# Pfizer’s Sutent is Recommended as First-Line Treatment for Kidney Cancer Patients by British Health Agency

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NICE Decision Expands Treatment Choices for Patients

NEW YORK--(BUSINESS WIRE)--Pfizer Inc said today that the United Kingdom’s National Institute for Health and Clinical Excellence (NICE) has issued its final appraisal document (FAD) recommending the use of Sutent (sunitinib malate) as a first-line treatment for patients with metastatic renal cell carcinoma mRCC (advanced kidney cancer). According to NICE, “Sutent provided a step-change in the first-line treatment of advanced and/or metastatic RCC and [NICE] noted that more than 20% of the public and patients that responded in consultation highlighted this impressive benefit from sunitinib.”

Sutent demonstrated a significant improvement in progression- free survival vs. IFN-α. The median survival of patients treated with Sutent exceeded two years. In September 2008, NICE had issued an appraisal consultation document (ACD) which advised against the use of all four medicines for the treatment of mRCC. Today’s announcement reverses their previous recommendation regarding the coverage of Sutent, and makes Sutent the only one of the four medicines, under review, that is recommended for coverage to date.

“Today’s recommendation is an important step forward for kidney cancer patients and also for physicians in the U.K. who now have a proven treatment option for this difficult-to treat cancer,” said Garry Nicholson, president and general manager, Oncology Business Unit at Pfizer. “We appreciate this recommendation by NICE on behalf of patients.”

It is estimated that more than 7,000 people are diagnosed with kidney cancer in the UK each year and approximately 3,600 people die from the disease. Worldwide, approximately 210,000 new cases will be diagnosed worldwide, and at diagnosis, approximately 25 percent to 35 percent of RCC patients will have advanced disease. Metastatic, recurrent or relapsed renal cancer has a very poor prognosis. The historic median survival for patients treated for metastatic disease was 10 to 13 months.

Sutent, an oral multi-kinase inhibitor, was first approved in January 2006 for advanced RCC. Sutent works by blocking multiple molecular targets implicated in the growth, proliferation and spread of cancer.

Note: Sunitinib is recommended as a first-line treatment option for people with advanced and/or metastatic renal cell carcinoma who are suitable for immunotherapy and have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 (patients without symptoms or only mildly symptomatic from their cancer).

Important SUTENT® (sunitinib malate) Safety Information

Women of child bearing age who are (or become) pregnant during therapy should be informed of the potential for fetal harm while on SUTENT.

Decreases in left ventricular ejection fraction (LVEF) to below the lower limit of normal (LLN) have been observed. Patients with concomitant cardiac conditions should be carefully monitored for clinical signs and symptoms of congestive heart failure.

Patients should be monitored for hypertension and treated as needed with standard antihypertensive therapy. CBCs with platelet count and serum chemistries should be performed at the beginning of each treatment cycle for patients receiving treatment with SUTENT.

The most common adverse reactions in clinical trials were fatigue, asthenia, diarrhea, nausea, mucositis/stomatitis, vomiting, dyspensia, abdominal pain, constipation, hypertension, rash, hand-foot syndrome, skin discoloration, altered taste, anorexia and bleeding.

For more information on SUTENT and Pfizer Oncology, including full prescribing information for SUTENT (sunitinib malate), please visit www.pfizer.com.

About Pfizer Oncology:

Pfizer Oncology is committed to the discovery, investigation and development of cancer treatments and currently has 22 innovative compounds in clinical development across four platforms. By leveraging the strength of its resources and scientific talent, Pfizer Oncology strives to discover and develop novel treatment options to improve the outlook for oncology patients.

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