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Pfizer Initiates Study Exploring Coadministration of Its 20-valent Pneumococcal Conjugate Vaccine Candidate Along With a Third Dose of the Pfizer-BioNTech COVID-19 Vaccine in Older Adults

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NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced that the first enrolled subjects have received their immunizations as part of a new study in adults ages 65 or older exploring the coadministration of the company's 20-valent pneumococcal conjugate vaccine (20vPnC) candidate following a booster dose of the Pfizer-BioNTech COVID-19 Vaccine, currently authorized by the Food and Drug Administration (FDA) under an Emergency Use Authorization (EUA). The primary objective in the trial is to describe safety when both vaccines are co-administered, with follow up six months after vaccination. Secondary objectives are to describe immune responses produced by each of the vaccines.

The trial will include 600 adults who will be recruited from the pivotal Phase 3 Pfizer-BioNTech COVID-19 Vaccine trial and will have received their second dose of the vaccine at least six months prior to entering the coadministration study. The participants are being randomized to one of three groups:

- 20vPnC plus Pfizer-BioNTech COVID-19 Vaccine booster, which is a third dose of the Pfizer-BioNTech COVID-19 Vaccine
- 20vPnC plus placebo
- Pfizer-BioNTech COVID-19 Vaccine booster plus placebo

About Pfizer-BioNTech COVID-19 Vaccine

The Pfizer-BioNTech COVID-19 Vaccine, developed with BioNTech SE (Nasdaq: BNTX) based on its proprietary mRNA technology, has been shipped to 91 countries and territories[1] around the world as part of an emergency use authorization or conditional marketing authorization. BioNTech is the Marketing Authorization Holder in the European Union, and the holder of emergency use authorizations or equivalent in the United States (jointly with Pfizer), United Kingdom, Canada and other countries in advance of a planned application for full marketing authorizations in these countries.

The Pfizer-BioNTech COVID-19 Vaccine has not been approved or licensed by the U.S. Food and Drug Administration (FDA), but has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 12 years of age and older. 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. Please see Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Full EUA Prescribing Information available at www.cvdvaccine-us.com.

AUTHORIZED USE IN THE U.S.:

The Pfizer-BioNTech COVID19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) 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 FROM U.S. FDA EMERGENCY USE AUTHORIZATION PRESCRIBING INFORMATION:

- Do not administer Pfizer BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (eg, anaphylaxis) to any component of the Pfizer BioNTech COVID-19 Vaccine
- Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer BioNTech COVID-19 Vaccine

Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/).

- Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting
- Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer?BioNTech COVID-19 Vaccine
- The Pfizer?BioNTech COVID-19 Vaccine may not protect all vaccine recipients
- In clinical studies, adverse reactions in participants 16 years of age and older included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%)
- In a clinical study, adverse reactions in adolescents 12 through 15 years of age included pain at the injection site (90.5%), fatigue (77.5%), headache (75.5%), chills (49.2%), muscle pain (42.2%), fever (24.3%), joint pain (20.2%), injection site swelling (9.2%), injection site redness (8.6%), lymphadenopathy (0.8%), and nausea (0.4%)
- Severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions, diarrhea, vomiting, and pain in extremity (arm) have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine outside of clinical trials

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine.

- Available data on Pfizer?BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy
- Data are not available to assess the effects of Pfizer?BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion
- There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19

Vaccine to complete the vaccination series
- Vaccination providers must report Adverse Events in accordance with the Fact Sheet to VAERS at https://vaers.hhs.gov/reportevent.html or by calling 1-800-822-7967. The reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report
- Vaccination providers should review the Fact Sheet for *Information to Provide to Vaccine Recipients/Caregivers and Mandatory Requirements for Pfizer-BioNTech COVID-19 Vaccine Administration Under Emergency Use Authorization*
- Before administration of Pfizer-BioNTech COVID-19 Vaccine, please see Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including Full EUA Prescribing Information available at www.cvdvaccine-us.com

About 20vPnC Adult

The 20vPnC candidate vaccine is in development for the prevention of invasive disease and pneumonia caused by 20 serotypes of *Streptococcus pneumoniae* in the vaccine in adults ages 18 years and older. In December 2020, Pfizer announced that the U.S. Food and Drug Administration (FDA) accepted for priority review a Biologics License Application (BLA) for 20vPnC with a Prescription Drug User Fee Act (PDUFA) goal date in June 2021. Also, in February 2021, Pfizer announced that the European Medicines Agency (EMA) accepted for review the Marketing Authorization Application (MAA) for 20vPnC for adults ages 18 years and older.

Pfizer's 20vPnC vaccine candidate includes capsular polysaccharide conjugates for the 13 serotypes in Prevnar 13® (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein]). The vaccine also contains capsular polysaccharide conjugates for seven additional serotypes that cause pneumococcal disease,[2,3,4,5,6] and have been associated with high case-fatality rates,[7,8,9,10] antibiotic resistance,[5,11,12] and/or meningitis.[13,14] Together, the 20 serotypes included in 20vPnC are responsible for a majority of currently circulating pneumococcal disease globally.[15,16,17,18,19,20,21]

INDICATIONS FOR PREVNAR 13®

- Prevnar 13® is a vaccine indicated in children 6 weeks through 17 years (prior to the 18th birthday) for active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F, and for children 6 weeks through 5 years of age (prior to the 6th birthday) for the prevention of otitis media caused by 7 of the 13 serotypes in the vaccine
- In adults 18 years of age and older, Prevnar 13® is indicated for active immunization for the prevention of pneumonia and invasive disease caused by *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F
- Prevnar 13® does not protect against disease caused by *S. pneumoniae* serotypes that are not in the vaccine

U.S. IMPORTANT SAFETY INFORMATION

- Severe allergic reaction (eg, anaphylaxis) to any component of Prevnar 13® or any diphtheria toxoid-containing vaccine is a contraindication
- Immunocompromised individuals or individuals with impaired immune responsiveness due to the use of immunosuppressive therapy may have reduced antibody response
- Apnea following intramuscular vaccination has been observed in some infants born prematurely. Vaccination of premature infants should be based on the infant's medical status, and the potential benefits and risks
- In infants and toddlers, the most commonly reported serious adverse events were bronchiolitis (0.9%), gastroenteritis (0.9%), and pneumonia (0.9%)

- In children 6 weeks through 17 years, the most commonly reported solicited adverse reactions were injection site tenderness, redness, or swelling, irritability, decreased appetite, decreased or increased sleep, and fever
- In adults, the most common side effects were pain, redness, and swelling at the injection site, limitation of arm movement, fatigue, headache, muscle pain, joint pain, decreased appetite, vomiting, fever, chills, and rash

For the full prescribing information for Prevnar 13®, please visit www.Pfizer.com.

About Pfizer: Breakthroughs That Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Disclosure Notice

The information contained in this release is as of May 24, 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 Pfizer's 20-valent pneumococcal conjugate vaccine (20vPnC) candidate, 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 the Pfizer-BioNTech COVID-19 Vaccine (BNT162b2) (including qualitative assessments of available data, potential benefits, expectations for clinical trials, the anticipated timing of regulatory submissions, regulatory approvals or authorizations and anticipated manufacturing, distribution and supply), involving substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preclinical and clinical data (including the Phase 3 data), including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the ability to produce comparable clinical or other results, including 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 the rolling submission of the BLA for BNT162b2 in the U.S. will be accepted for review 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, and whether and when applications may be filed for 20vPnC in any other jurisdictions; whether and when the BLA for BNT162b2 in the U.S. and any other applications that may be pending or filed for BNT162b2 (including any requested amendments to the emergency use or conditional marketing authorizations) or other vaccines that may result from the BNT162 program and whether and when the BLA for 20vPnC in the U.S., the MAA for 20vPnC in Europe and any other applications that may be pending or filed for 20vPnC 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.

[1] Pfizer Q1 Earnings Press Release. May 4, 2021. Page 12

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