Pfizer To Present New Research From Fifteen Compounds Highlighting Multiple Approaches To Targeting Cancer At 2011 ASCO Annual Meeting

Sunday, May 15, 2011 - 10:45pm

Pivotal Head-to-Head Phase 3 Data to be Presented for Axitinib Vs. Sorafenib in Patients with Previously Treated Advanced Renal Cell Carcinoma First Time Overall Survival Data to be Presented for Crizotinib in Patients with ALK-Positive Advanced Non-Small Cell Lung Cancer

"The research we are presenting at ASCO represents Pfizer’s continued commitment to finding novel treatment solutions and improving the lives of patients with cancer,"

(BUSINESS WIRE)--Pfizer Inc. will present more than 30 abstracts, including data from investigational compounds, axitinib,1 crizotinib,2 and bosutinib,3 as well as data evaluating Sutent® (sunitinib malate), across multiple tumor types,4,5 at the 47th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago from June 3-7. The Company will also share analyses from early stage compounds focused on the science behind tumor growth.6,7,8

“The research we are presenting at ASCO represents Pfizer’s continued commitment to finding novel treatment solutions and improving the lives of patients with cancer,” said Dr. Mace Rothenberg, senior vice president of clinical development and medical affairs for Pfizer’s Oncology Business Unit. “We are excited to present data demonstrating the efficacy and tolerability of several of our late-stage compounds, while also highlighting early phase clinical research exploring key mechanisms and promising pathways which

may help inspire new potential therapeutic approaches for many difficult to treat cancers.”

Axitinib

Pfizer is presenting results from the Phase 3 AXIS 1032 trial, comparing axitinib to sorafenib in patients with previously-treated advanced renal cell carcinoma (RCC). These are the first pivotal head-to-head data comparing active, targeted therapies in advanced RCC (Oral presentation, Abstract #4503, June 6).1 In addition, two other axitinib RCC abstracts will be presented.

Patient-reported outcomes (PRO) from the AXIS 1032 trial (Oral presentation, Abstract #4504, June 6)9 Five-year overall survival data from a Phase 2 trial of axitinib as a second-line treatment for patients with metastatic RCC (Poster discussion, Abstract #4547, June 7)10
Axitinib is an oral and selective inhibitor of vascular endothelial growth factor (VEGF) receptors 1, 2 and 3,1 receptors that can influence tumor growth, vascular angiogenesis and progression of cancer (the spread of tumors).

Crizotinib

At ASCO, Pfizer will publicly present for the first time data from an early stage study demonstrating the impact of crizotinib, an oral, first-in-class compound that inhibits the anaplastic lymphoma kinase, or ALK, compared to historical controls, on overall survival in patients with advanced ALK-positive non-small cell lung cancer (NSCLC) (Oral presentation, Abstract #7507, June 5).2

Updated progression-free survival (PFS) from a Part 2 expansion cohort of a Phase 1 study in patients with ALK-positive advanced NSCLC (Clinical Science Symposium, Abstract #2501, June 3)11 Initial Phase 2 results of crizotinib in advanced ALK-positive NSCLC (Poster discussion, Abstract #7514, June 6)12
Bosutinib

Pfizer continues to investigate the potential of targeting specific pathways in hematologic malignancies, and will provide an update on clinical trials of bosutinib as a single agent in both newly diagnosed3 and previously treated patients with Philadelphia chromosome positive (Ph+) chronic phase (CP) chronic myeloid leukemia (CML).13

18-month follow up data from the Bosutinib Efficacy and safety in chronic myeloid LeukemiA [BELA] Phase 3 study evaluating bosutinib as a first-line treatment in patients with CP CML (Poster discussion, Abstract #6509, June 3)3 Bosutinib as third-line therapy

for CP CML patients following failure of or intolerance to imatinib and dasatinib or nilotinib (Study 200) (Abstract #6535, June 6)15 Health-related quality of life in newly diagnosed (Abstract #6612, June 6)14 and imatinib-resistant or imatinib intolerant CP CML patients (Abstract #6620, June 6)15

Bosutinib is an investigational oral dual Src and Abl kinase inhibitor with minimal inhibitory activity against c-kit and PDGFR.16 It is believed that by dual inhibition of the Src and Abl tyrosine kinases, bosutinib may inhibit signaling in CML cells that allows the cells to grow, survive and reproduce.17

Sutent

Since its approval in 2006, Sutent has changed the treatment landscape for advanced RCC and imatinib-resistant or -intolerant gastrointestinal stromal tumors (GIST) and remains a standard of care in these indications.

In November 2010, Sutent was approved in Europe for the treatment of unresectable or metastatic, well-differentiated pancreatic neuroendocrine tumors (NET) with disease progression in adults. Experience with Sutent as first-line treatment is limited. Sutent is currently under review by the U.S. FDA for the treatment of unresectable pancreatic NET.

At ASCO, Pfizer will present new analyses from trials evaluating Sutent in patients with advanced unresectable pancreatic NET4 and in patients with metastatic RCC.5

Updated overall survival and progression-free survival data by blinded independent central review (BICR) of sunitinib versus placebo for patients with advanced unresectable pancreatic NET (Poster discussion, Abstract #4008, June 6)4 Circulating protein biomarkers of sunitinib and interferon-α efficacy in treatment-naïve patients with metastatic RCC (Poster discussion, Abstract #10525, June 4)18 A pooled analysis of the efficacy and safety of sunitinib in elderly patients with metastatic renal cell carcinoma (mRCC) (Abstract #4604, June 5)5
Additionally at ASCO, results from Phase 3 studies of sunitinib in metastatic castration-resistant prostate cancer (mCRPC)19 and advanced hepatocellular carcinoma (HCC)20 will be presented.

Pfizer announced last year that these studies did not meet their primary endpoints.

Phase 3 trial of sunitinib with prednisone versus prednisone alone in mCRPC (Oral presentation, Abstract #4515, June 6)19 Phase 3 trial of sunitinib versus sorafenib in advanced HCC (Oral presentation, Abstract #4000, June 7)20

Early Development Compounds

Pfizer will present data from its early stage pipeline evaluating multiple compounds targeting innovative pathways.

Phase 1 study of PF-04554878, a focal adhesion kinase (FAK) inhibitor, in patients with advanced solid tumors (Clinical Science Symposium, Abstract #3002, June 5)6 Phase 1 study of PF-03446962, a fully human monoclonal antibody (mAb) against activin receptor-like kinase 1 (ALK-1), a TGFβ receptor involved in tumor angiogenesis (Oral presentation, Abstract #3009, June 5)7 Randomized Phase 2 study of PD 0332991, a cyclin-dependent kinase (CDK) 4/6 inhibitor, in combination with letrozole for first-line treatment of patients with postmenopausal, estrogen receptor positive, HER2-negative advanced breast cancer (Abstract #TPS100, June 6)8
Data on the following compounds and investigational agents will also be presented: Torisel (temsirolimus) (mantle cell lymphoma),21 neratinib (breast cancer),22 PF-00299804 (head and neck cancer),23 figitumumab (colorectal cancer),24 tremelimumab (pancreatic cancer),25 gamma secretase inhibitor – PF-03084014 (solid tumors),26 PARP (poly ADP ribose polymerase) inhibitor – PF-01367338 (peripheral blood lymphocytes),27 dual angiopoietin-2 (Ang2) and VEGF inhibitor – CVX-241 (solid tumors).28

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 Torisel® (temsirolimus)

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

Based on preclinical studies, 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 Information

Torisel is contraindicated in patients with bilirubin >1.5 times the upper limit of normal (ULN). If Torisel must be given to patients with mild hepatic impairment, it should be used with caution and at a reduced dose.

Torisel has been associated with serious and sometimes fatal side effects including: hypersensitivity reactions, hyperglycemia/glucose intolerance, infections, interstitial lung disease, hyperlipidemia, bowel perforation, renal failure, wound healing complications, and intracerebral hemorrhage.

Live vaccines and close contact with those who received live vaccines should be avoided. Women of childbearing potential should be advised of the potential hazard to the fetus and avoid becoming pregnant.

The most common adverse reactions (incidence ≥ 30%) are rash, asthenia, mucositis, nausea, edema, and anorexia. The most common laboratory abnormalities (incidence ≥ 30%) are anemia, hyperglycemia, hyperlipidemia, hypertriglyceridemia, elevated alkaline phosphatase, elevated serum creatinine, lymphopenia, hypophosphatemia, thrombocytopenia, elevated AST, and leucopenia.

Strong inducers of CYP3A4/5 and inhibitors of CYP3A4 may affect concentrations of the primary metabolite of Torisel. If alternatives cannot be used, dose modifications of Torisel are recommended.

For more information on Torisel, 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, 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 May 16, 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 various oncology product candidates and potential additional indications for various in-line oncology products, 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 or supplemental drug applications that have been

or may be filed for any such oncology product candidates or any such additional indications for in-line oncology products as well as their decisions 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.

---

1 ASCO Accepted Abstract #4503. Axitinib versus sorafenib as second-line therapy for metastatic renal cell carcinoma (mRCC): Results of phase III AXIS trial. Oral Presentation, Monday, June 6, 2011: 8:00-8:15 AM. B. Rini – Presenter. 47th Annual Meeting of the American Society of Clinical Oncology (ASCO). Chicago, IL. June 3-7, 2011.

2 ASCO Accepted Abstract #7507. Impact of crizotinib on survival in patients with advanced, ALK-positive NSCLC compared with historical controls. Oral Presentation, Sunday, June 5, 2011: 10:45-11:00 AM. A. Shaw – Presenter. 47th Annual Meeting of the American Society of Clinical Oncology (ASCO). Chicago, IL. June 3-7, 2011.

3 ASCO Accepted Abstract #6509. Bosutinib (BOS) versus imatinib (IM) in patients (pts) with chronic phase chronic myeloid leukemia (CP CML) in the BELA trial: 18-month follow-up. Poster Discussion Session, Friday, June 3, 2011: 2:00-6:00 PM. C. Gambacorti–Passerini – Presenter. 47th Annual Meeting of the American Society of Clinical Oncology (ASCO). Chicago, IL. June 3-7, 2011.

4 ASCO Accepted Abstract #4008. Updated overall survival (OS) and progression-free survival (PFS) by blinded independent central review (BICR) of sunitinib (SU) versus placebo (PBO) for patients (Pts) with advanced unresectable pancreatic neuroendocrine tumors (NET). Poster Discussion Session, Monday, June 6, 2011: 2:00-6:00 PM. E. Raymond – Presenter. 47th Annual Meeting of the American Society of Clinical Oncology (ASCO). Chicago, IL. June 3-7, 2011.

5 ASCO Accepted Abstract #4604. A pooled analysis of the efficacy and safety of sunitinib in elderly patients (pts) with metastatic renal cell carcinoma (mRCC). Poster Session, Sunday, June 5, 2011: 8:00 AM – 12:00 PM. T. Hutson – Presenter. 47th Annual Meeting of the American Society of Clinical Oncology (ASCO). Chicago, IL. June 3-7, 2011.

6 ASCO Accepted Abstract #3002. Phase I study of PF-04554878, a second-generation focal adhesion kinase (FAK) inhibitor, in patients with advanced solid tumors. Clinical Science Symposium, Sunday, June 5, 2011: 5:30-5:45 PM. S. Jones – Presenter. 47th Annual Meeting of the American Society of Clinical Oncology (ASCO). Chicago, IL. June 3-7, 2011.

7 ASCO Accepted Abstract #3009. Phase I study of PF-03446962, a fully human mAb against ALK 1, a TGFß receptor involved in tumor angiogenesis. Oral Presentation, Sunday, June 5, 2011: 11:45 AM – 12:00 PM. L. Goff – Presenter. 47th Annual Meeting of the American Society of Clinical Oncology (ASCO). Chicago, IL. June 3-7, 2011.

8 ASCO Accepted Abstract #TPS100. A randomized phase II study of PD 0332991, cyclin-dependent kinase (CDK) 4/6 inhibitor, in combination with letrozole for first-line treatment of patients with postmenopausal, estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer. Trials in Progress Poster Session, Monday, June 6, 2011: 8:00 AM – 12:00 PM. R. Finn – Presenter. 47th Annual Meeting of the American Society of Clinical Oncology (ASCO). Chicago, IL. June 3-7, 2011.

9 ASCO Accepted Abstract #4504. Patient-reported outcomes (PROs) in a phase III AXIS trial of axitinib versus sorafenib as second-line therapy for metastatic renal cell carcinoma (mRCC). Oral Presentation, Monday, June 6, 2011: 8:15-8:30AM. D. Cella – Presenter. 47th Annual Meeting of the American Society of Clinical Oncology (ASCO). Chicago, IL. June 3-7, 2011.

10 ASCO Accepted Abstract #4547. Axitinib second-line therapy for metastatic renal cell carcinoma (mRCC): Five-year (yr) overall survival (OS) data from a phase II trial. Poster Discussion Session, Tuesday, June 7, 2011: 8:00 AM – 12:00 PM. R. Motzer – Presenter. 47th Annual Meeting of the American Society of Clinical Oncology (ASCO). Chicago, IL. June 3-7, 2011.

11 ASCO Accepted Abstract #2501. Progression-free survival (PFS) from a phase I study of crizotinib (PF-02341066) in patients with ALK-positive non-small cell lung cancer (NSCLC). Clinical Science Symposium, Friday, June 3, 2011: 3:30-3:45PM. R. Camidge – Presenter. 47th Annual Meeting of the American Society of Clinical Oncology (ASCO). Chicago, IL. June 3-7, 2011.

12 ASCO Accepted Abstract #7514. Initial phase 2 results with crizotinib in advanced ALK-positive non-small cell lung cancer (NSCLC): PROFILE 1005. Poster Discussion Session, Monday, June 6, 2011: 2:00 – 6:00 PM. L. Crinò – Presenter. 47th Annual Meeting

of the American Society of Clinical Oncology (ASCO). Chicago, IL. June 3-7, 2011.

13 ASCO Accepted Abstract #6535. Bosutinib (BOS) as third-line therapy for chronic phase (CP) chronic myeloid leukemia (CML) following failure with imatinib (IM) and dasatinib (DAS) or nilotinib (NIL). Poster Session, Monday, June 6, 2011: 1:00-6:00 PM. T. Brummendorf – Presenter. 47th Annual Meeting of the American Society of Clinical Oncology (ASCO). Chicago, IL. June 3-7, 2011.

14 ASCO Accepted Abstract #6612. Health-related quality of life (HRQoL) in newly diagnosed patients (pts) with chronic phase chronic myelogenous leukemia (CP CML) treated with bosutinib (BOS) or imatinib (IM). Poster Session, Monday, June 6, 2011: 1:00-5:00 PM. J. Lipton – Presenter. 47th Annual Meeting of the American Society of Clinical Oncology (ASCO). Chicago, IL. June 3-7, 2011.

15 ASCO Accepted Abstract #6620. Health-related quality of life (HRQoL) of bosutinib (SKI-606) in imatinib-resistant (IM-R) or imatinib-intolerant (IM-I) chronic phase chronic myeloid leukemia (CP CML). Poster Session, Monday, June 6, 2011: 1:00-5:00 PM. P. Trask – Presenter. 47th Annual Meeting of the American Society of Clinical Oncology (ASCO). Chicago, IL. June 3-7, 2011.

16 Gambacorti-Passerini C et al. Bosutinib (SKI-606) Demonstrates Clinical Activity and is Well Tolerated in Patients with AP and BP CML and Ph+ ALL. Poster Presented at the American Society of Hematology Meeting, December 6-9, 2008, San Francisco, CA. Wyeth.

17 Konig H et al. Effects of Dasatinib on Src Kinase Activity and Downstream Intracellular Signaling in Primitive Chronic Myelogenous Leukemia Hematopoietic Cells. Cancer Research. 2008; 68: 9624-9633.

18 ASCO Accepted Abstract # 10525. Circulating protein biomarkers of sunitinib (SU) and interferon-alpha (IFN-alpha) efficacy in treatment (Tx)-naïve patients (pts) with metastatic renal cell carcinoma (mRCC). Poster Discussion, Saturday, June 4, 2011: 5:00 – 6:00 PM. S. Harmon – Presenter. 47th Annual Meeting of the American Society of Clinical Oncology (ASCO). Chicago, IL. June 3-7, 2011.

19 ASCO Accepted Abstract #4515. Randomized, placebo-controlled, phase III trial of sunitinib in combination with prednisone (SU+P) versus prednisone (P) alone in men with progressive metastatic castration-resistant prostate cancer (mCRPC). Oral Presentation, Monday June 6, 2011: 1:00 – 1:15 PM. M.D. Michaelson – Presenter. 47th Annual Meeting of the American Society of Clinical Oncology (ASCO). Chicago, IL. June 3-7, 2011.

20 ASCO Accepted Abstract #4000. Phase III trial of sunitinib (Su) versus sorafenib (So) in advanced hepatocellular carcinoma (HCC). Oral Presentation, Tuesday, June 7, 2011: 9:30-9:45 AM. A. Cheng – Presenter. 47th Annual Meeting of the American Society of Clinical Oncology (ASCO). Chicago, IL. June 3-7, 2011.

21 ASCO Accepted Abstract #TPS222. Randomized phase IV trial comparing efficacy and tolerability of temsirolimus with and without an elevated starting dose in patients with relapsed, refractory mantle cell lymphoma. Trials in Progress Poster Session, Monday, June 6, 2011: 8:00 AM -12:00 PM. A. Blair – Presenter. 47th Annual Meeting of the American Society of Clinical Oncology (ASCO). Chicago, IL. June 3-7, 2011.

22 ASCO Accepted Abstract #TPS137. A phase III trial of adjuvant neratinib (NER) after trastuzumab (TRAS) in women with early-stage HER2+ breast cancer (BC). Trials in Progress Poster Session, Monday, June 6, 2011: 8:00 AM -12:00 PM. P. Goss – Presenter. 47th Annual Meeting of the American Society of Clinical Oncology (ASCO). Chicago, IL. June 3-7, 2011.

23 ASCO Accepted Abstract #5561. Phase II trial of the irreversible oral pan-human EGF receptor (HER) inhibitor PF-00299804 (PF) as first-line treatment in recurrent and/or metastatic (RM) squamous cell carcinoma of the head and neck (SCCHN). Poster Session, Saturday, June 4, 2011: 2:00 PM – 6:00 PM. L. Siu – Presenter. 47th Annual Meeting of the American Society of Clinical Oncology (ASCO). Chicago, IL. June 3-7, 2011.

24 ASCO Accepted Abstract #3525. Phase II trial of figitumumab in patients with refractory, metastatic colorectal cancer (mCRC). Poster Discussion Session, Monday, June 6, 2011: 8:00 AM – 12:00 PM. C. Becerra – Presenter. 47th Annual Meeting of the American Society of Clinical Oncology (ASCO). Chicago, IL. June 3-7, 2011.

25 ASCO Accepted Abstract #4081. Final toxicity results of a phase I dose-escalation trial of tremelimumab (CP-675206) in combination with gemcitabine in chemotherapy-naive patients (pts) with metastatic pancreatic cancer. Poster Session, Saturday, June 4, 2011: 8:00 AM – 12:00 PM. M. Aglietta – Presenter. 47th Annual Meeting of the American Society of Clinical Oncology (ASCO). Chicago, IL. June 3-7, 2011.

26 ASCO Accepted Abstract #3100. A phase I dose-escalation study of the novel gamma secretase inhibitor PF-03084014 in patients (pts) with advanced solid tumors. Poster Session, Monday, June 6, 2011: 8:00 AM – 12:00 PM. W. Messersmith – Presenter. 47th Annual Meeting of the American Society of Clinical Oncology (ASCO). Chicago, IL. June 3-7, 2011.

27 ASCO Accepted Abstract #3054. Poly (ADP ribose) polymerase (PARP) inhibition in peripheral blood lymphocytes (PBLs): Does it reflect PARP inhibition in tumor? Poster Session, Monday, June 6, 2011: 8:00 AM -12:00 PM. D. Shalinsky – Presenter. 47th Annual Meeting of the American Society of Clinical Oncology (ASCO). Chicago, IL. June 3-7, 2011.

28 ASCO Accepted Abstract #3055. First-in-human dose-escalation safety and PD trial of a novel humanized monoclonal CovX body inhibitor of angiopoietin 2 and vascular endothelial growth factor. Poster Session, Monday, June 6, 2011: 8:00 AM – 12:00 PM. D. Mendelson – Presenter. 47th Annual Meeting of the American Society of Clinical Oncology (ASCO). Chicago, IL. June 3-7, 2011.

Pfizer Inc. Media: Chris Loder, 212-733-7897 / 347-453-8199 (cell) or Investors: Jennifer Davis, 212-733-0717