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Pfizer Announces Top-Line Results From Two Phase 3 Trials Of Dacomitinib In Patients With Refractory Advanced Non-Small Cell Lung Cancer

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An Ongoing, Third Phase 3 Trial is Evaluating Dacomitinib in First-Line in EGFR-Mutant NSCLC

Pfizer Inc. (NYSE:PFE) today announced top-line results from two randomized Phase 3 studies of the irreversible pan-HER kinase inhibitor dacomitinib in patients with advanced non-small cell lung cancer (NSCLC).

Both trials evaluated dacomitinib in populations of previously treated patients with advanced NSCLC. The ARCHER 1009 trial, which included patients previously treated with chemotherapy (second/third line), did not meet its objective of demonstrating statistically significant improvement in progression-free survival (PFS) when compared with the EGFR inhibitor erlotinib.

Separately, the NCIC CTG BR.26 trial, which included patients with advanced NSCLC after standard therapy with both chemotherapy and an EGFR tyrosine kinase inhibitor had failed, did not meet its objective of prolonging overall survival (OS) versus placebo.

An ongoing, third Phase 3 trial, ARCHER 1050, is evaluating PFS of dacomitinib in a different patient population than was studied in ARCHER 1009 and BR26. ARCHER 1050 compares dacomitinib versus gefitinib in treatment-naïve (without prior treatment) patients with EGFR-mutant advanced NSCLC. The results are expected in 2015.

“While we are disappointed in the results, lung cancer is a complex disease, and the use of targeted agents to treat specific patient populations continues to evolve,” said Dr. Mace Rothenberg, senior vice president of Clinical Development and Medical Affairs and chief medical officer for Pfizer Oncology. “We are analyzing the findings from both ARCHER 1009 and BR.26 to better understand the effects of dacomitinib in molecularly defined subgroups of patients with advanced NSCLC, including those with EGFR mutations.”

The ARCHER 1009 trial evaluated dacomitinib versus erlotinib in two co-primary populations of patients with advanced NSCLC previously treated with at least one chemotherapy regimen – all patients and patients with KRAS wild-type NSCLC. The study did not demonstrate that dacomitinib improved PFS in either of the co-primary populations compared to erlotinib.

The BR.26 trial was a double-blind, placebo-controlled, randomized study evaluating dacomitinib in patients with locally advanced or metastatic NSCLC after prior treatment, which included at least one chemotherapy regimen and one EGFR inhibitor treatment regimen. This study was designed, conducted and led by NCIC Clinical Trials Group (NCIC CTG).

"We are pleased to have had the opportunity to assess dacomitinib in the BR.26 trial," said Dr. Peter Ellis, BR.26 Study Chair and Associate Professor in the Department of Oncology, McMaster University, and medical oncologist at the Juravinski Cancer Centre, Hamilton, Ontario, Canada. "While we are disappointed that the trial did not meet its primary endpoint, we are supportive of Pfizer's commitment to continue to evaluate dacomitinib in the ARCHER 1050 trial."

In both studies, the adverse events observed for dacomitinib generally were consistent with its known adverse event profile. Full efficacy and safety data from ARCHER 1009 and BR.26 will be submitted for presentation at an upcoming medical meeting.

About Dacomitinib

Dacomitinib is an oral, once-daily, irreversible pan-HER (pan-human epidermal growth factor receptor) kinase inhibitor. Dacomitinib irreversibly inhibits the kinase activity of HER1/EGFR, HER2, and HER4 by binding covalently to the receptor tyrosine kinase domains and preventing autophosphorylation, thereby inhibiting downstream signaling and leading to tumor-growth inhibition and apoptosis.

Dacomitinib is an investigational compound and has not received regulatory approval in any country.

Pfizer has entered into a collaborative development agreement with SFJ Pharmaceuticals Group to conduct ARCHER 1050 across multiple sites in Asia (including Japan) and Europe.

For more information on ongoing clinical trials of dacomitinib, please visit www.clinicaltrials.gov.

About Non-Small Cell Lung Cancer

Worldwide, lung cancer is the leading cause of cancer death in both men and women.[i] NSCLC accounts for about 85 percent of lung cancer cases and remains difficult to treat, particularly in the metastatic setting.[ii] Approximately 75 percent of NSCLC patients are diagnosed late with metastatic, or advanced, disease where the five-year survival rate is only 5 percent.[iii],[iv],[v]

About NCIC CTG

The NCIC Clinical Trials Group (NCIC CTG) is a cancer clinical trials cooperative group that conducts Phase I-III trials testing anti-cancer and supportive therapies across Canada and internationally. It is a national research program of the Canadian Cancer Society. The NCIC CTG's Central Operations and Statistics Office is located at Queen's University in Kingston, Ontario, Canada.

About NCIC CTG BR.26

Both Canadian and international investigators and patients participated in this trial. In Australia, the Australasian Lung Cancer Trials Group (ALTG) coordinated participation, in collaboration with the NHMRC Clinical Trials Centre at the University of Sydney. In Italy, the National Cancer Institute of Naples (Italy) lung cancer group coordinated participation.

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.

DISCLOSURE NOTICE: The information contained in this release is as of January 27, 2014. Pfizer assumes no obligation to updateforward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about a product candidate, dacomitinib, including its potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things: (i) the uncertainties inherent in research and development including, without limitation, the ability to meet anticipated clinical trial commencement and completion dates, as well as the possibility of unfavorable clinical trial results; (ii) whether additional analyses of data from ARCHER 1009 and BR.26 may provide information about subgroups of patients who may derive benefit from dacomitinib; (iii) whether and when any

applications may be filed with regulatory authorities in various jurisdictions for dacomitinib for the treatment of advanced non-small cell lung cancer in various patient populations, and whether and when regulatory authorities may approve any such applications, as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; and (iv) competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K/A for the fiscal year ended December 31, 2012, and in its reports on Form 10-Q and Form 8-K.

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[i] The International Agency for Research on Cancer, the World Health Organization, GLOBOCAN 2008,

Available at: http://globocan.iarc.fr/factsheets/cancers/lung.asp. Accessed October 11, 2013.

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

[iii] 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. *Ches*t.2005;128(1):452–462.

[iv] Govindan R, Page N, Morgensztern D, et al. Changing epidemiology of small-cell lung cancer in the United States over the last 30 years: analysis of the surveillance, epidemiologic, and end results database. *J Clin Oncol*. 2006;24(28):4539–4544.

[v] American Cancer Society. Detailed Guide: Lung Cancer (Non-Small Cell). Available at: http://www.cancer.org/acs/groups/cid/documents/webcontent/003115-pdf.pdf. Accessed October 14, 2013

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