Pfizer Logo

Pfizer and BioNTech Receive U.S. Emergency Use Authorization of Omicron BA.4/BA.5-Adapted Bivalent COVID-19 Booster in Children Under 5 Years

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NEW YORK and MAINZ, GERMANY, March 14, 2023 —Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) announced today that the U.S. Food and Drug Administration (FDA) granted emergency use authorization (EUA) to provide a single booster dose of the companies' Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine in children 6 months through 4 years of age (also referred to as under 5 years of age) at least 2 months after completion of primary vaccination with three doses of the Pfizer-BioNTech COVID-19 Original Vaccine. The bivalent vaccine is also authorized in this age group as the third dose of a three dose-primary series; for these children, a booster (fourth) dose is not authorized at this time.

The EUA is based on data from substudies within the companies' Phase 1/2/3 study (NCT05543616) evaluating the safety, tolerability and immunogenicity of a fourth dose of the bivalent vaccine in children 6 months through 4 years of age (n=300). Safety and immunogenicity were assessed in a subset of study participants 6 months through 4 years of age (n=60), demonstrating that a booster (fourth) dose of the Omicron BA.4/BA.5-adapted bivalent vaccine elicited improved Omicron BA.4/BA.5-neutralizing antibody responses compared to participants who received three doses of the companies' original vaccine. The safety and tolerability profile of the bivalent vaccine was similar to that of the original vaccine.[1]

Based on the latest real-world evidence, Omicron BA.4/BA.5-adapted bivalent vaccines appear to be protective against symptomatic COVID-19 disease in adults caused by both BA.4/BA.5 and XBB Omicron sublineages,[2] the latter of which currently account for more than 85% of COVID-19 cases in the U.S.[3] Additional real-world evidence collected between September 2022 and December 2022 shows that among older adults, receiving an mRNA-based bivalent booster provided greater vaccine effectiveness against COVID-19 hospitalization compared to receiving two or more doses of the companies' original wild-type vaccine administered two months earlier. [4,5,6] This was observed during a time when different Omicron sublineages were circulating, including XBB.1.5 which started to circulate in the second half of December.[3]

Pfizer and BioNTech have also submitted an application to the European Medicines Agency (EMA) to extend the Omicron BA.4/BA.5-adapted bivalent vaccine's marketing authorization to include use in children 6 months through 4 years of age as both primary series (all three doses) and booster vaccination (fourth dose). Currently, the bivalent vaccine is authorized in the European Union (EU) as a booster dose for ages 5 years and older. The companies plan to submit applications to other regulatory authorities worldwide for the use of their Omicron BA.4/BA.5-adapted bivalent vaccine among children under 5 years of age.

The Pfizer-BioNTech COVID-19 Vaccines (COMIRNATY®) are based on BioNTech's proprietary mRNA technology and were developed by both BioNTech and Pfizer. BioNTech is the Marketing Authorization Holder

for BNT162b2 (Original) and BNT162b2 Bivalent (Original/Omicron BA.4/BA.5) in the United States, the European Union, the United Kingdom, Canada and other countries, and the holder of emergency use authorizations or equivalents in the United States (jointly with Pfizer) and other countries.

U.S. INDICATION & AUTHORIZED USE

INDICATION AND AUTHORIZED USE

COMIRNATY® (COVID-19 Vaccine, mRNA) is a vaccine indicated 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. It is also authorized for emergency use to provide a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise.

AUTHORIZED USE

Pfizer-BioNTech COVID-19 Vaccine and Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) are FDA authorized under 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 6 months of age and older.

EMERGENCY USE AUTHORIZATION

Emergency uses of Pfizer-BioNTech COVID-19 Vaccine and Pfizer-BioNTech COVID-19 Vaccine, Bivalent 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.

Interchangeability of COMIRNATY and Pfizer-BioNTech COVID-19 Vaccine (Primary Series for Individuals 12 Years of Age and Older)

When prepared according to their respective instructions for use, the FDA-approved COMIRNATY and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older can be used interchangeably without presenting any safety or effectiveness concerns.

IMPORTANT SAFETY INFORMATION

Tell your vaccination provider about all the vaccine recipient's medical conditions, including if the vaccine recipient:

- has 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 is on a blood thinner
- is immunocompromised or is on a medicine that affects the immune system
- is pregnant, plans to become pregnant, or is breastfeeding
- has received another COVID-19 vaccine
- has ever fainted in association with an injection

- The vaccines may not protect all vaccine recipients

- The vaccine recipient should not receive 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 the vaccine recipient to stay at the place where the vaccine was administered for monitoring after vaccination. If the vaccine recipient experiences a severe allergic reaction, call 9-1-1 or go to the nearest hospital

Seek medical attention right away if the vaccine recipient has 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), Pfizer-BioNTech COVID-19 Vaccine, 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.

Seek medical attention right away if the vaccine recipient has any of the following symptoms:
- Chest pain
- Shortness of breath or difficulty breathing
- Feelings of having a fast-beating, fluttering, or pounding heart
- 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

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/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 of the vaccine. Call the vaccination provider or healthcare provider about bothersome side effects or side effects that do not go away.

- Indivduals 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. In addition, individuals can also report side effects to Pfizer Inc. at www.pfizersafetyreporting.com or by calling 1-800-438-1985

Full Prescribing Information and EUA Fact Sheets for Vaccination Providers and Recipients and Caregivers Fact Sheets:

COMIRNATY® Full Prescribing Information (12 years of age and older), DO NOT DILUTE, Gray Cap
EUA Fact Sheet for Vaccination Providers (12 years of age and older), BIVALENT (Original and Omicron BA.4/BA.5), DO NOT DILUTE, Gray Cap
EUA Fact Sheet for Vaccination Providers (5 through 11 years of age), BIVALENT (Original and Omicron BA.4/BA.5), DILUTE BEFORE USE, Orange Cap
EUA Fact Sheet for Vaccination Providers (12 years of age and older), DO NOT DILUTE, Gray Cap
EUA Fact Sheet for Vaccination Providers (5 through 11 years of age), DILUTE BEFORE USE, Orange Cap
EUA Fact Sheet for Vaccination Providers (6 months through 4 years of age), DILUTE BEFORE USE, Maroon Cap
EUA Fact Sheet for Recipients and Caregivers (12 years of age and older)
EUA Recipients and Caregivers Fact Sheet (6 months through 4 years of age)
EUA Recipients and Caregivers Fact Sheet (5 through 11 years of age)

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 and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Pfizer Disclosure Notice
The information contained in this release is as of March 14, 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, the collaboration between BioNTech and Pfizer to develop a COVID-19 vaccine, the BNT162b2 mRNA vaccine program, and the Pfizer-BioNTech COVID-19 Vaccine, also known as COMIRNATY (COVID-19 Vaccine, mRNA) (BNT162b2) (including an EUA of a booster (fourth) dose of the companies' Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine in children 6 months through 4 years of age (also referred to as under 5 years), planned regulatory submissions, 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) 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 Phase 1/2/3 or Phase 4 data), including the data discussed in this release for BNT162b2, any monovalent, bivalent or variant-adapted vaccine candidates or any other vaccine candidate in the 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, including the risk that additional data against newer Omicron sublineages could differ from the data discussed in this release; 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, in real world data studies or in larger, more diverse populations following commercialization; the ability of BNT162b2, any monovalent, bivalent or variant-adapted vaccine candidates or any future vaccine 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 submissions to request emergency use or conditional marketing authorizations for BNT162b2 in additional populations, for 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 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 BNT162b2 (including any requested amendments to the emergency use or conditional marketing authorizations), any monovalent, bivalent or variant-adapted 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 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; 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; the risk that other companies 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; 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 agreements will be reached or existing agreements will be completed or re-negotiated; 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, 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.

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.

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; the collaboration between BioNTech and Pfizer including the program to develop a COVID-19 vaccine and COMIRNATY® (COVID-19 vaccine, mRNA) (BNT162b2) (including the Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine, the FDA's grant of EUA for an Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine as the fourth 3-µg dose as a booster following a three-dose primary series for children 6 months through 4 years of age, submission of an application to the EMA to extend the Omicron BA.4/BA.5-adapted bivalent vaccine's marketing authorization to include use in children 6 months through 4 years of age as both primary series and booster vaccination (fourth dose) and plans to submit applications to other authorities worldwide, 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); and our expectations regarding the potential characteristics of BNT162b2 in our clinical trials, real world data studies, and/or in commercial use based on data observations to date, including preclinical and clinical data (including Phase 1/2/3

or Phase 4 data), including the descriptive data discussed in this release, for BNT162b2 or any other vaccine candidate in the BNT162 program in any of our studies in pediatrics, adolescents or adults or real world evidence. Any forward-looking statements in this press release are based on BioNTech's 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. These risks and uncertainties include, but are not limited to: the possibility of unfavorable new preclinical, clinical or safety data, including the risk that final or formal results from the clinical trial could differ from the topline data; the ability of BNT162b2 or a future vaccine to prevent COVID-19 caused by emerging virus variants; the expected time point for additional readouts on efficacy data of BNT162b2 and its adapted vaccine variations in our clinical trials; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; widespread use of BNT162b2 and its adapted vaccine variations 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 timing for submission of data for BNT162, or any future vaccine, in additional populations (potential future annual boosters or re-vaccinations), or receipt of any marketing approval or emergency use authorization or equivalent, including amendments or variations to such authorizations, 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; the development of other vaccine formulations, booster doses or potential future annual boosters or re-vaccinations or new variant based vaccines; the ability of BioNTech to supply the quantities of BNT162 and its adapted vaccine variations to support clinical development and market demand; challenges related to public vaccine confidence or awareness; 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, no longer exist or not meet expectations, which may lead to excess inventory on-hand and/or in the channel or reduced revenues; the availability of raw materials to manufacture BNT162 or other vaccine formulations; 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 agreements will be reached or existing agreements will be completed or re-negotiated; 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 and our contemplated shipping and storage plan, including our estimated product shelf life at various temperatures; uncertainties regarding the impact of COVID-19 on BioNTech's trials, business and general operations; the ability to meet the pre-defined endpoints in clinical trials; competition to create a vaccine for COVID-19; the ability to produce comparable clinical or other results, including our stated rate of vaccine effectiveness and safety and tolerability profile observed to date, in the remainder of the trial or in larger, more diverse populations upon commercialization; the ability to effectively scale our production capabilities; and other potential difficulties.

For a discussion of these and other risks and uncertainties, see BioNTech's Quarterly Report as 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. 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.

CONTACTS

Pfizer:
Media Relations
+1 (212) 733-1226

PfizerMediaRelations@pfizer.com

Investor Relations
+1 (212) 733-4848
IR@pfizer.com

BioNTech:
Media Relations
Jasmina Alatovic
+49 (0)6131 9084 1513
Media@biontech.de

Investor Relations
Michael Horowicz
+1 (617) 955 7420
Investors@biontech.de

1 Vaccines and Related Biological Products Advisory Committee January 26, 2023, Meeting Presentation. COVID-19 Pfizer-BioNTech Vaccines. Available at: https://www.fda.gov/media/164813/download

2 Centers for Disease Control and Prevention. Early Estimates of Bivalent mRNA Booster Dose Vaccine Effectiveness in Preventing Symptomatic SARS-CoV-2 Infection Attributable to Omicron BA.5– and XBB/XBB.1.5–Related Sublineages Among Immunocompetent Adults — Increasing Community Access to Testing Program, United States, December 2022–January 2023. Available at: https://www.cdc.gov/mmwr/volumes/72/wr/mm7205e1.htm

3 Centers for Disease Control and Prevention. COVID Data Tracker. Available at: https://covid.cdc.gov/covid-data-tracker

4 Surie D, DeCuir J, Zhu Y, et al. Early Estimates of Bivalent mRNA Vaccine Effectiveness in Preventing COVID-19–Associated Hospitalization Among Immunocompetent Adults Aged ?65 Years — IVY Network, 18 States, September 8-November 30, 2022. MMWR Morb Mortal Wkly Rep 2022; 71:1625–1630.

5 Advisory Committee on Immunization Practices, Center for Disease control and prevention. Live meeting February 22-24, 2023; https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-02/slides-02-24/COVID-07-Britton-508.pdf. Access: 03/13/2023

6 Vaccines and Related Biological Products Advisory Committee, Center for Disease Control and Prevention. Live meeting January 26, 2023; https://www.fda.gov/media/164816/download