

Pfizer To Present New Data in Lung And Kidney Cancers at The European Society For Medical Oncology 2012 Congress

Sunday, September 16, 2012 - 09:30pm

First Phase 3 Data Presentation on XALKORI® (crizotinib) versus Standard Chemotherapy in Previously Treated Patients with ALK-Positive Advanced Non-Small Cell Lung Cancer Data on Kidney Cancer Portfolio Broaden Clinical Understanding of the Continuum of Care for Renal Cell Carcinoma Patients

"We believe that the clinical trial results to be shared at ESMO 2012 substantially enhance our knowledge of both marketed and investigational therapies from our lung and kidney cancer portfolios,"

[\(BUSINESS WIRE\)](#)--Pfizer Oncology today announced that important data from its lung cancer and renal cell carcinoma (RCC) portfolios will be presented at the upcoming European Society for Medical Oncology (ESMO) Congress in Vienna, Austria, September 28 – October 2, 2012.

“We believe that the clinical trial results to be shared at ESMO 2012 substantially enhance our knowledge of both marketed and investigational therapies from our lung and kidney cancer portfolios,” said Mace Rothenberg, MD, senior vice president of clinical development and medical affairs for Pfizer’s Oncology Business Unit. “We are especially pleased to be able to share, for the first time, detailed results of PROFILE 1007, a randomized trial comparing XALKORI to standard chemotherapy in patients with recurrent, ALK-positive non-small cell lung cancer (NSCLC). These results, which will be presented at the Presidential Symposium, reinforce the value of Pfizer’s precision medicine approach to drug development, and demonstrate the benefit that targeted, efficient and science-driven cancer drug development can have on patient outcomes.”

Treating Lung Cancer Through a Targeted Approach

Data highlights relating to Pfizer’s lung cancer portfolio include:

- Phase 3 randomized study of crizotinib versus pemetrexed or docetaxel chemotherapy in advanced, ALK-positive NSCLC (PROFILE 1007) (Presidential Symposium, Abstract #LBA1, September 30, 16:00-18:00)¹
- Updated results of a global Phase 2 study with crizotinib in advanced ALK-positive NSCLC (Poster Discussion, Abstract #1230PD, September 30, 12:45-14:15)²
- Clinical activity of crizotinib in patients with advanced NSCLC harboring ROS1 gene rearrangement (Poster Discussion, Abstract #1191PD, September 30, 12:45-14:15)³

Updated data will be presented on dacomitinib, an investigational, irreversible pan-HER tyrosine kinase inhibitor (TKI), for first-line treatment of EGFR-mutant, HER2-mutant or amplified lung cancers (Oral Presentation, Abstract #1228O, September 30, 9:00-11:00).⁴ Additionally, data from a Phase 1 trial of dacomitinib in

combination with XALKORI (crizotinib) in previously treated advanced NSCLC will be presented (Poster Presentation, Abstract #1290P, September 29, 13:00-14:00).⁵

Pfizer Oncology Leadership in Renal Cell Carcinoma

Pfizer Oncology is committed to contributing to the science of advanced RCC and continues to support a number of studies evaluating established and novel compounds for the disease. Pfizer will present data from new and ongoing analyses of its RCC clinical trial program at ESMO 2012, broadening clinical understanding of INLYTA[®] (axitinib), SUTENT[®] (sunitinib malate) and TORISEL[®] (temsirolimus) across the spectrum of renal cancer.

INLYTA is an oral kinase inhibitor designed to inhibit tyrosine kinases including vascular endothelial growth factor (VEGF) receptors 1, 2 and 3. Data presentations for INLYTA include:

- Clinic and home blood pressure measurements are reliable for guiding therapy in patients with metastatic RCC receiving axitinib as first-line therapy (Poster Presentation, Abstract #811P, September 29, 13:00-14:00)⁶
- Axitinib vs sorafenib for advanced RCC: Phase 3 overall survival results and analysis of prognostic factors (Poster Discussion, Abstract #793PD, October 1, 13:00-14:00)⁷

As part of the continued evaluation of SUTENT, data to be presented at the meeting include:

- Comparative assessment of sunitinib-associated adverse events (AEs) as potential biomarkers of efficacy in metastatic mRCC (Oral Presentation, Abstract #785O, October 1, 14:00-15:00)⁸
- Sunitinib dosing schedule and data collection timepoints: impact on quality of life outcomes in metastatic RCC (Poster Presentation, Abstract #815P, September 29, 13:00-14:00)⁹

Late breaking data will be presented in oral sessions from two randomized Phase 3 studies evaluating TORISEL in patients with advanced RCC at different stages of disease, including results from the INTORSECT trial in previously treated patients compared with sorafenib. (Proffered Papers Session, Abstract #LBA22_PR, October 1, 14:00-15:50).¹⁰ Pfizer will also present results from the INTORACT trial evaluating TORISEL in combination with bevacizumab in treatment-naïve patients (Proffered Papers Session, Abstract #LBA21_PR, October 1, 14:00-15:50).¹¹

Pfizer previously announced that the INTORSECT and INTORACT trials did not meet their primary endpoints in May 2012 and August 2012, respectively.

About XALKORI[®] (crizotinib)

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

In June 2012, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a positive opinion recommending that XALKORI be granted conditional approval in the European Union (EU) for the treatment of adults with previously treated ALK-positive advanced NSCLC. Additional applications are under regulatory review in several countries worldwide.

Important XALKORI® (crizotinib) Safety Information¹²

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 alanine aminotransferase (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 in the United States.

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 INLYTA® (axitinib)

In January 2012, INLYTA® was approved by the U.S. Food and Drug Administration (FDA) for the treatment of advanced renal cell carcinoma after failure of one prior systemic therapy. INLYTA was approved by the European Commission on September 3, 2012, for the treatment of adult patients with advanced RCC after failure of prior treatment with sunitinib or a cytokine. INLYTA has also been approved in a number of other countries and regions, including Switzerland, Japan, Canada, Australia, and South Korea.

INLYTA, a kinase inhibitor, is an oral therapy that was designed to selectively inhibit vascular endothelial growth factor (VEGF) receptors 1, 2 and 3, which are proteins that can influence tumor growth, vascular angiogenesis and progression of cancer (tumor spread).

Important INLYTA® (axitinib) Safety Information¹³

Serious adverse reactions reported in patients receiving INLYTA were arterial embolic and thrombotic events, venous embolic and thrombotic events, haemorrhage (including gastrointestinal haemorrhage, cerebral haemorrhage and haemoptysis), gastrointestinal perforation and fistula formation, hypertensive crisis, and posterior reversible encephalopathy syndrome.

The most common (~20%) adverse reactions observed following treatment with INLYTA were diarrhoea, hypertension, fatigue, dysphonia, nausea, decreased appetite, and palmar-plantar erythrodysesthesia (hand-foot) syndrome.

About SUTENT® (sunitinib malate)

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

SUTENT is an oral multi-kinase inhibitor that works by blocking multiple molecular targets implicated in the growth, proliferation and spread of cancer.^{8b} 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 Information¹⁴

Serious adverse reactions associated with sunitinib are renal failure, heart failure, pulmonary embolism, intestinal perforation, and haemorrhages (e.g. respiratory, gastrointestinal, tumour haemorrhages).

The most common (~20%) adverse events (AEs) in patients receiving SUTENT were decreased appetite, taste disturbance, hypertension, fatigue, gastrointestinal disorders, skin discoloration, and hand-foot syndrome. Fatal events, other than those listed, included multi-system organ failure, disseminated intravascular coagulation, peritoneal hemorrhage, rhabdomyolysis, cerebrovascular accident, dehydration, adrenal insufficiency, renal failure, respiratory failure, pleural effusion, pneumothorax, shock, and sudden death.

About TORISEL® (temsirolimus)

TORISEL® is the only intravenous mammalian target of rapamycin (mTOR) inhibitor approved for the treatment of advanced renal cell carcinoma (RCC).

TORISEL inhibits the activity of mTOR, an intracellular protein implicated in multiple growth-related cellular functions including proliferation, growth and survival. The inhibition of mTOR also reduces levels of certain growth factors, such as vascular endothelial growth factor (VEGF), which are overexpressed in solid tumors like kidney cancer and are thought to play a crucial role in angiogenesis, the process by which tumors acquire blood vessels, nutrients and oxygen needed for growth.

Important TORISEL® (temsirolimus) Safety Information¹⁵

Serious reactions observed with TORISEL are hypersensitivity/infusion reactions (including some life-threatening and rare fatal reactions), hyperglycaemia/glucose intolerance, infections, interstitial lung disease (pneumonitis), hyperlipaemia, intracerebral bleeding, renal failure, bowel perforation, and wound healing complication.

The most common (~30%) adverse reactions (all grades) observed with TORISEL include anaemia, nausea, rash (including rash, pruritic rash, maculopapular rash, pustular rash), anorexia, oedema (including facial oedema and peripheral oedema), and asthenia.

Cataracts have been observed in some patients who received the combination of temsirolimus and interferon ?.

For more information on XALKORI (crizotinib), INLYTA (axitinib), SUTENT (sunitinib malate) and TORISEL (temsirolimus), 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 September 17, 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 potential indications for dacomitinib, Xalkori (crizotinib) and INLYTA (axitinib), including their potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, (i) the uncertainties inherent in research and development; (ii) decisions by the FDA, 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 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 (iii) 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 ESMO 2012 Accepted Late Breaking Abstract #LBA1. Phase 3 randomized study of crizotinib versus pemetrexed or docetaxel chemotherapy in advanced, ALK-positive NSCLC (PROFILE 1007). Sunday, September 30: 16:00 CEST. A. Shaw - Presenter. 37th Congress of the European Society for Medical Oncology. Vienna, Austria. September 28 – October 2, 2012.

² ESMO Accepted Abstract #1230. Updated Results of a Global Phase II Study with Crizotinib in Advanced ALK-positive Non-Small Cell Lung Cancer (NSCLC). Poster Discussion. Sunday, September 30: 13:00 CEST. D.W. Kim – Presenter. 37th Congress of the European Society for Medical Oncology. Vienna, Austria. September 28 – October 2, 2012.

³ ESMO Accepted Abstract #1191. Clinical Activity of Crizotinib in Patients with Advanced Non-Small Cell Lung Cancer (NSCLC) Harboring ROS1 Gene Rearrangement. Poster Discussion. Sunday, September 30: 13:15 CEST. S.-H. I. Ou – Presenter. 37th Congress of the European Society for Medical Oncology. Vienna, Austria. September 28 – October 2, 2012.

⁴ ESMO Accepted Abstract #1228. Dacomitinib (PF-00299804), an Irreversible Pan-HER Tyrosine Kinase Inhibitor (TKI), for First-Line Treatment of EGFR-Mutant or HER2-Mutant or Amplified Lung Cancers. Proffered Paper. Sunday, September 30: 10:30 CEST. M. Kris – Presenter. 37th Congress of the European Society for Medical Oncology. Vienna, Austria. September 28 – October 2, 2012.

⁵ ESMO Accepted Abstract #1290. Phase I Trial of Irreversible Pan-ERBB Inhibitor Dacomitinib (dac) in Combination with ALK/MET Inhibitor Crizotinib (criz) in Previously Treated Advanced Non-Small Cell Lung Cancer (NSCLC). Poster Presentation. Saturday, September 29: 13:00 – 14:00. X.-C. Zhang – Presenter. 37th Congress of the European Society for Medical Oncology. Vienna, Austria. September 28 – October 2, 2012.

⁶ ESMO Accepted Abstract #811. Clinic and Home Blood Pressure Measurements are Reliable for Guiding Therapy in Patients with Metastatic Renal Cell Carcinoma Receiving Axitinib as First-Line Therapy. Poster Presentation. Saturday, September 29: 13:00 – 14:00. V. Grünwald – Presenter. 37th Congress of the European Society for Medical Oncology. Vienna, Austria. September 28 – October 2, 2012.

⁷ ESMO Accepted Abstract #793. Axitinib vs Sorafenib for Advanced Renal Cell Carcinoma: Phase III Overall Survival Results and Analysis of Prognostic Factors. Poster Discussion. Monday, October 1: 13:00 CEST. R. Motzer – Presenter. 37th Congress of the European Society for Medical Oncology. Vienna, Austria. September 28 – October 2, 2012.

⁸ ESMO Accepted Abstract #785. Comparative Assessment of Sunitinib-Associated Adverse Events (AEs) as Potential Biomarkers of Efficacy in Metastatic Renal Cell Carcinoma (mRCC). Proffered Paper. Monday, October 1: 15:15 CEST. F. Donskov – Presenter. 37th Congress of the European Society for Medical Oncology. Vienna, Austria. September 28 – October 2, 2012.

⁹ ESMO Accepted Abstract #815. Sunitinib (SU) Dosing Schedule and Data Collection Timepoints: Impact on Quality of Life (QoL) Outcomes in Metastatic Renal Cell Carcinoma (mRCC). Poster Presentation. Saturday, September 29: 13:00-14:00 CEST. A. Bushmakina – Presenter. 37th Congress of the European Society for Medical Oncology. Vienna, Austria. September 28 – October 2, 2012.

¹⁰ ESMO 2012 Accepted Late Breaking Abstract #LBA22_PR. Randomized Phase 3 trial of temsirolimus versus sorafenib as second-line therapy in metastatic RCC (mRCC): Results From the INTORSECT Trial. Monday, October 1: 14:00 – 15:50 CEST. Proffered Papers Session. T. Hutson - Presenter. 37th Congress of the European Society for Medical Oncology. Vienna, Austria. September 28 – October 2, 2012.

¹¹ ESMO 2012 Accepted Late Breaking Abstract #LBA21_PR. Randomized Phase 3b trial of temsirolimus and bevacizumab versus Interferon and bevacizumab in metastatic RCC: Results from INTORACT. Monday, October 1: 14:00 – 15:50 CEST. Proffered Papers Session. B. Rini - Presenter. 37th Congress of the European Society for Medical Oncology. Vienna, Austria. September 28 – October 2, 2012.

¹² XALKORI (crizotinib) Prescribing Information. Pfizer Inc, New York, NY. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202570s003lbl.pdf.

¹³ Summary of Product Characteristics for INLYTA[®]. Sandwich, Kent: UK; 2012. Available at: http://www.emea.europa.eu/docs/en_GB/document_library/EPAR_-

[_Product_Information/human/002406/WC500132188.pdf](#)

¹⁴ Summary of Product Characteristics for SUTENT[®]. Sandwich, Kent: UK; 2012. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000687/WC500057737.pdf

¹⁵ Summary of Product Characteristics for TORISEL[®]. Sandwich, Kent: UK; 2011. Available at: <http://www.medicines.org.uk/emc/medicine/21260>.

Pfizer Media: Jenifer Antonacci, 610-427-0369 or Matti Ojanen, (+44) 7557 202394 or Investors: Jennifer Davis, 212-733-0717