



## **Pfizer and BioNTech Receive U.S. FDA Fast Track Designation for Single-Dose mRNA-Based Vaccine Candidate Against COVID-19 and Influenza**

December 9, 2022

**NEW YORK and MAINZ, GERMANY, DECEMBER 9, 2022** —[Pfizer Inc.](#) (NYSE: PFE) and [BioNTech SE](#) (Nasdaq: BNTX) today announced the companies have received Fast Track Designation from the U.S. Food and Drug Administration (FDA) for their mRNA-based combination vaccine candidate for influenza and COVID-19, which aims to help prevent two respiratory diseases with a single injection. Fast Track is a process designed to facilitate the development and expedite the review of new drugs and vaccines intended to treat or prevent serious conditions and address unmet medical need.<sup>1</sup>

Pfizer and BioNTech previously announced the start of a [Phase 1 trial](#) to examine the safety, tolerability, and immunogenicity of their combined influenza and COVID-19 candidate vaccine among healthy adults.

The vaccine candidate is based on BioNTech's proprietary mRNA platform technology and contains mRNA strands encoding the wild-type spike protein of SARS-CoV-2 and the spike protein of the Omicron sublineages BA.4/BA.5, as well as mRNA strands encoding the hemagglutinin of four different influenza strains, recommended for the Northern Hemisphere 2022/23 by the World Health Organization.

A combined vaccine for influenza and COVID-19 has the potential to simplify immunization practices against two severe respiratory diseases caused by evolving viruses that require vaccine adaptation.

### **About Respiratory Diseases**

SARS-CoV-2 led to a global pandemic with more than 6.5 million deaths<sup>2</sup> and a high socio-economic burden worldwide.<sup>3</sup> While vaccinations can help address the disease, COVID-19 is expected to continue circulating, and vaccines will likely require continual adjustments to address new variants of concern. Influenza is another respiratory disease that also requires repeated vaccinations due to continuous mutations in the surface hemagglutinin protein. Influenza accounts for up to 12,000 to 52,000 deaths in the United States every year<sup>4</sup> and causes substantial morbidity and mortality globally each year.<sup>5</sup>

### **U.S. INDICATION & AUTHORIZED USE**

#### **Pfizer-BioNTech COVID-19 Vaccine, Bivalent, (Original and Omicron BA.4/BA.5)**

##### **AUTHORIZED USE**

**Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)** is FDA authorized under Emergency Use Authorization (EUA) for use in individuals 5 years of age and older as a single booster dose administered at least 2 months after either:

- completion of primary vaccination with any authorized or approved monovalent\* COVID-19 vaccine; or
- receipt of the most recent booster dose with any authorized or approved monovalent\* COVID-19 vaccine

\*Monovalent refers to any authorized and approved COVID-19 vaccine that contains or encodes the spike protein of only the Original SARS-CoV-2 virus.

#### **COMIRNATY® (COVID-19 Vaccine, mRNA)**

##### **INDICATION**

COMIRNATY® (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine 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.

##### **AUTHORIZED USE**

**COMIRNATY® (COVID-19 Vaccine, mRNA)** is authorized under Emergency Use Authorization (EUA) to provide:

##### **Primary Series**

- a third primary series dose to individuals 12 years of age and older who have certain kinds of immunocompromise

#### **Pfizer-BioNTech COVID-19 Vaccine**

##### **AUTHORIZED USES**

**Pfizer-BioNTech COVID-19 Vaccine** is FDA authorized under Emergency Use Authorization (EUA) for use in individuals 6 months and older to provide:

##### **Primary Series**

- a 2-dose primary series to individuals 5 years of age and older
- a third primary series dose to individuals 5 years of age and older with certain kinds of immunocompromise

#### **Pfizer-BioNTech COVID-19 Vaccine and Pfizer-BioNTech COVID-19 Vaccine, Bivalent**

##### **AUTHORIZED USES**

**Pfizer-BioNTech COVID-19 Vaccine** and **Pfizer-BioNTech COVID-19 Vaccine, Bivalent** are FDA authorized under Emergency Use Authorization (EUA) for use in individuals 6 months to 4 years of age to provide:

#### **Primary Series**

- a 3-dose primary series as follows:
  - Dose 1: Pfizer-BioNTech COVID-19 Vaccine
  - Dose 2: Pfizer-BioNTech COVID-19 Vaccine
  - Dose 3: Pfizer-BioNTech COVID-19 Vaccine, Bivalent

#### **EMERGENCY USE AUTHORIZATION**

Emergency uses of the vaccines 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 aged 6 months 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.

#### **IMPORTANT SAFETY INFORMATION**

**Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), COMIRNATY® (COVID-19 Vaccine, mRNA), and Pfizer-BioNTech COVID-19 Vaccine**

**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 vaccine may not protect everyone
- You should not get COMIRNATY (COVID-19 Vaccine, mRNA), the Pfizer-BioNTech COVID-19 Vaccine, or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent if you have had a severe allergic reaction after a previous dose of COMIRNATY or the Pfizer-BioNTech COVID-19 Vaccine or any ingredient in these vaccines
- There is a remote chance that these vaccines 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 experience a severe allergic reaction, call 9-1-1 or go to the nearest hospital

**Seek medical attention right away if you have any of the following symptoms:**

- difficulty breathing, swelling of the face and throat, a fast heartbeat, a bad rash all over the body, 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 COMIRNATY® (COVID-19 vaccine, mRNA) or Pfizer-BioNTech COVID-19 Vaccine. The observed risk is higher among adolescent males and adult males under 40 years of age than among females and older males, and the observed risk is highest in males 12 through 17 years of age. In most of these people, symptoms began within a few days following receipt of the second dose of vaccine. The chance of having this occur is very low
- Side effects that have been reported with these 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
  - Tiredness
  - Headache
  - Muscle pain
  - Chills
  - Joint pain
  - Fever
  - Injection site swelling
  - Injection site redness
  - Nausea
  - Feeling unwell



candidate for influenza and COVID-19, BNT162b2 in additional populations, a potential booster dose for BNT162b2, any monovalent or bivalent vaccine candidates 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 the combination vaccine candidate for influenza and COVID-19, BNT162b2, any monovalent or bivalent vaccine candidates or any other potential vaccines that may arise from the BNT162 program, including a potential variant-based, higher dose, or bivalent vaccine, and if obtained, whether or when such emergency use authorizations or licenses will expire or terminate; whether and when any applications that may be pending or filed for the combination vaccine candidate for influenza and COVID-19, BNT162b2 (including any requested amendments to the emergency use or conditional marketing authorizations), any monovalent or bivalent vaccine candidates, 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 which may lead to reduced revenues or excess inventory; risks related to the availability of raw materials to manufacture 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; the risk that we may not be able to maintain or scale up manufacturing capacity on a timely basis or maintain access to logistics or supply channels commensurate with global demand for our vaccines, which would negatively impact our ability to supply the estimated numbers of doses of our vaccines within the projected time periods; whether and when supply agreements 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, 2021 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).

#### **About BioNTech**

Biopharmaceutical New Technologies is a next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. The Company exploits a wide array of computational discovery and therapeutic drug platforms for the rapid development of novel biopharmaceuticals. Its broad portfolio of oncology product candidates includes individualized and off-the-shelf mRNA-based therapies, innovative chimeric antigen receptor T cells, bispecific immune checkpoint modulators, targeted cancer antibodies and small molecules. Based on its deep expertise in mRNA vaccine development and in-house manufacturing capabilities, BioNTech and its collaborators are developing multiple mRNA vaccine candidates for a range of infectious diseases alongside its diverse oncology pipeline. BioNTech has established a broad set of relationships with multiple global pharmaceutical collaborators, including Genmab, Sanofi, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma, and Pfizer. For more information, please visit [www.BioNTech.com](http://www.BioNTech.com).

#### **BioNTech Forward-looking Statements**

This press release contains "forward-looking statements" of BioNTech within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may include, but may not be limited to, statements concerning: BioNTech's efforts to combat COVID-19 and influenza; the collaboration between BioNTech and Pfizer including the program to develop a COVID-19 vaccine and a combination vaccine candidate for influenza and COVID-19, mRNA technology, the BNT162b2 mRNA vaccine program, a combination vaccine candidate for influenza and COVID-19 and the Pfizer-BioNTech COVID-19 Vaccine, also known as COMIRNATY (COVID-19 Vaccine, mRNA), including the Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5 (BNT162b2) (including a combination vaccine candidate for influenza and COVID-19, qualitative assessments of available data, potential benefits, expectations for clinical trials, potential regulatory submissions, the anticipated timing of data readouts, regulatory submissions, regulatory approvals or authorizations and anticipated manufacturing, distribution and supply); our expectations regarding the potential characteristics of a combination vaccine candidate for influenza and COVID-19, BNT162b2 in our clinical trials and/or BNT162b2 in commercial use based on data observations to date; the ability of a combination vaccine candidate for influenza and COVID-19, BNT162b2, any monovalent or bivalent vaccine candidates or any future vaccine, to prevent COVID-19 caused by emerging virus variants; 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 Phase 1/2/3 or Phase 4 data), including the data discussed in this release for a combination vaccine candidate for influenza and COVID-19, BNT162b2, any monovalent or bivalent vaccine candidates or any other vaccine candidate in BNT162 program in any of our studies in pediatrics, adolescents, or adults or real world evidence, including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the expected time point for additional readouts on efficacy data of a combination vaccine candidate for influenza and COVID-19, BNT162b2 in our clinical trials; 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 nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; the timing for submission of data for, or receipt of, any marketing approval or Emergency Use Authorization; our contemplated shipping and storage plan, including our estimated product shelf life at various temperatures; the ability of BioNTech to supply the quantities of a combination vaccine candidate for influenza and COVID-19, BNT162, any monovalent or bivalent vaccine candidates or any future vaccine, to support clinical development and market demand, including our production estimates for 2022; that demand for any products may be reduced or no longer exist which may lead to reduced revenues or excess inventory; the availability of raw materials to manufacture a vaccine; a combination vaccine candidate for influenza and COVID-19, BNT162, any monovalent or bivalent vaccine candidates or any future vaccine, formulation, dosing schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery by Pfizer; the ability to successfully develop other vaccine formulations, booster doses or potential future annual boosters or re-vaccinations or new variant-adapted vaccines; the ability to maintain or scale up manufacturing capacity on a timely basis or maintain access to logistics or supply channels commensurate with global demand for our vaccines, 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 will be reached; 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; and uncertainties regarding the impact of COVID-19 on BioNTech's trials, business and general operations. Any forward-looking statements in this press release are based on BioNTech current expectations and beliefs of future events, and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements.

For a discussion of these and other risks and uncertainties, see BioNTech's quarterly report on Form 6-K for the quarter ended September 30, 2022, filed with the SEC on November 7, 2022, which is available on the SEC's website at [www.sec.gov](http://www.sec.gov). All information in this press release is as of the date of the release, and BioNTech undertakes no duty to update this information unless required by law.

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<sup>1</sup> U.S. Food and Drug Administration Fast Track. Available at <https://www.fda.gov/ForPatients/Approvals/Fast/ucm405399.htm>

<sup>2</sup> World Health Organization Coronavirus (COVID-19) Dashboard. Available at <https://covid19.who.int/>

<sup>3</sup> Delardas O, Kechagias KS, Pontikos PN, Giannos P. Socio-Economic Impacts and Challenges of the Coronavirus Pandemic (COVID-19): An Updated Review. Sustainability. 2022; 14(15):9699. <https://doi.org/10.3390/su14159699>

<sup>4</sup> Centers for Disease Control and Prevention. Disease Burden of Flu. Available at <https://www.cdc.gov/flu/about/burden/index.html>

<sup>5</sup> World Health Organization. Fact Sheet on Seasonal Influenza (Flu). Available at <http://www.who.int/mediacentre/factsheets/fs211/en/>