Pfizer and BioNTech Submit Applications to U.S. FDA for Omicron XBB.1.5-Adapted Monovalent COVID-19 Vaccine

June 23, 2023

- *The submissions reflect guidance from FDA and other major health authorities to provide COVID-19 vaccines better matched to currently circulating sublineages*
- *The companies expect to be ready to ship the adapted vaccines immediately following regulatory authorization/approval*

NEW YORK and MAINZ, GERMANY, JUNE 23, 2023 — Pfizer Inc. (NYSE: PFE, "Pfizer") and BioNTech SE (Nasdaq: BNTX, "BioNTech") today announced the companies have submitted regulatory applications to the U.S. Food and Drug Administration (FDA) for their Omicron XBB.1.5-adapted monovalent COVID-19 vaccine for individuals 6 months of age and older.

These filings follow guidance from the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) to manufacture an Omicron XBB.1.5-adapted monovalent COVID-19 vaccine for the 2023-2024 fall and winter season.

The Omicron XBB sublineages currently account for nearly all COVID-19 cases in the U.S.[i] and are further antigenically distant from prior circulating SARS-CoV-2 variants, including Omicron BA.4/BA.5 and the original SARS-CoV-2 strain. Although Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccines provide some protection against a range of outcomes from XBB-related COVID-19,[ii] evidence suggests that vaccines better matched to currently circulating sublineages can help further improve protection against symptomatic disease and severe COVID-19.[iii]

The U.S. regulatory applications are based on the full body of clinical, pre-clinical, and real-world evidence supporting the safety and efficacy of the Pfizer-BioNTech COVID-19 Vaccines. Following guidance from regulatory authorities on the requirements for strain changes, the applications include data showing that the Omicron XBB.1.5-adapted monovalent COVID-19 vaccine generates improved responses against circulating XBB sublineages, compared to the current Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine.

The companies have manufactured Omicron XBB.1.5-adapted monovalent COVID-19 vaccines at risk to ensure readiness ahead of the fall and winter season. Pending regulatory review and approval, the companies expect to be ready to ship Omicron XBB.1.5-adapted monovalent COVID-19 vaccines immediately. Pfizer and BioNTech have also submitted an application to the European Medicines Agency (EMA) and expect to initiate submissions to other regulatory authorities in the coming weeks.

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 and Omicron BA.4/BA.5) in 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. BioNTech is also the Biologics License Holder for BNT162b2 (Original) in the United States.

INDICATION & AUTHORIZED USE

AUTHORIZED USE

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

Pfizer-BioNTech COVID-19 Vaccine, Bivalent 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 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.

IMPORTANT SAFETY INFORMATION

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

• A person should **NOT** get Pfizer-BioNTech COVID-19 Vaccine, Bivalent if they have had a severe allergic reaction after a previous dose of Pfizer-BioNTech COVID-19 Vaccine*, Pfizer-BioNTech COVID-19 Vaccine, Bivalent, or COMIRNATY® (COVID-19 Vaccine, mRNA) 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 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 Pfizer-BioNTech COVID-19 Vaccine, Bivalent, Pfizer-BioNTech COVID-19 Vaccine, or COMIRNATY (COVID-19 Vaccine, mRNA). 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

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, Bivalent. 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, Bivalent

Side effects that have been reported with Pfizer-BioNTech COVID-19 Vaccine, Bivalent, Pfizer-BioNTech COVID-19 Vaccine, or COMIRNATY (COVID-19 Vaccine, mRNA) 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 these vaccines. Call the vaccination provider or healthcare provider about bothersome side effects or

side effects that do not go away.

- Individuals should always ask their 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 vaers.hhs.gov/reportevent.html. In addition, individuals can report side effects to Pfizer Inc. at www.pfizersafetyreporting.com or by calling 1-800-438-1985

Please click for Pfizer-BioNTech COVID-19 Vaccine, Bivalent Vaccination Provider and Recipient and Caregiver EUA Fact Sheets

*The Original Pfizer-BioNTech COVID-19 Vaccine is no longer authorized for use in the United States.

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 June 23, 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 BNT162 mRNA vaccine program, and the Pfizer-BioNTech COVID-19 Vaccine, the Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), the Comirnaty Original/Omicron BA.1 Vaccine, and Comirnaty Original/Omicron BA.4/BA.5 Vaccine, defined collectively herein as COMIRNATY (including submission of regulatory applications to the U.S. Food and Drug Administration (FDA) for a monovalent XBB.1.5-adapted COVID-19 vaccine for the 2023-2024 fall and winter season for individuals 6 months of age and older, plans to submit applications for a monovalent XBB.1.5-adapted COVID-19 vaccine to other regulatory authorities, 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 pre-clinical and clinical data (including Phase 1/2/3 or Phase 4 data for COMIRNATY, any monovalent, bivalent or variant-adapted vaccine candidates or any other vaccine candidate in the BNT162 program, 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 or further information regarding the quality of pre-clinical, clinical or safety data, including the risk that additional data against newer Omicron sublineages could differ from previously reported data; the ability to produce comparable clinical or other results for COMIRNATY, any monovalent, bivalent or variant-adapted vaccine candidates or other vaccines that may result from the BNT162 program or any other COVID-19 program, 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 COMIRNATY, any monovalent, bivalent or variant-adapted vaccine candidates or any future vaccine to prevent COVID-19 caused by 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 the BNT162 mRNA vaccine program or other COVID-19 programs 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 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 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 COMIRNATY, 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 or any other potential vaccines, 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 COMIRNATY (including any requested amendments to the emergency use or conditional marketing authorizations), any monovalent, bivalent or variant-adapted vaccine candidates (including the submissions of regulatory applications to the FDA and the market authorization application to the European Medicines Agency for the monovalent XBB.1.5-adapted COVID-19 vaccine), or other vaccines that may result from the BNT162 program or any other COVID-19 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, 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; 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; 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 renegotiated; 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 confidence in, or awareness of COMIRNATY; the uncertainties inherent in business and financial planning, including, without limitation, risks related to Pfizer's business and prospects, adverse developments in Pfizer's markets, or adverse developments in the U.S. or global capital markets, credit markets, regulatory environment or economies generally; 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 DualityBio, Genmab, Sanofi, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma, OncoC4, 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 submission to the FDA of a supplemental Biologics License Application to extend the approval of COMIRNATY to include the Omicron XBB.1.5-adapted monovalent COVID-19 vaccine for individuals 12 years of age and older and an application for an EUA for the Omicron XBB.1.5-adapted monovalent COVID-19 vaccine in individuals 6 months through 11 years of age, plans to submit an application to the European Medicines Agency for a variation of the Marketing Authorization for the Omicron XBB.1.5-adapted monovalent COVID-19 vaccine to also include the monovalent vaccine as a primary course of vaccination in individuals 6 months of age and older and planned regulatory submissions, 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; our expectations regarding the potential characteristics of BNT162b2, including the Omicron XBB.1.5-adapted monovalent COVID-19 vaccine, any other monovalent or bivalent vaccine candidates or any future vaccine, in our clinical trials and/or in commercial use based on data observations to date; the timing for submission of data for, or receipt of, any marketing approval or EUA; our contemplated shipping and storage plan, including our estimated product shelf life at various temperatures; and 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. 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 ability of BNT162b2, including any monovalent or bivalent vaccine candidates or any other 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 the Omicron XBB.1.5-adapted monovalent vaccine, any other monovalent or bivalent 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; the expected time point for additional readouts on efficacy data 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 ability of BioNTech to supply the quantities of BNT162, including any monovalent or bivalent vaccine candidates or any other future vaccine, to support clinical development and market demand; 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; our vaccine's formulation, dosing schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery by BioNTech or Pfizer; the ability to successfully develop other vaccine formulations, booster doses or potential future boosters or re-vaccinations or new variant-based vaccines; 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 any trial or in larger, more diverse populations; 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 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 will be reached; challenges related to public vaccine confidence or awareness; uncertainties regarding the impact of COVID-19 on BioNTech's trials, business and general operations; 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 March 31, 2023, filed with the U.S. Securities and Exchange Commission ("SEC") on May 8, 2023, 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.

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[i] *Centers for Disease Control and Prevention. COVID Data Tracker. Atlanta, GA: US Department of Health and Human Services, CDC. Available at: https://covid.cdc.gov/covid-data-tracker*

[ii] *Link-Gelles R, Ciesla AA, Roper LE, et al. 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. MMWR Morb Mortal Wkly Rep 2023;72:119–124. doi: http://dx.doi.org/10.15585/mmwr.mm7205e1*

[iii] *Khoury DS, Docken SS, Subbarao K, Kent SJ, Davenport MP, Cromer D. Predicting the efficacy of variant-modified COVID-19 vaccine boosters. Nature Medicine. 2023 Mar;29(3):574-8.*