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According to a new study, the drug sunitinib malate (Sutent®) is more effective than the current standard cytokine treatment given as an initial therapy for patients with advanced kidney cancer, also known as metastatic renal cell carcinoma (mRCC). The study is being presented today at the annual <u>American Society of Clinical Oncology</u> meeting.

"This drug has shown more activity as a single agent against advanced kidney cancer than any other drug I've studied in the past 15 years," said the study's lead author <u>Robert J. Motzer, MD</u>, a medical oncologist at Memorial Sloan Kettering Cancer Center (MSKCC). "I continue to be encouraged by its effectiveness in treating patients with this aggressive disease," said Dr. Motzer, who is a leader in the treatment of kidney cancer and conducted the earliest clinical trials on sunitinib (initially referred to as SU11248).

Interferon-alpha (IFN-alpha) is one of the standard treatments for advanced kidney cancer, however only about 15 percent of patients respond to this immunotherapy. Sunitinib targets receptors on kidney cancer cells that may play a role in tumor growth and the development of blood vessels that feed a tumor. Previous clinical trials, also led by Dr. Motzer, showed that sunitinib caused some renal cell cancers to shrink, but this study is the first to demonstrate its effectiveness as a first-line therapy compared with standard cytokine therapy with IFN-alpha.

The current randomized trial included 750 patients over the age of 60, half of whom were treated with a six-week cycle of sunitinib and half of whom were treated with a six-week cycle of the current treatment standard, IFN-alpha. The primary endpoint of the trial was a comparison of progression-free survival between sunitinib and IFN-alpha as assessed by independent third-party review. The median progression-free survival for treatment with sunitinib was 11 months, compared with 5 months following treatment with IFN-alpha. This outcome was statistically significant and met the primary question asked by investigators in the trial. In addition, 31 percent of the patients in the sunitinib arm of the study experienced substantial tumor shrinkage compared with 6 percent of the patients receiving the standard treatment.

"This drug offers new hope for the initial treatment of patients battling metastatic kidney cancer, which is otherwise resistant to chemotherapy," said Dr. Motzer.

Investigators from several US and international centers also contributed to the current study, including Baylor-Sammons Cancer Center, Dallas, TX; Texas Oncology PA, Bedford, TX.; Klinika Oncologii Oddzial Chemioterapii, Poznan, Poland; Massachusetts General Hospital, Boston, MA; The Cleveland Clinic Foundation, Cleveland, OH; Hospital Pitie-Salpetriere, Paris, France; Georges Pompidou European Hospital, Paris, France; and the University of California, Los Angeles. The study was sponsored by Pfizer, Inc.



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