have a brief remission, which is nice, but it's certainly not doing anything important. It's not saving anyone's life."

But some patients credit their survival to Avastin and say the FDA's decision could amount to a death sentence.

Christi Turnage of Madison, Miss., said her cancer has been undetectable for more than two years since starting therapy with Avastin. She was diagnosed with breast cancer in June 2006 and began taking the drug in 2008 after the tumors spread, or metastized, to her lungs. Breast cancer that spreads to other parts of the body is generally considered incurable.

"It's a miracle drug for me and for several of my friends, and to deny it to women being diagnosed with metastatic disease is wrong," Turnage said. "We know it doesn't work for everybody but it works for a lot of us."

More than 9,500 cancer patients and friends and family signed a petition written by Turnage urging the FDA to keep Avastin approved.

Some doctors say the removal of the drug's approval could make it more difficult to study Avastin in some rare forms of breast cancer where it has not yet been tested.

"There is still significant interest among clinicians to determine if Avastin is useful in some subsets of breast cancer patients," said Dr. Elisa Port of Mount Sinai Medical Center in New York.