

New FDA-Approved Treatment Provides More Options For Patients With Most Common Type Of Kidney Cancer

(NAPSA)—According to a recent study published in the *American Journal of Epidemiology*, the number of newly diagnosed cases of renal cell carcinoma, the most common form of kidney cancer, has been increasing over the past several decades. Fewer than 10 percent of late-stage kidney cancer patients will live five years; however, people battling metastatic renal cell carcinoma have hope for tomorrow thanks to a newly approved medicine that works differently than other available treatments.

In July 2009, the U.S. Food and Drug Administration approved Avastin® (bevacizumab) plus interferon alfa to treat people with metastatic renal cell carcinoma.

This approval is based on data from a Phase III study (AVOREN) that showed patients who received Avastin plus interferon alfa had a 67 percent improvement in the time they lived without the disease worsening (progression-free survival or PFS), compared to those who received interferon alfa alone (hazard ratio=0.60, 95 CI=0.49, 0.72, p<0.0001). In AVOREN, one-half of patients who received Avastin plus interferon alfa lived 10.2 months without their disease worsening, compared to 5.4 months for patients who received interferon alfa alone, corresponding to an 89 percent improvement in median PFS.

According to the American Cancer Society, kidney cancer is the eighth most commonly diagnosed cancer in the United States, and in 2009 nearly 58,000 individ-

"We hope that researchers someday find a cure for kidney cancer," said William P. Bro, chief executive officer of the Kidney Cancer Association. "Until then, each new medicine, like Avastin, offers patients an opportunity to find a treatment that best suits them."



uals will be diagnosed with the disease. Approximately 13,000 people in the United States will die from the disease.

What Is Kidney Cancer?

Kidney cancer is the uncontrolled growth of cancerous cells that originate in the kidney. While the specific cause is unknown, the most common type is renal cell carcinoma, which accounts for approximately 90 percent of cases. The average age of diagnosis is 65 and incidence is highest in people between the ages of 55 and 84. The disease is more common in men than women. Kidney cancer is found more frequently in African-Americans.

Treating Kidney Cancer

Despite recent advances in treatment and new medicines, kidney cancer finds ways to grow and spread throughout the body. Using Avastin with interferon alfa gives doctors and people with this often deadly disease a new treatment choice.

Avastin is designed to block the vascular endothelial growth factor (VEGF) protein to address a key underlying cause of cancer growth. Avastin works differently than other approved medicines for renal

cell carcinoma because it specifically binds to the VEGF protein, which is produced in elevated amounts in most kidney cancers.

Support groups like the Kidney Cancer Association can help support individuals battling kidney cancer. For more information, please visit www.kidneycancerassociation.org.

Adverse events in this study were similar to those previously reported for Avastin and interferon alfa as single agents. Specific severe (Grade 3 to 5) adverse events that occurred at a rate of at least 2 percent more often in patients who received Avastin plus interferon alfa versus interferon alfa alone included tiredness (13 percent vs. 8 percent), weakness (10 percent vs. 7 percent), too much protein in the urine (7 percent vs. 0 percent), high blood pressure (6 percent vs. 1 percent) and bleeding (3 percent vs. 0.3 percent).

For more than 20 years, Genentech has been helping patients who are uninsured or who have been denied coverage from their insurance company. All of Genentech's medicines are covered by the Genentech Access Solutions program. For eligible patients who are treated for FDA-approved uses in the United States, Genentech will provide free medicine to those who cannot afford it. To learn more about these programs or to speak with an Alternative Funding Specialist from Genentech Access Solutions, call 1-866-4-ACCESS or visit www.GenentechAccessSolutions.com.



BOXED WARNINGS and Additional Important Safety Information

Patients treated with Avastin may experience side effects. In clinical trials, some patients treated with Avastin experienced serious side effects, including:

Gastrointestinal (GI) perforation: Treatment with Avastin can result in the development of a serious side effect called GI perforation, which is the development of a hole in the stomach, small intestine or large intestine. In clinical trials, this side effect occurred in 0.3 to 2.4 percent of patients and in some cases resulted in fatality. Avastin therapy should be permanently stopped in people with GI perforation.

Surgery and wound-healing problems: Treatment with Avastin can lead to slow or incomplete wound healing (for example, when a surgical incision has trouble healing or staying closed). In some cases this event resulted in fatality. In a clinical trial, 15 percent of patients with metastatic colorectal cancer who had surgery while receiving Avastin treatment had serious and fatal complications. Avastin should not be initiated for at least 28 days following surgery and until the surgical wound is fully healed. Avastin therapy should be permanently stopped in patients with wound-healing problems that require medical treatment. The appropriate waiting time between stopping treatment with Avastin and having surgery has not been determined.

Severe bleeding: Severe or fatal bleeding, including hemoptysis (coughing up of blood), GI bleeding, hematemesis (bloody vomit), central nervous system (CNS) hemorrhage (bleeding in the brain), epistaxis (nosebleeds), and vaginal bleeding occurred up to fivefold more frequently in patients receiving Avastin. Grade 3 or higher (severe or fatal) bleeding events have occurred in 1.2 to 4.6 percent of patients receiving Avastin.

In patients with previously treated glioblastoma, intracranial hemorrhage (bleeding within the brain) occurred in eight of 163 patients and two people had Grade 3 to 4 (severe) bleeding. Some people receiving Avastin with chemotherapy for lung cancer experienced hemoptysis. In some cases, this event resulted in fatality. People with serious bleeding or recent hemoptysis should not receive Avastin.

In clinical trials, additional serious side effects seen across different cancer types, in some cases resulting in fatality, included the following: formation of an abnormal passage from parts of the body to another part (non-GI fistula formation—less than or equal to 0.3 percent); stroke or heart problems (arterial thromboembolic events—2.4 percent); high blood pressure (5 to 18 percent); nervous system and vision disturbances known as RPLS (reversible posterior leukoencephalopathy syndrome—less than 0.1 percent); severe infusion reactions (0.2 percent); and too much protein in the urine, which may be a sign of kidney problems, was increased.

The most common adverse reactions observed in Avastin patients at a rate of more than 10 percent and at least twice the control arm rate were nosebleeds, headache, high blood pressure, irritation of the nose (rhinitis), protein in the urine, taste alteration, dry skin, rectal bleeding, tear production disorder (lacrimation), back pain, and inflammation of the skin (exfoliative dermatitis).

Avastin may cause problems getting pregnant. People who are pregnant or thinking of becoming pregnant should talk with their doctor about the potential risks of loss of pregnancy or the potential risk of Avastin to the fetus. Nursing mothers should not breast-feed while receiving Avastin or for a short period of time after treatment is finished.

For Avastin full prescribing information, including Boxed WARNINGS and additional important safety information, please visit www.avastin.com.