

fact sheet

WHAT IT MEANS FOR YOU — A SERIES OF FACT SHEETS FOR PATIENTS ABOUT RESEARCH RESULTS

The Bevacizumab (Avastin®) Study: What it Means for You

This fact sheet is of particular interest to patients who are newly diagnosed with a locally recurrent or metastatic breast cancer.

The results from an interim analysis of the clinical trial, *A Randomized Phase III Trial of Paclitaxel (Taxol®) vs. Paclitaxel and Bevacizumab (Avastin®) as First Line Therapy for Locally Recurrent or Metastatic Breast Cancer*, showed that patients who received Taxol and Avastin did better than patients on Taxol alone. Avastin is a drug that blocks the growth of new blood vessels that tumors need to continue to grow.

You may want to consider discussing treatment with Avastin with your doctor, if you:

- have been newly diagnosed with locally recurrent or metastatic breast cancer and have not received chemotherapy for your recurrence.
- are a candidate for treatment with Taxol.

You are not a candidate for treatment with Avastin if you have:

- central nervous system (brain) metastasis
- a history of blood clots or are taking an anticoagulant (blood thinning) medication
- abnormally high blood pressure
- proteinuria (a condition in which urine contains an abnormal amount of protein)

Significant side effects associated with the addition of Avastin are:

- high blood pressure (hypertension) that requires treatment (13%)
- pain, loss of sensation, and inability to control muscles (peripheral neuropathy) especially in the hands and feet 20%. (The rate of peripheral neuropathy in patients receiving Taxol only was 14%.)
- protein in the urine (proteinuria) 2%

It is especially important to talk with your doctor if you are HER2 positive because this trial does not give significant information on patients who have HER2 positive tumors.

- This study excluded patients who had HER2 positive tumors unless they had previously received Herceptin® (in the adjuvant setting) or were unable to receive Herceptin.

Background

Tumors need an increased blood supply in order to grow. The process of growing new blood vessels is called angiogenesis and tumors have the ability to trigger this process. Avastin is a monoclonal antibody that can block the signals to the blood vessels that tell them to grow. Researchers believed that adding an anti-angiogenesis drug like Avastin to a chemotherapy drug that is known to be effective (Taxol) in women with metastatic breast cancer, might be more effective than the chemotherapy drug alone.

The clinical trial, *A Randomized Phase III Trial of Paclitaxel (Taxol) vs. Paclitaxel and Bevacizumab (Avastin) as First Line Therapy for Locally Recurrent or Metastatic Breast Cancer*, was designed to show if adding Avastin to Taxol would improve outcomes. A scheduled interim analysis determined that the trial met its primary endpoint of improving progression-free survival (PFS) with the addition of Avastin.

Trial Results

Median progression-free survival increased from 6 months to 10 months with the addition of Avastin. This is equivalent to a 50% reduction in the risk of cancer progression. The risk of death was decreased by 33% in the Avastin plus Taxol group. The overall survival data needs to continue to mature. There was an increase in the Avastin plus Taxol group of neuropathy (pain, loss of sensation, and inability to control muscles), hypertension (high blood pressure) and proteinuria (protein in the urine).

Mechanism of Action

Avastin works by binding to vascular endothelial growth factor (VEGF). VEGF is a protein that plays an important role in forming and maintaining blood vessels that feed tumors. By blocking VEGF Avastin interferes with the tumors supply of blood and nutrients. Without nourishment tumor growth slows and individual cancer cells die.

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References

Bevacizumab Combined With Chemotherapy Improves Progression-Free Survival for Patients With Advanced Breast Cancer <http://www.nih.gov/news/pr/apr2005/nci-14.htm>

Avastin® Improves Outcomes in Advanced Breast Cancer <http://patient.cancerconsultants.com/news.aspx?id=34140>

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