Pfizer Logo

Pfizer to Present Clinical Data from Oncology Portfolio at the 2011 European Multidisciplinary Cancer Congress

Monday, September 12, 2011 - 08:30pm

Data Presentations Focus on Personalized Medicine in Lung Cancer and Pfizer's Renal Cell Carcinoma Portfolio

"With data presentations at the meeting across compounds in lung and RCC, we are continuing to build on our experience and leadership in these disease areas."

(BUSINESS WIRE)--Pfizer Oncology announced today that data evaluating crizotinib in anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC), as well as data from Pfizer's renal cell carcinoma (RCC) portfolio on axitinib, an investigational compound, and SUTENT® (sunitinib malate) will be presented at the 2011 European Multidisciplinary Cancer Congress in Stockholm, Sweden, September 23 – 27, 2011.

"As SUTENT changed the treatment landscape for patients with advanced RCC, we have clinical evidence suggesting that crizotinib has the potential to change the treatment paradigm for patients with ALK-positive advanced NSCLC," said Dr. Mace Rothenberg, senior vice president of clinical development and medical affairs for Pfizer's Oncology Business Unit. "With data presentations at the meeting across compounds in lung and RCC, we are continuing to build on our experience and leadership in these disease areas."

Crizotinib Phase 2 Data

At the meeting, Pfizer will present updated data on the safety, efficacy and patient-reported outcomes (PROs) for crizotinib.

- A global Phase 2 study including efficacy, safety, and patient-reported outcomes with crizotinib in patients with ALK-positive NSCLC (Poster Presentation, Abstract #9084, September 26)
- Preliminary characterization of visual events reported by patients receiving crizotinib for the treatment of advanced ALK-positive NSCLC (Poster Presentation, Abstract #3030, September 26)

Pfizer Oncology: A Leader in RCC

As a leader in the treatment of advanced RCC, Pfizer Oncology is dedicated to offering multiple treatments and investigating new agents in different populations and stages of disease. We are committed to advancing the science of RCC through research into established and novel compounds, as well as the exploration of biomarkers to better personalize therapy and provide insights into treatment selection for patients with advanced kidney cancer.

SUTENT

As part of the ongoing evaluation of SUTENT, data being presented at the meeting include:

- Prognostic factors for progression-free survival (PFS), overall survival (OS), and long-term OS with sunitinib in 1,059 patients, treated on clinical trials, with metastatic RCC (Oral Presentation, Abstract #1006, September 26).

SUTENT is approved for gastrointestinal stromal tumors (GIST) after disease progression on or intolerance to imatinib mesylate, as well as advanced RCC, and progressive, well-differentiated pancreatic neuroendocrine tumors (pancreatic NET) in patients with unresectable locally advanced or metastatic disease.

Axitinib

Data presentations for axitinib, an oral and selective inhibitor of VEGF 1, 2 and 3, receptors, include:

- Association of single nucleotide polymorphisms (SNPs) in VEGF pathway genes with PFS and blood pressure in metastatic RCC in the Phase 3 trial of axitinib vs sorafenib (AXIS trial) (Oral presentation, Abstract #7103, September 24)
- Time to deterioration (TTD) in patient-reported outcomes in Phase 3 AXIS trial of axitinib vs. sorafenib as second-line therapy for metastatic RCC (Poster Discussion, Abstract #3006, September 26)
- A randomized Phase 2 study of axitinib dose titration in patients with advanced RCC: Preliminary pharmacokinetic and ambulatory blood pressure monitoring results (Poster Presentation, Abstract #7140, September 25)

Additionally, data on the following compounds will be presented: AROMASIN (exemestane) and neratinib.

About crizotinib

Outside of the U.S., crizotinib is an investigational oral first-in-class compound that inhibits the anaplastic lymphoma kinase, or ALK. By inhibiting ALK, crizotinib blocks signaling in a number of cell pathways that are believed to be critical for the growth and survival of tumor cells, which may lead to stabilization or regression of tumors. Alterations in the ALK gene are believed to be a key driver of tumor development in cancers like NSCLC. Although ALK is known to occur more frequently in patients with non-squamous cell carcinoma and histories of light or non-smoking, it has also been identified in smokers and in patients with squamous cell carcinoma histologies. Alterations in the ALK gene can occur independent of age, gender, ethnicity and smoking history.

Crizotinib has also demonstrated inhibition of the c-MET receptor tyrosine kinase and is under investigation.

Crizotinib was recently approved by the U.S. Food and Drug Administration (FDA) as the first-ever therapy targeting ALK, for the treatment of patients with locally advanced or metastatic NSCLC that is ALK-positive as detected by an FDA-approved test. This indication is based on response rate. There are no data available demonstrating improvement in patient reported outcomes or survival with crizotinib. Crizotinib is marketed in the U.S. under the trade name XALKORI®. Pfizer also recently announced that the European Medicines Agency has accepted Pfizer's regulatory submission for crizotinib for the treatment of patients with previously treated ALK-positive advanced NSCLC.

Important XALKORI(®) (crizotinib) Safety Information

XALKORI has been associated with severe, life-threatening or fatal treatment-related pneumonitis in clinical trials with a frequency of 4 in 255 (1.6%) patients. Other causes of pneumonitis should be excluded. XALKORI should be permanently discontinued in patients with treatment-related pneumonitis.

Grade 3 or 4 ALT elevation was observed in 7% of patients in Study A and 4% of patients in Study B. Three patients from Study A (2%) and 1 patient from Study B (<1%) required permanent discontinuation from treatment. Liver function tests, including ALT and total bilirubin, should be monitored once a month and as clinically indicated, with more frequent repeat testing for grade 2-4 transaminase elevations. Temporarily suspend, dose reduce, or permanently discontinue XALKORI as indicated.

QT prolongation has been observed. XALKORI should be avoided in patients with congenital long QT syndrome. In patients with congestive heart failure, bradyarrhythmias, electrolyte abnormalities, or who are taking medications that are known to prolong the QT interval, periodic monitoring with electrocardiograms and electrolytes should be considered. Permanently discontinue XALKORI for grade 4 QTc prolongation. XALKORI should be withheld for grade 3 QTc prolongation until recovery to ? grade 1. Permanently discontinue XALKORI if grade 3 QTc prolongation recurs.

Detection of ALK-positive NSCLC, using an FDA-approved test indicated for this use, is necessary for selection of patients for treatment with XALKORI.

XALKORI can cause fetal harm when administered to a pregnant woman based on its mechanism of action. Women of childbearing potential should be advised to avoid becoming pregnant while receiving XALKORI. If the patient or their partner becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.

Safety of XALKORI was evaluated in 255 patients with locally advanced or metastatic ALK-positive NSCLC in 2 single-arm clinical trials (Studies A and B). The most common adverse reactions (?25%) across both studies were vision disorder, nausea, diarrhea, vomiting, edema, and constipation. Grade 3/4 adverse reactions in ?4% of patients in both studies included ALT increased and neutropenia.

Vision disorders including visual impairment, photopsia (perceived flashes of light), vision blurred, vitreous floaters, photophobia (sensitivity to bright light), and diplopia (seeing double) were experienced in 159 (62%) patients in clinical trials.

Ophthalmological evaluation should be considered, particularly if patients experience photopsia or experience new or increased vitreous floaters. Severe or worsening vitreous floaters and/or photopsia could also be signs of a retinal hole or pending retinal detachment. Caution should be exercised when driving or operating machinery by patients who experience vision disorder.

About AROMASIN® (exemestane)

AROMASIN is a steroidal aromatase inhibitor (AI) that binds selectively to aromatase, an enzyme involved in the productions of estrogen. In the United States (US), AROMASIN is indicated for the adjuvant treatment of postmenopausal women with estrogen receptor-positive early breast cancer who have received two to three years of tamoxifen and are switched to AROMASIN for completion of a total of five consecutive years of adjuvant hormonal therapy, as well as for the treatment of advanced breast cancer in postmenopausal women whose disease has progressed following tamoxifen therapy. In Europe, AROMASIN is indicated for the adjuvant treatment of postmenopausal women with estrogen receptor-positive invasive early breast cancer, following two to three years of initial adjuvant tamoxifen therapy, as well as for the treatment of advanced breast cancer in women with natural or induced postmenopausal status whose disease has progressed following anti-estrogen therapy. Efficacy has not been demonstrated in patients with estrogen receptor-negative status.

Important AROMASIN (exemestane) Safety Information

AROMASIN should not be used in women who are premenopausal, are nursing or pregnant, have a known hypersensitivity to the drug, or are taking estrogen-containing agents. Dose modification is recommended for patients who are receiving certain medications, including strong CYP 3A4 inducers. In patients with early breast cancer, elevations in bilirubin, alkaline phosphatase, and creatinine were more common in those receiving AROMASIN than either tamoxifen or placebo. Reductions in bone mineral density over time are seen with the use of AROMASIN.

For more information on AROMASIN including full prescribing information please visit www.pfizer.com.

About SUTENT(®) (sunitinib malate)

SUTENT is an oral multi-kinase inhibitor that 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

Hepatotoxicity has been observed in clinical trials and post-marketing experience. This hepatotoxicity may be severe, and deaths have been reported. It is recommended to 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. SUTENT should not be restarted if patients subsequently experience severe changes in liver function tests or have other signs and symptoms of liver failure.

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 GIST, RCC and pancreatic NET clinical trials were diarrhea, fatigue, asthenia, nausea, mucositis/stomatitis, anorexia, vomiting, neutropenia, hypertension, dyspepsia, abdominal pain, constipation, rash, hand-foot syndrome, skin discoloration, hair color changes, altered taste and bleeding.

For more information on SUTENT, 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 to improve the outlook for cancer patients worldwide. Our strong pipeline, 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. Pfizer Oncology has biologics and small molecules in clinical development and more than 100 clinical trials underway. 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.

DISCLOSURE NOTICE: The information contained in this release is as of September 13, 2011. 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 Pfizer's oncology pipeline in general and about various oncology product candidates, axitinib, crizotinib and neratinib, in particular, 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 have been or may be filed for such oncology product candidates as well as the decisions of regulatory authorities 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, 2010 and in its reports on Form 10-Q and Form 8-K.

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