Pfizer Logo

Pfizer Broadens Portfolio of Respiratory Vaccines Recommended by CDC Advisory Committee with ABRYSVO™ for RSV

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- ABRYSVO recommended by CDC Advisory Committee for pregnant persons 32 through 36 weeks gestation to help protect infants from respiratory syncytial virus (RSV) from birth through first six months of life
- RSV maternal immunization recommendation adds to Pfizer's respiratory vaccines offerings already available to help protect against RSV in older adults, COVID-19, and pneumococcal pneumonia in adults

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) shared today it has broadened its portfolio of respiratory vaccines recommended by the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) following a favorable vote for ABRYSVO™ [*Respiratory Syncytial Virus Vaccine*], the company's bivalent RSV prefusion F (RSVpreF) vaccine, as a maternal immunization. This is the first-ever fall in which eligible individuals can receive Pfizer vaccines to help protect against RSV, COVID-19, and pneumococcal pneumonia.

"This fall marks the start of the annual respiratory infection season in the Northern Hemisphere, and we are prepared with vaccines against multiple infectious diseases and -- for the first time in history -- an available RSV vaccine to help prevent disease in two at-risk populations," said Luis Jodar, PhD, Chief Medical Affairs Officer, Vaccines/Antivirals and Evidence Generation, Pfizer. "Today's ACIP recommendation for maternal immunization with ABRYSVO reinforces the wide-ranging impact vaccines can have, including helping protect infants immediately at birth from the potentially severe and life-threatening complications that can develop from RSV. Approximately 75 percent of RSV-related hospitalizations in newborns and infants occur in the first six months of life."

Today, ACIP recommended:

- Maternal RSV vaccine for pregnant people during 32 through 36 weeks gestation, using seasonal administration, to prevent RSV lower respiratory tract infection in infants

This provisional recommendation will be official once it is reviewed and adopted by the director of the CDC. The ACIP recommendation follows the U.S. Food and Drug Administration's (FDA) approval of ABRYSVO in August as the first and only maternal vaccine for the prevention of lower respiratory tract disease (LRTD) and severe LRTD caused by RSV in infants from birth up to six months of age by active immunization of pregnant individuals at 32 through 36 weeks gestational age.

The action today by ACIP comes on the heels of recent and previous recommendations from the CDC.

- After FDA authorization and approval of our Pfizer-BioNTech COVID-19 Vaccine 2023-2024 Formula earlier this month, ACIP recommended everyone 6 months and older get an updated COVID-19 vaccine to protect against COVID-19 illness this fall and winter.

- ABRYSVO is currently available and recommended using shared clinical decision making for adults 60 years of age and older to help protect against RSV disease. With more than 77 million individuals aged 60 and older in the U.S.[1], the recommended use of this vaccine can help prevent the potentially serious consequences associated with RSV, which leads to the hospitalization of more than 60,000 of these adults each year.[2]

- PREVNAR 20® has been recommended by the CDC since October 2021 to help prevent pneumococcal disease among adults aged 65 years or older and adults 19-64 years old with certain medical conditions, such as asthma, diabetes or other risk factors. Pneumococcal pneumonia results in more than 180,000 adult hospital admissions and more than 150,000 adult outpatient visits in the U.S. each year.[3]

About ABRYSVO

Pfizer currently is the only company with an RSV vaccine to help protect older adults, as well as infants through maternal immunization. In May 2023, the FDA approved ABRYSVO for the prevention of LRTD caused by RSV in individuals 60 years of age or older. This was followed by the ACIP's official recommendation of the vaccine for use in adults 60 years of age and older, which occurred in June 2023.

In August 2023, Pfizer announced that the European Medicines Agency (EMA) granted marketing authorization for ABRYSVO for both older adults and maternal immunization to help protect infants. In February 2023, Pfizer Japan announced an application was filed with the Ministry of Health, Labor and Welfare for RSVpreF as a maternal immunization to help protect infants against RSV. In April 2023, Pfizer Canada announced Health Canada accepted RSVpreF for review for both individuals ages 60 and older and as a maternal immunization to help protect infants against RSV.

Pfizer has also initiated two additional clinical trials evaluating ABRYSVO. One trial is being conducted in children ages two to less than 18 years who are at higher risk for RSV disease. [4] A second trial is evaluating adults ages 18 to 60 years at higher risk for RSV due to underlying medical conditions such as asthma, diabetes and COPD, and adults ages 18 and older who are immunocompromised and at high risk for RSV.8 Pfizer also plans post-marketing studies and surveillance programs to further describe the safety of ABRYSVO.

INDICATIONS FOR ABRYSVO

ABRYSVO™ is a vaccine indicated for:

- the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in people 60 years of age and older
- pregnant individuals at 32 through 36 weeks gestational age for the prevention of LRTD and severe LRTD caused by RSV in infants from birth through 6 months of age

IMPORTANT SAFETY INFORMATION FOR ABRYSVO

- ABRYSVO should not be given to anyone with a history of severe allergic reaction (e.g., anaphylaxis) to any of its components
- For pregnant individuals: to avoid the potential risk of preterm birth, ABRYSVO should be given during 32 through 36 weeks gestational age

- Fainting can happen after getting injectable vaccines, including ABRYSVO. Precautions should be taken to avoid falling and injury during fainting
- Adults with weakened immune systems, including those receiving medicines that suppress the immune system, may have a reduced immune response to ABRYSVO
- Vaccination with ABRYSVO may not protect all people
- In adults 60 years of age and older, the most common side effects (?10%) were fatigue, headache, pain at the injection site, and muscle pain
- In pregnant individuals, the most common side effects (?10%) were pain at the injection site, headache, muscle pain, and nausea,
- In clinical trials where ABRYSVO was compared to placebo, infants born to pregnant individuals experienced low birth weight (5.1% ABRYSVO versus 4.4% placebo) and jaundice (7.2% ABRYSVO versus 6.7% placebo

View the full ABRYSVO Prescribing Information.

INDICATION, AUTHORIZED USE AND IMPORTANT SAFETY INFORMATION

INDICATION FOR COMIRNATY

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. You can also report side effects to Pfizer Inc. at 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. 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 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

INDICATIONS FOR PREVNAR 20

Prevnar 20 is a vaccine approved for:

- the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F in individuals 6 weeks of age and older
- the prevention of otitis media (middle ear infection) caused by 7 of the 20 strains in individuals 6 weeks through 5 years.
- the prevention of pneumonia caused by *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F in individuals 18 years of age and older

- The indication of Prevnar 20 for the prevention of pneumonia caused by *S. pneumoniae* serotypes 8, 10A, 11A, 12F, 15B, 22F, and 33F in individuals 18 years of age and older is approved based on immune responses. Continued approval may depend on a supportive study

IMPORTANT SAFETY INFORMATION

- Prevnar 20 should not be given to anyone who has had a severe allergic reaction to any component of Prevnar 20 or to diphtheria toxoid
- Individuals with weakened immune systems may have a lower immune response. Safety data are not available for these groups
- A temporary pause in breathing after getting the vaccine has been observed in some infants who were born prematurely. For premature infants, talk to your healthcare provider about the infant's medical status when deciding to get vaccinated with Prevnar 20.
- In individuals 2, 4, 6, and 12 through 15 months of age vaccinated with a 4-dose schedule, the most common side effects reported at a rate of >10% were irritability, pain at the injection site, drowsiness, decreased appetite, injection site redness, injection site swelling, and fever.
- In individuals 2, 4, 6, and 12 through 15 months of age vaccinated with a 4-dose schedule, the most common side effects reported at a rate of >10% were irritability, pain at the injection site, drowsiness, decreased appetite, injection site redness, injection site swelling, and fever.
- In individuals 18 years of age and older, the most common side effects (>10%) were pain at the injection site, muscle pain, fatigue, headache, and joint pain. Additionally, injection site swelling was also common in adults 18 through 59 years of age

View the full prescribing information for PREVNAR 20®.

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 September 22, 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 respiratory vaccines portfolio, including ABRYSVO (RSVpreF), PREVNAR 20 and Pfizer and BioNTech's COVID-19 vaccines, defined collectively herein as COMIRNATY, including their potential benefits, a vote by ACIP to recommend ABRYSVO as a maternal immunization in the U.S ., applications pending for RSVpreF in other jurisdictions, clinical trials initiated for ABRYSVO in other populations and plans for post-marketing studies and surveillance programs for

ABRYSVO, 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 ABRYSVO (RSVpreF), PREVNAR 20 and COMIRNATY; 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 or pre-clinical data for ABRYSVO (RSVpreF), PREVNAR 20 and COMIRNATY or any vaccine candidate in our respiratory vaccine portfolio, including the data discussed in this release) 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; risks associated with interim data, including the risk that final results from the Phase 3 trials for RSVpreF could differ from the 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 ABRYSVO (RSVpreF), PREVNAR 20 and COMIRNATY, or any vaccine candidate in our respiratory vaccine portfolio, including the rate of vaccine effectiveness and safety and tolerability profile observed to date, in additional analyses of the Phase 3 trial and additional studies, in real world data studies or in larger, more diverse populations following commercialization; the ability of ABRYSVO (RSVpreF) and COMIRNATY to be effective against emerging virus variants; the risk that use of the vaccine 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 ABRYSVO (RSVpreF), PREVNAR 20 and COMIRNATY programs, or any vaccine candidate in our respiratory vaccine portfolio 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 biologic license applications may be filed in particular jurisdictions for ABRYSVO (RSVpreF) or PREVNAR 20 for any potential indications; 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 other 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 ABRYSVO (RSVpreF), PREVNAR 20 or COMIRNATY or any vaccine candidate in our respiratory vaccine portfolio (including any requested amendments to the emergency use or conditional marketing authorizations) may be approved by 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 ABRYSVO (RSVpreF), PREVNAR 20 or COMIRNATY 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 ABRYSVO (RSVpreF), PREVNAR 20 or ABRYSVO, 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 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; challenges related to and uncertainties regarding the timing of a transition to the commercial market for any of our products; uncertainties related to the public's adherence to vaccines and boosters; risks related to our ability to achieve our revenue forecasts for COMIRNATY or any potential future COVID-19 vaccines; the risk that other companies may produce superior or competitive

products; risks related to the availability of raw materials to manufacture or test a vaccine; 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 doses or potential future annual boosters or re-vaccinations or new variant-based or next generation vaccines or potential combination respiratory vaccines; the risk that we may not be able to maintain manufacturing capacity or access to logistics or supply channels commensurate with global demand for our vaccines, which would negatively impact our ability to supply our vaccines within the projected time periods; 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 advisory or technical committees and other public health authorities regarding ABRYSVO (RSVpreF), PREVNAR 20 or ABRYSVO and uncertainties regarding the commercial impact of any such recommendations; uncertainties regarding the impact of COVID-19 on our 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 .

[1] United States Census Bureau. Older Americans Month: May 2023.
https://www.census.gov/newsroom/stories/older-americans-month.html
[2] Centers for Disease Control and Prevention. RSV Surveillance & Research.
https://www.cdc.gov/rsv/research/index.html
[3] Data on file. Pfizer Inc., New York, NY
[4] Pfizer Second-Quarter 2023 Earnings Teleconference Presentation, August 1, 2023, page, 24,
https://s28.q4cdn.com/781576035/files/doc_financials/2023/q2/Q2-2023-PFE-Earnings-Release.pdf

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