

FDA says breast cancer drug did not extend lives

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(AP) -- Federal health scientists said Friday that follow-up studies of a Roche breast cancer drug show it failed to slow tumor growth or extend patient lives, opening the door for a potential withdrawal in that indication.

The [Food and Drug Administration](#) approved Roche's blockbuster Avastin in 2008 based on early-stage trials showing it shrank tumors caused by breast cancer. The approval was controversial because drugs for cancer patients who have never been treated before must usually show evidence they extend lives.

FDA granted the drug accelerated approval on the condition that later studies would show a survival benefit.

But in briefing documents posted online, FDA reviewers said two follow-up studies recently submitted by Roche failed to show that Avastin significantly extended lives compared to chemotherapy alone.

Additionally, the FDA said more recent data did not confirm the tumor shrinkage results seen in earlier studies.

On Tuesday the FDA will ask a panel of outside cancer experts to review the evidence on Avastin.

The FDA has the option to remove drug's approval for [breast cancer](#).

Avastin is also approved for colon, lung, kidney and brain cancer. The drug was Roche's top-selling cancer treatment last year with global sales of \$5.9 billion.

Roche is headquartered in Basel, Switzerland, and its biotech unit [Genentech](#) is based in South San Francisco.

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