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Pfizer Announces Data Presentations For Investigational Compounds In Its Lung Cancer Portfolio

Monday, June 27, 2011 - 07:30pm

Preliminary Overall Survival Data from a Phase 2 Study Comparing PF-00299804 to Erlotinib in Second-/Third-line Advanced Non-Small Cell Lung Cancer

"Data being presented show survival outcomes for PF-299 and crizotinib, as well as quality-of-life or patient-reported outcomes after treatment for patients with non small cell lung cancer, which represent important considerations in determining the best treatment option for these patients."

(BUSINESS WIRE)--Pfizer Inc. will present early and mid-stage data from its lung cancer portfolio, including PF-00299804 (PF-299) an investigational, oral, pan-HER inhibitor;[1] and crizotinib, an investigational, oral, first-in-class compound that inhibits the anaplastic lymphoma kinase, or ALK,[2] at the International Association for the Study of Lung Cancer's (IASLC) 14th World Conference on Lung Cancer (WCLC), July 3-7 in Amsterdam, The Netherlands.

"While lung cancer remains a difficult-to-treat disease, we're learning more about how therapies like crizotinib and PF-299 may be able to specifically target ALK or the HER pathway, respectively, and how this may lead to more rationally selected and personalized therapy," said Maurizio Voi, MD, Thoracic Tumor Strategy Lead, Pfizer Oncology. "Data being presented show survival outcomes for PF-299 and crizotinib, as well as quality-of-life or patient-reported outcomes after treatment for patients with non small cell lung cancer, which represent important considerations in determining the best treatment option for these patients."

First Presentation of PF-299 Preliminary Overall Survival Data

Pfizer will present, for the first time, preliminary overall survival data from a Phase 2 study evaluating PF-299 vs erlotinib in patients with advanced non-small cell lung cancer (NSCLC) after progression on at least one chemotherapy regimen (oral presentation, Abstract #745, Monday, July 4).[1]

Pfizer also will present patient-reported outcomes (PRO) from clinical trials of PF-299 in refractory and second-/third-line NSCLC, which provide a better understanding of the patient's perspective of the burden of adverse events associated with treatment and how it may change over time.[3,4]

- Gastrointestinal toxicity of the pan-HER tyrosine kinase inhibitor (TKI) PF299804: Assessment by patient-reported outcomes in second-/third-line and refractory NSCLC (poster session, Abstract #957, Wednesday, July 6)[3]
- Dermatologic adverse events of the pan-HER tyrosine kinase inhibitor (TKI) PF299804: Assessment by patient-reported outcomes in second-/third-line and refractory NSCLC (poster session, Abstract #702, Wednesday, July 6)[4]

Based on results from across the PF-299 clinical trial program, Pfizer has initiated a Phase 3 trial, ARCHER 1009, evaluating PF-299 vs erlotinib for the treatment of patients with locally advanced or metastatic NSCLC following progression after, or intolerance to, at least one prior chemotherapy. ARCHER 1009 will assess the efficacy and safety of PF-299 in two co-primary populations: all enrolled patients, and enrolled patients with *KRAS* wild type status. The ARCHER 1009 study is open for enrollment in the US and will be enrolling soon in other countries.[5]

PF-299 targets multiple receptors of the HER pathway. PF-299 is an irreversible inhibitor of HER-1 (EGFR), HER-2 and HER-4 tyrosine kinases. [6]

Crizotinib Data to be presented:

At the WCLC, data on the anti-tumor activity, safety, overall survival, patient-reported and quality-of-life outcomes observed in clinical trials of Pfizer's crizotinib will be presented.[2,7,8]

- Phase 2 data for crizotinib in ALK-positive advanced NSCLC: PROFILE 1005 (oral presentation, Abstract #1618, Wednesday, July 6)[2]
- PROFILE 1005: Preliminary patient-reported outcomes (PROs) from an ongoing Phase 2 study of crizotinib in ALK-positive advanced NSCLC (oral presentation, Abstract #1510, Wednesday, July 6)[7]
- Crizotinib improves overall survival of ALK-positive patients with advanced NSCLC compared with historical controls (oral presentation, Abstract #1207, Wednesday, July 6)[8]
- Efficacy of crizotinib in retrospective comparisons with standard-of-care (SOC) regimens from three Pfizer-sponsored clinical trials in patients with advanced NSCLC (poster session, Abstract #1349, Wednesday, July 6)[9]

Crizotinib is an investigational agent that inhibits ALK, [10] which blocks signaling in a number of cell pathways that are believed to be critical for the growth and survival of tumor cells.[11,12] Preliminary epidemiology suggests that approximately 3-5 percent of NSCLC tumors are ALK-positive.[11]

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 June 28, 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, 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 that have been or may be filed for any such oncology product candidates 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] World Lung Accepted Abstract #745. Overall Survival (OS) Results of a Randomized Phase 2 Trial of PF299804 versus Erlotinib in Patients with Advanced Non-Small Cell Lung Cancer (NSCLC) After Failure of Chemotherapy. Oral Session, Monday July 4, 2011: 3:35 PM – 3:45 PM CEST. M. Boyer – Presenter. International Association for the Study of Lung Cancer's (IASLC) 14th World Conference on Lung Cancer (WCLC), Amsterdam, The Netherlands. July 3-7, 2011.

[2] World Lung Accepted Abstract #1618. Phase 2 Data for Crizotinib (PF-02341066) in ALK-Positive Advanced Non-Small Cell Lung Cancer (NSCLC): PROFILE 1005. Oral Session, Wednesday July 6, 2011: 3:10 PM – 3:20 PM CEST. G. Riely – Presenter. International Association for the Study of Lung Cancer's (IASLC) 14th World Conference on Lung Cancer (WCLC), Amsterdam, The Netherlands. July 3-7, 2011.

[3] World Lung Accepted Abstract #957. Gastrointestinal Toxicity of the Pan-HER Tyrosine Kinase Inhibitor (TKI) PF299804: Assessment by Patient-Reported Outcomes in 2nd/3rd-Line and Refractory Non-Small Cell Lung Cancer (NSCLC). Poster Session, Wednesday July 6, 2011: 12:15 PM – 2:15 PM CEST. A. Campbell – Presenter. International Association for the Study of Lung Cancer's (IASLC) 14th World Conference on Lung Cancer (WCLC), Amsterdam, The Netherlands. July 3-7, 2011.

[4] World Lung Accepted Abstract #702. Dermatologic Adverse Events of the Pan-HER Tyrosine Kinase Inhibitor (TKI) PF299804: Assessment by Patient-Reported Outcomes in 2nd/3rd-line and Refractory Non-Small Cell Lung Cancer (NSCLC). Poster Session, Wednesday July 6, 2011: 12:15 PM – 2:15 PM CEST. A. Campbell – Presenter. International Association for the Study of Lung Cancer's (IASLC) 14th World Conference on Lung Cancer (WCLC), Amsterdam, The Netherlands. July 3-7, 2011.

[5] Clinicaltrials.gov. ARCHER 1009: A Phase 3 Study of PF-00299804, a Pan-HER Inhibitor, Vs. Erolotinib in the Treatment of Advanced Non-Small Cell Lung Cancer. Available here: http://www.clinicaltrials.gov/ct2/show/NCT01360554?term=ARCHER&rank=1. Accessed June 21, 2011.

[6] Gonzales AJ, Hook KE, Althaus IW et al. Antitumor activity and pharmacokinetic properties of PF-00299804, a second-generation irreversible pan-erbBreceptor tyrosine kinase inhibitor. *Mol Cancer Ther*. 2008;7:1880-89.

[7] World Lung Accepted Abstract #1510. PROFILE 1005: Preliminary Patient-Reported Outcomes (PROs) from an Ongoing Phase 2 Study of Crizotinib (PF-02341066) in Anaplastic Lymphoma Kinase (ALK)-Positive Advanced Non-Small Cell Lung Cancer (NSCLC). Oral Session, Wednesday July 6, 2011: 3:30 PM – 3:40 PM CEST. F. Blackhall – Presenter. Presenter. International Association for the Study of Lung Cancer's (IASLC) 14th World Conference on Lung Cancer (WCLC), Amsterdam, The Netherlands. July 3-7, 2011.

[8] World Lung Accepted Abstract #1207. Crizotinib improves overall survival of ALK-positive patients with advanced NSCLC compared with historical controls. Oral Session, Wednesday July 6, 2011: 3:20 PM – 3:30 PM CEST. A. Shaw – Presenter. International Association for the Study of Lung Cancer's (IASLC) 14th World Conference on Lung Cancer (WCLC), Amsterdam, The Netherlands. July 3-7, 2011.

[9] World Lung Accepted Abstract #1349. Efficacy of Crizotinib in Retrospective Comparisons with Standard-Of-Care (SOC) Regimens from Three Pfizer-Sponsored Clinical Trials in Patients with Advanced Non-Small Cell Lung Cancer (NSCLC). Poster Session, Wednesday July 6, 2011: 12:15 PM – 2:15 PM CEST. Y. Tang – Presenter. International Association for the Study of Lung Cancer's (IASLC) 14th World Conference on Lung Cancer (WCLC), Amsterdam, The Netherlands. July 3-7, 2011.

[10] Bang Y et al. Clinical Activity of the Oral ALK Inhibitor, Crizotinib (PF-02341066), in Patients with *ALK*-positive Non-Small Cell Lung Cancer. Accepted Plenary Presentation at the American Society of Clinical Oncology Annual Meeting, June 4-8, 2010. Chicago, IL.

[11] 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.

[12] 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.

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