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LORBRENA® (lorlatinib) sNDA in Previously Untreated ALK-Positive Lung Cancer Accepted for Priority Review by U.S. FDA

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Supplemental New Drug Application being reviewed under FDA Real-Time Oncology Review (RTOR) and Project ORBIS pilot programs

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE:PFE) today announced that the U.S. Food and Drug Administration (FDA) has accepted for Priority Review the supplemental New Drug Application (sNDA) for LORBRENA ® (lorlatinib) as a first-line treatment for people with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC). The sNDA is based on data from the pivotal CROWN study and is being reviewed by the FDA under its Real-Time Oncology Review (RTOR) pilot program. The Prescription Drug User Fee Act (PDUFA) goal date for a decision by the FDA is in April 2021.

LORBRENA is a third-generation ALK inhibitor specifically developed to inhibit the most common tumor mutations that drive resistance to current medications and to address brain metastases. Up to 40% of people with ALK-positive lung cancer present with brain metastases.[1,2,3]

“The decision by the FDA to evaluate our application for LORBRENA under its innovative review pathways, which aim to speed up availability of potentially life-changing medicines, underscores the significance of the CROWN data and potential impact of LORBRENA as an initial therapy for people with ALK-positive advanced non-small cell lung cancer,” said Chris Boshoff, M.D., Ph.D., Chief Development Officer, Oncology, Pfizer Global Product Development. “We look forward to working with the FDA to bring this treatment option to patients as quickly as possible.”

The RTOR program is intended to create a more efficient review process to bring safe and effective treatments to people as early as possible. The program allows the FDA to review clinical trial data from certain applications before the complete application is formally submitted. Review under the program does not guarantee or influence the approvability of the application.[4]

The FDA also will conduct the review under Project ORBIS, an initiative introduced in 2019, which provides a framework for potential concurrent submissions and collaborative review with health authorities in Canada, Singapore, Switzerland, Australia, Brazil and the United Kingdom. Under Project ORBIS, collaboration among international regulators may allow patients with cancer to receive earlier access to products in other countries.[5]

The submission is supported by positive results from the Phase 3 CROWN trial, which met the primary endpoint of improved progression-free survival (PFS) versus XALKORI® (crizotinib) in people with previously untreated advanced ALK-positive NSCLC. Detailed results were published in the *New England Journal of Medicine* and

previously presented at the European Society for Medical Oncology (ESMO) Virtual Congress 2020.

In 2018, the FDA approved LORBRENA for the treatment of patients with ALK-positive metastatic NSCLC whose disease has progressed on crizotinib and at least one other ALK inhibitor for metastatic disease; or whose disease has progressed on alectinib or ceritinib as the first ALK inhibitor therapy for metastatic disease. This indication was approved under accelerated approval based on tumor response rate and duration of response. Data from the CROWN study will also support the conversion to a full approval for the use of LORBRENA for this indication.

About the CROWN Study

CROWN is a Phase 3, randomized, open-label, parallel 2-arm trial in which 296 people with previously untreated advanced ALK-positive NSCLC were randomized 1:1 to receive LORBRENA monotherapy (n=149) or XALKORI monotherapy (n=147). The primary endpoint of the CROWN trial is progression-free survival (PFS) based on blinded independent central review (BICR). Secondary endpoints include PFS based on investigator's assessment, overall survival (OS), objective response rate (ORR), intracranial objective response, and safety.

About Non-Small Cell Lung Cancer

Lung cancer is the number one cause of cancer-related death around the world.[5] NSCLC accounts for approximately 80-85% of lung cancers,[6] with ALK-positive tumors occurring in about 3-5% of NSCLC cases.[7] In 2020, an estimated 13,000 new cases of ALK-positive NSCLC will be diagnosed in the G7.[8]

About LORBRENA® (lorlatinib)

LORBRENA is a tyrosine kinase inhibitor (TKI) that has been shown to be highly active in preclinical lung cancer models harboring chromosomal rearrangements of ALK. LORBRENA was specifically developed to inhibit tumor mutations that drive resistance to other ALK inhibitors and to penetrate the blood brain barrier. LORBRENA is approved in the U.S. for the treatment of patients with ALK-positive metastatic NSCLC whose disease has progressed on:

- crizotinib and at least one other ALK inhibitor for metastatic disease; or
- alectinib as the first ALK inhibitor therapy for metastatic disease; or
- ceritinib as the first ALK inhibitor therapy for metastatic disease.
- This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

The full prescribing information for LORBRENA can be found here.

IMPORTANT LORBRENA® (lorlatinib) SAFETY INFORMATION FROM THE U.S. PRESCRIBING INFORMATION

Contraindications: LORBRENA is contraindicated in patients taking strong CYP3A inducers, due to the potential for serious hepatotoxicity.

Risk of Serious Hepatotoxicity with Concomitant Use of Strong CYP3A Inducers: Severe hepatotoxicity occurred in 10 of 12 healthy subjects receiving a single dose of LORBRENA with multiple daily doses of rifampin, a strong CYP3A inducer. Grade 4 ALT or AST elevations occurred in 50% of subjects, Grade 3 in

33% of subjects, and Grade 2 in 8% of subjects. ALT or AST elevations occurred within 3 days and returned to within normal limits after a median of 15 days (7 to 34 days); median time to recovery in subjects with Grade 3 or 4 or Grade 2 ALT or AST elevations was 18 days and 7 days, respectively. Discontinue strong CYP3A inducers for 3 plasma half-lives of the strong CYP3A inducer prior to initiating LORBRENA. Avoid concomitant use of LORBRENA with moderate CYP3A inducers. If concomitant use of moderate CYP3A inducers cannot be avoided, monitor AST, ALT, and bilirubin 48 hours after initiating LORBRENA and at least 3 times during the first week after initiating LORBRENA. Depending upon the relative importance of each drug, discontinue LORBRENA or the CYP3A inducer for persistent Grade 2 or higher hepatotoxicity.

Central Nervous System (CNS) Effects: A broad spectrum of CNS effects can occur; overall, CNS effects occurred in 54% of 332 patients receiving LORBRENA. These included seizures (3%, sometimes in conjunction with other neurologic findings), hallucinations (7%; 0.6% severe [Grade 3 or 4]), and changes in cognitive function (29%; 2.1% severe), mood (including suicidal ideation) (24%; 1.8% severe), speech (14%; 0.3% severe), mental status (2.1%; 1.8% severe), and sleep (10%). Median time to first onset of any CNS effect was 1.2 months (1 day to 1.7 years). Overall, 1.5% and 9% of patients required permanent or temporary discontinuation of LORBRENA, respectively, for a CNS effect; 8% required dose reduction. Withhold and resume at same or reduced dose or permanently discontinue based on severity.

Hyperlipidemia: Increases in serum cholesterol and triglycerides can occur. Grade 3 or 4 elevations in total cholesterol occurred in 17% and Grade 3 or 4 elevations in triglycerides occurred in 17% of the 332 patients who received LORBRENA. Median time to onset was 15 days for both hypercholesterolemia and hypertriglyceridemia. Approximately 7% and 3% of patients required temporary discontinuation or dose reduction of LORBRENA, respectively, for elevations in cholesterol and in triglycerides. Eighty percent of patients required initiation of lipid-lowering medications, with a median time to onset of start of such medications of 21 days. Initiate or increase the dose of lipid-lowering agents in patients with hyperlipidemia. Monitor serum cholesterol and triglycerides before initiating LORBRENA, 1 and 2 months after initiating LORBRENA, and periodically thereafter. Withhold and resume at same dose for the first occurrence; resume at same or reduced dose of LORBRENA for recurrence based on severity.

Atrioventricular (AV) Block: PR interval prolongation and AV block can occur. In 295 patients who received LORBRENA at a dose of 100 mg orally once daily and who had a baseline electrocardiography (ECG), 1% experienced AV block and 0.3% experienced Grade 3 AV block and underwent pacemaker placement. Monitor ECG prior to initiating LORBRENA and periodically thereafter. Withhold and resume at reduced or same dose in patients who undergo pacemaker placement. Permanently discontinue for recurrence in patients without a pacemaker.

Interstitial Lung Disease (ILD)/Pneumonitis: Severe or life-threatening pulmonary adverse reactions consistent with ILD/pneumonitis can occur. ILD/pneumonitis occurred in 1.5% of patients, including Grade 3 or 4 ILD/pneumonitis in 1.2% of patients. One patient (0.3%) discontinued LORBRENA for ILD/pneumonitis. Promptly investigate for ILD/pneumonitis in any patient who presents with worsening of respiratory symptoms indicative of ILD/pneumonitis. Immediately withhold LORBRENA in patients with suspected ILD/pneumonitis. Permanently discontinue LORBRENA for treatment-related ILD/pneumonitis of any severity.

Embryo-fetal Toxicity: LORBRENA can cause fetal harm. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use an effective non-hormonal method of contraception, since LORBRENA can render hormonal contraceptives ineffective, during treatment with LORBRENA and for at least 6 months after the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with LORBRENA and for 3 months after the final dose.

Adverse Reactions: Serious adverse reactions occurred in 32% of the 295 patients; the most frequently reported serious adverse reactions were pneumonia (3.4%), dyspnea (2.7%), pyrexia (2%), mental status changes (1.4%), and respiratory failure (1.4%). Fatal adverse reactions occurred in 2.7% of patients and included pneumonia (0.7%), myocardial infarction (0.7%), acute pulmonary edema (0.3%), embolism (0.3%), peripheral artery occlusion (0.3%), and respiratory distress (0.3%). The most common (?20%) adverse reactions were (all Grades; Grade 3 or 4): edema (57%; 3.1%), peripheral neuropathy (47%; 2.7%), cognitive effects (27%; 2.0%), dyspnea (27%; 5.4%), fatigue (26%; 0.3%), weight gain (24%; 4.4%), arthralgia (23%; 0.7%), mood effects (23%; 1.7%), and diarrhea (22%; 0.7%); the most common (?20%) laboratory abnormalities were (all Grades; Grade 3 or 4): hypercholesterolemia (96%; 18%), hypertriglyceridemia (90%; 18%), anemia (52%; 4.8%), hyperglycemia (52%; 5%), increased AST (37%; 2.1%), hypoalbuminemia (33%; 1.0%), increased ALT (28%; 2.1%), increased lipase (24%; 10%), and increased alkaline phosphatase (24%; 1.0%).

Drug Interactions: LORBRENA is contraindicated in patients taking strong CYP3A inducers. Avoid concomitant use with moderate CYP3A inducers and strong CYP3A inhibitors. If concomitant use of moderate CYP3A inducers cannot be avoided, monitor ALT, AST, and bilirubin as recommended. If concomitant use with a strong CYP3A inhibitor cannot be avoided, reduce the LORBRENA dose as recommended. Avoid concomitant use of LORBRENA with CYP3A substrates and P-gp substrates, which may reduce the efficacy of these substrates.

Lactation: Because of the potential for serious adverse reactions in breastfed infants, instruct women not to breastfeed during treatment with LORBRENA and for 7 days after the final dose.

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

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

About XALKORI® (crizotinib)

XALKORI is a TKI indicated for the treatment of patients with metastatic NSCLC whose tumors are 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.

The full prescribing information for XALKORI can be found here.

IMPORTANT XALKORI® (crizotinib) SAFETY INFORMATION FROM THE U.S. PRESCRIBING INFORMATION

Hepatotoxicity: Drug-induced hepatotoxicity with fatal outcome occurred in 0.1% of patients treated with XALKORI across clinical trials (n=1719). Increased transaminases 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 increased transaminases. 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% of 1582 patients 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 next lower dosage.

Bradycardia: Symptomatic bradycardia can occur. Across clinical trials, bradycardia occurred in 13% of patients treated with XALKORI (n=1719). Avoid use in combination with other medications known to cause bradycardia. Monitor heart rate and blood pressure regularly. If bradycardia occurs, re-evaluate for the use of concomitant medications known to cause bradycardia. 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% of 1719 patients. 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% 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: Use 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 where minimal concentration changes may lead to serious adverse reactions. If concomitant use of XALKORI is unavoidable, decrease the CYP3A substrate dosage in accordance with approved product labeling.

Lactation: Because of the potential for adverse reactions in breastfed children, advise women 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 dosage 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.

About Pfizer Oncology

At Pfizer Oncology, we are committed to advancing medicines wherever we believe we can make a meaningful difference in the lives of people living with cancer. Today, we have an industry-leading portfolio of 23 approved innovative cancer medicines and biosimilars across more than 30 indications, including breast, genitourinary, colorectal, blood and lung cancers, as well as melanoma.

Pfizer Inc.: Breakthroughs that change patients' lives

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, including innovative medicines and vaccines. 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 December 28, 2020. 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 LORBRENA® (lorlatinib), including a potential indication in the U.S. for the first-line treatment of people with ALK-positive metastatic NSCLC and its 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 LORBRENA; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when any drug applications may be filed in any additional jurisdictions for LORBRENA for treatment of patients with ALK-positive metastatic non-small cell lung cancer or in any jurisdictions for any other potential indications for LORBRENA; whether and when the FDA may approve the sNDA for LORBRENA for the first-line treatment of people with ALK-positive metastatic NSCLC and whether and when any such other applications may be approved by regulatory authorities, which will depend on a myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether such product candidate will be commercially successful; whether and when the accelerated approval for the existing indication for LORBRENA in the U.S. will be converted to full approval; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of LORBRENA; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; 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, 2019 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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