Pfizer Logo

Pfizer and BioNTech Submit Application for U.S. Emergency Use Authorization for a COVID-19 Vaccine Booster Dose in Children 5 Through 11 Years of Age

Tuesday, April 26, 2022 - 04:30pm

NEW YORK and MAINZ, GERMANY, APRIL 26, 2022 — Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today submitted an application to the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) of a 10-µg booster dose of the Pfizer-BioNTech COVID-19 Vaccine for children 5 through 11 years of age (also referred to as children ages 5 through <12).

The submission included data from the Phase 2/3 clinical trial in children ages 5 through 11 years who received a booster dose approximately 6 months after the second dose of the Pfizer-BioNTech COVID-19 Vaccine 10-µg two-dose primary series, which was authorized under EUA for this age group in October 2021. Data from this study demonstrated a strong immune response in this age group following a booster dose of the Pfizer-BioNTech COVID-19 Vaccine with no new safety signals.

The companies also plan to submit these data to the European Medicines Agency (EMA) and other regulatory agencies around the world for authorization in the coming weeks.

The Pfizer-BioNTech COVID-19 Vaccine, which is based on BioNTech's proprietary mRNA technology, was developed by both BioNTech and Pfizer. BioNTech is the Marketing Authorization Holder in the United States, the European Union, the United Kingdom, Canada 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.

About the Phase 1/2/3 Trial in Children

The Phase 1/2/3 trial initially enrolled up to 4,500 children ages 6 months to under 12 years of age in the United States, Finland, Poland, and Spain from more than 90 clinical trial sites. Additional children have been enrolled in all age groups following study amendments and the trial currently includes more than 10,000 children. The trial was originally designed to evaluate the safety, tolerability, and immunogenicity of the Pfizer-BioNTech COVID-19 Vaccine on a two-dose schedule (approximately 21 days apart) in three age groups: ages 5 to under 12 years; ages 2 to under 5 years; and ages 6 months to under 2 years. Based on the Phase 1 dose-escalation portion of the trial, children ages 5 to under 12 years received a two-dose schedule of 10-µg each while children under age 5 received a lower 3-µg dose for each injection in the Phase 2/3 study. The trial enrolled children with or without prior evidence of SARS-CoV-2 infection. In December 2021, Pfizer and BioNTech announced the companies would test a third 3-µg dose given at least two months after the second dose in children under age 5 and a third dose of the 10-µg formulation in children 5 to under 12 years of age. The companies expect to share data from the ongoing study in children 6 months to under 5 years of age later this quarter.

U.S. Indication & Authorized Use

Pfizer-BioNTech COVID-19 Vaccine 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 5 years of age and older.
Pfizer-BioNTech COVID-19 Vaccine is FDA authorized 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

Booster Series

- a first booster dose to individuals 12 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY® (COVID-19 Vaccine, mRNA)
- a first booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized or approved COVID-19 vaccine. The booster schedule is based on the labeling information of the vaccine used for the primary series
- a second booster dose to individuals 50 years of age and older who have received a first booster dose of any authorized or approved COVID-19 vaccine
- a second booster dose to individuals 12 years of age and older with certain kinds of immunocompromise and who have received a first booster dose of any authorized or approved COVID-19 vaccine

COMIRNATY® 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 16 years of age and older.

- COMIRNATY® is administered as a 2-dose primary series

COMIRNATY® AUTHORIZED USES

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

Primary Series

- a 2-dose primary series to individuals 12 through 15 years of age
- a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise

Booster Dose

- a first booster dose to individuals 12 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY®
- a first booster dose to individuals 18 years of age and older who have completed primary vaccination with another authorized or approved COVID-19 vaccine. The booster schedule is based on the labeling information of the vaccine used for the primary series

- a second booster dose to individuals 50 years of age and older who have received a first booster dose of any authorized or approved COVID-19 vaccine
- a second booster dose to individuals 12 years of age and older with certain kinds of immunocompromise and who have received a first booster dose of any authorized or approved COVID-19 vaccine

Emergency Use Authorization

Emergency uses of the vaccine 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 either individuals 12 years of age and older, or in individuals 5 through 11 years of age, as appropriate. 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

FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine FDA-authorized for Emergency Use Authorization (EUA) for individuals 12 years of age and older can be used interchangeably by a vaccination provider when prepared according to their respective instructions for use.

The formulation of the Pfizer-BioNTech COVID-19 Vaccine authorized for use in children 5 through 11 years of age differs from the formulations authorized for individuals 12 years of age and older and should therefore not be used interchangeably. The Pfizer-BioNTech COVID-19 Vaccine authorized for use in children 5 through 11 years of age should not be used interchangeably with COMIRNATY® (COVID-19 Vaccine, mRNA).

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

• Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY® (COVID-19 Vaccine, mRNA) may not protect all vaccine recipients

• You should **not** receive Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY® (COVID-19 Vaccine, mRNA) if you have had a severe allergic reaction to any of its ingredients or had a severe allergic reaction to a previous dose of Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY®

• There is a remote chance that Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY® (COVID-19 Vaccine, mRNA) 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 the vaccine, more commonly in males under 40 years of age than among females and older males. In most of these people, symptoms began within a few days following receipt of the second dose of the vaccine. The chance of having this occur is very low

Seek medical attention right away if you have any of the following symptoms after receiving the vaccine:

- chest pain
- shortness of breath
- feelings of having a fast-beating, fluttering, or pounding heart

• Fainting can happen after getting injectable vaccines, including Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY® (COVID-19 Vaccine, mRNA). Sometimes people who faint can fall and hurt themselves. For this reason, your vaccination provider may ask you to sit or lie down for 15 minutes after receiving the vaccine

• Some people with weakened immune systems may have reduced immune responses to Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY® (COVID-19 Vaccine, mRNA)

• Additional side effects include 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; and fainting in association with injection of the vaccine

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.

- You 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. You can also report side effects to Pfizer Inc. at www.pfizersafetyreporting.com or by calling 1-800-438-1985

Click for Fact Sheets and Prescribing Information for individuals 5 years of age and older:

Recipients and Caregivers Fact Sheet (5 through 11 years of age)
Recipients and Caregivers Fact Sheet (12 years of age and older)
COMIRNATY® Full Prescribing Information (16 years of age and older), DILUTE BEFORE USE, Purple Cap
COMIRNATY® Full Prescribing Information (16 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 (12 years of age and older), DILUTE BEFORE USE, Purple Cap
EUA Fact Sheet for Vaccination Providers (12 years of age and older), DO NOT DILUTE, Gray Cap

About Pfizer: Breakthroughs That Change Patients' Lives
At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues

work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Pfizer Disclosure Notice
The information contained in this release is as of April 26, 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 an application submission to the FDA for EUA of a potential booster dose of the Pfizer-BioNTech COVID-19 Vaccine for children 5 through 11 years of age and planned submissions to other regulatory agencies, 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) 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 and further analyses of existing preclinical, clinical or safety data; the ability to produce comparable clinical or other results, including the rate of vaccine effectiveness and safety and tolerability profile observed to date, in additional analyses of the Phase 3 trial and additional studies, in real world data studies or in larger, more diverse populations following commercialization; the ability of BNT162b2 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 or any potential future vaccines (including potential submissions for a potential booster dose for children 5 through 11 years of age and 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 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 the application submission to the FDA for EUA of a potential booster dose for children 5 through 11 years of age or any requested amendments to the emergency use or conditional marketing

authorizations) 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; 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 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 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; 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, bi-specific checkpoint immuno-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.de.

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 an application submission to the FDA for EUA of a potential booster dose of the Pfizer-BioNTech COVID-19 Vaccine for children 5 through 11 years of age, who have previously received a two-dose primary series of the Pfizer-BioNTech COVID-19 vaccine, and planned submissions to other regulatory agencies, 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; 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 in our clinical trials; 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 BNT162, or any future vaccine, in additional populations, or receipt of, any marketing approval or emergency use authorization or equivalent, including or amendments or variations to such authorizations; 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 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; 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 Annual Report as Form 20-F for the Year Ended December 31, 2021, filed with the SEC on March 30, 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) 733-7410 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 Sylke Maas, Ph.D. +49 (0)6131 9084 1074 Investors@biontech.de