

# Pfizer Amends U.S. Government Paxlovid Supply Agreement and Updates Full-Year 2023 Guidance

Friday, October 13, 2023 - 04:30pm

- Removes a Significant Uncertainty by Providing Pathway to U.S. Commercialization of Paxlovid on January 1, 2024 with Amended Supply Agreement
  - In a Non-Cash Transaction, U.S. Government to Return Estimated 7.9 Million EUA-Labeled Paxlovid Treatment Courses at end of 2023 and Receive Credit for Future NDA-labeled Treatment Courses from Pfizer
  - Credit will Support a Patient Assistance Program to Provide Paxlovid Free of Charge to Federally Insured Patients through 2024, and Uninsured/Underinsured Patients through 2028, with Pfizer to Recognize Revenue as Product is Delivered
  - Pfizer to Commercialize Paxlovid for the Treatment of Privately Insured Commercial Patients with Prices to be Negotiated with Payers
  - Pfizer to Provide U.S. Government with 1.0 Million Treatment Courses for a Strategic National Stockpile
- Updates Full-Year 2023 Guidance<sup>(1)</sup>
  - Revises 2023 Revenue Guidance<sup>(1)</sup> Range to \$58.0 to \$61.0 Billion Solely due to COVID Products
    - Reduces Guidance<sup>(1)</sup> for Paxlovid Revenues by Approximately \$7.0 Billion, which includes a \$4.2 Billion Non-Cash Revenue Reversal for the Return of Approximately 7.9 Million Treatment Courses of EUA-Labeled U.S. Government Inventory
    - Reduces Guidance<sup>(1)</sup> for Comirnaty Revenues by Approximately \$2.0 Billion
  - Records \$5.5 Billion Non-Cash Charge in 2023 Third Quarter Primarily for COVID Inventory Write-Offs due to Lower-Than-Expected Demand
  - Reaffirms Full-Year 2023 Non-COVID Product Operational Revenue Growth Expectations of 6% to 8%
  - Launches Enterprise-Wide Cost Realignment Program Expected to Deliver Targeted Savings of at least \$3.5 Billion, of which Approximately \$1.0 Billion is Expected to be Realized in 2023 and at least \$2.5 Billion is Expected to be Realized in 2024
  - Revises 2023 Adjusted<sup>(2)</sup> Diluted EPS Guidance<sup>(1)</sup> to \$1.45 to \$1.65 to Account for Lower Expected Revenues for COVID Products and Inventory Write-Offs, Partially Offset by \$1.0 Billion of Anticipated 2023 Cost Reductions
- Pfizer to hold analyst and investor call at 8 a.m. EDT Monday, October 16, 2023

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE:PFE) today announced that it has amended its supply agreement with the U.S. government for Paxlovid, the first oral antiviral pill approved by the U.S. Food and Drug Administration (FDA) and is updating its Full-Year 2023 Guidance.

**Paxlovid Amended Agreement with U.S. Government Facilitates Commercialization**

At the end of 2023, Pfizer will accept a *non-cash* return of any remaining Emergency Use Authorized (EUA)-labeled U.S. government inventory, estimated to be 7.9 million treatment courses, and in the fourth quarter, will reverse the associated revenues currently estimated to be approximately \$4.2 billion.

The commercial transition will begin in November 2023, as the U.S. government begins to discontinue the distribution of EUA-labeled Paxlovid. Pfizer will ensure commercial readiness by providing NDA-labeled commercial supply to all channels by the end of 2023, however, EUA-labeled Paxlovid will remain available free-of-charge to all eligible patients until the end of the year, and therefore Pfizer expects only minimal uptake of NDA-labeled commercial product before January 1, 2024.

Any remaining EUA-labeled treatment courses previously purchased by the U.S. government will be converted to a volume-based credit. This credit will support continued access to Paxlovid through a patient assistance program (PAP) operated by Pfizer on behalf of the U.S. government. As part of the PAP, all federally insured patients (Medicare and Medicaid) and the uninsured will receive Paxlovid, free of charge, through 2024. Beginning in 2024, Pfizer will sell Paxlovid to privately insured patients (commercial) with prices to be negotiated with payers and offer a copay program through 2028. The PAP will continue to provide access to Paxlovid to eligible uninsured and underinsured patients through that same period.

Additionally, Pfizer will manage and supply 1.0 million treatment course U.S. Strategic National Stockpile (SNS) to enable future pandemic preparedness and refresh stock prior to expiry through 2028.

Pfizer will recognize revenues as product is delivered beginning in 2024.

### **Updates Outlook for COVID-19 Products**

Pfizer also announced additional clarity on its full-year 2023 outlook for its COVID products – Comirnaty and Paxlovid. Clarity on the underlying vaccination and treatment rates will be observed by year end and will set a reliable base for the prediction of future product utilization.

As previously announced, the European Union (EU) contract for Comirnaty supply was renegotiated with amended purchasing obligations through 2026. The U.S. market for Comirnaty transitioned to commercially available product in September 2023. Due to the recent commencement of the fall vaccination period, the outlook for year-end vaccination rates and market shares requires more time for more determinable estimates.

As previously announced, Paxlovid also received full NDA approval from the FDA earlier this year. The global utilization rates for Paxlovid are currently trending slightly above last year's utilization but lower than our original expectations.

### **Launches Cost Realignment Program**

In addition, in the fourth quarter of 2023, Pfizer announced that the company has launched a multi-year, enterprise-wide cost realignment program that will realign its costs with its longer-term revenue expectations. The program is expected to deliver targeted savings of at least \$3.5 billion, of which \$1.0 billion is expected to be realized in 2023 and an additional \$2.5 billion is expected to be realized in 2024. The one-time costs to achieve the savings associated with the new cost realignment program are expected to be approximately \$3.0 billion, of which the majority is expected to be cash. These costs will primarily include severance and implementation costs. Pfizer will continue to refine the estimated targeted savings and their associated costs over the remainder of the year and will incorporate them into its full-year guidance for 2024.

### **Updates Full-Year 2023 Revenue and Adjusted<sup>(2)</sup> Diluted EPS Guidance <sup>(1)</sup> Ranges**

Pfizer also announced that it now anticipates full-year 2023 revenues to be in the range of \$58.0 to \$61.0 billion, versus its previous guidance range of \$67.0 to \$70.0 billion solely due to its COVID products. Full-year 2023 revenues for Paxlovid and Comirnaty are expected to be approximately \$12.5 billion, a decline of \$9.0 billion versus original expectations. The company is reducing its full-year 2023 revenue expectations for Paxlovid by approximately \$7.0 billion which includes a *non-cash* \$4.2 billion revenue reversal for the return of the 7.9 million treatment courses of EUA-labeled U.S. government inventory, as well as the delayed commercialization to January 2024 versus our previous expectation of commercialization in the second half of 2023. The company is also reducing its full-year 2023 revenue expectations for Comirnaty by approximately \$2.0 billion due to lower-than-expected vaccination rates.

Pfizer's non-COVID products remain on track to achieve an expected 6% to 8% operational revenue growth year over year in 2023.

Due to lower-than-expected utilization for our COVID products, Pfizer recorded a *non-cash* charge of \$5.5 billion to Cost of Goods Sold in the third quarter of 2023 primarily related to inventory write-offs for Paxlovid of \$4.6 billion and to a lesser extent for inventory write-offs and other charges for Comirnaty of \$0.9 billion.

The company expects to deliver approximately \$1.0 billion in savings in 2023 through its cost realignment program.

Revised guidance also reflects anticipated improvement in our Effective Tax Rate on Adjusted<sup>(2)</sup> Income for 2023 from approximately 15% in our original guidance to approximately 12%.

Due to the aforementioned items, the company now expects full-year 2023 Adjusted<sup>(2)</sup> diluted EPS to be in the range of \$1.45 to \$1.65 versus its original guidance range of \$3.25 to \$3.45.

The Company's updated Revenues and Adjusted<sup>(2)</sup> diluted EPS guidance<sup>(1)</sup> is presented below.

	<b>2023 Previous Guidance<sup>(1)</sup> (August 1, 2023)</b>	<b>One-Time Items<sup>(a)</sup></b>	<b>All Other Adjustments<sup>(b)</sup></b>	<b>2023 Revised Guidance<sup>(1)</sup></b>
<b>Revenues*</b>	\$67.0 to \$70.0 billion	~\$(4.2) billion	~\$(4.8) billion	\$58.0 to \$61.0 billion
<b>Non-cash Inventory Write-offs<sup>(a)</sup></b>		\$5.5 billion		
<b>Adjusted<sup>(2)</sup> Diluted EPS*</b>	\$3.25 to \$3.45	\$(1.46)	\$(0.34)	\$1.45 to \$1.65

(a) One-time items include approximately \$4.2 billion of a *non-cash* revenue reversal related to the return of an estimated 7.9 treatment courses of U.S. government EUA-labeled Paxlovid and a *non-cash* \$5.5 billion inventory write-off of COVID products.

(b) All other adjustments include approximately \$4.8 billion reduction in COVID product revenue due to the delayed commercialization of Paxlovid to January 2024 versus our previous expectation of commercialization in second half of 2023 as well as lower-than-expected vaccination rates for Comirnaty partially offset by \$1.0 billion in anticipated savings from the cost realignment program.

\* Changes in foreign exchange rates have had a minimal incremental impact since full-year 2023 guidance was issued. Please refer to Press Release Footnote (1) for additional information.

## Executive Commentary

Dr. Albert Bourla, Pfizer Inc. Chairman and Chief Executive Officer, stated: “Pfizer’s non-COVID product portfolio remains strong, and we continue to expect these products to achieve year-over-year operational revenue growth in the range of 6% to 8% in 2023.

“At the same time, this agreement with the U.S. government makes it easier for patients to access Paxlovid; enables the United States to have a robust stockpile for future use; and provides Pfizer with greater clarity regarding the transition to a commercial market for this important treatment, which has helped remove some of the uncertainty around our business expectations for our COVID products. We expect additional clarification on global vaccination and treatment rates by the end of the year, which we expect will be a good predictor of utilization in future years.

“We remain proud that our scientific breakthroughs played a significant role in getting the global health crisis under control. Over the past several years, we have continued to ensure supply readiness for our COVID products, and as we gain additional clarity around vaccination and treatment rates for COVID, we will be better able to estimate the appropriate level of supply to meet demand and continue to address any ongoing public health needs. As a result, we continue to expect our COVID-related revenues to contribute to our business in future periods, helping us to further invest in activities that drive Pfizer’s long-term growth potential.”

Pfizer intends to provide additional commentary and all components of its updated full-year 2023 guidance in its Third-Quarter 2023 Performance Report to be issued on Tuesday, October 31, 2023.

## **Pfizer COVID-19 Treatment Transition**

Albert Bourla announces an important agreement with the U.S. government that will make it easier for patients to access Pfizer’s oral antiviral treatment for COVID-19. This will help ensure that the United States will have a robust stockpile for future use and helps provide more clarity on the commercial market for COVID related products. This is the next logical step in Pfizer’s unrelenting effort to help ensure every eligible patient continues to have access to this potentially life-saving medicine.

*This video includes forward-looking statements that are subject to substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Please refer to [Pfizer press release](#) for more information. We also encourage you to read our reports filed with the U.S. Securities and Exchange Commission (SEC), including the sections captioned “Risk Factors” and “Forward Looking Information and Factors that May Affect Future Results,” for a description of such substantial risks and uncertainties. These reports are available at [pfizer.com](#) and the [SEC’s website](#).*

## **Investor Call Details**

Pfizer Inc. invites investors and the general public to view and listen to a webcast of a live conference call with investment analysts at 8 a.m. EDT on Monday, October 16, 2023.

To view and listen to the webcast visit Pfizer’s web site at [www.pfizer.com/investors](http://www.pfizer.com/investors). Information on accessing and pre-registering for the webcast, including dial-in numbers, will be available at [www.pfizer.com/investors](http://www.pfizer.com/investors) and participants are advised to pre-register in advance of the conference call.

The transcript and webcast replay of the call will be made available on Pfizer’s web site at [www.pfizer.com/investors](http://www.pfizer.com/investors) within 24 hours after the end of the live conference call and will be accessible for at least 90 days.

(1) Pfizer does not provide guidance for GAAP Reported financial measures (other than revenues and acquired in-process R&D (IPR&D) expenses) or a reconciliation of forward-looking non-GAAP financial measures to the most directly comparable GAAP Reported financial measures on a forward-looking basis because it is unable to predict with reasonable certainty the ultimate outcome of unusual gains and losses, certain acquisition-related expenses, gains and losses from equity securities, actuarial gains and losses from pension and postretirement plan remeasurements, potential future asset impairments and pending litigation without unreasonable effort. These items are uncertain, depend on various factors, and could have a material impact on GAAP Reported results for the guidance period.

Financial guidance for full-year 2023 reflects the following:

- Exchange rates assumed are a blend of actual rates in effect through the second quarter of 2023 and end of September 2023 rates for the remainder of the year. Financial guidance reflects the anticipated unfavorable impact of approximately \$1.0 billion on revenues and approximately \$0.19 on Adjusted<sup>(2)</sup> diluted EPS as a result of changes in foreign exchange rates relative to the U.S. dollar compared to foreign exchange rates from 2022.
- Guidance for Adjusted<sup>(2)</sup> diluted EPS assumes diluted weighted-average shares outstanding of approximately 5.72 billion shares, and assumes no share repurchases in 2023.

(2) Adjusted income and Adjusted diluted EPS are defined as U.S. GAAP net income attributable to Pfizer Inc. common shareholders and Reported diluted EPS attributable to Pfizer Inc. common shareholders before the impact of amortization of intangible assets, certain acquisition-related items, discontinued operations and certain significant items. Adjusted income and its components and Adjusted diluted EPS measures are not, and should not be viewed as, substitutes for U.S. GAAP net income and its components and diluted EPS. See the Non-GAAP Financial Measure: Adjusted Income section of Management's Discussion and Analysis of Financial Condition and Results of Operations in Pfizer's 2022 Annual Report on Form 10-K for a definition of each component of Adjusted income as well as other relevant information.

## **INDICATION, AUTHORIZED USE AND IMPORTANT SAFETY INFORMATION FOR PAXLOVID**

### **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**

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 of HIV-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 PAXLOVID in 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:**

For Consumers:

[EUA Fact sheet for Patients, Parents, and Caregivers](#)

For Healthcare Professionals:

[EUA Fact Sheet for HCPs](#)

## **INDICATION, AUTHORIZED USE AND IMPORTANT SAFETY INFORMATION FOR COMIRNATY**

### **INDICATION**

COMIRNATY® (COVID-19 Vaccine, mRNA) is a vaccine approved for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older.

### **IMPORTANT SAFETY INFORMATION**

- You should **NOT** receive COMIRNATY® (COVID-19 Vaccine, mRNA) if you have had a severe allergic reaction to any ingredient of COMIRNATY or a previous dose of a Pfizer-BioNTech COVID-19 vaccine
- There is a remote chance that COMIRNATY could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to 1 hour after getting a dose of the vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received the vaccine for monitoring after vaccination. **If you or your pre-teen or teenager experience a severe allergic reaction, call 9-1-1 or go to the nearest hospital.** Signs of a severe allergic reaction can include:
  - difficulty breathing, swelling of the face and throat, a fast heartbeat, a bad rash all over the body, dizziness and weakness
- Authorized or approved mRNA COVID-19 vaccines show increased risks of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart), particularly within the first week following vaccination. For COMIRNATY, the observed risk is highest in males 12 through 17 years of age. **Seek medical attention right away if you have any of the following symptoms after receiving the vaccine, particularly during the 2 weeks after receiving a dose of the vaccine:**
  - chest pain
  - shortness of breath
  - feelings of having a fast-beating, fluttering, or pounding heart
- Additional symptoms, particularly in children, may include:
  - Fainting
  - Unusual and persistent fatigue or lack of energy
  - Persistent vomiting
  - Persistent pain in the abdomen
  - Unusual and persistent cool, pale skin
- Fainting can happen after getting injectable vaccines including COMIRNATY. Your vaccination provider may ask you to sit or lie down for 15 minutes after receiving the vaccine
- People with weakened immune systems may have a reduced immune response to COMIRNATY
- COMIRNATY may not protect all vaccine recipients
- **Tell your vaccination provider about all of your medical conditions, including if you:**
  - have any allergies
  - have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
  - have a fever
  - have a bleeding disorder or are on a blood thinner
  - are immunocompromised or are on a medicine that affects the immune system
  - are pregnant, plan to become pregnant, or are breastfeeding
  - have received another COVID-19 vaccine
  - have ever fainted in association with an injection
- The **most commonly reported adverse reactions** (?10%) after a dose of COMIRNATY were pain at the injection site (up to 90.5%), fatigue (up to 77.5%), headache (up to 75.5%), chills (up to 49.2%), muscle pain (up to 45.5%), joint pain (up to 27.5%), fever (up to 24.3%), injection site swelling (up to 11.8%), and injection site redness (up to 10.4%).

These may not be all the possible side effects of the vaccine. Call the vaccination provider or healthcare provider about bothersome side effects or side effects that do not go away.

You should always ask your healthcare providers for medical advice about adverse events. Report vaccine side effects to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to [www.vaers.hhs.gov/reportevent.html](http://www.vaers.hhs.gov/reportevent.html). You can also report side effects to Pfizer Inc. at

[www.pfizersafetyreporting.com](http://www.pfizersafetyreporting.com) or by calling 1-800-438-1985.

Please click here for full Prescribing Information for [COMIRNATY](#).

## AUTHORIZED USE

**Pfizer-BioNTech COVID-19 Vaccine** (2023-2024 Formula)\*is FDA authorized under Emergency Use Authorization (EUA) to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 6 months through 11 years of age.

\*Hereafter referred to as Pfizer-BioNTech COVID-19 Vaccine

## EMERGENCY USE AUTHORIZATION

Pfizer-BioNTech COVID-19 Vaccine has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals aged 6 months through 11 years of age. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b) (1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

## IMPORTANT SAFETY INFORMATION

- A person should **NOT** get Pfizer-BioNTech COVID-19 Vaccine if they had a severe allergic reaction after a previous dose of any Pfizer-BioNTech COVID-19 vaccine or to any ingredients in these vaccines.
- There is a remote chance that the vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the vaccine. For this reason, the vaccination provider may ask you to stay at the place where you received the vaccine for monitoring after vaccination. **If your child experiences a severe allergic reaction, call 9-1-1, or go to the nearest hospital.** Signs of a severe allergic reaction can include:
  - difficulty breathing, swelling of the face and throat, a fast heartbeat, a bad rash all over the body, or dizziness and weakness
- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received mRNA COVID-19 vaccines. Myocarditis and pericarditis following Pfizer-BioNTech COVID-19 vaccines have occurred most commonly in adolescent males 12 through 17 years of age. In most of these individuals, symptoms began within a few days following vaccination. The chance of having this occur is very low. **Seek medical attention right away if your child has any of the following symptoms after receiving the vaccine, particularly during the 2 weeks after receiving a dose of the vaccine:**
  - Chest pain
  - Shortness of breath or difficulty breathing
  - Feelings of having a fast-beating, fluttering, or pounding heart
- Additional symptoms, particularly in children, may include:
  - Fainting
  - Unusual and persistent irritability
  - Unusual and persistent poor feeding
  - Unusual and persistent fatigue or lack of energy
  - Persistent vomiting
  - Persistent pain in the abdomen
  - Unusual and persistent cool, pale skin

- Fainting can happen after getting injectable vaccines, including Pfizer-BioNTech COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received the vaccine for monitoring after vaccination
- People with weakened immune systems may have a reduced immune response to Pfizer-BioNTech COVID-19 Vaccine
- The Pfizer-BioNTech COVID-19 Vaccine may not protect everyone
- **Tell your vaccination provider about all of your medical conditions, including if you:**
  - have any allergies
  - has had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
  - has a fever
  - has a bleeding disorder or are on a blood thinner
  - is immunocompromised or are on a medicine that affects the immune system
  - is pregnant or is breastfeeding
  - has received another COVID-19 vaccine
  - has ever fainted in association with an injection
- Side effects that have been reported with Pfizer-BioNTech COVID-19 vaccines include:
  - Severe allergic reactions
  - Non-severe allergic reactions such as rash, itching, hives, or swelling of the face
  - Myocarditis (inflammation of the heart muscle)
  - Pericarditis (inflammation of the lining outside the heart)
  - Injection site pain/tenderness
  - Tiredness
  - Headache
  - Muscle pain
  - Chills
  - Joint pain
  - Fever
  - Injection site swelling
  - Injection site redness
  - Nausea
  - Feeling unwell
  - Swollen lymph nodes (lymphadenopathy)
  - Decreased appetite
  - Diarrhea
  - Vomiting
  - Arm pain
  - Fainting in association with injection of the vaccine
  - Dizziness
  - Irritability

These may not be all the possible side effects. Serious and unexpected side effects may occur. Call the vaccination provider or healthcare provider about bothersome side effects or side effects that do not go away.

Report vaccine side effects to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to [www.vaers.hhs.gov/reportevent.html](http://www.vaers.hhs.gov/reportevent.html). Please include “Pfizer-BioNTech COVID-19 Vaccine(2023-2024 Formula) EUA” in the first line of box #18 of the report form.

In addition, individuals can report side effects to Pfizer Inc. at [www.pfizersafetyreporting.com](http://www.pfizersafetyreporting.com) or by calling 1-800-438-1985.

Please click here for [Pfizer-BioNTech COVID-19 Vaccine Healthcare Providers Fact Sheet](#) and [Vaccine Recipient and Caregiver EUA Fact Sheet](#).

## **DISCLOSURE NOTICE:**

*The information contained in this release is as of October 13, 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, Paxlovid (including an amended supply agreement with the U.S. government for Paxlovid, anticipated timing of commercialization and potential benefits), Pfizer's and BioNTech's COVID-19 vaccines, defined collectively herein as Comirnaty (including potential benefits), Pfizer's anticipated operating and financial performance and expectations for Pfizer's product pipeline, in-line products and product candidates (including revenue contribution and projections), utilization rates and an enterprise-wide cost realignment program (including anticipated costs, savings and 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 Paxlovid and Comirnaty; uncertainties regarding the commercial success of Pfizer's other products or product candidates; 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 risks associated with pre-clinical and clinical data (including Phase 1/2/3 or Phase 4 data for Paxlovid and Comirnaty or any of Pfizer's other products or product candidates) in any of our studies in pediatrics, adolescents, or adults or real world evidence, including the possibility of unfavorable new pre-clinical, clinical or safety data and further analyses of existing pre-clinical, clinical or safety data or further information regarding the quality of pre-clinical, clinical or safety data; risks associated with interim data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; the ability to produce comparable clinical or other results for Paxlovid and Comirnaty or any of Pfizer's other products or product candidates, including the rate of effectiveness and/or efficacy, safety and tolerability profile observed to date, in additional analyses of the Phase 3 trial for any such products and additional studies, in real world data studies or in larger, more diverse populations following commercialization; the ability of Comirnaty, any vaccine candidate or any future vaccine to prevent, or Paxlovid or any future COVID-19 treatment to be effective against, COVID-19 caused by emerging virus variants; the risk that use of Comirnaty or Paxlovid will lead to new information about efficacy, safety or other developments, including the risk of additional adverse reactions, some of which may be serious; the risk that pre-clinical 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 and when additional data from the BNT162 mRNA vaccine program, Paxlovid or other COVID-19 programs will be published in scientific journal publications and, if so, when and with what modifications and interpretations; whether regulatory authorities will be satisfied with the design of and results from existing or future pre-clinical 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 submissions to request emergency use or conditional marketing authorizations for Comirnaty or any future vaccines in additional populations, for a potential booster dose for Comirnaty, any vaccine candidate or any potential future vaccines (including*

potential future annual boosters or re-vaccinations), and/or biologics license and/or emergency use authorization applications or amendments to any such applications may be filed in particular jurisdictions for Comirnaty, any vaccine candidates or any other potential vaccines that may arise from the BNT162 program, and if obtained, whether or when such emergency use authorizations or licenses, or existing emergency use authorizations, will expire or terminate; whether and when any applications that may be pending or filed for Paxlovid, Comirnaty or any of Pfizer's other products or product candidates (including any requested amendments to the emergency use or conditional marketing authorizations) may be approved by particular regulatory authorities, 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 Paxlovid, Comirnaty or any of Pfizer's other products or product candidates for any such indications will be commercially successful; intellectual property and other litigation; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of Paxlovid, Comirnaty or any of Pfizer's other products or product candidates, including the authorization or approval of products or therapies developed by other companies; disruptions in the relationships between us and our collaboration partners, clinical trial sites or third-party suppliers, including our relationship with BioNTech; the risk that demand for Paxlovid, Comirnaty or any of Pfizer's other products may be reduced, no longer exist or not meet expectations, which may lead to reduced revenues, excess inventory on-hand and/or in the channel which, for Paxlovid and Comirnaty, has resulted in a significant inventory write-off in the third quarter of 2023 and could continue to result in inventory write-offs or other unanticipated changes; challenges related to and uncertainties regarding the timing of a transition to the commercial market for any of our products, and in particular, Paxlovid; uncertainties related to the public's adherence to vaccines and boosters; risks related to our ability to achieve our revenue forecasts for Paxlovid, Comirnaty or any of Pfizer's other products or product candidates; the risk that other companies may produce superior or competitive products; risks related to the availability of raw materials to manufacture or test Paxlovid, Comirnaty or any of Pfizer's other products or product candidates; challenges related to our vaccine's formulation, dosing schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery by Pfizer; the risk that we may not be able to successfully develop other vaccine formulations, booster treatment courses or potential future annual boosters or re-vaccinations or new variant-based or next generation vaccines or potential combination respiratory vaccines or next generation COVID-19 treatments; the risk that we may not be able to recoup costs associated with our R&D and manufacturing efforts; risks associated with any changes in the way we approach or provide research funding for the BNT162 program, Paxlovid or any other COVID-19 program; challenges and risks associated with the pace of our development programs; 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 our COVID-19 or other products; whether and when additional supply or purchase agreements will be reached or existing agreements will be completed or renegotiated; uncertainties regarding the ability to obtain recommendations from vaccine or treatment advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; pricing and access challenges; challenges related to public confidence in, or awareness of Paxlovid, Comirnaty or any of Pfizer's other products or product candidates; uncertainties around future changes to applicable healthcare policies and guidelines issued by the U.S. federal government in connection with the declared termination of the federal government's COVID-19 public health emergency as of May 11, 2023; trade restrictions; potential third party royalties or other claims; the uncertainties inherent in business and financial planning, including, without limitation, risks related to Pfizer's business and prospects, adverse developments in Pfizer's markets, or adverse developments in the U.S. or global capital markets, credit markets, regulatory environment or economies generally; uncertainties regarding the impact of COVID-19 on our business, operations and financial results; competitive developments; uncertainties regarding the impact, success and associated costs of our enterprise-wide cost realignment program; and risks and uncertainties related to, restructurings and internal reorganizations, as well as any other corporate strategic initiatives and growth

*strategies, and cost-reduction and productivity initiatives, each of which requires upfront costs but may fail to yield anticipated benefits and may result in unexpected costs or organizational disruption.*

*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](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com) .*

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