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Targeted therapy better for repeat kidney cancer patients than FDA-approved counterpart

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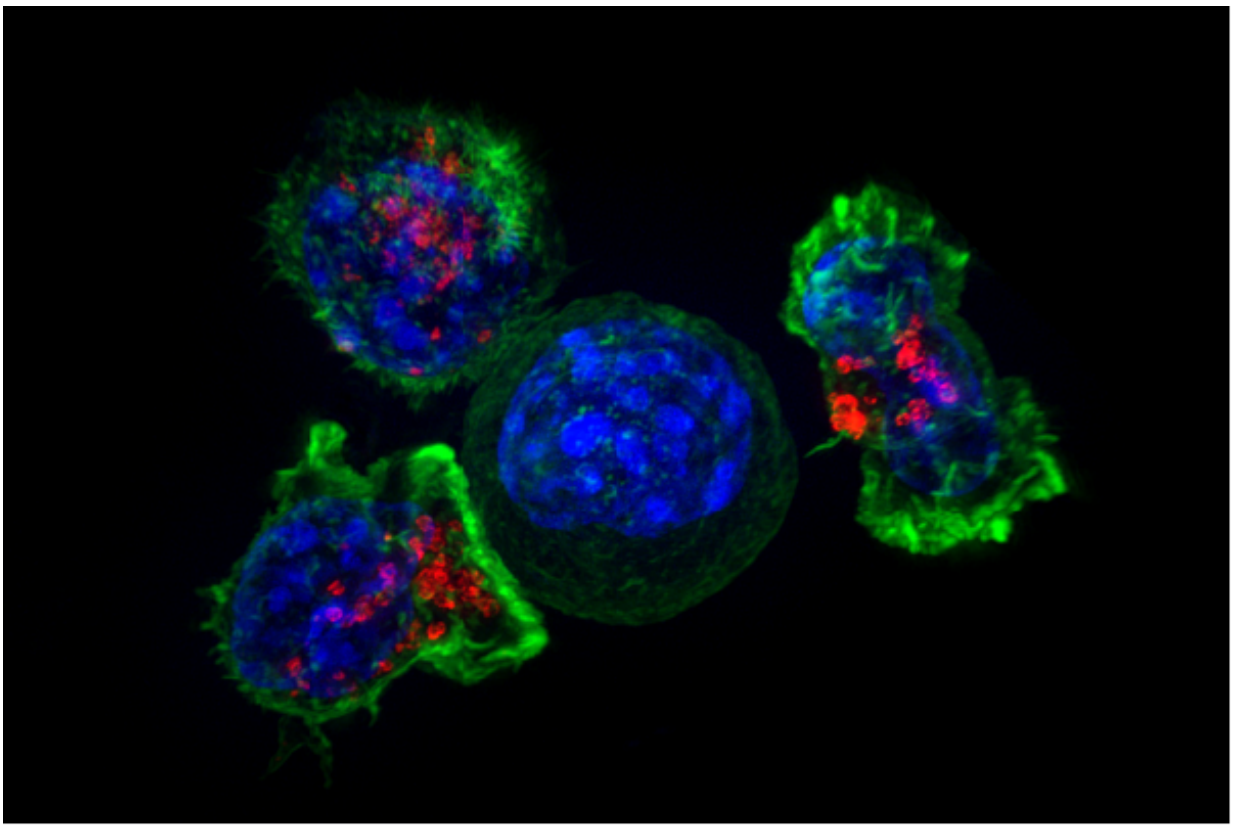

Killer T cells surround a cancer cell. Credit: NIH

Kidney cancer patients who had already tried two or three different treatments had improved chances of preventing cancer progression with

an experimental drug called tivozanib compared to an alternative approved by the U.S. Food and Drug Administration, according to a City of Hope-led study.

"This agent has shown in clinical trials to be effective in delaying cancer growth beyond established standards for patients who have returning kidney cancer," said Sumanta Pal, M.D., a medical oncologist at City of Hope and co-lead author of the new study. "Although there are many options for patients with kidney cancer today, most are intended for first- and second-line therapy. We need a treatment that works for kidney cancer patients who have failed several lines of therapy."

Published in *The Lancet Oncology* on Dec. 3, the study is the first to show the benefit of tivozanib for patients with renal cell carcinoma (the most common form of kidney cancer) who had received two or more previous therapies, Pal said. Although not yet approved in the United States, tivozanib is a blood vessel growth inhibitor that has been approved by the European Medicines Agency for first-line treatment of adults with renal cell carcinoma.

The multicenter phase 3 study randomly assigned 350 adult patients with metastatic renal cell carcinoma to receive either tivozanib or the FDA-approved sorafenib for a median of 19 months. This targeted therapy, a "VEGFR inhibitor," hinders the growth of new blood vessels, the fuel source for tumors.

The patients had a median age of 63 and were based at 120 centers in 12 different countries. They had received at least one VEGFR inhibitor treatment in their previous two or three treatments. Yet, they had never received tivozanib or sorafenib.

At one year, progression-free survival was 28% with tivozanib compared to 11% with sorafenib. At the two-year mark, progression-free survival

was 18% with tivozanib and 5% with sorafenib. The therapeutic benefit of tivozanib appeared to extend to patients who had received checkpoint inhibitors and those who were treated with two previous blood vessel growth inhibitors.

"City of Hope has a robust clinical trial program that often leads to practice-changing findings, and this is just one example of that," Pal said. "We are well known for working on investigational new drugs, and this is a late-stage study that is providing new options for patients with kidney cancer."

At the study's end, 70 patients in the tivozanib group (40%) and 82 patients in the sorafenib group (47%) had received subsequent anti-cancer therapy, meaning their cancer had progressed.

Tivozanib (FOTIVDA) is owned by AVEO Oncology, which plans to submit a new drug application in the first quarter of 2020 to the FDA so that this targeted therapy can used by patients with relapsed/refractory renal cell carcinoma, according to AVEO Oncology website.

More information: Brian I Rini et al, Tivozanib versus sorafenib in patients with advanced renal cell carcinoma (TIVO-3): a phase 3, multicentre, randomised, controlled, open-label study, *The Lancet Oncology* (2019). DOI: 10.1016/S1470-2045(19)30735-1

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