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Pfizer’s Sutent is Recommended for Reimbursement for Gastrointestinal Stromal Tumor Patients by British Health Agency

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NICE Decision Expands Treatment Choices for Patients

(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 reimbursement for Sutent (sunitinib malate) as a second-line treatment for patients with advanced gastrointestinal stromal tumor (GIST). This recommendation follows NICE’s recently published guidance recommending reimbursement for Sutent for the first-line treatment of advanced kidney cancer.

The guidance states that Sutent is recommended for reimbursement as a treatment option for patients with advanced GIST after disease progression on or intolerance to imatinib mesylate, and who have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.* According to NICE, “the benefits seen in time to tumor progression and progression free survival were such that a substantial improvement in overall survival with sunitinib treatment was probable.”

“NICE’s decision gives hope to patients with GIST who develop resistance to imatinib,” said Dr. Mace Rothenberg, senior vice president, clinical development and medical affairs, Pfizer’s Oncology Business Unit. “Insights into the causative pathways involved with cancers like GIST will help us bring Sutent to the right patient at the right time.”

NICE’s decision was based on data from a pivotal Phase 3 trial of Sutent compared with placebo in patients with advanced GIST. Sutent increased time to tumor progression in the study by almost five months (6.4 weeks vs. 27.3 weeks, P <0.0001). Following these early findings, 84 percent of patients receiving placebo switched to Sutent treatment. Updated analyses of this trial demonstrated a median overall survival of 73.9 weeks for Sutent patients vs. 64.9 weeks for those initially receiving placebo (P = 0.161). However, according to an exploratory analysis calculating what the difference may have been if the patients had remained on placebo, estimated overall survival for Sutent patients was 73.9 weeks, compared to 35 weeks for those receiving placebo.

“It’s a terrible thing to have to tell a patient with terminal cancer that a treatment is no longer working for them, their cancer is growing again and there are no other treatments available,” said Dr. Beatrice Seddon, consultant clinical oncologist, University College London Hospitals. “Before the arrival of sunitinib, this was the situation for people with advanced GIST in the U.K. NICE’s decision today means that finally, we have something else to offer our patients, and with it the hope of extra time and quality life with their families and loved ones.”

Sutent has played an important role in re-shaping the treatment landscape for GIST and advanced renal cell carcinoma (RCC), two historically difficult-to-treat cancers. The benefit/risk profile of Sutent has been well-established through large, randomized clinical trials evaluating the safety and efficacy in both second-line GIST and first-line advanced RCC. To date, approximately 50,500 patients globally have been treated with Sutent.

NICE, the independent organization responsible for issuing guidance for drug reimbursement to the British National Health Service, plans to publish final guidance in July, which will then be implemented by the local funding bodies in England and Wales.

About Advanced Gastrointestinal Stromal Tumor

Gastrointestinal stromal tumor (GIST) is found in the gastrointestinal (GI) tract and belongs to a group of rare cancers called soft tissue sarcomas. Sarcomas begin in muscle, fat, fibrous tissue, blood vessels, or other supporting tissue of the body. Advanced GIST affects approximately 90 to 150 people in the U.K. each year, with an annual worldwide incidence of approximately 1.5 cases per 100,000 persons.

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 innovative treatment options for cancer patients worldwide. Our robust pipeline consists of 21 biologics and small molecules in clinical development across four scientific platforms – anti-angiogenesis, signal transduction, immuno-oncology, and cytotoxic potentiators. Pfizer Oncology has over 200 clinical trials including robust Phase 3 clinical trial programs in renal cell carcinoma, prostate cancer, non-small cell lung cancer, metastatic breast cancer, colorectal cancer, and hepatocellular carcinoma.

By working collaboratively with academic institutions, researchers, governments, and licensing partners, Pfizer Oncology strives to transform treatment by targeting the right drug for the right patient at the right time. For more information please visit www.Pfizer.com.

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Founded in 1849, Pfizer is the world's premier biopharmaceutical company taking new approaches to better health. We discover, develop, manufacture and deliver quality, safe and effective prescription medicines to treat and help prevent disease for both people and animals. We also partner with healthcare providers, governments and local communities around the world to expand access to our medicines and to provide better quality health care and health system support. At Pfizer, more than 80,000 colleagues in more than 90 countries work every day to help people stay happier and healthier longer and to reduce the human and economic burden of disease worldwide.

**Patients without symptoms or only mildly symptomatic from their cancer.*

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