Hearing may be end of road for breast cancer drug

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This undated photo provided Jan. 31, 2011, by California-based Genentech Inc., shows the blockbuster cancer drug Avastin. A new analysis raises fresh questions about the risks of Avastin, suggesting the chance of dying from side effects linked to it is higher than the risk for patients on chemotherapy alone. (AP Photo/Genentech Inc.)

(AP) -- The best-selling cancer drug in the world comes under federal scrutiny once again this week, as drugmaker Roche makes a last-ditch

effort to keep Avastin approved for breast cancer, despite evidence that it is ineffective against the disease.

The two-day meeting at the Food and Drug Administration is unprecedented since the agency has already ruled against the drug, saying it neither extends nor improves life for breast cancer patients. Roche has taken the rare step of challenging government regulators.

Experts say the fact that the agency granted another hearing on the issue is testament to the difficulty of withdrawing approval of a cancer therapy.

"It says to me that either they've gotten a great deal of negative feedback from various quarters, or there's some kind of internal disagreement within the agency," said Dr. Gary Lyman, professor at the Duke Cancer Institute in North Carolina. Lyman was part of the majority of FDA advisers who voted 12-1 to revoke Avastin's approval last July.

Roche faces a smaller and even tougher panel this Tuesday: five out of six panelists voted against the drug last year. Only one voting member is new. The other panelists either couldn't make the hearing or were recused because of potential conflicts of interest. The FDA weighs the advice of its panels, though agency commissioner Margaret Hamburg will make the final decision.

For doctors and breast cancer patients still using Avastin, the meeting is the latest twist in a winding, bureaucratic saga that began with the drug's surprise approval in 2008. The FDA granted the drug accelerated approval based on evidence that it slowed growth of breast cancer tumors for more than five months when combined with chemotherapy.

But that delay shrunk to less than three months in follow-up studies, and patients did not live any longer. Along with that, many suffered side

effects like hypertension and blood clots.

Most cancer experts say the drug should remain available for patients who are already responding well. They say Avastin benefits a subset of patients, though it's not yet clear how to identify them.

The Swiss drugmaker will ask the FDA for more time to study if patients with certain genetic proteins respond better to the drug, a years-long process.

The drug is approved for advanced breast cancer that has spread, or metastasized, to other parts of the body, which is considered incurable.

Avastin's supporters say those patients need every option available, despite the side effects.

"There seems to be this perception that there are all these kinder, gentler treatments for metastatic breast cancer, but I'm not aware of those treatments, said Dr. Kimberly Blackwell of Duke Cancer Institute.

Blackwell helped conduct the trials of Avastin in breast cancer and believes the FDA is "moving the goal posts" on the drug's effectiveness, which could discourage drugmakers from pursuing new drugs.

"If the label is withdrawn, we will not see a new drug for metastatic breast cancer for another decade," said Blackwell, who directs Duke's breast cancer program.

The panel will hear from a handful of patients whose cancer has been in remission since using Avastin. But some doctors say such anecdotes are not scientifically sound and ignore the vast majority of patients.

"You've got a patient who is on a drug and they're doing well, but in any

individual case you can't say what caused it," said Dr. Frederick Tucker, a cancer specialist based in Fredericksburg, Va. "The difficult point to make is that there are many patients who were on the drug that didn't do well, and so they're not here to give their testimony."

Avastin was Roche's best-selling drug last year, with global sales of $6.8 billion. It is FDA-approved for various types of colon, lung, kidney and brain cancer, which are not part of the meeting. Use of the drug has already waned in the U.S., with sales falling 14 percent last quarter. Most of the decline was attributed to reduced use for breast cancer.

Since Avastin is approved for other cancers, doctors will still be able to prescribe it "off-label," for breast cancer, even if it loses that indication.

But analysts expect insurers to eventually drop coverage of the drug, making it unaffordable for most patients.

A year's treatment with Avastin can run more than $100,000, when infusion charges are included. Roche caps spending at $57,000 per year for patients who meet certain financial criteria.

The FDA is legally barred from considering cost when making decisions about drugs. But Lyman and other doctors say the issue will soon become unavoidable and FDA must set clear standards for cancer drugs now.

"There are literally hundreds of children of Avastin coming down the pike that will be very pricey and we need to have clarity about the expectation for benefit and harm," Lyman said.