Data to Be Presented At ESMO 2008 Highlight Pfizer Commitment to Cancer Care and Research

Monday, September 08, 2008 - 06:41am

Data on SUTENT

(BUSINESS WIRE)--Pfizer announced today that important study results involving the company’s leading anticancer agent, SUTENT® (sunitinib malate), as well as data examining an investigational agent, CP-751,871, will be presented at the 33rd European Society for Medical Oncology (ESMO) Congress in Stockholm, 12—16 September 2008.

Researchers will present results of several analyses evaluating the cost effectiveness of SUTENT® as first-line therapy in patients with metastatic renal cell carcinoma (mRCC), as well as updated data from a pivotal Phase III trial in mRCC. In addition, researchers will present updated results for CP-751,871, a novel anti-IGF-1R antibody, and the first in its class to initiate Phase III trials in patients with non-small cell lung cancer (NSCLC).

“Pfizer has made a major commitment to oncology, and invests a significant portion of R&D funds in cancer research across four scientific platforms and 22 compounds,” said Garry Nicholson, senior vice president, General Manager, Pfizer Oncology Business Unit. “ We are eager to share with the international oncology community key study results at the 2008 ESMO Congress.”

Details on the key studies to be presented at the meeting during podium presentations and poster discussions are as follows:

SUTENT® (sunitinib malate) clinical studies:

Abstract 723P: Cost-effectiveness of sunitinib (SU), sorafenib (SFN), temsirolimus (TMS), and bevacizumab plus interferon-alfa (BEV/IFN) as first-line therapy for metastatic renal cell carcinoma (mRCC) – an indirect comparison:

A new cost-effectiveness analysis indirectly comparing SUTENT with sorafenib, temsirolimus, and bevacizumab from a third party payor perspective will be presented by Ágnes Benedict, MSc, United BioSource Corporation. An adaptation of the cost effectiveness analysis for the Swedish Health Service (Abstract 725P), as well as an analysis of cost effectiveness and cost utility in Spain (Abstract 724P) will also be presented by Rickard Sandin, Outcome Research Manager, Pfizer Sweden. Monday, 15 September 2008, 12:30 – 13:30: Poster Area Hall A.

Abstract 588P: Overall survival with sunitinib versus interferon (IFN)-alfa as first-line treatment of metastatic renal cell carcinoma (mRCC):

Updated overall survival data from an international Phase 3 trial evaluating single-agent, oral SUTENT® (sunitinib malate) versus interferon-alfa (IFN-α) in the first-line treatment of mRCC will be presented in a poster discussion by Professor Sylvie Négrier, Centre Léon Berard. Saturday, 13 September 2008, 12:45 – 13:45: Poster Area Hall A.

CP-751,871 clinical studies:

Abstract 229PD: Addition of CP-751,871, an anti-IGF-1R antibody, to paclitaxel and carboplatin results in high activity in non-small cell lung cancer (NSCLC), particularly in squamous subtype:

A new analysis of Phase II data evaluating the activity of anti-IGF-1R antibody CP-751,871 in combination with paclitaxel and carboplatin in NSCLC will be presented by Dr. Luis Paz-Ares, Chief, Division of Medical Oncology, Virgen del Rocio University Hospital, Seville, Spain. Saturday, 13 September 2008, 12:45 - 13:45: Auditorium K21.
Abstract 132O: Correlative Science: IGF-IR markers in NSCLC patients on anti-IGF-1R therapy:

An updated analysis of ancillary studies exploring correlative science underlying response to CP-751,871, an anti-IGF-1R monoclonal antibody, will be presented in an oral session by Dr. Antonio Gualberto, Pfizer Global Research and Development. Monday, 15 September 2008, 14:45 - 15:00: Victoria Hall.
Other Pfizer Compounds:

Data on the following compounds will also be presented at ESMO: Aromasin(®) (exemestane), Campto(®) (irinotecan HCl), axitinib and tremelimumab.

About SUTENT(®) (sunitinib malate)

Sunitinib, an oral treatment, was approved in Europe as a first line treatment for mRCC in January 2007. Sunitinib is also indicated for the treatment of unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST) after failure of imatinib mesylate.

SUTENT works by blocking multiple molecular targets implicated in the growth, proliferation and spread of cancer. Two important sunitinib malate targets, vascular endothelial growth factor receptor (VEGFR) and platelet-derived growth factor receptor (PDGFR) are expressed by many types of solid tumours, and are thought to play a crucial role in angiogenesis, the process by which tumours acquire blood vessels, oxygen and nutrients needed for growth. SUTENT also inhibits other targets important to tumour growth, including KIT, FLT3 and RET.

Important SUTENT(®) (sunitinib malate) Safety Information

The recommended starting dose for Sutent is 50 mg once daily for four weeks followed by two weeks off. The dose can be modified in 12.5 mg increments not to exceed 75 mg or decrease below 25 mg. Sutent is available in 12.5 mg, 25 mg, and 50 mg capsules. Please refer to the Summary of Product Characteristics (SPC) for additional dosing recommendations regarding co-administration with cytochrome P450 3A4 inducers or inhibitors.

Adverse events (AEs) were generally mild to moderate. Most adverse events were reversible, and generally did not result in discontinuation. In clinical trials, the most common treatment related adverse events (>20%) included fatigue; gastrointestinal disorders, such as diarrhoea, nausea, stomatitis, dyspepsia, and vomiting; skin discoloration; dysgeusia (loss of taste); and anorexia. Fatigue, hypertension and neutropenia were the most common grade 3 treatment related adverse events. Increased lipase (2%) was the most common grade 4 treatment related adverse event. Hepatitis and hepatic failure occurred in <1% of patients and prolonged QT interval events occurred in less than 0.1%.

The most important treatment related serious adverse events associated with Sutent treatment of solid tumour patients were pulmonary embolism (1%), thrombocytopenia (1%), tumour haemorrhage (0.9%), febrile neutropenia (0.4%), and hypertension (0.4%).

Patients should be screened for hypertension and appropriately controlled with medical management. Temporary suspension of Sutent is recommended in patients with severe hypertension that is not controlled with medical management.

Developed by Pfizer, Sutent is being studied alone and in combination with other medicines as a potential treatment for a number of other solid tumours, including breast, lung, prostate, and colorectal cancers.

About CP-751,871

CP-751,871, a fully human monoclonal antibody, is a highly specific inhibitor of the IGF-1R pathway. The IGF-1R pathway is one of the key signaling pathways in cancer cells that lead to uncontrolled growth and survival of tumour cells.

Pfizer initiated a global Phase III clinical trial registration program for CP-751,871 in NSCLC. The program initially includes two studies in patients with non-adenocarcinoma NSCLC; ADVIGO 1016 in first-line patients and ADVIGO 1018 in refractory patients. In addition, Pfizer is studying CP-751,871 in clinical trials for the potential treatment of many other cancers, including prostate, breast and colon cancers and Ewing’s sarcoma. To date, more than 700 patients have participated in CP-751,871 clinical trials in multiple tumour types.

About Pfizer Oncology

Pfizer Oncology is committed to the discovery, investigation and development of treatments and currently has 22 innovative compounds in clinical development across four platforms. By leveraging the strength of our resources and scientific talent, Pfizer Oncology strives to discover and develop novel treatment options to improve the outlook for oncology patients. Pfizer currently devotes more than 22 percent of its total R&D budget to the field of oncology, investing annually in worldwide research initiatives. We also partner with healthcare providers, governments and local communities around the world to provide better quality healthcare and health system support.

For more information, please visit http://www.pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of September 8, 2008. 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 Sutent and CP-751,871, including with respect to potential indications, 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 indications as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of any such indications; 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, 2007 and in its reports on Form 10-Q and Form 8-K.

Media:PfizerVanessa Aristide, 212-733-3784orInvestor:Jennifer Davis, 212-733-0717