Phase 3 Results Published in The New England Journal of Medicine Show Superiority of Pfizer's XALKORI® (crizotinib) Compared to Platinum-Based Chemotherapy in Previously Untreated Patients With ALK-Positive Advanced Non-Small Cell Lung Cancer

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Pfizer Inc. (NYSE:PFE) announced today the publication of results from the PROFILE 1014 study in the December 4 issue of The New England Journal of Medicine. PROFILE 1014 is a Phase 3 study of anaplastic lymphoma kinase (ALK) inhibitor XALKORI® (crizotinib) in previously untreated patients with ALK-positive advanced non-small cell lung cancer (NSCLC). These results demonstrated that XALKORI 250 mg twice daily significantly prolonged progression-free survival (PFS) in previously untreated patients with ALK-positive advanced NSCLC when compared to standard platinum-based chemotherapy regimens. The adverse events were consistent with the known safety profile for XALKORI.

"This study showed that XALKORI was superior to standard platinum-based chemotherapy regimens in previously untreated patients with ALK-positive advanced NSCLC," said lead author Benjamin Solomon, MD, PhD, of the Peter MacCallum Cancer Centre in Melbourne, Australia. "These data underscore the importance for all newly diagnosed patients to have their tumor tissue tested as early as possible for ALK gene

rearrangements before determining the most appropriate treatment option.”

As previously announced, the PROFILE 1014 study met its primary objective, with XALKORI significantly prolonging PFS in previously untreated patients with ALK-positive advanced NSCLC when compared to standard platinum-based chemotherapy regimens (median PFS 10.9 vs. 7.0 months; HR: 0.45; 95% CI: 0.35−0.60; P<0.001). XALKORI also demonstrated significantly higher objective response rate (ORR) when compared to standard platinum-based chemotherapy regimens (74% vs. 45%; P<0.001). With the majority of patients still in follow-up for survival at the time of the final PFS analysis and over two-thirds of the patients randomized to the chemotherapy arm of the study subsequently receiving XALKORI, median overall survival was not reached in either treatment arm (hazard ratio, 0.82; 95% CI, 0.54 to 1.26; P=0.36).

“PROFILE 1014 is an example of what can be accomplished through precision drug development. By identifying and enrolling only those patients whose advanced NSCLC tumors were ALK-positive, this trial was able to demonstrate the superiority of XALKORI over an intravenous platinum-based chemotherapy regimen that has been a standard first-line treatment for more than a decade,” said Dr. Mace Rothenberg, senior vice president of Clinical Development and Medical Affairs and chief medical officer for Pfizer Oncology. “We are delighted that these results are being published just 18 months after publication of PROFILE 1007, which demonstrated superiority of XALKORI over standard chemotherapy when used in the second-line setting to treat patients with ALK-positive advanced NSCLC.”

No unexpected safety issues were identified in the PROFILE 1014 study. The most commonly reported adverse events with XALKORI were vision disorder (71%), diarrhea (61%), nausea (56%) and edema (49%), and with chemotherapy, nausea (59%), fatigue (38%), vomiting (36%) and decreased appetite (34%). Most adverse events in both treatment groups were grade 1 or 2 in severity. Grade 3 or 4 elevations of aminotransferase levels occurred in 14% of patients in the XALKORI group and 2% of patients in the chemotherapy group, and these elevations were managed primarily with dose interruptions or dose reductions. Grade 3 or 4 neutropenia occurred in 11% and 15% of patients in the XALKORI and chemotherapy groups, respectively, with no cases of febrile neutropenia reported with XALKORI and two with chemotherapy.

PROFILE 1014 is a global, randomized, open-label, two-arm Phase 3 study evaluating the efficacy and safety of XALKORI in patients previously untreated for ALK-positive advanced NSCLC. A total of 343 patients were randomized into the trial, with approximately half of the patients in the XALKORI arm and the other half of the patients in the platinum doublet

chemotherapy arm.

These findings from PROFILE 1014 build upon the data from the pivotal Phase 3 PROFILE 1007 trial comparing XALKORI to standard chemotherapy in previously treated patients with ALK-positive advanced NSCLC. The results of the PROFILE 1007 study were published in the June 20, 2013 issue of The New England Journal of Medicine.

About Non-Small Cell Lung Cancer

Lung cancer is the leading cause of cancer death worldwide.1 NSCLC accounts for about 85 percent of lung cancer cases and remains difficult to treat, particularly in the metastatic setting.2 Approximately 75 percent of NSCLC patients are diagnosed late with metastatic, or advanced, disease where the five-year survival rate is only 5 percent.3,4,5

About XALKORI® (crizotinib)

XALKORI is a kinase inhibitor indicated in the U.S. for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test. The U.S. indication is not limited to any specific line of therapy. In the EU, XALKORI is indicated for the treatment of adults with previously treated ALK-positive advanced NSCLC. XALKORI has received approval in 80 countries6 including Australia, Canada, China, Japan, South Korea and the European Union.

XALKORI® Important Safety Information

Hepatotoxicity: Across three main clinical trials fatal hepatotoxicity occurred in 0.2% of patients. Monitor with periodic liver testing. Temporarily suspend, dose reduce, or permanently discontinue XALKORI.

Pneumonitis: Across three main clinical trials interstitial lung disease (ILD)/pneumonitis occurred in 2% of patients. Permanently discontinue in patients with ILD/pneumonitis.

QT Interval Prolongation: Across three main clinical trials QT interval prolongation occurred in 2.7% of patients. Monitor with electrocardiograms and electrolytes in patients who have a history of or predisposition for QTc prolongation, or who are taking medications that prolong QT. Temporarily suspend, dose reduce, or permanently discontinue XALKORI.

Bradycardia: XALKORI can cause bradycardia. Across three main clinical trials 11% of patients experienced a heart rate of less than 50 beats per minute. Monitor heart rate

and blood pressure regularly. Temporarily suspend, dose reduce, or permanently discontinue XALKORI.

Embryofetal Toxicity: XALKORI can cause fetal harm when administered to a pregnant woman. Women of childbearing potential should be advised to avoid becoming pregnant while receiving XALKORI.

Adverse Reactions: Across three main clinical trials the most common adverse reactions (≥25%) were vision disorders, nausea, diarrhea, vomiting, constipation, edema, elevated transaminases, and fatigue.

In a phase 3 study in patients with previously treated ALK-positive metastatic NSCLC randomized to XALKORI (n=172) or chemotherapy (n=171), serious adverse reactions were reported in 37.2% of patients treated with XALKORI. The most frequent serious adverse reactions reported in patients treated with XALKORI were pneumonia (4.1%), pulmonary embolism (3.5%), dyspnea (2.3%), and ILD (2.9%). Fatal adverse reactions in XALKORI-treated patients occurred in 9 (5%) patients, consisting of: acute respiratory distress syndrome, arrhythmia, dyspnea, ILD, pneumonia, pneumonitis, pulmonary embolism, respiratory failure, and sepsis. Grade 3 or 4 events occurring at a higher incidence with XALKORI than with chemotherapy and at greater than 2%, were syncope (3%), QT prolongation (3%), and pulmonary embolism (5%). Elevation of ALT of any grade occurred in 76% of patients and grade 3 or 4 in 17% of patients. Neutropenia of any grade occurred in 49% of patients and grade 3 or 4 in 12% of patients. Lymphopenia of any grade occurred in 51% of patients and grade 3 or 4 in 9% of patients. Renal cysts occurred in 4% and neuropathy occurred in 19% of patients treated with XALKORI.

Drug Interactions: Exercise caution with concomitant use of moderate CYP3A inhibitors. Avoid grapefruit or grapefruit juice which may increase plasma concentrations of crizotinib. Avoid concomitant use of strong CYP3A inducers and inhibitors. Dose reduction may be needed for co-administered drugs that are predominantly metabolized by CYP3A.

Nursing Mothers: Given the potential for serious adverse reactions in nursing infants, consider whether to discontinue nursing or discontinue XALKORI.

Hepatic Impairment: XALKORI has not been studied in patients with hepatic impairment. As crizotinib is extensively metabolized in the liver, hepatic impairment is likely to increase plasma crizotinib concentrations. Use caution in patients with hepatic impairment.

Renal Impairment: Administer XALKORI at a starting dose of 250 mg taken orally once daily in patients with severe renal impairment (CLcr<30 mL/min) not requiring dialysis. No starting dose adjustment is needed for patients with mild and moderate renal impairment.

For more information and full prescribing information, please visit www.XALKORI.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.

Pfizer Inc.: Working together for a healthier world®

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more, please visit us at www.pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of December 3, 2014. 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 XALKORI (crizotinib), including its potential benefits, and about the PROFILE 1014 trial, that involves substantial risks and

uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development; uncertainty regarding the commercial impact of the outcome of the PROFILE 1014 trial; whether and when regulatory submissions may be made for XALKORI for the first-line treatment of patients with ALK-positive, advanced, non-small cell lung cancer in jurisdictions in which that indication has not been approved, and whether and when regulatory authorities in such jurisdictions will approve any such submissions, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of that indication for XALKORI in those jurisdictions; 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, 2013 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information That May Affect Future Results," as well as in its subsequent reports on Form 8-K, all of which are filed with the SEC and available at www.sec.gov and www.pfizer.com.

1 The International Agency for Research on Cancer, the World Health Organization, GLOBOCAN 2008, Available at:http://globocan.iarc.fr/Pages/fact_sheets_cancer.aspx (select "Lung" from the drop-down menu). Accessed October 31, 2014.

2 Reade CA, Ganti AK. EGFR targeted therapy in non-small cell lung cancer: potential role of cetuximab. Biologics. 2009; 3: 215–224.

3 Reade CA, Ganti AK. EGFR targeted therapy in non-small cell lung cancer: potential role of cetuximab. Biologics. 2009; 3: 215–224.

4 Yang P, Allen MS, Aubry MC, et al. Clinical features of 5,628 primary lung cancer patients: experience at Mayo Clinic from 1997 to 2003. Chest. 2005;128(1):452–462

5 American Cancer Society. Detailed Guide: Lung Cancer (Non-Small Cell). Available at: http://www.cancer.org/cancer/lungcancer-non-smallcell/detailedguide/non-small-cell-lung-cancer-survival-rates. Accessed October 31, 2014.

6 Pfizer data on file.

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