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Pfizer’s PAXLOVID™ Receives FDA Approval for Adult Patients at High Risk of Progression to Severe COVID-19

Thursday, May 25, 2023 - 11:21am

- *PAXLOVID is the first FDA-approved oral treatment for COVID-19; has been authorized for emergency use since December 2021*
- *Approval is based on the totality of scientific evidence submitted, including efficacy data from the Phase 2/3 EPIC-HR study showing an 86% reduction in risk of COVID-19-related hospitalization or death from any cause in patients who took PAXLOVID within five days of symptom onset*
- *PAXLOVID remains available to eligible patients via prescription at no charge**

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) announced today that the U.S. Food and Drug Administration (FDA) approved PAXLOVID™ (nirmatrelvir tablets and ritonavir tablets) for the treatment of mild-to-moderate COVID-19 in adults who are at high risk for progression to severe COVID-19, including hospitalization or death. PAXLOVID has been available in the U.S. since December 2021 under Emergency Use Authorization (EUA), and the overall benefit/risk profile and indication for use in eligible adults remain consistent with the EUA. More than 11.6 million treatment courses of PAXLOVID have been prescribed in the U.S. to date.[1]

“Great advancements have been made in the fight against COVID-19, yet the virus remains a present and unpredictable concern. This is especially true for the hundreds of millions of American adults who are age 50 or older or are otherwise at high risk for progression to severe illness, even if symptoms are initially mild,” said Albert Bourla, Chairman and Chief Executive Officer, Pfizer. “Today marks a monumental milestone as PAXLOVID became the first COVID-19 oral treatment to be approved by the U.S. FDA, underscoring the value it brings to patients, providers, and health systems alike.”

COVID-19 continues to cause significant burden in the U.S. with approximately 14,500 reported cases each week as of the end of April 2023;[2] but the majority of cases are not reported.[3] In addition, data show that the impact of COVID-19 extends beyond an acute infection; an estimated 10-31 million Americans may experience persisting, recurring or new symptoms after the acute phase of COVID-19 infection.[4,5]

The FDA approval of PAXLOVID is based on the totality of scientific evidence shared by Pfizer, including safety and efficacy data from the EPIC (**E**valuation of **P**rotease **I**nhibition for **C**OVID-19) clinical development program. This included results from the Phase 2/3 EPIC-HR (**E**valuation of **P**rotease **I**nhibition for **C**OVID-19 in **H**igh-**R**isk Patients) study, which enrolled unvaccinated, non-hospitalized adults, aged 18 years and older, with confirmed COVID-19 who were at increased risk of progressing to severe disease. The data showed an 86% reduction in risk of COVID-19-related hospitalization or death from any cause through Day 28 in patients who initiated treatment with PAXLOVID within five days of symptoms onset, compared to placebo. The FDA approval was further supported by the results from a secondary endpoint of the Phase 2/3 EPIC-SR (**E**valuation of **P**rotease **I**nhibition for **C**OVID-19 in **S**tandard-**R**isk Patients) study, which showed a numerical reduction in

COVID-19-related hospitalizations or death from any cause through Day 28 in a sub-group of non-hospitalized adults, aged 18 years and older, with confirmed COVID-19 who had at least one risk factor for progression to severe disease and who were fully vaccinated. Available safety data have been consistent in participants across the EPIC clinical program, as well as across reported post-authorization safety experience in millions of patients prescribed PAXLOVID to date.

Recent real-world studies of PAXLOVID support the efficacy conclusions from Pfizer's EPIC clinical program, providing additional data on the use of PAXLOVID in the post-authorization setting of Omicron sub-lineage predominance and where high levels of pre-existing immunity occur. These real-world studies also have shown that PAXLOVID is effective amongst both vaccinated and unvaccinated high-risk patients.[6,7,8,9,10]

Based on the relative risk reduction seen across both clinical and real-world data, the FDA provided an estimate in March 2023 that more than 1,500 lives could be saved, and 13,000 hospitalizations avoided each week with PAXLOVID use in eligible patients.[11]

At this time, the U.S. government will continue to oversee the distribution of PAXLOVID, and U.S. residents eligible for PAXLOVID will continue to receive the medicine at no charge.*

PAXLOVID remains available for eligible children, 12 to 17 years of age (and weighing at least 40 kg), under the existing EUA. Pfizer continues to gather pediatric data from the ongoing clinical trial, EPIC-Peds (**E**valuation of **P**rotease **I**nhibition for **C**OVID-19 in **Ped**iatric Patient**s**) and intends to submit a supplemental New Drug Application (sNDA) to support the FDA approval of PAXLOVID in children at a future date.

PAXLOVID is currently approved or authorized for conditional or emergency use in more than 70 countries across the globe to treat COVID-19 patients who are at increased risk for progressing to severe illness.

***** *Other administrative fees may apply*

About PAXLOVID™ (nirmatrelvir tablets and ritonavir tablets)

PAXLOVID is a SARS-CoV-2 main protease (M^{pro}) inhibitor (also known as SARS-CoV-2 3CL protease inhibitor) therapy. It was developed to be administered orally so that it can be prescribed early after infection, potentially helping patients avoid severe illness (which can lead to hospitalization and death). Nirmatrelvir, which originated in Pfizer laboratories, is designed to block the activity of the M^{pro}, an enzyme that the coronavirus needs to replicate. Co-administration with a low dose of ritonavir helps slow the metabolism, or breakdown, of nirmatrelvir in order for it to remain active in the body for longer periods of time at higher concentrations to help combat the virus.

Nirmatrelvir is designed to inhibit viral replication at a stage known as proteolysis, which occurs before viral RNA replication. In preclinical studies, nirmatrelvir did not demonstrate evidence of mutagenic DNA interactions.

Current variants of concern can be resistant to treatments that work by binding to the spike protein found on the surface of the SARS-CoV-2 virus. PAXLOVID, however, works intracellularly by binding to the highly conserved M^{pro} (3CL protease) of the SARS-CoV-2 virus to inhibit viral replication. Nirmatrelvir has consistently shown *in vitro* antiviral activity against the variants Alpha, Beta, Delta, Gamma, Lambda, Mu, and Omicron BA.1, BA.2, BA.2.12.1, BA.4, BA.4.6, BA.5, BF.7, BQ.1.11, BQ.1 and XBB.1.5. Work is ongoing to evaluate activity against recently identified variants as they become available for testing.

PAXLOVID is generally administered at a standard dose of 300 mg (two 150 mg tablets) of nirmatrelvir with one 100 mg tablet of ritonavir, given twice-daily for five days. One standard dose carton contains blister packs of PAXLOVID, as co-packaged nirmatrelvir tablets with ritonavir tablets, providing all required doses for a full five-day treatment course. The modified dose for patients with moderate renal impairment (eGFR ?30 to <60 mL/min) is reduced to 150 mg nirmatrelvir (one 150 mg tablet) with 100 mg ritonavir (one 100 mg tablet), with both tablets taken together twice daily for five days (PAXLOVID is not recommended in patients with severe renal impairment [eGFR <30 mL/min]).

For more information, please visit www.PAXLOVID.com.

Our Commitment to Access

Pfizer is committed to working toward equitable access to our oral COVID-19 treatment, PAXLOVID, for high-risk patients in need. Pfizer has established a comprehensive strategy in close partnership with worldwide governments, international global health leaders, including WHO's Access to COVID-19 Tools Accelerator (ACT-A), and global manufacturers to optimize supply and access of PAXLOVID all around the world. This includes:

- ***Multilateral Supply Agreements*** : Signed agreement with **UNICEF** to supply up to 4 million treatment courses of PAXLOVID to 137 low- and middle-income countries; Signed letter of intent with **Global Fund** for up to 6 million PAXLOVID treatment courses for supply to 132 Global-Fund eligible countries.
- ***Expanding Access to Patent-Protected Medicines in Lower-Income Countries*** *:* Launched **An Accord for a Healthier World,** to support access for PAXLOVID and many other medicines and vaccines in lower-income countries. In addition to offering the full portfolio of medicines and vaccines for which we hold global rights on a not-for-profit-bases to 45 lower-income countries, through the Accord, Pfizer has committed to collaborate with country governments and global health organizations to help address barriers to access for these medicines and vaccines – like diagnostics, training, storage and more – to get PAXLOVID and other medicines to patients who need them in these countries.
- ***Voluntary Licensing:*** Signed a voluntary license agreement with **Medicines Patent Pool (MPP)** for the oral COVID-19 treatment to help expand access, pending country regulatory authorization or approval, for approximately 53% of the world's population. The 35 generics manufacturers will develop generic versions of Pfizer's COVID-19 oral treatment for distribution to 95 low- and lower-middle-income countries and some upper-middle-income countries in Sub-Saharan Africa as well as countries that have transitioned from lower-middle to upper-middle-income status in the past five years, subject to approval or authorization.

U.S. Indication

PAXLOVID is indicated for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults who are at high risk for progression to severe COVID-19, including hospitalization or death.

Limitations of Use

PAXLOVID is not approved for use as pre-exposure or post-exposure prophylaxis for prevention of COVID-19.

U.S. FDA Emergency Use Authorization Statement

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of PAXLOVID for the treatment of adults and pediatric patients (12 years of age and older weighing at least 40 kg) with mild to moderate coronavirus disease 2019 (COVID-19) and who are at high risk

for progression to severe COVID-19, including hospitalization or death.

PAXLOVID has not been approved, but has been authorized for emergency use by FDA under an EUA, for the treatment of mild-to-moderate COVID-19 in pediatric patients (12 years of age and older weighing at least 40 kg) who are at high risk for progression to severe COVID-19, including hospitalization or death. The emergency use of PAXLOVID is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.

IMPORTANT SAFETY INFORMATION

WARNING: SIGNIFICANT DRUG INTERACTIONS WITH PAXLOVID

- **PAXLOVID includes ritonavir, a strong CYP3A inhibitor, which may lead to greater exposure of certain concomitant medications, resulting in potentially severe, life-threatening, or fatal events**
- **Prior to prescribing PAXLOVID: 1) Review all medications taken by the patient to assess potential drug-drug interactions with a strong CYP3A inhibitor like PAXLOVID and 2) Determine if concomitant medications require a dose adjustment, interruption, and/or additional monitoring**
- **Consider the benefit of PAXLOVID treatment in reducing hospitalization and death, and whether the risk of potential drug-drug interactions for an individual patient can be appropriately managed**

PAXLOVID is **contraindicated in patients with a history of clinically significant hypersensitivity reactions** (eg, toxic epidermal necrolysis or Stevens-Johnson syndrome) to its active ingredients (nirmatrelvir or ritonavir) or any other components of the product. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue PAXLOVID and initiate appropriate medications and/or supportive care.

PAXLOVID is **contraindicated with drugs that are primarily metabolized by CYP3A and for which elevated concentrations are associated with serious and/or life-threatening reactions and drugs that are strong CYP3A inducers where significantly reduced nirmatrelvir or ritonavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance**. There are certain other drugs for which concomitant use with PAXLOVID should be avoided and/or dose adjustment, interruption, or therapeutic monitoring is recommended. Drugs listed here are a guide and not considered a comprehensive list of all drugs that may be contraindicated with PAXLOVID. The healthcare provider should consult other appropriate resources such as the prescribing information for the interacting drug for comprehensive information on dosing or monitoring with concomitant use of a strong CYP3A inhibitor like PAXLOVID.

Drugs that are primarily metabolized by CYP3A for which elevated concentrations are associated with serious and/or life-threatening reactions:

- Alpha 1-adrenoreceptor antagonist: alfuzosin
- Antianginal: ranolazine
- Antiarrhythmic: amiodarone, dronedarone, flecainide, propafenone, quinidine
- Anti-gout: colchicine (in patients with renal and/or hepatic impairment)
- Antipsychotics: lurasidone, pimozide
- Benign prostatic hyperplasia agents: silodosin
- Cardiovascular agents: eplerenone, ivabradine
- Ergot derivatives: dihydroergotamine, ergotamine, methylergonovine

- HMG-CoA reductase inhibitors: lovastatin, simvastatin (these drugs can be temporarily discontinued to allow PAXLOVID use)
- Immunosuppressants: voclosporin
- Microsomal triglyceride transfer protein inhibitor: lomitapide
- Migraine medications: eletriptan, ubrogepant
- Mineralocorticoid receptor antagonists: finerenone
- Opioid antagonists: naloxegol
- PDE5 inhibitor: sildenafil (Revatio®) when used for pulmonary arterial hypertension
- Sedative/hypnotics: triazolam, oral midazolam
- Serotonin receptor 1A agonist/serotonin receptor 2A antagonist: flibanserin
- Vasopressin receptor antagonists: tolvaptan

Drugs that are strong CYP3A inducers: PAXLOVID cannot be started immediately after discontinuation of any of the following medications due to the delayed offset of the recently discontinued CYP3A inducer:

- Anticancer drugs: apalutamide
- Anticonvulsant: carbamazepine, phenobarbital, primidone, phenytoin
- Antimycobacterials: rifampin, rifapentine
- Cystic fibrosis transmembrane conductance regulator potentiators: lumacaftor/ivacaftor
- Herbal Products: St. John's Wort (*hypericum perforatum*)

Risk of Serious Adverse Reactions Due to Drug Interactions: Initiation of PAXLOVID, which contains ritonavir, a strong CYP3A inhibitor, in patients receiving medications metabolized by CYP3A or initiation of medications metabolized by CYP3A in patients already receiving PAXLOVID, may increase plasma concentrations of medications metabolized by CYP3A. Medications that induce CYP3A may decrease concentrations of PAXLOVID. These interactions may lead to:

- Clinically significant adverse reactions, potentially leading to severe, life-threatening, or fatal events from greater exposures of concomitant medications
- Loss of therapeutic effect of PAXLOVID and possible development of viral resistance

Severe, life-threatening, and/or fatal adverse reactions due to drug interactions have been reported in patients treated with PAXLOVID. The most commonly reported concomitant medications resulting in serious adverse reactions were calcineurin inhibitors (eg, tacrolimus, cyclosporine), followed by calcium channel blockers.

Hepatotoxicity: Hepatic transaminase elevations, clinical hepatitis, and jaundice have occurred in patients receiving ritonavir. Therefore, caution should be exercised when administering PAXLOVID to patients with **pre-existing liver diseases, liver enzyme abnormalities, or hepatitis**.

Because nirmatrelvir is coadministered with ritonavir, there may be a **risk ofHIV-1 developing resistance to HIV protease inhibitors** in individuals with uncontrolled or undiagnosed HIV-1 infection.

The most common **adverse reactions** in the PAXLOVID group (?1%) that occurred at a greater frequency than in the placebo group were dysgeusia (5% and <1%, respectively) and diarrhea (3% and 2%, respectively).

The following adverse reactions have been identified during use of PAXLOVID under Emergency Use Authorization:

Immune System Disorders: Anaphylaxis, hypersensitivity reactions
Skin and Subcutaneous Tissue Disorders: Toxic epidermal necrolysis, Stevens-Johnson syndrome

Nervous System Disorders: Headache
Vascular Disorders: Hypertension
Gastrointestinal Disorders: Abdominal pain, nausea, vomiting
General Disorders and Administration Site Conditions: Malaise

PAXLOVID is a strong inhibitor of CYP3A, and an inhibitor of CYP2D6, P-gp, and OATP1B1. Coadministration of PAXLOVID with drugs that are primarily metabolized by CYP3A and CYP2D6 or are transported by P-gp or OATP1B1 may result in increased plasma concentrations of such drugs and increase the risk of adverse events. Coadministration with other CYP3A substrates may require a dose adjustment or additional monitoring.

Pregnancy: Available data on the use of nirmatrelvir during pregnancy are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Published observational studies on ritonavir use in pregnant women have not identified an increase in the risk of major birth defects. Published studies with ritonavir are insufficient to identify a drug-associated risk of miscarriage. There are maternal and fetal risks associated with untreated COVID-19 in pregnancy.

Lactation: There are no available data on the presence of nirmatrelvir in human or animal milk, the effects on the breastfed infant, or the effects on milk production. A transient decrease in body weight was observed in the nursing offspring of rats administered nirmatrelvir. Limited published data report that ritonavir is present in human milk. There is no information on the effects of ritonavir on the breastfed infant or the effects of the drug on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for PAXLOVID and any potential adverse effects on the breastfed infant from PAXLOVID or from the underlying maternal condition.

Contraception: Use of ritonavir may reduce the efficacy of combined hormonal contraceptives. Advise patients using combined hormonal contraceptives to use an effective alternative contraceptive method or an additional barrier method of contraception.

Pediatrics: The optimal dose of PAXLOVID has not been established in pediatric patients.

Systemic exposure of nirmatrelvir increases in renally impaired patients with increase in the severity of renal impairment. No dosage adjustment is recommended in patients with mild renal impairment. **Reduce the dose of PAXLOVIDin patients with moderate renal impairment** (eGFR ?30 to <60 mL/min). **PAXLOVID is not recommended in patients with severe renal impairment** (eGFR <30 mL/min) **or in patients with end-stage renal disease** (eGFR <15 mL/min).

PAXLOVID is not recommended for use in patients with severe hepatic impairment (Child-Pugh Class C)**.**

Please see Full Prescribing Information , including BOXED WARNING and Patient Information

Click for Fact Sheets:

There may be a delay as the documents are updated with the latest information. It will be available as soon as possible. Please check back for the updated full information shortly.

For Consumers:
EUA Fact sheet for Patients, Parents, and Caregivers

For Healthcare Professionals:
EUA Fact Sheet for HCPs

About Pfizer: 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 170 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 May 25, 2023. 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 Pfizer's efforts to combat COVID-19 and PAXLOVID (including an approval in the U.S. of PAXLOVID for the treatment of mild-to-moderate COVID-19 in adults who are at high risk for progression to severe COVID-19, including hospitalization or death, intention to submit a supplemental New Drug Application to support the FDA approval of PAXLOVID in children at a future date, the transition to a more traditional U.S. commercial model, efforts toward equitable access, the anticipated timing of data readouts, regulatory submissions, regulatory approvals or authorizations, and anticipated manufacturing, distribution and supply), involving 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 endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preclinical and clinical data, including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the ability to produce comparable clinical or other results including efficacy, safety and tolerability profile observed to date, in additional studies or in larger, more diverse populations following commercialization; uncertainties regarding the commercial impact of the results of the EPIC-SR and EPIC-PEP trials; the ability of PAXLOVID to maintain efficacy against emerging virus variants; the risk that serious and unexpected adverse events may occur that have not been previously reported with PAXLOVID use; the risk that preclinical and clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from these and any future preclinical and clinical studies; whether and when any drug applications or submissions to request emergency use or conditional marketing authorization for any potential indications for PAXLOVID or any of Pfizer's other products or product candidates may be filed in particular jurisdictions and if obtained, whether or when such emergency use authorization or licenses will expire or terminate; whether and when regulatory authorities in any jurisdictions may approve any applications or submissions for PAXLOVID or any of Pfizer's other products or product candidates that may be pending or filed, which will depend on 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 it will be commercially successful; decisions by regulatory authorities impacting labeling or marketing, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of PAXLOVID or any of Pfizer's other products or product candidates, including the authorization or approval of products or therapies developed by other companies; the risk that other companies may produce superior or competitive products; risks related to the availability of raw materials to manufacture or test PAXLOVID; manufacturing capabilities or capacity; the risk that we may not be able to maintain manufacturing capacity or access to logistics or supply channels commensurate with global demand, which would negatively impact our ability to supply the estimated numbers of courses of PAXLOVID within the projected time periods; whether and when additional purchase agreements will be reached or existing agreements will be completed or re-negotiated; challenges related to a transition to the commercial market for PAXLOVID; the risk that demand for any products may be reduced, no longer exist or not meet expectations, which may lead to excess inventory on-hand and/or in the channel or reduced revenues; 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, 2022 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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[1] IQVIA National Prescription Audit data through May 05, 2023, containing retail pharmacy, mail order and long-term care channels; U.S. Department of Health and Human Services data through February 2023, for non-retail channels. Note: This information is an estimate derived from the use of information under license from the following IQVIA information service: National Prescription Audit, for the period January 1, 2022-May 05, 2023. IQVIA expressly reserves all rights, including rights of copying, distribution and republication.

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