



Health Bulletin



Increasing The Options For Those With Advanced Kidney Cancer

(NAPSA)—A new treatment may offer some good news for those with advanced kidney cancer.

Kidney cancer develops when cancerous cells grow in the lining of the kidney's tubes and form a tumor. If left untreated, the tumor can spread to neighboring lymph nodes and eventually other organs. In 2008, an estimated 54,000 new cases of kidney cancer were diagnosed in the U.S. and more than 13,000 people died from the disease.

Afinitor® (everolimus) tablets, recently approved by the U.S. Food and Drug Administration (FDA), is a treatment for patients with advanced kidney cancer after failure of treatment with Sutent® (sunitinib) or Nexavar® (sorafenib).

Prior to Afinitor, no other therapy had been studied in a Phase III trial in this patient population where there are limited treatment options. The addition of Afinitor to the current kidney cancer therapies provides the first proven option after failure of treatment with Sutent or Nexavar.

Important safety information

Afinitor is contraindicated in patients with hypersensitivity to everolimus, to other rapamycin derivatives or to any of the excipients. Potentially serious adverse reactions include non-infectious pneumonitis and infections for which patients should be monitored carefully and treated as needed. In addition, non-infectious pneumonitis may require temporary dose reduction and/or interruption or discontinuation. Patients with systemic invasive fungal infections should not receive Afinitor. Oral ulceration is a common side effect with Afinitor. Renal function, blood glucose, lipids and hematological parameters should be evaluated prior to the start of therapy with Afinitor and periodically thereafter. Strong or moderate CYP3A4 or P-glycoprotein inhibitors should be avoided. An increase in the dose of Afinitor is recommended when co-administered with a strong CYP3A4 inducer. Live vaccinations and close contact with those who have received live vaccines should be avoided. Afinitor should not be used in patients with severe hepatic impairment. Afinitor may cause fetal harm in pregnant women.

The most common adverse reactions (incidence $\geq 30\%$) were stomatitis, infections, asthenia, fatigue, cough and diarrhea. The most common grade 3/4 adverse reactions (incidence $\geq 3\%$) were infections, dyspnea, fatigue, stomatitis, dehydration, pneumonitis, abdominal pain and asthenia. The most common laboratory abnormalities (incidence $\geq 50\%$) were anemia, hypercholesterolemia, hypertriglyceridemia, hyperglycemia, lymphopenia and increased creatinine. The most common grade 3/4 laboratory abnormalities (incidence $\geq 3\%$) were lymphopenia, hyperglycemia, anemia, hypophosphatemia and hypercholesterolemia. Deaths due to acute respiratory failure (0.7%), infection (0.7%) and acute renal failure (0.4%) were observed for patients receiving Afinitor.

Sutent is a registered trademark of Pfizer, Inc. Nexavar is a registered trademark of Bayer Healthcare Pharmaceuticals, Inc. and Onyx Pharmaceuticals.



A new drug has been approved, providing an important additional treatment option for people with advanced kidney cancer.

"This medication is a useful tool for treating advanced kidney cancer by targeting a certain protein inside the cancer cell that is responsible for tumor cell growth and division," said Robert J. Motzer, M.D., attending physician, Memorial Sloan-Kettering Cancer Center, New York, and cancer researcher. "The FDA approval is

an important step forward for patients who have been told their treatment with sunitinib or sorafenib was no longer effective."

In clinical trials, when compared to placebo, Afinitor significantly reduced the risk of disease progression or death and more than doubled the time without tumor growth or death in patients with advanced kidney cancer.

Advanced kidney cancer is most commonly found in people between the ages of 55 and 84, and more commonly affects men. Several factors can be attributed to an increased risk, including family history of the disease, smoking and genetics. Additionally, patients who require dialysis treatment tend to be at greater risk. Signs of advanced kidney cancer can include blood in the urine, lower back pain on one side that does not go away, a mass or lump in the abdomen and unexplained weight loss.

To learn more about Afinitor, please talk to your doctor or visit www.afinitor.com.