Pfizer Logo

Pfizer and BioNTech Receive Positive CHMP Opinion for Omicron BA.4/BA.5-Adapted Bivalent COVID-19 Vaccine Booster for Children 5 Through 11 Years of Age in European Union

Thursday, November 10, 2022 - 09:45am

NEW YORK and MAINZ, GERMANY, NOVEMBER 10, 2022 — Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today announced a booster dose of their Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine (COMIRNATY® Original/Omicron BA.4/BA.5 5/5 µg) has been recommended for marketing authorization by the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) for children 5 through 11 years of age. The European Commission will review the CHMP recommendation and is expected to make a final decision soon.

The Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine is currently authorized in the European Union (EU) as a booster dose for individuals aged 12 years and older. Today's CHMP recommendation to include children 5 through 11 years of age was based on safety and immunogenicity data from the companies' Omicron BA.1-adapted bivalent vaccine in individuals 12 years and older, data from the initially approved 10-µg pediatric formulation of the companies' original COVID-19 vaccine, manufacturing data from the companies' pediatric formulation of the Omicron BA.4/BA.5-adapted bivalent vaccine, and preclinical data from the companies' Omicron BA.4/BA.5-adapted bivalent vaccine.

Recent clinical data from an ongoing Phase 2/3 trial of the companies' BA.4/BA.5-adapted bivalent booster in adults 18 years of age and older demonstrated a strong immune response against the BA.4 and BA.5 sublineages, measured 30 days after immunization, with a safety and tolerability profile is similar to the companies' original COVID-19 vaccine. In addition to this trial and the already submitted data, a Phase 1/2/3 pediatric study is ongoing that evaluates different dosing regimens and dose levels of the Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine across age groups. Data from both these trials will be shared with regulatory authorities around the world as soon as they become available.

COMIRNATY® and its adapted vaccine variations (COMIRNATY® Original/Omicron BA.1 and COMIRNATY® Original/Omicron BA.4-5) are based on BioNTech's proprietary mRNA technology and were developed by both BioNTech and Pfizer. BioNTech is the Marketing Authorization Holder for BNT162b2 Wild Type 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. Submissions to pursue regulatory approvals in those countries where emergency use authorizations or equivalent were initially granted are planned.

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 a vaccine approved 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 FDA-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 3-dose primary series to individuals 6 months through 4 years of age
- 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

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 for the Pfizer-BioNTech COVID-19 Vaccine and 5 years and older for the Pfizer-BioNTech COVID-19 Vaccine, Bivalent. 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
- Swollen lymph nodes (lymphadenopathy)
- Decreased appetite
- Diarrhea
- Vomiting
- Arm pain
- Fainting in association with injection of the vaccine
- Unusual and persistent irritability
- Unusual and persistent poor feeding
- Unusual and persistent fatigue or lack of energy
- Unusual and persistent cool, pale skin

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.
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 www.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.

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

EUA Fact Sheet for Vaccination Providers (12 Years & Up), BIVALENT (Original and Omicron BA.4/BA.5), DO NOT DILUTE, Gray Cap

EUA Fact Sheet for Vaccination Providers (5 through 11 Years), BIVALENT (Original and Omicron BA.4/BA.5), DO NOT DILUTE, Orange Cap

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), DO NOT DILUTE, Gray Cap

EUA Fact Sheet for Vaccination Providers (6 months through 4 years of age), DILUTE BEFORE USE, Maroon Cap

EUA Fact Sheet for Vaccination Providers (5 through 11 years of age), DILUTE BEFORE USE, Orange Cap

EUA Fact Sheet for Recipients and Caregivers (12 years of age and older)

EUA Fact Sheet for Recipients and Caregivers (5 through 11 years of age)

EUA Fact Sheet for Recipients and Caregivers (6 months through 4 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 November 10, 2022. 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 the Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), a submission pending with the EMA and a CHMP opinion for a booster dose of the Omicron BA.4/BA.5 adapted bivalent COVID-19 vaccine for children 5 through 11 years of age, updated data from an ongoing Phase 2/3 clinical trial, a Phase 1/2/3 pediatric study of the Omicron BA.4/BA.5 adapted bivalent COVID-19 vaccine, 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 from the Phase 2/3 trial 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 or bivalent vaccine candidates (including the submission pending with the EMA for a booster dose of the Omicron BA.4/BA.5 adapted bivalent COVID-19 vaccine for children 5 through 11 years of age), 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 additional 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 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 (including a submission pending with the EMA and a CHMP opinion for a 3-µg dose of COMIRNATY (COVID-19 vaccine, mRNA), which is based on the wild-type spike protein of SARS-CoV-2, as a three-dose series for children ages 6 months to less than 5 years (also referred to as 6 months through 4 years of age, a regulatory pathway for potential authorization of the companies’ Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine for use in children under 5 years of age and a Phase 1/2/3 pediatric study of the Omicron BA.4/BA.5 adapted bivalent COVID-19 vaccine, 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 in our clinical trials, real world data studies, and/or in commercial use based on data observations to date; 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, including 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, (including in children 6 months to less than 5 years of age, potential future annual boosters or re-vaccinations), or receipt of, any marketing approval or emergency use authorization or equivalent, including or 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; our contemplated shipping and storage plan, including our estimated product shelf life at various temperatures; the ability of BioNTech to supply the quantities of BNT162 and its adapted vaccine variations to support clinical development and market demand, including our production estimates for 2022; 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 or no longer exist which may lead to reduced revenues or excess inventory; the availability of raw material to manufacture BNT162 or other vaccine formulation; 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 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. These risks and uncertainties include, but are not limited to: 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 productions 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 June 30, 2022, filed with the SEC on August 8, 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.

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