New Pfizer Data Helps to Identify Kidney Cancer Patients Who May Be Most Likely to Benefit from Treatment

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Anti-tumor Activity Also Shown in Prostate Cancer Patients Treated with Sutent

(BUSINESS WIRE)--Pfizer announced today, at the 45th American Society of Clinical Oncology (ASCO) Annual Meeting, the results of several clinical studies that may help identify patients who are more likely to benefit when treated with Sutent® (sunitinib malate) or axitinib (AG-013736), an investigational compound. The data identifies prognostic and predictive factors associated with longer overall survival among subgroups of patients with metastatic renal cell carcinoma (mRCC), or advanced kidney cancer. In addition, Phase 2 study results showing anti-tumor activity of Sutent in patients with metastatic hormone-refractory prostate cancer (mHRPC) will be presented at ASCO.

“Sunitinib has helped reshape the treatment landscape in advanced kidney cancer,” said Dr. Robert Motzer, attending physician at Memorial Sloan-Kettering Cancer Center and lead investigator on the sunitinib Phase 3 trial in RCC. “Over time, research with this drug continues to inform our understanding of how individual patients respond to treatment, driving towards a more customized treatment approach for this difficult-to-treat cancer.”

Data from a large, randomized, pivotal Phase 3 trial demonstrating superior progression-free survival with Sutent (50mg/day on a 4 weeks on 2 weeks off schedule) compared to interferon-alfa (IFN-α) (9mU three times per week) in 750 treatment-naïve mRCC patients, and a median overall survival of more than two years in patients treated with Sutent, were analyzed to determine prognostic factors for overall survival.

Based on the analysis, prognostic factors associated with longer overall survival in patients treated with Sutent include time from diagnosis to treatment (≥ 1 year vs. < 1 year, p = 0.0008), Eastern Cooperative Oncology Group (ECOG) performance status of 1 vs. 0 (p = 0.0085), lower corrected calcium (p < 0.0001), absence of bone metastases (p = 0.015), higher hemoglobin (p = 0.0008) and lower lactic dehydrogenase (LDH), an enzyme involved in energy production in cells (p < 0.0001).

Predictive Factors to Identify Subgroups of mRCC Patients who may Benefit from Treatment with Axitinib

In a separate retrospective analysis of two Phase 2 studies of axitinib, an investigational compound being studied in mRCC, elevated diastolic blood pressure (dBP ≥ to 90 mmHg) was shown to be a predictor of clinical efficacy in mRCC patients (n=109) treated with axitinib, an oral, selective inhibitor of VEGFR 1, 2 and 3 (vascular endothelial growth factor receptors 1, 2 and 3). The median overall survival for patients with at least one elevated dBP reading (n=59) was about three times longer than patients with no elevation in dBP (n=50) (130 weeks vs. 42 weeks, respectively; p < 0.01).

Advanced renal cell carcinoma, a rare but serious type of kidney cancer, is among the most treatment-resistant tumors. Nearly 58,000 people in the United States will be diagnosed with kidney cancer this year and nearly 13,000 people will die from the disease.

Pfizer is committed to further research in kidney cancer populations. Currently underway are two Phase 3 trials studying the role of Sutent in adjuvant renal cell carcinoma, immediately after surgery, in patients at risk for cancer recurrence. Additionally, axitinib is being investigated in a Phase 3 clinical trial for second-line therapy in mRCC.

Phase 2 Study of Sunitinib Malate in First-line Hormone-Refractory Prostate Cancer

Pfizer is also conducting clinical trials of sunitinib malate in other tumor types, including prostate cancer, one of the most common cancers in men, with more than 780,000 new cases diagnosed each year worldwide. Pfizer has initiated a randomized Phase 3 clinical trial evaluating the efficacy and safety of sunitinib plus prednisone versus placebo and prednisone in metastatic HRPC patients after disease progression on a docetaxel-based chemotherapy regimen.

Positive data from a Phase 2 trial evaluating 55 patients with metastatic HRPC will be presented this week at ASCO. In this study, sunitinib in combination with docetaxel and prednisone appeared to be well-tolerated and showed anti-tumor activity in patients with

mHRPC, as indicated by both prostate-specific antigen (PSA) and RECIST-defined (Response Evaluation Criteria In Solid Tumors) tumor responses.3

Findings showed anti-tumor activity of sunitinib in combination with docetaxel and prednisone, with a PSA response occurring in 56 percent of patients with a median time to PSA progression of 42.1 weeks. In addition, 53 percent of patients on the study for longer than 12 weeks had a 30 percent or greater decline in PSA at that time, and 22 percent of patients had a PSA drop to below 4.0 ng/mL. Out of 33 patients with measurable disease, 42 percent (n=14) had a confirmed partial response and another 18 percent (n=6) had an initial partial response. The median progression-free survival was 9.7 months (95 percent CI: 5.8, 10.4).

In this study, the most commonly reported treatment-related grade 3-4 adverse events were neutropenia (53 percent), leukopenia (28 percent), fatigue (17 percent), febrile neutropenia (15 percent), stomatitis (7 percent) and anorexia (7 percent).

“We continue to see encouraging results with Sutent across numerous cancers, both as a single agent and in combination with standard therapies,” said Dr. Mace Rothenberg, head of oncology development at Pfizer. “Between Sutent and our robust pipeline, we are committed to delivering tailored treatment options for people living with cancer.”

About Axitinib

Axitinib is an oral, selective inhibitor of vascular endothelial growth factor receptors 1, 2 and 3. Axitinib may work by inhibiting blood vessel formation, which may starve tumors of blood supply needed for growth. Based on preclinical studies, axitinib is being studied as both a single agent and in combination with other cancer therapies across many tumor types. Axitinib is an investigational agent and has not yet been approved by the U.S. Food and Drug Administration or other global regulatory agencies.

About Sutent® (sunitinib malate)

Sutent is an oral multi-kinase inhibitor approved for the treatment of gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib mesylate and advanced/metastatic RCC.

Sutent works by blocking multiple molecular targets implicated in the growth, proliferation and spread of cancer. Two important Sutent targets, vascular endothelial growth factor receptor (VEGFR) and platelet-derived growth factor receptor (PDGFR), are expressed by many types of solid tumors and are thought to play a crucial role in

angiogenesis, the process by which tumors acquire blood vessels, oxygen and nutrients needed for growth. Sutent also inhibits other targets important to tumor growth, including KIT, FLT3 and RET.

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. Complete blood counts (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 advanced RCC and GIST clinical trials were fatigue, asthenia, diarrhea, nausea, mucositis/stomatitis, vomiting, dyspepsia, 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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DISCLOSURE NOTICE: The information contained in this release is as of May 29, 2009. Pfizer assumes no obligation to update any forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information that involves substantial risks and uncertainties about data that may help identify kidney cancer patients who are more likely to benefit from treatment with Sutent or axitinib; about various potential indications, including advanced kidney cancer, for axitinib, and various potential additional indications, including prostate cancer, for Sutent; and about the potential benefits of axitinib and Sutent. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by regulatory authorities regarding whether and when to approve any drug applications or supplemental drug applications that may be filed for any such indications or additional indications as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of any such indications or additional indications; and competitive developments.

A further list and description of risks and uncertainties can be found in Pfizer’s Annual Report on Form 10-K for the fiscal year ended December 31, 2008 and in its reports on Form 10-Q and Form 8-K.

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