

FDA advisory panel unanimously recommends new kidney cancer drug

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There is probably no other cancer that has seen such breakthroughs in the past five years than kidney cancer. Less than a decade ago, patients with advanced renal cell carcinoma were treated with biological therapies, including interferon and interleukin, with few results. But in the past five years, there have been five drugs approved for the cancer--Sutent, Nexavar, Avastin, Torisel, and Afinitor.

Yesterday, the Oncologic Drugs Advisory Committee, a panel that reports to the Food and Drug Administration on whether a cancer drug should be approved or not, unanimously gave its recommendation for pazopanib. The panel said the drug appeared to be effective and its side effects were no more severe than other recently approved kidney cancer drugs.

The drug may also be a better alternative to some patients unable to tolerate the side effects of pazopanib's competitors. While studies show that pazopanib had a lower risk of rash and fatigue than with other kidney cancer drugs, some patients did develop diarrhea, hypertension, and nausea. The risk of severe liver injury, although rare, has also been noted.

Pazopanib, recently given a brand name of Votrient, was highlighted at this year's American Society of Clinical Oncology annual meeting where a phase III study compared the drug to placebo. Results showed the median progression-free survival in all patients more than doubled from 4.2 months with placebo to 9.2 months on pazopanib. (Newly diagnosed patients had improved PFS from 2.8 months to 11.1 months, while patients with prior biological treatment improved from 4.2 months to 7.4 months on the drug.)

Because there are so many kidney cancer drugs on the market now, some question whether pazopanib should be approved based on a placebo study. A phase III trial looking at the drug versus Sutent--the standard treatment for advanced kidney cancer--in locally advanced or metastatic RCC is currently ongoing. ODAC recommended the study be completed and that side effects continue to be monitored.

However, patients may not need to wait until the study is completed. The FDA is expected to make a decision on whether to approve the drug later this month.

Pazopanib, like some of the other approved kidney cancer drugs, including Sutent, is an antiangiogenic. These drugs inhibit the growth of new blood vessels that feed the tumor by targeting the vascular endothelial growth factor receptor. Other kidney cancer drugs, including Afinitor, on the other hand, target a protein called mTOR.

Robert Figlin, MD, interim director of City of Hope Comprehensive Cancer Center in Duarte, California, and director of the center's kidney cancer program, told *CURE* earlier this year that, in addition to the recent kidney cancer drug approvals, there may still be more on the horizon.

"We are already embarking on next-generation drugs," he says, including pazopanib, and another angiogenesis inhibitor, axitinib. "Both of these may have more activity than our currently available drugs." They might also have a better side effect profile, he says. "That's what we're looking for--better tolerance and more effectiveness."

And the increase in the number of treatment options for kidney cancer patients has an added benefit.

"This is a waterfall time for patients," he says. "The challenges for both doctors and patients are now how to choose the proper drugs, in what sequence, and whether or not to use them in combination."

For more on kidney cancer advancements, read "[Reining in Renal Cancer](#)" from the Summer 2009 issue of *CURE*.