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Positive Top-line Results of Pfizer's Phase 3 Study Exploring Coadministration of Prevnar 20™ With Seasonal Flu Vaccine in Older Adults Released

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NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE:PFE) today announced positive top-line results from a Phase 3 study (B7471004) evaluating the safety and immunogenicity of PREVNAR 20™ (Pneumococcal 20-valent Conjugate Vaccine) in adults 65 years of age or older when administered at the same time as the seasonal influenza vaccine (SIIV, Fluad Quadrivalent [adjuvanted], 2020/2021 strains). Responses elicited by PREVNAR 20 for all 20 serotypes and by seasonal influenza vaccine when given together were noninferior (the study's primary immunogenicity objectives) to those elicited by the vaccines when administered one month apart. The safety profile of PREVNAR 20 was similar when the vaccines were coadministered as compared to when each vaccine was administered separately, one month apart.

"We are encouraged by these results showing that these two vaccines can be administered at the same time without affecting the immune protection provided by either vaccine or changing the safety profile," said Kathrin U. Jansen, Ph.D., Senior Vice President and Head of Vaccine Research & Development, Pfizer. "This study adds to the body of evidence further supporting that pneumococcal conjugate vaccines may be coadministered with influenza vaccines, this time studied with the adjuvanted influenza vaccine. We are committed to vaccine development to help address needs across many respiratory diseases."

Across 66 investigator sites in the United States, a total of 1,796 participants were enrolled and randomized, with 1,727 of participants completing the study.

"Both PREVNAR 20 and the influenza vaccine are important for helping protect adults against pneumococcal pneumonia and the flu respectively; however, vaccination rates decline when someone needs to make multiple appointments to receive these vaccines," said Luis Jodar, Ph.D., Senior Vice President and Chief Medical Officer, Pfizer Vaccines. "The results of this trial supports current CDC clinical guidance allowing coadministration during a single doctor or pharmacy appointment, so that more adults are able to help protect themselves against both of these respiratory diseases."

Pfizer will seek to present and publish detailed outcomes from this clinical trial at a future date. Additionally, in May 2021, Pfizer announced the initiation of a Phase 3 clinical trial exploring coadministration of PREVNAR 20 and a booster dose of COMIRNATY® (COVID-19 Vaccine, mRNA) in adults ages 65 or older.

About PREVNAR 20

PREVNAR 20 is Pfizer's next-generation pneumococcal conjugate vaccine that includes capsular polysaccharide conjugates for the 13 serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F) already

included in Prevnar 13® (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM_{197} Protein]). The vaccine also contains capsular polysaccharide conjugates for seven additional serotypes (8, 10A, 11A, 12F, 15B, 22F and 33F) that cause invasive pneumococcal disease (IPD),[1,2,3,4,5] and have been associated with high case-fatality rates,[6,7,8,9] antibiotic resistance,[10,11,12] and/or meningitis.[13,14] PREVNAR 20 contains the broadest serotype coverage and helps protect against more strains of the bacteria that cause pneumococcal pneumonia than any other conjugate vaccine available.

On June 8, 2021, Pfizer announced the U.S. Food and Drug Administration (FDA) approved, based on accelerated approval and priority review, PREVNAR 20 for the prevention of invasive disease and pneumonia in adults age 18 years or older. On February 26, 2021, the European Medicines Agency (EMA) accepted for review Pfizer's Marketing Authorization Application (MAA) for the 20-valent pneumococcal conjugate vaccine candidate, as submitted for the prevention of invasive disease and pneumonia caused by *S. pneumoniae* serotypes in the vaccine in adults ages 18 years and older. The formal review process by the EMA's Committee for Medicinal Products for Human Use (CHMP) currently is ongoing.

PREVNAR 20™ U.S. Indications

- PREVNAR 20™ is a vaccine indicated for active immunization for the prevention of pneumonia and 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 adults 18 years of age and older
- This indication for the prevention of pneumonia caused by *S. pneumoniae* serotypes 8, 10A, 11A, 12F, 15B, 22F, and 33F is approved under accelerated approval based on immune responses as measured by opsonophagocytic activity (OPA) assay. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

IMPORTANT SAFETY INFORMATION

- PREVNAR 20™ should not be given to anyone with a history of severe allergic reaction to any component of PREVNAR 20™ or any diphtheria toxoid–containing vaccine
- Some adults with weakened immune systems may have a lower response to PREVNAR 20™. Safety data are not available for these groups. Your healthcare provider can tell you if PREVNAR 20™ is right for you
- In adults 18 years of age and older, the most common side effects were pain at the injection site, muscle pain, fatigue, and headache
- Ask your healthcare provider about the risks and benefits of PREVNAR 20™. Only a healthcare provider can decide if PREVNAR 20™ is right for you

Please see full prescribing information for PREVNAR 20™.

COMIRNATY® U.S. Indication & Authorized Use

HOW IS THE VACCINE GIVEN?

The vaccine will be given to you as an injection into the muscle.

Primary Series: The vaccine is administered as a 2-dose series, 3 weeks apart. A third dose may be administered at least 4 weeks after the second dose to individuals who are determined to have certain kinds of immunocompromise.

Booster Dose: A single booster dose of the vaccine may be administered to individuals:

- 65 years of age and older
- 18 through 64 years of age at high risk of severe COVID-19
- 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID?19

WHAT IS THE INDICATION AND AUTHORIZED USE?

The FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably. Although they may be manufactured in different facilities, the products offer the same safety and effectiveness.

COMIRNATY (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech.

- It is approved as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older.
- It is also authorized under EUA to be administered to provide:
    - a two-dose primary series in individuals 12 through 15 years;
    - a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and
    - a single booster dose in individuals:
        - 65 years of age and older
        - 18 through 64 years of age at high risk of severe COVID-19
        - 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID ?19

The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA to provide:

- a two-dose primary series in individuals 12 years of age and older;
- a third primary series dose for individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and
- a single booster dose in individuals:
    - 65 years of age and older
    - 18 through 64 years of age at high risk of severe COVID-19
    - 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID?19

EUA Statement

Emergency uses of the vaccine have not been approved or licensed by FDA, but have been authorized by FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) in individuals 12 years of age and older. The emergency uses are 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. Please see EUA Fact Sheet at www.cvdvaccine-us.com.

IMPORTANT SAFETY INFORMATION

Individuals should **not** get the Pfizer-BioNTech COVID-19 Vaccine if they:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

Individuals should tell the vaccination provider about all of their medical conditions, including if they:

- 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 vaccine may not protect everyone.

Side effects reported with the vaccine include:

- 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, vaccination providers may ask individuals to stay at the place where they received the vaccine for monitoring after vaccination
    - 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
    - If an individual experiences a severe allergic reaction, they should call 9-1-1 or go to the nearest hospital
- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of the vaccine. The chance of having this occur is very low. Individuals should seek medical attention right away if they have any of the following symptoms after receiving the vaccine:
    - chest pain
    - shortness of breath
    - feelings of having a fast-beating, fluttering, or pounding heart
- Side effects that have been reported with the vaccine 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; 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
- These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials. Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away

Data on administration of this vaccine at the same time as other vaccines has not yet been submitted to FDA. Individuals considering receiving this vaccine with other vaccines, should discuss their options with their healthcare provider.

Patients should always ask their healthcare providers for medical advice about adverse events. Individuals are encouraged to report negative side effects of vaccines to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Visit http://www.vaers.hhs.gov or call 1?800?822?7967. In addition, side effects can be reported to Pfizer Inc. at www.pfizersafetyreporting.com or by calling 1-800-438-1985.

Please click here for full Prescribing Information (16+ years of age). Please click here for Fact Sheet for Vaccination Providers (12+ years of age). Please click here for the Recipients and Caregivers Fact Sheet.

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 29, 2021. 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 PREVNAR 20™ (Pneumococcal 20-valent Conjugate Vaccine [Diphtheria CRM197 Protein]), Pfizer's efforts to combat COVID-19, the collaboration between BioNTech and Pfizer to develop a COVID-19 vaccine, the BNT162 mRNA vaccine program and COMIRNATY (COVID-19 Vaccine, mRNA) (BNT162b2), including their potential benefits, 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, uncertainties regarding the commercial success of our vaccines; 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 Phase 3 data), including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; whether and when our Phase 3 clinical trial for BNT162b2 will demonstrate protection from infection or disease following a booster (third) dose, which is the subject of ongoing study; the ability to produce comparable clinical or other results, 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 or in larger, more diverse populations following commercialization; the ability of BNT162b2 to prevent COVID-19 caused by emerging virus variants; the risk that more widespread 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 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 and when additional data from the BNT162 mRNA vaccine program 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 these and any future preclinical and clinical studies; whether and when any biologics license applications may be filed in any other jurisdictions for PREVNAR 20 for the prevention of invasive disease and pneumonia in adults age 18 years or older and in any jurisdictions for any other potential indications, whether and when data from BNT162b2 in younger pediatric populations will be submitted to the FDA and other regulatory authorities to request amendments to emergency use or conditional marketing authorizations, whether and when applications for a potential booster (third) dose of BNT162b2 will be filed in any other jurisdictions and whether and when other biologics license and/or emergency use authorization applications or amendments to any such applications may be filed in particular jurisdictions for BNT162b2 or any other potential vaccines that may arise from the BNT162 program, and if obtained, whether or when such emergency use authorization or licenses will expire or terminate; whether and when the MAA pending in the EU for the 20-valent pneumococcal conjugate vaccine candidate may be approved, whether and when any such other applications that may be pending or filed for PREVNAR 20 may be approved by particular regulatory authorities and whether and when any applications that may be pending or filed for BNT162b2 (including the potential amendments to request use in younger pediatric populations, a potential booster (third) dose or any other requested amendments to the emergency use or conditional marketing authorizations) or other vaccines that may result from the BNT162 program may be approved by particular regulatory authorities, which will depend on myriad factors, including making a determination as to whether the vaccine's benefits outweigh its known risks and determination of the vaccine'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 a vaccine, including development of products or therapies by other companies; disruptions in the relationships between us and our collaboration partners, clinical trial sites or third-party suppliers; the risk that demand for any products may be reduced or no longer exist; risks related to the availability of raw materials to manufacture a vaccine; challenges related to BNT162b2's ultra-low temperature formulation, two-dose 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 new variant-specific vaccines; the risk that we may not be able to create or scale up manufacturing capacity on a timely basis or maintain access to logistics or supply channels commensurate with global demand for our vaccine, which would negatively impact our ability to supply the estimated numbers of doses of our vaccine within the projected time periods as previously indicated; whether and when additional supply agreements for BNT162b2 will be reached; uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; challenges related to public vaccine confidence or awareness; 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, 2020 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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