U.S. FDA Approves VIZIMPRO® (dacomitinib) for the First-Line Treatment of Patients with EGFR-Mutated Metastatic Non-Small Cell Lung Cancer

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Approval Supported by Data from Phase 3 Head-to-Head Study vs. Gefitinib

NEW YORK--(BUSINESS WIRE)--Pfizer Inc. (NYSE:PFE) today announced that the U.S. Food and Drug Administration (FDA) has approved VIZIMPRO® [vih-ZIM-pro] (dacomitinib), a kinase inhibitor for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test.

“Improving outcomes for patients is the central focus of why we develop and deliver new medicines. VIZIMPRO is yet another example of Pfizer’s commitment to providing more options in lung cancer where there is great unmet need,” said Andy Schmeltz, Global President, Pfizer Oncology. “With today’s approval, Pfizer has medicines that target three unique lung cancer biomarkers, marking real progress for patients which has been achieved through a diverse and persistent drug development approach.”

The safety and efficacy of VIZIMPRO was demonstrated in ARCHER 1050, a randomized, multicenter, multinational, open-label study. Patients were required to have unresectable, metastatic NSCLC with no prior therapy for metastatic disease or recurrent disease with a minimum of 12 months disease-free after completion of systemic therapy; an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; EGFR exon 19 deletion

or exon 21 L858R substitution mutations. A total of 452 patients were randomized 1:1 to VIZIMPRO (n=227) or gefitinib (n=225). The primary endpoint was progression-free survival (PFS) as determined by blinded Independent Radiologic Central (IRC) review, and additional efficacy outcomes included overall response rate (ORR), duration of response (DoR) and overall survival (OS). A statistically significant improvement in PFS as determined by the IRC was demonstrated for patients randomized to VIZIMPRO compared with gefitinib (HR = 0.59 [95% CI: 0.47, 0.74], p <0.0001). Median PFS in the VIZIMPRO group was 14.7 months (95% CI: 11.1, 16.6) compared with 9.2 months (95% CI: 9.1, 11.0) in the gefitinib arm.

“EGFR-mutated advanced non-small cell lung cancer is a common illness, especially in the Asian population, and new treatment options will ultimately benefit patients,” said Professor Tony Mok, MD, primary investigator for the ARCHER 1050 study and Chair of Department of Clinical Oncology, The Chinese University of Hong Kong. “The findings from ARCHER 1050 suggest that VIZIMPRO should be considered as a new first-line treatment option for patients with EGFR-mutated non-small cell lung cancer exon 19 deletion or exon 21 L858R substitution mutations.”

Among 227 patients with EGFR-mutated metastatic NSCLC who received VIZIMPRO in ARCHER 1050, the most common (> 20%) adverse reactions were diarrhea (87%), rash (69%), paronychia (64%), stomatitis (45%), decreased appetite (31%), dry skin (30%), decreased weight (26%), alopecia (23%), cough (21%), and pruritus (21%). Serious adverse reactions occurred in 27 percent of patients treated with VIZIMPRO. The most common (≥1%) serious adverse reactions reported were diarrhea (2.2%) and interstitial lung disease (1.3%). The full prescribing information for VIZIMPRO can be found here.

"Today’s approval of VIZIMPRO is a direct result of our commitment to precision drug development and improving outcomes for patients with mutation-driven lung cancers. Pfizer now has two medicines that can tackle three different forms of mutation-driven lung cancer: XALKORI for patients with ALK-positive or ROS1-positive non-small cell lung cancer and VIZIMPRO for patients with EGFR-mutated non-small cell lung cancer,” said Mace Rothenberg, MD, chief development officer, Oncology, Pfizer Global Product Development.

Earlier this year, the FDA granted Priority Review for VIZIMPRO for the first-line treatment of patients with locally advanced or metastatic NSCLC with EGFR-activating mutations. The FDA grants Priority Review to medicines that may offer significant advances in treatment or may provide a treatment where no adequate therapy exists.

Pfizer is committed to ensuring that patients living with lung cancer have access to this innovative therapy. Patients in the U.S. who are prescribed VIZIMPRO have access to Pfizer Oncology TogetherTM, which offers personalized patient support including financial assistance and additional resources to help them manage day-to-day life with their condition.

About VIZIMPRO® (dacomitinib)

VIZIMPRO is a kinase inhibitor indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test. VIZIMPRO was reviewed and approved under the FDA's Priority Review program.

The recommended dose of VIZIMPRO is 45 mg taken orally, once daily, with or without food. If dose reduction is necessary, then the first dose reduction should be to 30 mg once daily and second dose reduction should be to 15 mg once daily.

In 2012, Pfizer and SFJ Pharmaceuticals entered into a collaborative development agreement to conduct ARCHER 1050 across multiple sites. 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. Under the terms of this agreement, SFJ Pharmaceuticals provided the funding and conducted the trial to generate the clinical data used to support this application. Pfizer retains all rights to commercialize VIZIMPRO globally.

About ARCHER 1050

The efficacy of VIZIMPRO was demonstrated in ARCHER 1050, a global Phase 3 head-to-head trial conducted in patients with unresectable, metastatic non-small cell lung cancer (NSCLC) harboring epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations, with no prior therapy for metastatic disease or recurrent disease with a minimum of 12 months disease-free after completion of systemic therapy. A total of 452 patients were randomized 1:1 to VIZIMPRO 45mg (n=227) or gefitinib 250mg (n=225). Randomization was stratified by region and EGFR mutation status. The major efficacy outcome measure was PFS as determined by blinded IRC review, and additional efficacy outcomes included ORR, DoR and OS.

The hierarchical statistical testing order was PFS followed by ORR and then OS. No formal testing of OS was conducted since the formal comparison of ORR was not statistically

significant.

VIZIMPRO® (dacomitinib) IMPORTANT SAFETY INFORMATION FROM THE U.S. PRESCRIBING INFORMATION

There are no contraindications for VIZIMPRO.

Interstitial Lung Disease (ILD): Severe and fatal ILD/pneumonitis occurred in patients treated with VIZIMPRO and occurred in 0.5% of the 394 VIZIMPRO-treated patients; 0.3% of cases were fatal. Monitor patients for pulmonary symptoms indicative of ILD/pneumonitis. Withhold VIZIMPRO and promptly investigate for ILD in patients who present with worsening of respiratory symptoms which may be indicative of ILD (e.g., dyspnea, cough, and fever). Permanently discontinue VIZIMPRO if ILD is confirmed.

Diarrhea: Severe and fatal diarrhea occurred in patients treated with VIZIMPRO. Diarrhea occurred in 86% of the 394 VIZIMPRO-treated patients. Grade 3 or 4 diarrhea was reported in 11% of patients and 0.3% of cases were fatal. Withhold VIZIMPRO for Grade 2 or greater diarrhea until recovery to less than or equal to Grade 1 severity, then resume VIZIMPRO at the same or a reduced dose depending on the severity of diarrhea. Promptly initiate anti-diarrheal treatment (loperamide or diphenoxylate hydrochloride with atropine sulfate) for diarrhea.

Dermatologic Adverse Reactions: Rash and exfoliative skin reactions occurred in patients treated with VIZIMPRO. Rash occurred in 78% of the 394 VIZIMPRO-treated patients. Grade 3 or 4 rash was reported in 21% of patients. Exfoliative skin reactions of any severity were reported in 7% of patients. Grade 3 or 4 exfoliative skin reactions were reported in 1.8% of patients. Withhold VIZIMPRO for persistent Grade 2 or any Grade 3 or 4 dermatologic adverse reaction until recovery to less than or equal to Grade 1 severity, then resume VIZIMPRO at the same or a reduced dose depending on the severity of the dermatologic adverse reaction. The incidence and severity of rash and exfoliative skin reactions may increase with sun exposure. At the time of initiation of VIZIMPRO, initiate use of moisturizers and appropriate measures to limit sun exposure. Upon development of Grade 1 rash, initiate treatment with topical antibiotics and topical steroids. Initiate oral antibiotics for Grade 2 or more severe dermatologic adverse reactions.

Embryo-Fetal Toxicity: VIZIMPRO can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with VIZIMPRO and for at least 17 days after the final dose.

Adverse Reactions: The most common (>20%) adverse reactions were diarrhea (87%), rash (69%), paronychia (64%), stomatitis (45%), decreased appetite (31%), dry skin (30%), decreased weight (26%), alopecia (23%), cough (21%), and pruritus (21%). The most common (≥1%) serious adverse reactions were diarrhea (2.2%) and interstitial lung disease (1.3%).

Drug Interactions: Concomitant use with a proton pump inhibitor (PPI) decreases dacomitinib concentrations, which may reduce VIZIMPRO efficacy. Avoid the concomitant use of PPIs with VIZIMPRO. As an alternative to PPIs, use locally-acting antacids or an H2-receptor antagonist. Administer VIZIMPRO at least 6 hours before or 10 hours after taking an H2-receptor antagonist. Concomitant use of VIZIMPRO increases the concentration of drugs that are CYP2D6 substrates which may increase the risk of toxicities of these drugs. Avoid concomitant use of VIZIMPRO with CYP2D6 substrates where minimal increases in concentration of the CYP2D6 substrate may lead to serious or life-threatening toxicities.

Lactation: Because of the potential for serious adverse reactions in breastfed infants from VIZIMPRO, advise women not to breastfeed during treatment with VIZIMPRO and for at least 17 days after the last dose.

Hepatic Impairment: No dose adjustment is recommended in patients with mild or moderate hepatic impairment. The recommended dose of VIZIMPRO has not been established for patients with severe hepatic impairment.

Renal Impairment: No dose adjustment is recommended for patients with mild or moderate renal impairment. The recommended dose of VIZIMPRO has not been established for patients with severe renal impairment.

About XALKORI® (crizotinib)

XALKORI is a tyrosine kinase inhibitor (TKI) indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK) or ROS1-positive as detected by an FDA-approved test. XALKORI has received approval for patients with ALK-positive NSCLC in more than 90 countries including Australia, Canada, China, Japan, South Korea and the European Union. XALKORI is also approved for ROS1-positive NSCLC in more than 60 countries.

XALKORI® Important Safety Information

Hepatotoxicity: Drug-induced hepatotoxicity with fatal outcome occurred in 0.1% of patients treated with XALKORI across clinical trials (n=1719). Transaminase elevations

generally occurred within the first 2 months. Monitor liver function tests, including ALT, AST, 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=1719), 2.9% of XALKORI-treated patients had any grade ILD, 1.0% had Grade 3/4, and 0.5% had fatal ILD. ILD 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=1616), 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 ECGs. Avoid use in patients with congenital long QT syndrome. Monitor 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 12.7% of patients treated with XALKORI (n=1719). 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.

Severe Visual Loss: Across clinical trials, the incidence of Grade 4 visual field defect with vision loss was 0.2% (n=1719). 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.

Vision Disorders: Most commonly visual impairment, photopsia, blurred vision or vitreous floaters, occurred in 63.1% of 1719 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.

Embryo-Fetal 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.

ROS1-positive Metastatic NSCLC: Safety was evaluated in 50 patients with ROS1-positive metastatic NSCLC from a single-arm study, and was generally consistent with the safety profile of XALKORI evaluated in patients with ALK-positive metastatic NSCLC. Vision disorders occurred in 92% of patients in the ROS1 study; 90% of patients had Grade 1 vision disorders and 2% had Grade 2.

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%), esophagitis (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 breastfeed during treatment with XALKORI and for 45 days after the final dose.

Hepatic Impairment: Crizotinib concentrations increased in patients with pre-existing moderate (any AST and total bilirubin >1.5x ULN and ≤3x ULN) or severe (any AST and total bilirubin >3x ULN) hepatic impairment. Reduce XALKORI dose in patients with moderate or severe hepatic impairment. The recommended dose of XALKORI in patients with pre-existing moderate hepatic impairment is 200 mg orally twice daily or with pre-existing severe hepatic impairment is 250 mg orally once daily.

Renal Impairment: Decreases in estimated glomerular filtration rate occurred in patients treated with XALKORI. 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.

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

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 five percent.3,4,5

EGFR is a protein that helps cells grow and divide. When the EGFR gene is mutated it can cause the protein to be overactive resulting in cancer cells to form. EGFR mutations may occur in 10 to 35 percent of NSCLC tumors globally, and most common activating mutations are deletions in exon 19 and exon 21 L858R substitutions, which together account for more than 80 percent of known activating EGFR mutations. The disease is associated with low survival rates and disease progression remains a challenge.5,6

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

At Pfizer Oncology, we are committed to advancing medicines wherever we believe we can make a meaningful difference on the lives of patients. Today, Pfizer Oncology has an industry-leading portfolio of 11 approved cancer medicines across 19 indications, including breast, prostate, kidney, lung and hematology. We also have one of the deepest oncology biosimilars pipelines, with two medicines approved globally and several assets in mid to late-stage development for the treatment of cancer or as supportive care. Pfizer Oncology is striving to change the trajectory of 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 September 27, 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 VIZIMPRO® (dacomitinib) and an approval in the U.S. for the first-line treatment of patients with metastatic NSCLC with EGFR exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test, 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, uncertainties regarding the commercial success of VIZIMPRO; 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 VIZIMPRO or for any other oncology products; whether and when any such 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 VIZIMPRO 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 VIZIMPRO 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 “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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