Pfizer Logo

New Pfizer Oncology Data Across Numerous Cancer Types to be Presented at ASCO

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Company Expands Phase III Research Program Evaluating SUTENT in Metastatic Breast Cancer

(BUSINESS WIRE)--Pfizer said today that results showing potential across numerous types of cancer, such as melanoma, thyroid, liver, non-small cell lung (NSCLC), colorectal (CRC) and renal cell carcinoma (RCC) – a type of advanced kidney cancer – will be presented next week at the American Society of Clinical Oncology (ASCO) annual meeting in Chicago.

“Each person with cancer responds differently to treatment, so it’s critical that physicians have the flexibility of trying new options and tailoring regimens to patients’ individual needs,” said Joe Feczko, MD, chief medical officer at Pfizer. “Pfizer is focused on exploring additional uses for approved products and investigating promising new compounds in a number of different tumor types.”

Researchers will present cutting-edge data from the breadth of Pfizer’s oncology portfolio, focused in three areas of discovery: anti-angiogenesis, signal transduction and immuno-oncology.

Anti-Angiogenesis

SUTENT® (sunitinib malate):

- Data will be presented from multiple SUTENT abstracts across a wide range of cancers. Highlights include:
    - New data from the phase III trial of SUTENT versus Interferon-alfa (IFN-?) in previously untreated patients with metastatic RCC.
    - Phase II trial that evaluated the anti-tumor activity of sunitinib malate as a single agent in liver cancer.
    - Phase II study that examined the efficacy and safety of continuous daily dosing of single-agent sunitinib malate in previously treated patients with advanced NSCLC.

Axitinib:

-- Phase II data will be presented from five trials evaluating the efficacy of axitinib as a single agent and combined treatment for a number of cancers including advanced pancreatic, thyroid, kidney, NSCLC and metastatic breast cancer. Three key presentations include:

- Efficacy and safety of axitinib as a single agent in patients with advanced refractory thyroid cancer.
- Overall survival in patients with advanced pancreatic cancer treated with axitinib in combination with gemcitabine or gemcitabine alone.

- Single-agent efficacy and safety of axitinib in advanced, refractory NSCLC.

Signal Transduction

- A phase II trial evaluated the safety and efficacy of the investigational compound CP-751,871 in combination with paclitaxel and carboplatin as first-line treatment for NSCLC and standard therapy (paclitaxel and carboplatin alone).

Immuno-Oncology

- Four different presentations evaluating CP-675,206 in metastatic melanoma and one presentation evaluating CP-675,206 in refractory CRC will be unveiled at ASCO.
- Results from a multi-dose phase I/II clinical trial that evaluated safety, response, and survival in patients with advanced metastatic melanoma treated with CP-675,206 will be presented in an oral presentation. Two different dosing regimens were evaluated in the phase II arm, providing information on the selected dosing regimen in the phase III program.

Pfizer also announced the expansion of the clinical trial program evaluating the efficacy and safety of sunitinib malate in the treatment of breast cancer. Pfizer has initiated three additional phase III trials to further evaluate sunitinib malate in metastatic breast cancer. This robust research program now includes a total of four phase III and two phase II trials and will include more than 2,600 patients worldwide.

Phase III programs evaluating sunitinib malate in CRC, NSCLC and liver cancer will also be initiated. Professionals interested in learning more about sunitinib malate trials in various cancers can access www.suntrials.com – a clinical resource for healthcare providers.

“SUTENT has proven to be an important therapy in the treatment of advanced kidney cancer and imatinib-resistant gastrointestinal stromal tumor, for which it is currently approved by the FDA,” said Charles Baum, MD, vice president of Pfizer Global Research and Development. “We are committed to investigating the role SUTENT may play in the treatment of advanced breast cancer through a comprehensive phase III program.”

SUTENT (sunitinib malate) Phase III Trials in Breast Cancer

This phase III research program in advanced breast cancer will investigate sunitinib malate in multiple settings, including first, second and later lines, as both a single agent and in various combinations, including: combined with standard of care (SOC) chemotherapies versus SOC chemotherapies alone and combined with SOC chemotherapies versus other targeted therapies. The studies will evaluate sunitinib malate in patients with various types of advanced breast cancer including HER2 negative and positive, and previously treated advanced triple receptor negative (ER-, PR- and HER2-).

The phase II and III randomized, open-label studies that are currently enrolling include:

Phase III

- SUN 1094: Sunitinib malate + paclitaxel versus bevacizumab + paclitaxel in first-line advanced breast cancer
- SUN 1064: Sunitinib malate + docetaxel versus docetaxel alone in HER2- advanced breast cancer
- SUN 1099: Sunitinib malate + capecitabine versus capecitabine alone in previously treated advanced breast cancer
- SUN 1107: Single-agent sunitinib malate versus capecitabine in previously treated advanced breast cancer

Phase II

- SUN 1077: Single-agent sunitinib malate versus chemotherapy in previously treated advanced triple receptor negative (ER-, PR-, and HER2-) breast cancer
- SUN 1067: Sunitinib malate + trastuzumab versus trastuzumab + placebo in advanced breast cancer

About SUTENT® (sunitinib malate)

SUTENT is a multi-kinase inhibitor approved for the treatment of advanced renal cell carcinoma (RCC) and gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib meylate.

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 are 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 please visit www.pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of May 29, 2007. 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 about various products in development, including their potential benefits, that involves substantial risks and uncertainties. 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 that may be filed for any such products in development as well as their decisions regarding labeling and other matters that could affect their availability or commercial potential; 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, 2006 and in its reports on Form 10-Q and Form 8-K.

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