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Roche's Avastin Fails to Help Early-Stage Colon Cancer Patients in Study

By Carey Sargent - Sep 18, 2010

[Roche Holding AG's](#) Avastin tumor medicine failed to meet the main goal of a late-stage study in early colon cancer.

A combination of Avastin and chemotherapy given immediately after surgery didn't extend disease-free survival compared with chemotherapy alone, Basel, Switzerland-based Roche said today in a statement. Preliminary data from the study suggest that chemotherapy alone is more effective in treating the tumors, Roche said.

While the company hoped the benefit of giving Avastin seen in studies of late-stage colorectal cancer would "translate to the early setting, it is becoming increasingly clear that the effects of Avastin are different in the metastatic and early disease settings" in colon cancer, Hal Barron, chief medical officer at Roche, said in the statement.

The company said it is examining data from this and another study looking at a similar use of the drug to "help define the next steps" for the development of Avastin in this use.

The Food and Drug Administration yesterday said it needed more data to decide whether Avastin, in combination with certain chemotherapies, should gain approval for initial treatment of breast cancer that has spread. The regulator, which had been expected to decide by yesterday, said it would now take action by Dec. 17.

Drug Failure

Avastin in 2008 won the accelerated approval for use of the drug in breast cancer with the chemotherapy treatment paclitaxel. The FDA may be debating whether to revoke that 2008 decision after an advisory panel in July voted 12 to 1 in favor of rescinding approval.

Study data required to convert the accelerated approval to standard approval failed to convince the panel that the drug had a "clinically meaningful" benefit over chemotherapy alone in terms of its ability to keep cancer at bay. The drug also failed to prolong survival and was associated with increased serious side effects, the panel found.

Avastin generated 1.73 billion Swiss francs (\$1.71 billion) in revenue during the second quarter. The medicine was developed by the company's South San Francisco, California-Genentech unit, fully acquired by the European drugmaker last year for \$46.8 billion.

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