FDA expands approval of Sutent to reduce the risk of kidney cancer returning

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Adjuvant treatment is a form of therapy that is taken after an initial surgical removal to lower the risk of the cancer coming back.

Singapore – The U.S. Food and Drug Administration approved Sutent (sunitinib malate) for the adjuvant treatment of adult patients who are at a high risk of kidney cancer (renal cell carcinoma) returning after a kidney has been removed (nephrectomy). Adjuvant treatment is a form of therapy that is taken after an initial surgical removal to lower the risk of the cancer coming back.

“This is the first adjuvant treatment approved for patients with renal cell carcinoma, which is significant because patients with this disease who have a nephrectomy are often at high risk of the cancer returning,” said Richard Pazdur, M.D., director of the FDA’s Oncology Center of Excellence and acting director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research. “There is now an approved therapy for patients who previously did not have options to potentially reduce cancer recurrence.”

The National Cancer Institute (NCI) at the National Institutes of Health estimates approximately 63,990 patients will be diagnosed with kidney and renal cell pelvis cancer this year, and 14,440 will die of the disease.

Sutent is a kinase inhibitor that works by blocking several enzymes that promote cell growth. Sutent was first approved in 2006 for the treatment of certain patients with gastrointestinal stromal tumors and advanced renal cell carcinoma. It is also approved for patients with a certain type of pancreatic cancer.

The approval of Sutent for the adjuvant treatment of renal cell carcinoma was based on a randomized trial of 615 patients with high risk of recurrent renal cell carcinoma following nephrectomy. The study measured the amount of time after the start of the trial that it took for the cancer to come back, for the patient to develop another unrelated cancer, or for death to occur from any cause (disease-free survival). After five years, 59.3 percent of patients treated with Sutent had not experienced cancer recurrence or death compared with 51.3 percent of patients receiving placebo.
The FDA granted the approval of Sutent to Pfizer Inc.