

Avastin disappoints against ovarian cancer

December 28 2011, By MARILYNN MARCHIONE , AP Chief Medical Writer

Avastin, the blockbuster drug that just lost approval for treating breast cancer, now looks disappointing against ovarian cancer, too. Two studies found it did not improve survival for most of these patients and kept their disease from worsening for only a few months, with more side effects.

The Genentech drug won approval in Europe last week for advanced ovarian cancer. But its maker has no immediate plans to seek the same approval in the United States. After talking with the [Food and Drug Administration](#), "we do not believe the data will support approval" although no final decision has been made, said Charlotte Arnold, a spokeswoman for Genentech, part of the Swiss company Roche.

Results of the studies are in Thursday's [New England Journal of Medicine](#).

In November, the FDA revoked Avastin's approval for [breast cancer](#) because it did not meaningfully extend life and can have serious side effects. Without approval, doctors can prescribe the drug but insurers may not pay. Treatment with it can cost \$100,000 a year.

Avastin can still be sold for some colon, lung, kidney and brain cancers. The new research was aimed at adding ovarian cancer to the list.

One study, led by Dr. Robert Burger of Fox Chase Cancer Center in Philadelphia, involved nearly 1,900 women with advanced ovarian

cancer given one of three treatment combinations. The time until the disease got worse was a median of 10 months in those given just chemotherapy; adding Avastin improved that by just one to four months for the other two groups.

Survival was similar among the groups, and side effects were higher among those on Avastin - mostly high blood pressure but also some stomach and gut problems that needed treatment.

In the other study, led by researchers from England, more than 1,500 ovarian cancer patients were given chemo with or without Avastin. The drug kept cancer at bay just one to two months longer than chemo alone did, with more cases of [high blood pressure](#). There was a trend toward improved survival for those on [Avastin](#), but the difference was too small to say the drug was responsible.

Genentech helped pay for the studies and some of the researchers consult for the company.

Dr. Gary Lyman, a Duke University researcher who was on the FDA advisory panel that recommended revoking Avastin's approval for breast cancer, wrote in an email that he agreed with the company's decision not to seek approval for ovarian cancer.

"The situation is very similar" to the results in breast cancer, and approval is unlikely unless a biological marker or test can show which patients might benefit, he wrote.

About 220,000 new cases of [ovarian cancer](#) are diagnosed each year around the world, and it causes 140,000 deaths. In the United States, the National Cancer Institute estimates 22,000 new cases and 15,000 deaths each year.

More information: Studies: www.nejm.org

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