Pfizer Announces Positive Results From Phase 3 Study PROFILE 1007 Evaluating XALKORI® (crizotinib) In Previously Treated Patients With ALK-Positive Advanced Non-Small Cell Lung Cancer

Monday, June 18, 2012 - 10:30pm

Detailed Study Results to be Presented at an Upcoming Medical Congress

"This study provides further support for the precision medicine approach to drug development being taken at Pfizer by demonstrating how knowledge about the underlying genetic abnormalities within a cancer can be used to improve the standard of care for that disease."

(BUSINESS WIRE)--Pfizer Inc. announced today that the PROFILE 1007 study met its primary endpoint, demonstrating that XALKORI® (crizotinib) significantly improved progression-free survival (PFS) when compared with pemetrexed or docetaxel, in previously treated patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC). PROFILE 1007 is the first randomized Phase 3 study in ALK-positive advanced NSCLC patients.

"These results are important because they demonstrate, for the first time, that XALKORI is superior to standard chemotherapy in prolonging survival without progression in patients with previously-treated ALK-positive advanced NSCLC," said Dr. Mace Rothenberg, senior vice president of Clinical Development and Medical Affairs for Pfizer's

Oncology Business Unit. "This study provides further support for the precision medicine approach to drug development being taken at Pfizer by demonstrating how knowledge about the underlying genetic abnormalities within a cancer can be used to improve the standard of care for that disease."

The adverse events observed on crizotinib and chemotherapy in PROFILE 1007 were generally consistent with their respective known adverse event profiles. Full efficacy and safety data from this study will be presented at an upcoming medical congress.

Ongoing Studies of XALKORI®

Pfizer is committed to the development program for XALKORI, and continues to study the therapy in several ongoing trials including PROFILE 1014 (A8081014), a Phase 3, open-label, randomized, two-arm study to evaluate the safety and efficacy of XALKORI in comparison with pemetrexed plus cisplatin or carboplatin in patients previously untreated for ALK-positive advanced NSCLC.1 In addition, PROFILE 1005 (A8081005)is an ongoing Phase 2 open-label, single-arm study on the efficacy and safety of XALKORI in patients with ALK-positive advanced NSCLC who have failed more than one line of treatment with prior chemotherapy.2 For more information on these clinical trials, please contact the Pfizer Oncology Clinical Trial Information Service at 1-877-369-9753 (US/Canada), via email at PfizerHPTrials@emergingmed.com or visit www.pfizercancertrials.com.

About Non-Small Cell Lung Cancer

Worldwide, lung cancer is the leading cause of cancer death in both men and women.3 In Europe, lung cancer accounts for 20 percent of all cancer-related deaths.4 NSCLC accounts for about 85 percent of lung cancer cases and remains difficult to treat, particularly in the metastatic setting.5 Approximately 75 percent of NSCLC patients are diagnosed late with metastatic, or advanced, disease, where the five-year survival rate is only 6 percent.6,7,8

About XALKORI®

XALKORI received an accelerated approval by the U.S. Food and Drug Administration (FDA) for the treatment of 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 improvements in patient reported outcomes or survival with XALKORI. XALKORI also has received approval in a number of other countries including Canada, Korea, Japan and Switzerland.

XALKORI has played a significant role in advancing the treatment of personalized medicine in NSCLC and has rapidly become a standard of care in ALK-positive advanced NSCLC. XALKORI blocks signaling in a number of cellular pathways that are believed to be critical for the growth and survival of tumor cells, which may lead to stabilization or regression of tumors.3,9 Alterations in the ALK gene are believed to be a key driver of tumor development in cancers like NSCLC.10 Although ALK rearrangement is known to occur more frequently in patients with non-squamous cell carcinoma and histories of light or never smoking, it has also been shown to occur in smokers and in patients with squamous cell carcinoma histology.11 Alterations in the ALK gene can occur independent of age, gender, ethnicity and smoking history.12

XALKORI has demonstrated inhibition of c-MET, the hepatocyte growth factor receptor, and its activity is under investigation.12 XALKORI has also been shown to demonstrate a response in a Phase 1 trial in advanced NSCLC patients whose tumors have the ROS-1 gene rearrangement and its activity is continuing to be studied in this patient population.13

For more information and full prescribing information please visit www.XALKORI.com.

Important XALKORI® 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.

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 June 19, 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 an oncology product, XALKORI (crizotinib), including its benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by the European Commission and regulatory authorities in other jurisdictions regarding whether and when to approve drug applications that have been or may be filed for such product as well as their decisions regarding labeling and other matters that could affect its 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, 2011 and in its reports on Form 10-Q and Form 8-K.

1 ClinicalTrials.gov. A Clinical Trial Testing The Efficacy Of Crizotinib Versus Standard Chemotherapy Pemetrexed Plus Cisplatin Or Carboplatin In Patients With ALK Positive Non Squamous Cancer Of The Lung (PROFILE 1014). Available at: http://clinicaltrials.gov/ct2/show/NCT01154140?term=pemetrexed+crizotinib&rank=3. Accessed May 31, 2012.

2 ClinicalTrials.gov. An Investigational Drug, PF-02341066, Is Being Studied In Patients With Advanced Non-Small Cell Lung Cancer With A Specific Gene Profile Involving The Anaplastic Lymphoma Kinase (ALK) Gene. Available at: http://clinicaltrials.gov/ct2/show/NCT00932451?term=crizotinib+AND+Anaplastic+Lymphoma+ Accessed May 31, 2012.

3 World Health Organization. Cancer fact sheet. http://www.who.int/mediacentre/factsheets/fs297/en/. Accessed May 31, 2012.

4 European Lung Foundation. What is Lung Cancer? Available at: http://www.european-lung-foundation.org/index.php?id=65. Accessed May 31, 2012.

5 American Cancer Society. Detailed Guide: Lung Cancer (Non-Small Cell). Available at: http://www.cancer.org/acs/groups/cid/documents/webcontent/003115-pdf.pdf. Accessed July 12, 2011.

6 Yang P, Allen MS, Aubry MC, et al. Clinical features of 5,628 primary lung cancer patients: experience at Mayo Clinic from 1997 to 2003. Chest. 2005;128(1):452–462.

7 Govindan R, Page N, Morgensztern D, et al. Changing epidemiology of small-cell lung cancer in the United States over the last 30 years: analysis of the surveillance, epidemiologic, and end results database. J Clin Oncol. 2006;24(28):4539–4544.

8 American Cancer Society. Detailed guide: lung cancer – non-small cell. Non-small cell lung cancer survival rates by stage. http://www.cancer.org/Cancer/LungCancer-Non-SmallCell/DetailedGuide/non-small-cell-lung-cancer-survival-rates. Accessed February 8, 2011.

9 Chiarle R, Voena C, Ambrogio C et al. The anaplastic lymphoma kinase in the pathogenesis of cancer. Nat Rev Cancer. 2008;8(1): 11-23.

10 Zou HY, Li Q, Lee JH, et al. An orally available small-molecule inhibitor of c-MET, PF-2341066, exhibits cytoreductive antitumor efficacy through antiproliferative and antiangiogenic mechanisms. Cancer Res. 2007;67:4408-4417.

11 Choi Y et al. Mutations of EML4-ALK in Lung Cancer That Confer Resistance to ALK Inhibitors. The New England Journal of Medicine. October 28, 2010

12 Soda M, Choi YL, Enomoto M, et al. Identification of the transforming EML4-ALK fusion gene in non-small-cell lung cancer. Nature. 2007;448:561-566.

13 ASCO Accepted Abstract #7508. Clinical activity of crizotinib in advanced non-small cell lung cancer (NSCLC) harboring ROS1 gene rearrangement. Clinical Science Symposium. Alice T. Shaw. Saturday, June 2, 2012. 8:00 AM – 8:15 AM.

Pfizer Inc. Media: Jenifer Antonacci, 610-427-0369 or Investors: Jennifer Davis, 212-733-0717