

IN EVERY ISSUE

Prostate, Brain & Kidney Cancers

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Avodart Reduces Prostate Cancer Risk

Avodart (dutasteride), an approved drug for benign prostate enlargement, reduces the risk of prostate cancer, according to a study reported at the American Urological Association's annual meeting in late April.

The phase III trial showed a 23 percent relative reduction in the risk of prostate cancer over a four-year period with Avodart compared with placebo. The more than 8,000 trial participants, ages 50 to 75, had elevated levels of prostate-specific antigen, a predictor of prostate cancer. Side effects in the Avodart study included erectile dysfunction (9 percent), decreased libido (3 percent), and breast enlargement (2 percent).

Avodart blocks the action of two types of 5-alpha reductase enzymes, which convert testosterone to dihydrotestosterone—a potent male hormone in the prostate. In 2003, another 5-alpha reductase inhibitor called Proscar (finasteride) was shown to lower the risk of prostate cancer after seven years, but in men with average prostate cancer risk.

Nearly 200,000 men will be diagnosed with prostate cancer this year, and more than 27,000 will die, making it the second-leading cause of cancer death in men. However, prostate cancer mortality is decreasing, likely because of early detection. For more information, visit www.avodart.com or call 888-825-5249 (site is owned by GlaxoSmithKline, maker of Avodart).

Avastin Approved for Brain Cancer

Avastin (bevacizumab) was granted accelerated approval by the Food and Drug Administration on May 5 to treat an aggressive brain cancer called glioblastoma multiforme. Affecting about 10,000 people annually in the United States, glioblastoma is often initially treated with radiation and chemotherapy after surgery, but most patients have a recurrence. Now, Avastin is available to patients as a second-line therapy if the cancer progresses on the standard treatment.

The accelerated approval is based on a phase II trial that showed about 26 percent of patients' tumors shrank, an effect that lasted an average of about four months. However, no data are available to show Avastin improves disease symptoms or survival.

Accelerated approval is intended to offer treatments for life-threatening diseases based on early trial data that are considered to predict benefit. Patients in the trial were previously treated with Temodar (temozolomide) and radiation. Common side effects included fatigue, high blood pressure, headache, and infection.

Avastin is a monoclonal antibody that binds to vascular endothelial growth factor (VEGF), a protein that can spur blood vessel growth. Blood vessels carry oxygen and nutrients to the tumor to help it grow, so when Avastin binds to VEGF, it blocks the protein from binding to its receptor, ultimately causing the tumor to die.

First approved in 2004 for metastatic colorectal cancer, Avastin is also approved for non-small cell lung cancer and metastatic breast cancer. For more information, visit www.avastin.com or call 877-436-3683 (site is owned by Genentech, maker of Avastin).

Prostate Cancer Vaccine Shows Positive Results

The therapeutic cancer vaccine Provenge (sipuleucel-T) extended survival in men with advanced hormone-independent prostate cancer, based on preliminary data from the phase III IMPACT study. Unlike preventive vaccines, Provenge utilizes the patient's immune system to create a specific long-term response against cancer cells.

The results, which were announced at the American Urological Association's annual meeting in late April, demonstrated the vaccine extended median survival by about four months, from 21.7 months with placebo to 25.8 months with Provenge. It also improved three-year survival from 23 percent to 31.7 percent, and reduced the risk of death by a relative amount of 22.5 percent. However, the vaccine has not been shown to delay disease progression. Side effects included chills, fever, and headache, but were mild and short-term, occurring for one to two days after treatment.

The Food and Drug Administration reviewed the approval application for Provenge in May 2007, but asked for more evidence. Dendreon, the vaccine's manufacturer, proceeded with the IMPACT trial to gather further data, and plans to resubmit Provenge for approval later this year. For more information, visit www.dendreon.com or call 866-477-6782.

New Kidney Cancer Drug OKed

After a flurry of new drug approvals in a field that, before 2005, only had decades-old immunotherapy agents available, kidney cancer has one more drug

to add to the arsenal. In late March, Afinitor (everolimus) joined Torisel (temsirolimus), Nexavar (sorafenib), and Sutent (sunitinib) as targeted agents for renal cell carcinoma when the Food and Drug Administration approved the agent for second-line therapy (see “[Reining In Renal Cancer](#)”).

The approval is based on a phase III trial that compared Afinitor with placebo in 416 patients with advanced renal cell carcinoma whose tumors had progressed on Sutent and/or Nexavar. Afinitor delayed tumor progression in half of patients by about five months compared with two months in patients on -placebo. Data also showed that 25 percent of patients on Afinitor had no tumor growth after 10 months.

Common side effects include stomatitis, rash, and fatigue. For more information, visit www.afinitor.com or call 888-669-6682 (site is owned by Novartis, maker of Afinitor).