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# Pfizer Launches Phase 3 Clinical Trial With Novel Alk Inhibitor In Non-Small Cell Lung Cancer Patients With Specific Gene Mutation

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"Best of 2009" Data Presentation at ECCO15/ESMO34 Highlights Clinical Activity with PF-02341066 in a Phase I Dose Escalation Study

(BUSINESS WIRE)--Pfizer Oncology announced today that it will initiate a global, Phase 3 clinical trial of its investigational oral c-Met and ALK inhibitor, PF-02341066, versus standard of care chemotherapy in patients with advanced non-small cell lung cancer (NSCLC) carrying the ALK (anaplastic lymphoma kinases) fusion gene, who have progressed on one prior treatment with a platinum-based chemotherapy. Updated data from an expansion cohort of a Phase 1 study with PF-02341066 in NSCLC patients with tumors carrying this fusion gene were featured today at the ECCO15/ESMO34 meeting in Berlin, Germany (Abstract #6G).

PF-02341066 is an investigational, selective, ATP-competitive small molecule dual inhibitor of mesenchymal epithelial transition growth factor (c-Met or hepatocyte growth factor) and ALK tyrosine kinases, which are implicated in the progression of several cancers, including NSCLC. A subset of NSCLC patients have been identified whose tumors carry a unique mutation in which the echinoderm microtubule-associated protein-like 4 (EML4) gene is fused to ALK, also known as an EML4-ALK translocation. This fusion/translocation has been reported in 3–7 percent of all NSCLC patients, with the incidence increasing to 10-20 percent among NSCLC patients with adenocarcinoma histology and those who have a never-to-light smoking history, and represents one of the newest molecular targets in NSCLC.

"We see this as an extraordinary opportunity for rational drug development. This represents a shift from large trials designed to detect a small benefit in a large group of patients towards looking for a bigger effect in a smaller, better characterized group of patients. By focusing on the subset of patients whose lung cancers carry the EML4-ALK translocation, we will be in the best position to determine the clinical effects of PF-02341066, both good and bad, in comparison to standard chemotherapy," said Dr. Mace Rothenberg, senior vice president of clinical development and medical affairs for Pfizer's Oncology Business Unit.

Lung cancer is the most common cancer worldwide, with NSCLC accounting for approximately 85 percent of lung cancer cases· Nearly 60 percent of NSCLC patients are diagnosed late with Stage IIIB/IV advanced disease. For Stage IIIB/IV NSCLC, the five-year survival rate is only 12 percent.

**Phase 3 Study Open and Enrolling Patients in Select Centers**

A Phase 3 randomized, open-label study of the anti-tumor activity and safety of PF-02341066 versus pemetrexed or docetaxel in patients with measurable NSCLC who have tested positive for the ALK fusion gene and who have progressed on a platinum-based chemotherapy is currently open and enrolling in the United States and will be enrolling globally by the end of 2009. The study is expected to enroll 318 patients.

The primary objective of the study is progression-free survival (PFS), and secondary outcomes include assessment of overall survival, objective response rate, duration of response, disease control rate, and patient-reported outcomes. Patients in the study will be randomized to receive PF-02341066 (250 mg orally BID) or pemetrexed (500 mg/m$^2$ on Day 1 of each 21 day cycle) or docetaxel (75 mg/m$^2$ on Day 1 of each 21 day cycle).

Those interested in learning more about the trial should contact the Pfizer Oncology Clinical Trial Information Services (patients: Pfizer http://pfizercancertrials.com; physicians: www.pfizeroncology.com/clinicaltrials).

**Data Featured at ECCO/ESMO Support Initiation of Phase 3 Study**

Updated study results from an expansion cohort of a Phase 1 study in patients with NSCLC carrying the ALK fusion gene showed early clinical activity with PF-02341066.

In this study, patients carrying the EML4-ALK translocation were recruited into an expanded cohort at the recommended Phase 2 dose of 250 mg twice daily (BID). To date, 31 NSCLC ALK patients have been evaluated for response.

The overall response rate, to date, is 65 percent (20/31 patients [95 percent CI: 45 percent, 81 percent]) and disease control rate (DCR) at 8 weeks is 84 percent (26/31 patients [95 percent CI: 66 percent, 95 percent]). Median PFS has not yet been reached. The median duration of treatment is 24.5+ weeks.

In the Phase 1 study, the most common adverse events were mild or moderate, and included nausea, vomiting and diarrhea. Treatment-related severe toxicity (elevated liver transaminases) was infrequent and reversible.

“Now that the EML4-ALK translocation has been validated as a therapeutic target in a small, but significant subset of NSCLC patients, we look forward to seeing how our early stage research translates in a larger Phase 3 trial,” added Mr. Rothenberg.

This expansion cohort was part of a dose-escalation study which enrolled 38 advanced cancer patients in the escalation phase, and 57 patients in the expansion cohort, with various tumors, including NSCLC, colorectal, pancreatic, sarcoma and anaplastic large cell lymphoma tumors.

**About Pfizer Oncology**

Pfizer Oncology is committed to the discovery, investigation and development of innovative treatment options for cancer patients worldwide. Our robust pipeline consists of 21 biologics and small molecules in clinical development. Pfizer Oncology has over 200 clinical trials, including robust Phase 3 clinical trial programs in renal cell carcinoma, prostate cancer, non-small cell lung cancer, metastatic breast cancer, and hepatocellular carcinoma.

By working collaboratively with academic institutions, researchers, governments, and licensing partners, Pfizer Oncology strives to transform treatment by targeting the right drug for the right patient at the right time.

For more information please visit www.Pfizer.com.

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*DISCLOSURE NOTICE: The information contained in this release is as of September 24, 2009. 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 the product candidate PF-02341066, including with respect to its 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 may be filed for such product candidate 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, 2008 and in its reports on Form 10-Q and Form 8-K.*

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