Dacomitinib Shows More than Seven-Month Improvement in Overall Survival Compared to an Established Therapy in Advanced NSCLC with EGFR-Activating Mutations

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Overall Survival Data from Head-to-Head Phase 3 ARCHER 1050 Trial Comparing Dacomitinib to Gefitinib Presented at ASCO 2018

Pfizer Inc. (NYSE:PFE) today announced overall survival (OS) data from the ARCHER 1050 trial evaluating dacomitinib as a first-line treatment for patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with EGFR-activating mutations compared to gefitinib. The trial showed a median OS of 34.1 months for patients receiving dacomitinib (95% CI: 29.5, 37.7), representing a more than seven-month improvement compared to 26.8 months with gefitinib (95% CI: 23.7, 32.1). The OS data from ARCHER 1050 were presented today as an oral presentation [Abstract #9004] at the 54th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago and have been published simultaneously in the Journal of Clinical Oncology.

“Overall survival is an important measure to assess efficacy of investigational compounds. These data presented today are particularly significant as dacomitinib is the first EGFR tyrosine kinase inhibitor in a Phase 3 head-to-head study comparing two tyrosine kinase inhibitors to show an improvement in overall survival,” said Professor Tony Mok, Chair of Department of Clinical Oncology, The Chinese University of Hong Kong. “I look forward to having dacomitinib as a potential first-line treatment option for non-small cell lung cancer patients with EGFR-activating mutations.”

Overall survival was a secondary endpoint of ARCHER 1050, a randomized, open label Phase 3 study comparing the efficacy and safety of dacomitinib to gefitinib for the first-line treatment of locally advanced or metastatic NSCLC in subjects with EGFR-activating mutations. At the OS data cutoff, median OS was 34.1 months with dacomitinib (95% CI: 29.5, 37.7) compared to 26.8 months with gefitinib (95% CI: 23.7, 32.1). Patients receiving dacomitinib had a 56.2 percent survival rate at 30 months compared with 46.3 percent for patients who received gefitinib. Subgroup analyses were consistent with the primary OS analysis across most baseline characteristics, including patients with common sub-mutations exon 19 and 21.

The adverse events (AEs) observed with dacomitinib in the study were consistent with findings from previous dacomitinib trials. The most common AEs were diarrhea (87%), nail changes (62%), rash/dermatitis acneiform (49%) and mouth sores (44%). The most common Grade 3 AEs with dacomitinib were rash (14%) and diarrhea (8%). Grade 4 AEs occurred in two percent of dacomitinib-treated patients. There was one case of Grade 5 diarrhea and one case of Grade 5 liver disease. The discontinuation rate due to treatment-related AEs for dacomitinib was 10 percent compared to seven percent for gefitinib.

“What is most encouraging about these results is that patients with non-small cell lung cancer harboring EGFR-activating mutations who received dacomitinib achieved a median overall survival of nearly three years, a marked improvement compared to an established treatment in this setting,” said Mace Rothenberg, MD, chief development officer, Oncology, Pfizer Global Product Development. “With today’s podium presentation at the American Society of Clinical Oncology annual meeting and the U.S. Food and Drug Administration Priority Review granted earlier this year, we are encouraged by these data and committed to deliver this promising investigational medicine to patients as quickly as possible.”

In April 2018, the U.S. Food and Drug Administration (FDA) granted priority review for dacomitinib for the first-line treatment of patients with locally advanced or metastatic NSCLC with EGFR-activating mutations. The FDA Prescription Drug User Fee Act (PDUFA) target action date is in September 2018. The European Medicines Agency also accepted the Marketing Authorization Application for dacomitinib for the same indication.

About Dacomitinib

Dacomitinib is an investigational, oral, once-daily, irreversible pan-human epidermal growth factor receptor tyrosine kinase inhibitor (TKI). It has not received regulatory

approval in any country.

In 2012, Pfizer and SFJ Pharmaceuticals entered into a collaborative development agreement to conduct ARCHER 1050 across multiple sites.

About Non-Small Cell Lung Cancer

Lung cancer is the leading cause of cancer deaths worldwide.1 Non-small cell lung cancer (NSCLC) accounts for about 85 percent of lung cancer cases and remains difficult to treat, particularly in the metastatic setting.2 Biomarker therapies dramatically changed the care of patients with metastatic NSCLC. Approximately 75 percent of NSCLC patients are diagnosed late with metastatic or advanced disease where the five-year survival rate is only five percent.2,3,4

EGFR is a protein that helps cells grow and divide. When the EGFR protein is mutated it can cause cancer cells to form. EGFR mutations occur in 10 to 35 percent of NSCLC tumors globally, yet the disease is associated with low survival rates and disease progression remains a challenge.5,6

About the SFJ Pharmaceuticals

SFJ is a global drug development company, which provides a unique and highly customized co-development partnering model for the world’s top pharmaceutical and biotechnology companies. SFJ provides at-risk funding and oversight of global clinical development necessary for regulatory submissions of some of the most promising drug development programs in Pharmaceutical and Biotechnology companies. SFJ’s mission is to leverage its financial strength and global team of clinical development experts to accelerate the development of life-saving and life enhancing drugs for the benefit of physicians and the patients they serve.

About Pfizer in Lung Cancer

Pfizer Oncology is committed to addressing the unmet needs of a broad range of patients with lung cancer, the leading cause of cancer-related death worldwide and a particularly difficult-to-treat disease. Pfizer strives to address the diverse and evolving needs of patients with non-small cell lung cancer (NSCLC) by developing efficacious and safe therapies, including biomarker-driven therapies and combinations with immuno-oncology (IO) agents. By combining leading scientific insights with a patient-centric approach, Pfizer is continually advancing its work to match the right patient with the right medicine at the right time. Through our research pipeline and collaboration efforts, we are

committed to delivering renewed hope to patients living with NSCLC.

About Pfizer Oncology

Pfizer Oncology is committed to pursuing innovative treatments that have a meaningful impact on people living with cancer. Our growing pipeline of biologics, small molecules, and immunotherapies is focused on identifying and translating the best scientific breakthroughs into clinical application for patients across a diverse array of solid tumors and hematologic cancers. Today, we have 10 approved oncology medicines and 14 assets currently in clinical development. By maximizing our internal scientific resources and collaborating with other companies, government and academic institutions, as well as patients and non-profit and professional organizations, we are bringing together the brightest and most enterprising minds to take on the toughest cancers. Together we can accelerate breakthrough treatments to patients around the world and work to redefine life with cancer.

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, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on www.pfizer.com and follow us on Twitter at @Pfizer and @Pfizer_News, LinkedIn, YouTube, and like us on Facebook at Facebook.com/Pfizer.

DISCLOSURE NOTICE: The information contained in this release is as of June 4, 2018. 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 a product candidate, dacomitinib, and Pfizer Oncology, including their potential benefits, 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, including 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; the risk that clinical trial data are subject to differing interpretations, and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate, regulatory authorities may not share our views and may require additional data or may deny approval altogether; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when new drug applications may be filed in any other jurisdictions for dacomitinib or for any other oncology products; whether and when the applications for dacomitinib pending with the FDA and the European Medicines Agency or any such other applications may be approved by regulatory authorities, 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, and, if approved, whether dacomitinib or any such other oncology products will be commercially successful; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of dacomitinib or any other oncology products; 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, 2017 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned “Risk Factors” and- 6 -

“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 U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com .

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4 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 May 2018.

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