Pfizer Oncology To Present New Clinical Data Across Ten Tumor Types and Multiple Molecular Targets

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Updated Study Results to be Presented on ALK inhibitor (PF-02341066) and Pan-HER Inhibitor (PF-00299804) in Non-Small Cell Lung Cancer Presentations in Rare Tumor Types Include Data on IGF-1R Inhibitor (Figitumumab) in Ewing's Sarcoma

"Pfizer (NYSE: PFE) has focused its oncology research on targeting molecular drivers and pathways in various cancers, such as EGFR, ALK and IGF-1R,"

NEW YORK--(BUSINESS WIRE)--Pfizer Oncology will present new data across its portfolio representing novel approaches to researching treatments for patients with rare and difficult-to-treat cancers. These results will be presented at the 35th European Society for Medical Oncology (ESMO) Congress in Milan, Italy from October 8-12.

"Pfizer (NYSE: PFE) has focused its oncology research on targeting molecular drivers and pathways in various cancers, such as EGFR, ALK and IGF-1R," said Dr. Mace Rothenberg, senior vice president of clinical development and medical affairs for Pfizer's Oncology Business Unit. "We are committed to using this approach to seek treatments for well-known, difficult-to-treat and rare tumor types that have few or no therapeutic options and where we can make a big impact in defined patient populations."

At ESMO, Pfizer will present data on key compounds from its portfolio, which includes:

-- PF-00299804

Updated results from a global, randomized Phase 2 trial evaluating the anti-tumor activity and safety of PF-00299804 compared to erlotinib in patients with NSCLC following

progression on treatment with one or more chemotherapy regimens (Abstract #365PD, October 10).(1) In addition, preliminary efficacy and safety data from a Phase 2 study evaluating PF-00299804 as first-line treatment in patients with advanced NSCLC whose tumors are likely to carry the EGFR mutation will be presented as a late breaker in a Proffered Paper session (Abstract #LBA18, October 11).(2)

PF-00299804 is an investigational, oral, pan-HER (pan-human epidermal growth factor receptor) inhibitor.(2) PF-00299804 is currently being evaluated in the BR.26 clinical trial, a Phase 3, double-blind, placebo-controlled, randomized study in patients with stage IIIB/IV NSCLC who have progressive disease following standard chemotherapy and EGFR inhibitor therapy.(3) BR.26 is led by the NCIC Clinical Trials Group (CTG).(3)

-- Crizotinib (PF-02341066)

Updated data on crizotinib (PF-02341066), a first-in-class, oral ALK inhibitor, will also be presented, from the ongoing expansion cohort from the Phase 1 study evaluating the compound in patients with ALK-positive advanced NSCLC (Abstract #366PD, October 10).(4)

-- Sunitinib

Pfizer will also present results from SUN 1087, a Phase 3 trial evaluating sunitinib plus erlotinib compared to erlotinib alone in patients with advanced NSCLC who have received at least one previous treatment with a platinum-based regimen (Abstract #LBA6, October 11).(5) In August, Pfizer announced that this study demonstrated a statistically significant improvement in progression-free survival but not in overall survival. Overall survival was the primary endpoint of the study and progression free survival was the secondary endpoint of the study.

Pfizer will also present progression-free survival (PFS) data as determined by blinded independent central review (BICR) from the pivotal, placebo-controlled SUN 1111 Phase 3 trial evaluating sunitinib in patients with progressive, well-differentiated pancreatic neuroendocrine tumor (NET) (Abstract #747P, October 9).(6)

-- Figitumumab

Results from a Phase 1/2 study evaluating figitumumab (CP-751,871), a selective fully human IgG2 monoclonal antibody against the IGF-1R (insulin-like growth factor 1 receptor) pathway, in patients with refractory Ewing's sarcoma and other sarcomas will be presented in a Proffered Paper session (Abstract #1344O, October 10).(7)

Pfizer continues to investigate approved therapies within its portfolio, including Aromasin® (exemestane tablets). At the Congress, research findings for the compound will be presented in two key presentations.

- Distant recurrences at median of 5-years among 9,779 postmenopausal women with hormone receptor-positive early breast cancer treated on the TEAM trial of adjuvant endocrine therapy (Abstract #213O, October 11)(8)

- Effects of exemestane or tamoxifen on bone health within the Tamoxifen Exemestane Adjuvant Multinational (TEAM) trial: a meta-analysis (Abstract #225P, October 10)(9)

Data on the following compounds and investigational agents will also be presented: neratinib (HER2 positive breast, solid tumors),(10),(11) axitinib (renal cell carcinoma or RCC),(12) inotuzumab (non-Hodgkin's lymphoma),(13) and Torisel® (temsirolimus) (RCC, solid tumors).(14),(15)

For more news and information, follow Pfizer Oncology at ESMO through Twitter @pfizer_news (http://twitter.com/pfizer_news).

About Sutent® (sunitinib malate)

Sutent is an oral multi-kinase inhibitor approved for the treatment of advanced RCC and for the treatment of GIST after disease progression on or intolerance to imatinib mesylate.

Sutent 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 and RCC clinical trials were diarrhea, fatigue, asthenia, nausea, mucositis/stomatitis, anorexia, vomiting, hypertension, dyspepsia, abdominal pain, constipation, rash, hand-foot syndrome, skin discoloration, altered taste and bleeding.

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

About Aromasin® (exemestane tablets)

Aromasin is the only aromatase inhibitor indicated for sequential therapy in postmenopausal women with hormone-receptor (HR) positive early breast cancer after two to three years of tamoxifen for a total of five years of adjuvant therapy. The use of Aromasin in this setting is supported by the landmark IES trial. Aromasin is also indicated for the treatment of advanced breast cancer in postmenopausal women whose disease has progressed following tamoxifen therapy.

Important Aromasin (exemestane tablets) 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 Torisel® (temsirolimus)

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

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

Patients with moderate or severely impaired liver function should not receive Torisel. Torisel should be used with caution and at a reduced dose in those with mild liver function impairment. The use of Torisel may result in a serious allergic reaction, therefore patients should be prescribed an antihistamine before Torisel treatment.

Hypersensitivity reactions manifested by symptoms, including, but not limited to anaphylaxis, dyspnea, flushing, and chest pain have been observed with Torisel. Serum glucose, serum cholesterol, and triglycerides should be tested before and during treatment with Torisel. The use of Torisel is likely to result in hyperglycemia and hyperlipemia. This may result in the need for an increase in the dose of, or initiation of, insulin and/or oral hypoglycemic agent therapy and/or lipid-lowering agents, respectively.

The use of Torisel may result in immunosuppression. Patients should be carefully observed for the occurrence of infections, including opportunistic infections. Cases of interstitial lung disease, some resulting in death, have occurred. Some patients were asymptomatic and others presented with symptoms. Some patients required discontinuation of Torisel and/or treatment with corticosteroids and/or antibiotics. Cases of fatal bowel perforation occurred with Torisel. These patients presented with fever, abdominal pain, metabolic acidosis, bloody stools, diarrhea, and/or acute abdomen. Cases of rapidly progressive and sometimes fatal acute renal failure not clearly related to disease progression occurred in patients who received Torisel.

Due to abnormal wound healing, use Torisel with caution in the perioperative period. Patients with central nervous system tumors (primary CNS tumor or metastases) and/or receiving anticoagulation therapy may be at an increased risk of developing intracerebral bleeding (including fatal outcomes) while receiving Torisel. Live vaccinations and close contact with those who received live vaccines should be avoided. Patients and their partners should be advised to avoid pregnancy throughout treatment and for 3 months after Torisel therapy has stopped.

The most common (incidence >/= 30 percent) adverse reactions observed with Torisel are: rash (47 percent), asthenia (51 percent), mucositis (41 percent), nausea (37 percent), edema (35 percent), and anorexia (32 percent). The most common laboratory abnormalities (incidence >/= 30 percent) are anemia (94 percent), hyperglycemia (89 percent), hyperlipemia (87 percent, hypertriglyceridemia (83 percent), elevated alkaline phosphatase (68 percent), elevated serum creatinine (57 percent), lymphopenia (53 percent), hypophosphatemia (49 percent), thrombocytopenia (40 percent), elevated AST (38 percent), and leukopenia (32 percent). Most common grades 3/4 adverse events included asthenia (11 percent), dyspnea (9 percent), hemoglobin decreased (20 percent), lymphocytes decreased (16 percent), glucose increased (16 percent), phosphorus decreased (18 percent), and triglycerides increased (44 percent).

Strong inducers of CYP3A4/5 (e.g., dexamethasone, rifampin) and strong inhibitors of CYP3A4 (e.g., ketoconazole, atazanavir) may decrease and increase concentrations of the major metabolite of TORISEL, respectively. If alternatives cannot be used, dose modifications of Torisel are recommended. St. John's Wort may decrease Torisel plasma concentrations, and grapefruit juice may increase plasma concentrations of the major metabolite of Torisel, and therefore both should be avoided. The combination of Torisel and sunitinib resulted in dose-limiting toxicity (Grade 3/4 erythematous maculopapular rash, and gout/cellulitis requiring hospitalization).

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, including lung, breast, prostate, sarcoma,

melanoma, and various hematologic cancers. Pfizer Oncology has biologics and small molecules in clinical development and more than 200 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 October 7, 2010. Pfizer assumes no obligation to update any 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, 2009 and in its reports on Form 10-Q and Form 8-K.

(1) ESMO Accepted Abstract #365PD. Randomized phase 2 study of PF299804, an irreversible human epidermal growth factor receptor (EGFR) inhibitor, versus (v) erlotinib (E) in patients (pts) with advanced non-small cell lung cancer (NSCLC) after chemotherapy (CT) failure: quantitative and qualitative benefits. Poster Discussion. Sunday, October 10: 12:30 pm. Suresh Ramalingam – Presenter. 35th Congress of the European Society for Medical Oncology. Milan, Italy. October 8 - 12, 2010.

(2) ESMO Accepted Abstract # LBA18. Efficacy and safety of PF299804 as first-line treatment (tx) of patients (pts) with advanced non-small cell lung cancer (NSCLC) selected for activating mutation (mu) of epidermal growth factor receptor (EGFR). Proffered Paper (Oral Presentation). Monday, October 11: 14:00. Tony Mok - Presenter. 35th Congress of the European Society for Medical Oncology. Milan, Italy. October 8 - 12, 2010.

(3) ClinicalTrials.gov. PF-00299804 in Treating Patients With Stage IIIB or Stage IV Non-Small Cell Lung Cancer That Has Not Responded to Standard Therapy for Advanced or Metastatic Cancer. Available at: http://clinicaltrials.gov/ct2/show/NCT01000025. Accessed April 29, 2010.

(4) ESMO Accepted Abstract # 366PD. Clinical Activity of Crizotinib (PF-02341066), in ALK-Positive Patients with Non-Small Cell Lung Cancer (NSCLC). Poster Discussion. Sunday, October 10: 12:30. David Ross Camidge - Presenter. 35th Congress of the European Society for Medical Oncology. Milan, Italy. October 8 - 12, 2010.

(5) ESMO Accepted Abstract # LBA6. Sunitinib (SU) in combination with erlotinib (E) for the treatment of advanced/metastatic non-small cell lung cancer (NSCLC): a phase III study. Proferred Paper. Monday, October 11: 10:30-10:45. Giorgio V Scagliotti - Presenter. 35th Congress of the European Society for Medical Oncology. Milan, Italy. October 8 - 12, 2010.

(6) ESMO Accepted Abstract #747P. Evaluation of progression-free survival (PFS) by blinded independent central review (BICR) in patients (pts) with progressive, well-differentiated pancreatic neuroendocrine tumours (NET) treated with sunitinib (SU) or placebo. Poster Presentation. Saturday, October 9: 13:00-14:00. Eric van Cutsem - Presenter. 35th Congress of the European Society for Medical Oncology. Milan, Italy. October 8 - 12, 2010.

(7) ESMO Accepted Abstract #1344O. Safety and Efficacy Results from a Phase 1/2 Study of the Anti-IGF-IR Antibody Figitumumab in Patients with Refractory Ewing's and Other Sarcomas. Proferred Paper. Sunday, October 10: 9:15-9:30. Heribert Juergens - Presenter. 35th Congress of the European Society for Medical Oncology. Milan, Italy. October 8 - 12, 2010.

(8) ESMO Accepted Abstract #213O. Distant recurrences at median of 5-years among 9.779 postmenopausal women with hormone receptor-positive early breast cancer treated on the TEAM trial of adjuvant endocrine therapy. Proffered Paper. Monday, October 11: 9:00-9:15. Hans Nortier - Presenter. 35th Congress of the European Society for Medical Oncology. Milan, Italy. October 8 - 12, 2010.

(9) ESMO Accepted Abstract #225P. Effects of exemestane or tamoxifen on bone health within the Tamoxifen Exemestane Adjuvant Multinational (TEAM) trial: a meta-analysis. Poster Presentation. Sunday, October 11: 12:30-13:30. Peyman Hadji - Presenter. 35th Congress of the European Society for Medical Oncology. Milan, Italy. October 8 - 12, 2010.

(10) ESMO Accepted Abstract #292P. Evaluation of Neratinib (HKI-272) and Paclitaxel Pharmacokinetics (PK) in Asian and Caucasian Patients with ErbB2+ Breast Cancer: A Phase 1/2 Study of Neratinib in Combination with Paclitaxel. Poster Presentation. Saturday, October 9: 13:00-14:00. Richat Abbas - Presenter. 35th Congress of the European Society for Medical Oncology. Milan, Italy. October 8 - 12, 2010.

(11) ESMO Accepted Abstract #298P. A Phase 1 Study of Neratinib (HKI-272) in Combination with Paclitaxel in Japanese Patients with Solid Tumors. Poster Presentation. Saturday, October 9: 13:00-14:00. Yoshinori Ito - Presenter. 35th Congress of the European Society for Medical Oncology. Milan, Italy. October 8 - 12, 2010.

(12) ESMO Accepted Abstract #907P. Axitinib Pharmacokinetics and Blood Pressure Changes in Front-line Metastatic Renal Cell Carcinoma (RCC) Patients. Poster Presentation. Saturday, October 9: 13:00-14:00. Mayer N. Fishman - Presenter. 35th Congress of the European Society for Medical Oncology. Milan, Italy. October 8 - 12, 2010.

(13) ESMO Accepted Abstract #1152P. Modeling the Pharmacokinetic/Pharmacodynamic Platelet Response of Inotuzumab Ozogamicin, a Novel Antibody Drug Conjugate, Administered Alone or in Combination with Rituximab in Patients With Non-Hodgkin's Lymphoma. Poster Presentation. Monday, October 11: 12:30-13:30. Joseph Boni - Presenter. 35th Congress of the European Society for Medical Oncology. Milan, Italy. October 8 - 12, 2010.

(14) ESMO Accepted Abstract #926P. A phase 2 study of safety and efficacy of temsirolimus (CCI-779) administered as a single agent in East Asian patients with advanced renal cell carcinoma. Poster Presentation. Saturday, October 9: 13:00-14:00. Yan Sun - Presenter. 35th Congress of the European Society for Medical Oncology. Milan, Italy. October 8 – 12, 2010.

(15) ESMO Accepted Abstract #549P. Population Pharmacokinetics of Temsirolimus in Pediatric Patients with Relapsed/Refractory Solid Tumors. Poster Presentation. Monday, October 11: 12:30-13:30. Sam Liao - Presenter. 35th Congress of the European Society for Medical Oncology. Milan, Italy. October 8 - 12, 2010.

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