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Pfizer Reports Positive Topline Results from Phase 3 Trial Comparing XALKORI® (crizotinib) to Chemotherapy in Previously Untreated East Asian Patients with ALK-Positive Advanced Non-Small Cell Lung Cancer (NSCLC)

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Data Reinforces XALKORI Superiority Over Chemotherapy in Prolonging PFS in Patients with ALK-Positive Advanced NSCLC

Pfizer Inc. announced today that PROFILE 1029, a Phase 3 study of anaplastic lymphoma kinase (ALK) inhibitor XALKORI® (crizotinib), met its primary objective of significantly prolonging progression-free survival (PFS) in previously untreated East Asian patients with ALK-positive advanced non-small cell lung cancer (NSCLC) when compared to a standard chemotherapy doublet. In this study, XALKORI was used as the first systemic therapy for patients with advanced ALK-positive NSCLC, and patients could have received therapy and/or surgery for early stage disease before they were diagnosed with metastatic disease.

The adverse events observed with XALKORI in the study were generally consistent with findings from previous trials. No unexpected adverse events were observed. Efficacy and safety data from PROFILE 1029 will be submitted for presentation at a future medical meeting.

PROFILE 1029 is the second positive Phase 3 study for XALKORI in the first-line setting and the third positive Phase 3 study for XALKORI in ALK-positive NSCLC. The PROFILE 1014 and PROFILE 1007 trials demonstrated that XALKORI was superior to chemotherapy in the first-line and the second-line settings, respectively.

“When evaluated specifically in East Asian patients with ALK-positive NSCLC, XALKORI was demonstrated to be superior to chemotherapy in terms of prolonging progression-free survival. This is consistent with the results of previous global randomized clinical trials that included Asian and Western patients, which also demonstrated an improvement in progression-free survival compared to standard-of-care chemotherapy” said Dr. Mace Rothenberg, senior vice president of Clinical Development and Medical Affairs and chief medical officer for Pfizer Oncology. “These results also underscore the importance of early and routine biomarker testing in patients with advanced NSCLC so that these patients can be identified and treated appropriately.”

XALKORI was the first ALK inhibitor approved by regulatory authorities in the United States (U.S.), European Union, China and Japan, and it is now approved in more than 85 countries. XALKORI is widely recognized as a standard of care for patients with ALK-positive advanced NSCLC. To date, more than 20,000 patients have been treated with XALKORI worldwide.1

About Non-Small Cell Lung Cancer

Worldwide, lung cancer is the leading cause of cancer death in both men and women.2 NSCLC accounts for about 85 percent of lung cancer cases and remains difficult to treat, particularly in the metastatic setting.3 Approximately 57 percent of NSCLC patients are diagnosed late with metastatic, or advanced, disease where the five-year survival rate is only 5 percent.4

XALKORI® (crizotinib) Indication and Important Safety Information (as per U.S. Prescribing Information)

XALKORI is a kinase inhibitor indicated 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.

Hepatotoxicity: Drug-induced hepatotoxicity with fatal outcome occurred in 0.1% of patients treated with XALKORI across clinical trials (n=1669). Transaminase elevations generally occurred within the first 2 months. Monitor with liver function tests including ALT and total bilirubin every 2 weeks during the first 2 months of treatment, then once a month and as clinically indicated, with more frequent repeat testing for increased liver transaminases, alkaline phosphatase, or total bilirubin in patients who develop transaminase elevations. Permanently discontinue for ALT/AST elevation >3 times ULN with concurrent total bilirubin elevation >1.5 times ULN (in the absence of cholestasis or hemolysis); otherwise, temporarily suspend and dose-reduce XALKORI as indicated.

Interstitial Lung Disease (Pneumonitis): Severe, life-threatening, or fatal interstitial lung disease (ILD)/pneumonitis can occur. Across clinical trials (n=1669), 2.9% of XALKORI-treated patients had any grade ILD, 1.1% had Grade 3/4, and 0.5% had fatal ILD. These cases generally occurred within 3 months after initiation of treatment. Monitor for pulmonary symptoms indicative of ILD/pneumonitis. Exclude other potential causes and permanently discontinue XALKORI in patients with drug-related ILD/pneumonitis.

QT Interval Prolongation: QTc prolongation can occur. Across clinical trials (n=1560), 2.1% of patients had QTcF (corrected QT by the Fridericia method) ?500 ms and 5.0% had an increase from baseline QTcF ?60 ms by automated machine-read evaluation of ECG. Avoid use in patients with congenital long QT syndrome. Consider periodic monitoring with ECGs and electrolytes in patients with congestive heart failure, bradyarrhythmias, electrolyte abnormalities, or who are taking medications that prolong the QT interval. Permanently discontinue XALKORI in patients who develop QTc >500 ms or ?60 ms change from baseline with Torsade de pointes, polymorphic ventricular tachycardia, or signs/symptoms of serious arrhythmia. Withhold XALKORI in patients who develop QTc >500 ms on at least 2 separate ECGs until recovery to a QTc ?480 ms, then resume at a reduced dose.

Bradycardia: Symptomatic bradycardia can occur. Across clinical trials, bradycardia occurred in 12.3% of patients treated with XALKORI (N=1669). Avoid use in combination with other agents known to cause bradycardia. Monitor heart rate and blood pressure regularly. In cases of symptomatic bradycardia that is not life-threatening, hold XALKORI until recovery to asymptomatic bradycardia or to a heart rate of ?60 bpm, re-evaluate the use of concomitant medications, and adjust the dose of XALKORI. Permanently discontinue for life-threatening bradycardia due to XALKORI; however, if associated with concomitant medications known to cause bradycardia or hypotension, hold XALKORI until recovery to asymptomatic bradycardia or to a heart rate of ?60 bpm. If concomitant medications can be adjusted or discontinued, restart XALKORI at 250 mg once daily with frequent monitoring.

Vision Disorders: Most commonly visual impairment, photopsia, blurred vision or vitreous floaters, occurred in 62% of 1669 patients. The majority (95%) of these patients had Grade 1 visual adverse reactions. 0.8% of

patients had Grade 3 and 0.2% had Grade 4 visual impairment. The majority of patients on the XALKORI arms in Studies 1 and 2 (>50%) reported visual disturbances which occurred at a frequency of 4-7 days each week, lasted up to 1 minute, and had mild or no impact on daily activities.

Severe Visual Loss: Across clinical trials, the incidence of Grade 4 visual field defect with vision loss was 0.2% (N=1669). Discontinue XALKORI in patients with new onset of severe visual loss (best corrected vision less than 20/200 in one or both eyes). Perform an ophthalmological evaluation. There is insufficient information to characterize the risks of resumption of XALKORI in patients with a severe visual loss; a decision to resume should consider the potential benefits to the patient.

Embryofetal Toxicity: XALKORI can cause fetal harm when administered to a pregnant woman. Advise of the potential risk to the fetus. Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment and for at least 45 days (females) or 90 days (males) respectively, following the final dose of XALKORI.

Adverse Reactions: Safety was evaluated in a phase 3 study in previously untreated patients with ALK-positive metastatic NSCLC randomized to XALKORI (n=171) or chemotherapy (n=169). Serious adverse events were reported in 34% of patients treated with XALKORI, the most frequent were dyspnea (4.1%) and pulmonary embolism (2.9%). Fatal adverse events in XALKORI-treated patients occurred in 2.3% of patients, consisting of septic shock, acute respiratory failure, and diabetic ketoacidosis. Common adverse reactions (all grades) occurring in ?25% and more commonly (?5%) in patients treated with XALKORI vs chemotherapy were vision disorder (71% vs 10%), diarrhea (61% vs 13%), edema (49% vs 12%), vomiting (46% vs 36%), constipation (43% vs 30%), upper respiratory infection (32% vs 12%), dysgeusia (26% vs 5%), and abdominal pain (26% vs 12%). Grade 3/4 reactions occurring at a ?2% higher incidence with XALKORI vs chemotherapy were QT prolongation (2% vs 0%), and constipation (2% vs 0%). In patients treated with XALKORI vs chemotherapy, the following occurred: elevation of ALT (any grade [79% vs 33%] or Grade 3/4 [15% vs 2%]); elevation of AST (any grade [66% vs 28%] or Grade 3/4 [8% vs 1%]); neutropenia (any grade [52% vs 59%] or Grade 3/4 [11% vs 16%]); lymphopenia (any grade [48% vs 53%] or Grade 3/4 [7% vs 13%]); hypophosphatemia (any grade [32% vs 21%] or Grade 3/4 [10% vs 6%]). In patients treated with XALKORI vs chemotherapy, renal cysts occurred (5% vs 1%). Nausea (56%) decreased appetite (30%), fatigue (29%), and neuropathy (21%) also occurred in patients taking 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. Avoid concomitant use of CYP3A substrates with narrow therapeutic range in patients taking XALKORI. If concomitant use of CYP3A substrates with narrow therapeutic range is required in patients taking XALKORI, dose reductions of the CYP3A substrates may be required due to adverse reactions.

Lactation: Because of the potential for adverse reactions in breastfed infants, advise females not to breast feed during treatment with XALKORI and for 45 days after the final dose.

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 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 visitwww.pfizer.com.

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DISCLOSURE NOTICE: *The information contained in this release is as of November 18, 2015. 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 that involves substantial risks and uncertainties regarding XALKORI, including its potential benefits, and about the PROFILE 1029 trial. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including further investigation of the clinical benefit of XALKORI, the ability to meet anticipated clinical trial commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing clinical data; uncertainty concerning the commercial impact of the outcome of the PROFILE 1029 trial; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of XALKORI; 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, 2014 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors 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.

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1 Pfizer data on file.

2 The International Agency for Research on Cancer, the World Health Organization, GLOBOCAN 2012, Available at:http://globocan.iarc.fr/Pages/fact_sheets_cancer.aspx. Accessed October 8, 2015.

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

4 National Cancer Institute. Surveillance, Epidemiology, and End Results Program. Seer Stat Fact Sheets: Lung and Bronchus Cancer. http://seer.cancer.gov/statfacts/html/lungb.html. Accessed October 8, 2015.

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