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New data from an international, multicenter Phase III clinical trial has found that the experimental targeted therapy everolimus (RAD001) significantly delays cancer progression in patients with metastatic [kidney cancer](#) whose disease had worsened on other treatments. The study was led by [Robert Motzer, MD](#), an attending physician at Memorial Sloan Kettering Cancer Center (MSKCC), who will present the findings on May 31 at the annual meeting of the American Society for Clinical Oncology.

"This study has given us a new and clearly useful tool for treating renal cell tumors, and everolimus is an important step forward in terms of disease management and quality of life for patients living with this disease," said Dr. Motzer.

Kidney cancer is among the ten most common cancers in both men and women. The American Cancer Society estimates that there will be about 54,390 new cases of kidney cancer diagnosed in the US in 2008, and that about 13,010 people will die from the disease.

Everolimus, a once-daily oral therapy, targets the mTOR protein, which acts as a central regulator of tumor cell division, cell metabolism, and blood

vessel growth. It is currently being evaluated for the treatment of several other cancers including [lymphoma](#) and neuroendocrine tumors.

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More than 400 patients participated in this study, all of whom had disease that had progressed with currently available targeted therapies sunitinib and/or sorafenib. Patients were randomized to receive everolimus or placebo. After six months, 26 percent of patients in the everolimus group had disease that had not progressed, compared to only 2 percent of the placebo group. The average difference in progression free survival was four months for everolimus, compared to 1.9 months for the placebo group.

In February, 2008, an independent monitoring committee stopped the Phase III trial after interim results were positive and allowed researchers to offer everolimus to the patients receiving placebo.

“For almost 20 years, we made no headway in the management of advanced kidney cancer,” notes Dr. Motzer. “Recently, the identification of several new angiogenesis- targeted agents has provided us with new treatment options and an improved outlook for patients with advanced kidney cancer. Based on the results of this trial, everolimus could become another tool in our armamentarium and, in the future, kidney cancer is likely to be managed as a chronic disease with these types of treatment advances.”

Everolimus was well tolerated by patients and the most common side effects were mouth ulcers, [anemia](#), skin rash and weakness.

In addition to Dr. Motzer, contributors to the study included researchers from Institut Gustave Roussy in Villejuif, France; Georges Pompidou European Hospital in Paris, France; San Matteo University Hospital in Pavia, Italy; US Oncology, Baylor-Sammons Cancer Center/TOPA in Dallas, Texas; Azienda Ospedaliera in Perugia, Italy; Novartis Pharmaceuticals in Florham Park, New Jersey; and Hôpital Saint André CHU in Bordeaux, France. The study was funded by grants from Novartis Pharmaceuticals.

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