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Pfizer Announces Positive Top-Line Results From Phase 3 S-TRAC Trial of SUTENT® (sunitinib) as Adjuvant Therapy in Patients at High Risk of Recurrent Renal Cell Carcinoma

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S-TRAC is the First RCC Trial of a Tyrosine Kinase Inhibitor to Prolong Disease-Free Survival in the Adjuvant Setting

“SUTENT has long been a standard of care for the treatment of advanced RCC, and has reached more than 250,000 patients across diagnoses around the world since its initial approval 10 years ago”

Pfizer Inc. (NYSE:PFE) today announced that the S-TRAC clinical trial (Sunitinib Trial in Adjuvant Renal C ancer), a Phase 3 study of SUTENT versus placebo in the adjuvant setting, met its primary endpoint of improving disease-free survival (DFS) as determined by blinded independent central review in patients with renal cell carcinoma (RCC) who are at high risk for recurrence after surgery. The S-TRAC trial is the first RCC trial of a tyrosine kinase inhibitor (TKI) to prolong DFS in the adjuvant setting. The concept of adjuvant therapy is to help lower the risk of cancer recurrence in patients with early-stage cancer.

“SUTENT has long been a standard of care for the treatment of advanced RCC, and has reached more than 250,000 patients across diagnoses around the world since its initial approval 10 years ago,” said Mace Rothenberg, MD, Chief Development Officer, Oncology, Pfizer Global Product Development. “We believe the results from the S-TRAC trial support the potential for SUTENT to be a treatment option in a broader range of patients. We look forward to sharing the detailed results of S-TRAC with the oncology community and discussing these data with health authorities to determine an appropriate regulatory path forward.”

The adverse events observed for SUTENT in the S-TRAC trial were consistent with its known safety profile. Full efficacy and safety data will be submitted for presentation at the ESMO 2016 Congress in Copenhagen, 07-11 October 2016.

SUTENT (sunitinib malate) is an oral multi-kinase inhibitor that was approved in the United States in 2006 for the treatment of advanced RCC. It is currently approved in 119 countries[1] and is the most prescribed among oral medications approved for the treatment of advanced RCC in the United States. Worldwide more than 250,000 patients across diagnoses have been treated with SUTENT in its approved indications of advanced RCC, imatinib-resistant or -intolerant gastrointestinal stromal tumors (GIST) and advanced pancreatic neuroendocrine tumors (pNET).[2]

Pfizer is a leader in advanced RCC treatment with several approved therapies that have contributed to the treatment for patients with advanced RCC worldwide.

About S-TRAC

The S-TRAC trial is a randomized double-blind Phase 3 trial of adjuvant SUTENT vs. placebo in more than 670 patients at high risk of recurrent RCC. Patients were on SUTENT or placebo for one year. The trial has two cohorts: Global and China.

The primary objective for the Global cohort is to demonstrate an improvement in disease-free survival (DFS) in patients at high risk of recurrent RCC randomly assigned to adjuvant SUTENT vs. placebo after surgery. DFS is defined as the time interval from the date of randomization to the first date of recurrence or the occurrence of a secondary malignancy or death. Recurrence refers to relapse of the primary tumor in-situ or at metastatic sites.

This top-line analysis comprises the Global cohort only. Results from the China cohort are not yet mature and will be reported at a later date.

About Renal Cell Carcinoma (RCC)

Renal cell carcinoma (RCC) is the most common type of kidney cancer, accounting for around 90 percent of all kidney cancers.[3] Early stage renal cancers tend to have a better prognosis, while advanced cancers have a worse prognosis.[4] At diagnosis, 30 percent of kidney cancer patients show signs of advanced disease and 15 to 25 percent of patients have metastatic RCC, where the cancer has spread to other parts of the body.[5] Approximately 338,000 new cases of kidney cancer are diagnosed worldwide each year, representing approximately 2 percent of all cancers.[6] Patients with advanced RCC have five-year survival rates of approximately 16 percent.[7]

SUTENT Important Safety Information

Boxed Warning/Hepatotoxicity: **Hepatotoxicity has been observed in clinical trials and post-marketing experience. This hepatotoxicity may be severe, and deaths have been reported.** Monitor liver function tests before initiation of treatment, during each cycle of treatment, and as clinically indicated. SUTENT should be interrupted for Grade 3 or 4 drug-related hepatic adverse events and discontinued if there is no resolution. Do not restart SUTENT if patients subsequently experience severe changes in liver function tests or have other signs and symptoms of liver failure.

Pregnancy: Women of childbearing potential should be advised of the potential hazard to the fetus and to avoid becoming pregnant.

Nursing mothers: Given the potential for serious adverse reactions (ARs) in nursing infants, a decision should be made whether to discontinue nursing or SUTENT.

Cardiovascular events: Cardiovascular events, including heart failure, cardiomyopathy, myocardial ischemia, and myocardial infarction, some of which were fatal, have been reported. Use SUTENT with caution in patients who are at risk for, or who have a history of, these events. Monitor patients for signs and symptoms of congestive heart failure (CHF) and, in the presence of clinical manifestations, discontinuation is recommended. Patients who presented with cardiac events, pulmonary embolism, or cerebrovascular events within the previous 12 months were excluded from clinical studies.

QT interval prolongation and Torsades de Pointes: SUTENT has been shown to prolong QT interval in a dose-dependent manner, which may lead to an increased risk for ventricular arrhythmias including Torsades de

Pointes, which has been seen in <0.1% of patients. Monitoring with on-treatment electrocardiograms and electrolytes should be considered.

Hypertension: Hypertension may occur. Monitor blood pressure and treat as needed with standard antihypertensive therapy. In cases of severe hypertension, temporary suspension of SUTENT is recommended until hypertension is controlled.

Reversible posterior leukoencephalopathy syndrome (RPLS): There have been (<1%) reports, some fatal, of subjects presenting with seizures and radiological evidence of RPLS.

Hemorrhagic events: Hemorrhagic events, including tumor-related hemorrhage such as pulmonary hemorrhage, have occurred. Some of these events were fatal. Perform serial complete blood counts (CBCs) and physical examinations.

Tumor lysis syndrome (TLS): Cases of TLS have been reported primarily in patients with high tumor burden. Monitor these patients closely and treat as clinically indicated.

Thrombotic microangiopathy (TMA): TMA, including thrombotic thrombocytopenic purpura and hemolytic uremic syndrome, sometimes leading to renal failure or a fatal outcome, has been reported in patients who received SUTENT as monotherapy and in combination with bevacizumab. Discontinue SUTENT in patients developing TMA. Reversal of the effects of TMA has been observed after treatment was discontinued.

Proteinuria: Proteinuria and nephrotic syndrome have been reported. Some of these cases have resulted in renal failure and fatal outcomes. Perform baseline and periodic urinalysis during treatment, with follow-up measurement of 24-hour urine protein as clinically indicated. Interrupt SUTENT and dose reduce if 24-hour urine protein is ?3 g; discontinue SUTENT in cases of nephrotic syndrome or repeat episodes of urine protein ?3 g despite dose reductions.

Dermatologic toxicities: Severe cutaneous reactions have been reported, including cases of erythema multiforme (EM), Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), some of which were fatal. If signs or symptoms of EM, SJS, or TEN are present, SUTENT treatment should be discontinued. If a diagnosis of SJS or TEN is suspected, treatment must not be re-started. Necrotizing fasciitis, including fatal cases, has been reported, including of the perineum and secondary to fistula formation. Discontinue SUTENT in patients who develop necrotizing fasciitis.

Thyroid dysfunction: Thyroid dysfunction may occur. Monitor thyroid function in patients with signs and/or symptoms of thyroid dysfunction, including hypothyroidism, hyperthyroidism, and thyroiditis, and treat per standard medical practice.

Hypoglycemia: SUTENT has been associated with symptomatic hypoglycemia, which may result in loss of consciousness or require hospitalization. Reductions in blood glucose levels may be worse in patients with diabetes. Check blood glucose levels regularly during and after discontinuation of SUTENT. Assess whether anti-diabetic drug dosage needs to be adjusted to minimize the risk of hypoglycemia.

Osteonecrosis of the jaw (ONJ): ONJ has been reported. Consider preventive dentistry prior to treatment with SUTENT. If possible, avoid invasive dental procedures, particularly in patients receiving bisphosphonates.

Wound healing: Cases of impaired wound healing have been reported. Temporary interruption of therapy with SUTENT is recommended in patients undergoing major surgical procedures.

Adrenal function: Adrenal hemorrhage was observed in animal studies. Monitor adrenal function in case of stress such as surgery, trauma, or severe infection.

Laboratory tests: CBCs with platelet count and serum chemistries including phosphate should be performed at the beginning of each treatment cycle for patients receiving treatment with SUTENT.

CYP3A4 coadministration: Dose adjustments are recommended when SUTENT is administered with CYP3A4 inhibitors or inducers. During treatment with SUTENT, patients should not drink grapefruit juice, eat grapefruit, or take St John's Wort.

Most common ARs & most common grade 3/4 ARs (advanced RCC): The most common ARs occurring in ? 20% of patients receiving SUTENT for treatment-naïve metastatic RCC (all grades, vs IFN?) were diarrhea (66% vs 21%), fatigue (62% vs 56%), nausea (58% vs 41%), anorexia (48% vs 42%), altered taste (47% vs 15%), mucositis/stomatitis (47% vs 5%), pain in extremity/limb discomfort (40% vs 30%), vomiting (39% vs 17%), bleeding, all sites (37% vs 10%), hypertension (34% vs 4%), dyspepsia (34% vs 4%), arthralgia (30% vs 19%), abdominal pain (30% vs 12%), rash (29% vs 11%), hand-foot syndrome (29% vs 1%), back pain (28% vs 14%), cough (27% vs 14%), asthenia (26% vs 22%), dyspnea (26% vs 20%), skin discoloration/yellow skin (25% vs 0%), peripheral edema (24% vs 5%), headache (23% vs 19%), constipation (23% vs 14%), dry skin (23% vs 7%), fever (22% vs 37%), and hair color changes (20% vs <1%). The most common grade 3/4 ARs (occurring in ?5% of patients with RCC receiving SUTENT vs IFN?) were fatigue (15% vs 15%), hypertension (13% vs <1%), asthenia (11% vs 6%), diarrhea (10% vs <1%), hand-foot syndrome (8% vs 0%), dyspnea (6% vs 4%), nausea (6% vs 2%), back pain (5% vs 2%), pain in extremity/limb discomfort (5% vs 2%), vomiting (5% vs 1%), and abdominal pain (5% vs 1%).

Most common grade 3/4 lab abnormalities (advanced RCC): The most common grade 3/4 lab abnormalities (occurring in ?5% of patients with RCC receiving SUTENT vs IFN?) included lymphocytes (18% vs 26%), lipase (18% vs 8%), neutrophils (17% vs 9%), uric acid (14% vs 8%), platelets (9% vs 1%), hemoglobin (8% vs 5%), sodium decreased (8% vs 4%), leukocytes (8% vs 2%), glucose increased (6% vs 6%), phosphorus (6% vs 6%), and amylase (6% vs 3%).

Most common ARs & most common grade 3/4 ARs (imatinib-resistant or -intolerant GIST): The most common ARs occurring in ?20% of patients with GIST and more commonly with SUTENT than placebo (all grades, vs placebo) were diarrhea (40% vs 27%), anorexia (33% vs 29%), skin discoloration (30% vs 23%), mucositis/stomatitis (29% vs 18%), asthenia (22% vs 11%), altered taste (21% vs 12%), and constipation (20% vs 14%). The most common grade 3/4 ARs (occurring in ?4% of patients with GIST receiving SUTENT vs placebo) were asthenia (5% vs 3%), hand-foot syndrome (4% vs 3%), diarrhea (4% vs 0%), and hypertension (4% vs 0%).

Most common grade 3/4 lab abnormalities (imatinib-resistant or -intolerant GIST): The most common grade 3/4 lab abnormalities (occurring in ?5% of patients with GIST receiving SUTENT vs placebo) included lipase (10% vs 7%), neutrophils (10% vs 0%), amylase (5% vs 3%), and platelets (5% vs 0%).

Most common ARs & most common grade 3/4 ARs (advanced pNET): The most common ARs occurring in ?20% of patients with advanced pNET and more commonly with SUTENT than placebo (all grades, vs placebo) were diarrhea (59% vs 39%), stomatitis/oral syndromes (48% vs 18%), nausea (45% vs 29%), abdominal pain (39% vs 34%), vomiting (34% vs 31%), asthenia (34% vs 27%), fatigue (33% vs 27%), hair color changes (29% vs 1%), hypertension (27% vs 5%), hand-foot syndrome (23% vs 2%), bleeding events (22% vs 10%), epistaxis (21% vs 5%), and dysgeusia (21% vs 5%). The most commonly reported grade 3/4 ARs (occurring in ?5% of patients with advanced pNET receiving SUTENT vs placebo) were hypertension (10% vs 1%), hand-foot syndrome (6% vs 0%), stomatitis/oral syndromes (6% vs 0%), abdominal pain (5% vs 10%), fatigue (5% vs

9%), asthenia (5% vs 4%), and diarrhea (5% vs 2%).

Most common grade 3/4 lab abnormalities (advanced pNET): The most common grade 3/4 lab abnormalities (occurring in ?5% of patients with advanced pNET receiving SUTENT vs placebo) included decreased neutrophils (16% vs 0%), increased glucose (12% vs 18%), increased alkaline phosphatase (10% vs 11%), decreased phosphorus (7% vs 5%), decreased lymphocytes (7% vs 4%), increased creatinine (5% vs 5%), increased lipase (5% vs 4%), increased AST (5% vs 3%), and decreased platelets (5% vs 0%).

Indications

SUTENT® (sunitinib malate) is indicated for the treatment of advanced renal cell carcinoma (RCC), gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib mesylate, and progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in patients with unresectable locally advanced or metastatic disease.

Please see ***full Prescribing Information***, **including BOXED WARNING and Medication Guide, for SUTENT® (sunitinib malate)**.

About Pfizer Oncology

Pfizer Oncology is committed to the discovery, investigation and development of innovative treatment options to improve the outlook for cancer patients worldwide. Our strong pipeline of biologics and small molecules, one of the most robust in the industry, is studied with precise focus on identifying and translating the best scientific breakthroughs into clinical application for patients across a wide range of cancers. By working collaboratively with academic institutions, individual researchers, cooperative research groups, governments, and licensing partners, Pfizer Oncology strives to cure or control cancer with breakthrough medicines, to deliver the right drug for each patient at the right time. For more information, please visit www.pfizer.com.

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DISCLOSURE NOTICE: The information contained in this release is as of July 8, 2016. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about SUTENT and a potential new indication for SUTENT for the treatment of RCC in the adjuvant setting (the “potential indication”), including their potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties

inherent in research and development, including the ability to meet anticipated regulatory submission dates, as well as the possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing clinical data; whether and when any supplemental new drug applications may be filed in any jurisdictions for the potential indication; whether and when any such applications may be approved by regulatory authorities, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of SUTENT; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2015 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

[1] Pfizer Data on File

[2] Pfizer Data on File

[3] What is Kidney Cancer. James Whale Fund for Kidney Cancer. Available via http://www.jameswhalefund.org/kidneycancer/what-is-kidney-cancer/; Accessed November, 2015.

[4] American Cancer Society. Detailed Guide: Kidney Cancer. (Adult) – Renal Cell Carcinoma. Available at: http://www.cancer.org/acs/groups/cid/documents/webcontent/003107-pdf.pdf. Accessed November, 2015.

[5] Kidney Cancer Association. About Kidney Cancer. Available at: http://www.kidneycancer.org/knowledge/learn/about-kidney-cancer/ November, 2015.

[6] Ferlay J, Shin HR, Bray F, Forman D, Mathers C and Parkin DM.GLOBOCAN 2008 v1.2, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 10 Lyon, France: International Agency for Research on Cancer; 2010. Available from: http://globocan.iarc.fr, Accessed November, 2015.

[7] National Cancer Institute: SEER Stat Fact Sheets: Kidney and Renal Pelvis. Key fact available at http://seer.cancer.gov/statfacts/html/kidrp.html. Accessed November, 2015.

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