Pfizer To Present New Data In Advanced Kidney, Lung And Hematologic Cancers At 2012 ASCO Annual Meeting

Sunday, May 13, 2012 - 10:30pm

Data from Kidney Cancer Portfolio Further Demonstrate Efficacy and Safety Across Multiple Lines of Therapy Additional Results from Investigational Compounds in Early- and Late-Stage Development Will Also Be Featured

"We are very proud of the breadth, depth and quality of research results that will be presented involving Pfizer Oncology compounds at ASCO this year. These data demonstrate Pfizer Oncology’s commitment to accelerating the science of therapeutic innovation in some of the most challenging cancers,"

(BUSINESS WIRE)--New data will be presented on targeted cancer treatments from the Pfizer Oncology portfolio across three key therapeutic categories, including tumors of the kidney, lung and hematologic malignancies, at the Annual Meeting of the American Society of Clinical Oncology in Chicago, IL, from June 1-5. Approximately 100 abstracts featuring Pfizer’s cancer treatments and investigational compounds across 20 cancer types will be presented during the meeting.

“We are very proud of the breadth, depth and quality of research results that will be presented involving Pfizer Oncology compounds at ASCO this year. These data demonstrate Pfizer Oncology’s commitment to accelerating the science of therapeutic innovation in some of the most challenging cancers,” said Mace Rothenberg, MD, senior vice president of clinical development and medical affairs for Pfizer’s Oncology Business Unit. “We are leveraging resources and expertise by collaborating with academia, cooperative groups and patient advocacy groups with the goal of bringing the next wave of breakthrough medicines to cancer patients in need worldwide.”

Advancing Research and Understanding in Advanced RCC

Pfizer will present data that provide further clinical insights on the use of axitinib, an oral inhibitor of tyrosine kinases including VEGF receptors 1, 2 and 3, across multiple lines of therapy.

Inlyta® (axitinib)

At ASCO, Pfizer will present blinded analyses of the association between blood pressure and clinical response from an ongoing Phase 2 study (AGILE 1046) evaluating axitinib in the first-line metastatic RCC (mRCC) treatment setting (Oral presentation, Abstract #4503, June 2).

Other research further evaluating axitinib in the second-line setting will also be presented:

Results from an ongoing randomized registrational study (AGILE 1051) evaluating axitinib vs sorafenib as a second-line therapy in Asian patients with metastatic RCC (Late breaker, Poster discussion, Abstract #LBA4537, June 2) Updated results among patients previously treated with cytokines who enrolled in the Phase 3 AXIS pivotal trial of axitinib vs sorafenib in metastatic renal cell carcinoma (Poster discussion, Abstract #4546, June 2)
Sutent® (sunitinib malate)

As part of the ongoing evaluation of Sutent, an inhibitor of multiple tyrosine kinases, data being presented at the meeting in advanced RCC include:

Cardiac safety analysis for a Phase 3 adjuvant trial (ECOG 2805) of sunitinib or sorafenib or placebo in patients with resected renal cell carcinoma (Oral presentation, Abstract #4500, June 2) Sunitinib objective response in metastatic renal cell carcinoma: Analysis of 1,059 patients treated on clinical trials (Poster discussion, Abstract #4542, June 2) Characterizing fatigue associated with sunitinib in patients with metastatic renal cell carcinoma (Abstract #6092, June 4)
New Approaches in Advanced Non-Small Cell Lung Cancer (NSCLC)

Data will be presented that continue to build upon the clinical understanding of crizotinib, a first-in-class compound that inhibits anaplastic lymphoma kinase (ALK), and its activity in lung cancer patients whose tumors are driven by other unique molecular characteristics.

Xalkori® (crizotinib)

Results will also be presented from an expansion cohort of a Phase 1 study evaluating the clinical activity of crizotinib in advanced non-small cell lung cancer harboring ROS-1 gene rearrangement (Clinical science symposium, Abstract #7508, June 2).

Data presentations from other clinical trials evaluating crizotinib in subsets of patients with non-small cell lung cancer include:

Results of a global Phase 2 study with crizotinib in advanced ALK-positive non-small cell lung cancer (Poster discussion, Abstract #7533, June 5) Phase 1/2 dose-finding study of crizotinib in combination with erlotinib in patients with advanced non-small cell lung cancer (Abstract #2610, June 4). This is the first study report of crizotinib in combination with another targeted agent.
Pfizer continues to evaluate crizotinib in two open-label Phase 3 clinical trials. PROFILE 1007 (A8081007) compares crizotinib with standard-of-care chemotherapy in patients with previously treated ALK-positive advanced NSCLC. PROFILE 1014 (A8081014) evaluates the safety and efficacy of crizotinib in previously untreated patients with ALK-positive NSCLC.

Dacomitinib (PF-00299804)

Pfizer will also present data featuring dacomitinib, an investigational, irreversible pan-HER inhibitor, in patients with NSCLC across lines of therapy and molecular subtypes:

First-line dacomitinib (PF-00299804), an irreversible pan-HER tyrosine kinase inhibitor, for patients with EGFR-mutant lung cancers (Poster discussion, Abstract #7530, June 5) ARCHER: Dacomitinib (PF-00299804) versus erlotinib for advanced non-small cell lung cancer; a randomized double-blind Phase 3 study (Trials in progress, Abstract #TPS7615, June 2). Pfizer initiated the ARCHER study globally last year and is currently enrolling patients with NSCLC who have received prior chemotherapy.
New Data in Hematologic Malignancies

Data being presented from Pfizer’s hematology portfolio include:

Bosutinib

Pfizer continues to study bosutinib, an investigational oral dual Src and Abl kinase inhibitor, in patients with chronic myeloid leukemia (CML):

BELA trial update: bosutinib vs imatinib in patients with newly diagnosed chronic phase myeloid leukemia after 30 months of follow-up (Poster discussion, Abstract #6512, June 1). Late last year, 24-month follow-up data from the Bosutinib Efficacy and safety in

chronic myeloid Leukemia (BELA) Phase 3 study was presented at the 54th annual meeting of the American Society of Hematology (ASH). Efficacy and safety of bosutinib for Philadelphia chromosome-positive (Ph+) leukemia in older versus younger patients (Poster discussion, Abstract #6511, June 1). Study 200 is a Phase 1/2 trial in previously treated patients with CML.

Inotuzumab ozogamicin

Data will also be presented featuring inotuzumab ozogamicin, an antibody-drug conjugate (ADC) that is one of several investigational therapies in Pfizer's ADC portfolio. These agents use a targeted antibody to deliver a cytotoxin directly to specific tumor cells, with the goal of enhancing the anti-tumor effect while reducing the toxicity of the cytotoxin on healthy cells.

Inotuzumab ozogamicin, an anti-CD22 monoclonal antibody conjugated to calecheamicin, given weekly, is active in refractory-relapse acute lymphocytic leukemia (Oral presentation, Abstract #6501, June 4)
Pfizer is committed to understanding the potential role of the investigational therapy inotuzumab ozogamicin in acute lymphocytic leukemia (ALL), and a Phase 3 study evaluating inotuzumab ozogamicin in this patient population will soon be open for enrollment. Pfizer is also evaluating inotuzumab ozogamicin in an ongoing global, randomized Phase 3 study in patients with relapsed or refractory CD22-positive aggressive non-Hodgkin lymphoma (NHL) who are not candidates for intensive high-dose chemotherapy and stem cell transplantation.

Emerging Science from Pfizer's Early-Development Portfolio

Additionally, data will be presented from Pfizer's early-stage pipeline evaluating several compounds targeting novel pathways:

Phase 2 trial of the CDK 4 inhibitor PD-0332991 in CDK4-amplified liposarcoma (Oral presentation, Abstract #10002, June 4). Data was presented earlier this month at the 4th IMPAKT Breast Cancer Conference from another Phase 2 study of this investigational compound exploring its potential as a treatment for patients with estrogen receptor (ER) positive, HER2-negative advanced breast cancer in combination with standard of care anti-estrogens. Phase 1b safety trial of CVX-060, an intravenous humanized monoclonal CovX body inhibiting angiopoietin 2 (ang-2), with sunitinib (Poster discussion, Abstract #3032, June 2) Pharmacokinetic modeling and simulation (PK M&S) supported dose escalation of PF-03446962, a monoclonal antibody (mAb) against activin receptor-like kinase 1, in patients with solid tumors (Abstract #2595, June 4)

About INLYTA® (axitinib)

INLYTA is indicated for the treatment of advanced renal cell carcinoma (RCC) after failure of one prior systemic therapy.

Important INLYTA® (axitinib) Safety Information

Hypertension including hypertensive crisis has been observed. Blood pressure should be well controlled prior to initiating INLYTA. Monitor for hypertension and treat as needed. For persistent hypertension, despite use of antihypertensive medications, reduce the dose. Discontinue INLYTA if hypertension is severe and persistent despite use of anti-hypertensive therapy and dose reduction of INLYTA, and discontinuation should be considered if there is evidence of hypertensive crisis.

Arterial and venous thrombotic events have been observed and can be fatal. Use with caution in patients who are at increased risk or who have a history of these events.

Hemorrhagic events, including fatal events, have been reported. INLYTA has not been studied in patients with evidence of untreated brain metastasis or recent active gastrointestinal bleeding and should not be used in those patients. If any bleeding requires medical intervention, temporarily interrupt the INLYTA dose.

Gastrointestinal perforation and fistula, including death, have occurred. Use with caution in patients at risk for gastrointestinal perforation or fistula. Monitor for symptoms of gastrointestinal perforation or fistula periodically throughout treatment.

Hypothyroidism requiring thyroid hormone replacement has been reported. Monitor thyroid function before initiation of, and periodically throughout, treatment.

Stop INLYTA at least 24 hours prior to scheduled surgery.

Reversible Posterior Leukoencephalopathy Syndrome (RPLS) has been observed. If signs or symptoms occur, permanently discontinue treatment.

Monitor for proteinuria before initiation of, and periodically throughout, treatment. For moderate to severe proteinuria, reduce the dose or temporarily interrupt treatment.

Liver enzyme elevation has been observed during treatment with INLYTA. Monitor ALT, AST, and bilirubin before initiation of, and periodically throughout, treatment.

For patients with moderate hepatic impairment, the starting dose should be decreased. INLYTA has not been studied in patients with severe hepatic impairment.

Women of childbearing potential should be advised of potential hazard to the fetus and to avoid becoming pregnant while receiving INLYTA.

Avoid strong CYP3A4/5 inhibitors. If unavoidable, reduce the dose.

Avoid strong CYP3A4/5 inducers and, if possible, avoid moderate CYP3A4/5 inducers.

The most common (≥20%) adverse events (AEs) occurring in patients receiving INLYTA (all grades, vs sorafenib) were diarrhea, hypertension, fatigue, decreased appetite, nausea, dysphonia, hand-foot syndrome, weight decrease, vomiting, asthenia, and constipation.

The most common (≥10%) grade 3/4 AEs occurring in patients receiving INLYTA (vs sorafenib) were hypertension, diarrhea, and fatigue.

The most common (≥20%) lab abnormalities occurring in patients receiving INLYTA (all grades, vs sorafenib) included increased creatinine, decreased bicarbonate, hypocalcemia, decreased hemoglobin, decreased lymphocytes (absolute), increased ALP, hyperglycemia, increased lipase, increased amylase, increased ALT, and increased AST.

About SUTENT® (sunitinib malate)

SUTENT is indicated for the treatment of advanced renal cell carcinoma (RCC).

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. 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.

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

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

Cardiovascular events, including heart failure, myocardial disorders, and cardiomyopathy, some of which were fatal, have been reported. 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.

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 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.

There have been rare (<1%) nonfatal reports of subjects presenting with seizures and radiological evidence of reversible posterior leukoencephalopathy syndrome (RPLS).

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.

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

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

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

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

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

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.

Dose adjustments are recommended when administered with CYP3A4 inhibitors or inducers.

The most common ARs occurring in ≥20% of patients receiving SUTENT for treatment-naïve metastatic RCC (all grades, vs IFNα) were diarrhea, fatigue, nausea, anorexia, altered taste, mucositis/stomatitis, pain in extremity/limb discomfort, vomiting, bleeding, all sites, hypertension, dyspepsia, arthralgia, abdominal pain, rash, hand-foot syndrome, back pain, cough, asthenia, dyspnea, skin discoloration/yellow skin, peripheral edema, headache, constipation, dry skin, fever, and hair color changes. The most common grade 3/4 ARs (occurring in ≥5% of patients with RCC receiving SUTENT vs IFNα) were fatigue, hypertension, asthenia, diarrhea, hand-foot syndrome, dyspnea, nausea, back pain, pain in extremity/limb discomfort, vomiting, and abdominal pain.

The most common grade 3/4 lab abnormalities (occurring in ≥5% of patients with RCC receiving SUTENT vs IFNα) included lymphocytes, lipase, neutrophils, uric acid, platelets, hemoglobin, sodium decreased, leukocytes, glucose increased, phosphorus, and amylase.

About XALKORI® (crizotinib)

XALKORI is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (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 XALKORI.

Important XALKORI® (crizotinib) Safety Information

Drug-induced hepatotoxicity with fatal outcome has occurred. Transaminase elevations generally occurred within the first 2 months of treatment. Monitor with liver function tests including ALT and total bilirubin once a month and as clinically indicated, with more frequent repeat testing for increased liver transaminases, alkaline phosphatase, or total bilirubin in patients who develop transaminase elevations. Temporarily suspend, dose reduce, or permanently discontinue XALKORI as indicated.

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. All of these cases occurred within 2 months after the initiation of treatment. Monitor patients for pulmonary symptoms indicative of pneumonitis. Exclude other causes and permanently discontinue XALKORI in patients with treatment-related pneumonitis.

QTc prolongation has been observed. Avoid use of XALKORI in patients with congenital long QT syndrome. Consider periodic monitoring with electrocardiograms (ECGs) and electrolytes in patients with congestive heart failure, bradyarrhythmias, electrolyte abnormalities, or who are taking medications that are known to prolong the QT interval. 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, apprise the patient of the potential hazard to the fetus.

Among the 397 patients for whom information on deaths and serious adverse reactions is available, deaths within 28 days of the last dose of study drug occurred in 45 patients. Ten (2.5%) patients died within 28 days of their first dose of study drug. Causes of death included disease progression (32 patients), respiratory events (9), and other (4).

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, vision blurred, vitreous floaters, photophobia, and diplopia were reported in 159 (62%) patients in clinical trials. Consider ophthalmological evaluation, 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. Advise patients to exercise caution when driving or operating machinery due to the risk of developing a vision disorder.

For more information on INLYTA (axitinib), SUTENT (sunitinib malate) and XALKORI (crizotinib), including full prescribing information, 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 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.

DISCLOSURE NOTICE:

The information contained in this release is as of May 14, 2012. 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 various oncology products and product candidates, 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, including the ability to meet anticipated clinical trial commencement and completion dates, regulatory submission and approval dates, and launch dates; decisions by regulatory authorities regarding whether and when to approve drug applications that have been or may be filed for such product candidates or for additional indications for such products as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of such product candidates or additional indications for such products; 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, 2011 and in its reports on Form 10-Q and Form 8-K.

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