

Tivozanib exhibits antitumor activity in renal cancer

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(HealthDay) -- The potent, selective vascular endothelial growth factor receptor-1, -2, and -3 inhibitor, tivozanib, demonstrates antitumor activity and is well tolerated in patients with advanced/metastatic renal cell carcinoma (RCC), according to research published online April 9 in the *Journal of Clinical Oncology*.

Dmitry A. Nosov, M.D., Ph.D., of the Blokhin Oncology Research Center in Moscow, and colleagues conducted a phase II randomized discontinuation trial (RDT) involving 272 patients with advanced or metastatic RCC to evaluate the antitumor activity and safety of

tivozanib. Patients were given 1.5 mg/d orally for 16 weeks, where one cycle was defined as three treatment weeks followed by a one-week break. During the first open-label phase of the trial, patients who experienced 25 percent or more [tumor shrinkage](#) continued to take tivozanib, while those with less than 25 percent shrinkage progressed to the second 12-week, double-blind phase and were randomized to receive either tivozanib or placebo. If patients experienced 25 percent or more [tumor growth](#), they were discontinued from the trial. Safety, objective response rate (ORR) at 16 weeks, and percentage of patients who were progression free after 12 weeks of double-blind treatment were primary end points, and progression-free survival was a secondary end point.

The researchers found that, overall, 83 percent of participants had tumors with clear-cell histology, 73 percent had undergone [nephrectomy](#), and 54 percent were treatment naive. In the 16-week open-label phase, the ORR was 18 percent. Among the 118 patients randomized to treatment with tivozanib or placebo, a statistically significant between-group difference in the percentage of patients who remained progression free after 12 weeks was observed (49 and 21 percent, respectively). Grade 3 and 4 hypertension was the most common treatment-related adverse event.

"Results from this RDT demonstrated promising activity and an acceptable safety and tolerability profile for tivozanib in advanced/metastatic RCC," the authors write.

The study was supported by AVEO Pharmaceuticals; several authors disclosed financial relationships (including employment) with AVEO.

More information: [Abstract](#)
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