Pfizer Logo

Pfizer and BioNTech Receive U.S. FDA Emergency Use Authorization of COVID-19 Vaccine Booster for Individuals 12 Years of Age and Older

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- *First emergency use authorization in the United States for a COVID-19 vaccine booster in adolescents 12 through 15 years of age*
- *Today's FDA action also reduces time between completion of primary series and booster dose for all eligible individuals, and authorizes a third primary series dose for individuals 5 through 11 years of age with certain kinds of immunocompromise*
- *Pfizer and BioNTech fulfill their goal to deliver 1 billion doses of their COVID-19 vaccine to low- and middle-income countries in 2021*

NEW YORK & MAINZ, Germany--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today announced that the U.S. Food and Drug Administration (FDA) has expanded the Emergency Use Authorization (EUA) of a booster dose of the Pfizer-BioNTech COVID-19 Vaccine to include individuals 12 years of age and older. The booster dose is the same dosage strength (30-µg) as the dose approved in the primary series.

A booster dose of the Pfizer-BioNTech COVID-19 Vaccine was previously authorized by the FDA for emergency use after completion of a primary series in individuals 16 years of age and older. The vaccine is also authorized for eligible individuals 18 and older who have completed primary vaccination with a different authorized COVID-19 vaccine.

"The recent rise in COVID-19 cases is concerning to all and today's decision by the FDA to further expand the Emergency Use Authorization of a booster dose of our vaccine is critical to help us ultimately defeat this pandemic," said Albert Bourla, Chairman and Chief Executive Officer, Pfizer. "We continue to believe that broad use of boosters is essential to preserving a high level of protection against this disease and reducing the rate of hospitalizations."

"The booster vaccination increases the level of immunity and improves protection against COVID-19 across all age groups that have been authorized to receive one," said Ugur Sahin, M.D., CEO and Co-founder of BioNTech. "In the current situation, it is important to offer all eligible individuals a booster, particularly against the backdrop of the newly-emerging variants such as Omicron."

Real world evidence from the Ministry of Health of Israel on the administration of over 4.1 million third doses of the Pfizer-BioNTech COVID-19 Vaccine given at least 5 months after the primary series revealed no new safety concerns in adolescents 12 through 17 years of age.[1]

Additional EUA Amendments

Separately, the FDA is also amending the existing EUA to reduce the time for administration of a booster dose from at least six months to at least five months following completion of the primary series for individuals 12 years of age and older. The reduction of time between the primary series is supported by real world evidence from the Ministry of Health of Israel on the administration of third doses of the Pfizer-BioNTech COVID-19 Vaccine given at least 5 months after the primary series, which revealed no new safety concerns in adults.[1]

Finally, the FDA has expanded the current Emergency Use Authorization to include administration of a third primary series dose at least 28 days following the second dose for individuals 5 through 11 years of age who have who have been determined to have certain kinds of immunocompromise. This authorization is based on information extrapolated from an independent report evaluating safety and effectiveness of a third dose in adults who received solid organ transplants. A third primary dose of the Pfizer-BioNTech vaccine was previously authorized for administration to individuals at least 12 years of age who have been determined to have certain kinds of immunocompromise.

The companies continue to supply the vaccine, including booster doses, under their existing supply agreement with the U.S. government, which continues through April 2022. The companies do not expect that today's news will impact the existing supply agreements in place with governments and international health organizations around the world. As of December 29, 2021, Pfizer and BioNTech have delivered 1 billion doses of the Pfizer-BioNTech COVID-19 Vaccine to low- and middle-income countries. The companies expect to deliver an additional 1 billion doses to these nations in 2022. These doses are part of Pfizer and BioNTech's previously announced pledge to provide 2 billion doses of the COVID-19 vaccine to low- and middle-income countries between 2021 and 2022.

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 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

HOW IS THE VACCINE GIVEN?

The vaccine will be given as an injection into the muscle.

Primary Series:

In individuals 5 years of age and older, the vaccine is administered as a 2-dose series, 3 weeks apart. In individuals 5 years of age and older, a third primary series dose may be administered at least 28 days after the second dose to individuals who are determined to have certain kinds of immunocompromise.

Booster Dose:

- A single booster dose of the vaccine may be administered at least 5 months after completion of a primary series of the Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY® (COVID-19 Vaccine, mRNA) to individuals 12 years of age and older
- A single booster dose of the vaccine may be administered to individuals 18 years of age and older who have completed primary vaccination with a different authorized COVID-19 vaccine. Individuals should check with their healthcare provider regarding timing of the booster dose

WHAT IS THE INDICATION AND AUTHORIZED USE?

The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA to provide:

- 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 who have been determined to have certain kinds of immunocompromise
- a single 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 single booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized COVID-19 vaccine. The booster schedule is based on the labeling information of the vaccine used for the primary series

COMIRNATY® (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech.

- It is approved as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older
- It is also authorized under EUA to provide:
    - 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 who have been determined to have certain kinds of immunocompromise
    - a single 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 single booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized COVID-19 vaccine. The booster schedule is based on the labeling information of the vaccine used for the primary series

EUA Statement

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 individuals 5 years of age 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. Please see EUA Fact Sheets at www.cvdvaccine-us.com.

IMPORTANT SAFETY INFORMATION

Individuals should **not** get the vaccine if they:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

Individuals should tell the vaccination provider about all of their medical conditions, including if they:

- 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.

Side effects reported with the vaccine include:

- 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, vaccination providers may ask individuals to stay at the place where they received the vaccine for monitoring after vaccination
    - Signs of a severe allergic reaction can include difficulty breathing, swelling of the face and throat, a fast heartbeat, a bad rash all over the body, dizziness, and weakness
    - If an individual experiences a severe allergic reaction, they should call 9-1-1 or go to the nearest hospital
- 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. Individuals should seek medical attention right away if they 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
- Additional side effects that have been reported with the vaccine 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
- These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials. Call the vaccination provider or healthcare provider about bothersome side effects or side effects that do not go away

Data on administration of this vaccine at the same time as other vaccines have not yet been submitted to FDA. Individuals considering receiving this vaccine with other vaccines, should discuss their options with their healthcare provider.

Patients should always ask their healthcare providers for medical advice about adverse events. Individuals are encouraged to report negative side effects of vaccines to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Visit https://www.vaers.hhs.gov or call 1-800-822-7967. In addition, side effects can be reported to Pfizer Inc. at www.pfizersafetyreporting.com or by calling 1-800-438-1985.

Click for

Fact Sheets and Prescribing Information for individuals 12 years of age and older

Full Prescribing Information (16 years of age and older)

EUA Fact Sheet for Vaccination Providers (12 years of age and older), Purple Cap

EUA Fact Sheet for Vaccination Providers (12 years of age and older), Gray Cap

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

Fact Sheets for individuals 5 through 11 years of age

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

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 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 January 3, 2021. 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 emergency use authorization of a booster dose for individuals 12 years and older in the U.S., reduction of time between completion of primary series and booster dose, authorization of a third primary series does authorized for individuals 5 through 11 years old with certain kinds of immunocompromise, qualitative assessments of available data, potential benefits, expectations for clinical trials, supply agreements with the U.S. government, as well as governments and international health organizations around the world, and the timing of delivery of doses thereunder, 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 the Phase 3 data), 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 or in larger, more diverse populations following commercialization; the ability of BNT162b2 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 a potential booster dose, pediatric populations 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-specific 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) 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 new variant-specific vaccines; the risk that we may not be able to create 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, 2020 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, Bayer Animal Health, 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: a planned submission of a supplemental BLA for a potential booster dose of BNT162b2 in individuals 16 years of age and older, a supplemental BLA to support potential full FDA approval of BNT162b2 in individuals 12 through 15 years, 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 and/or in commercial use based on data observations to date; the ability of BNT162b2 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 risk of further widespread use of our 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; decisions by regulatory authorities that may impact labeling or marketing, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of our vaccine, including development of products or therapies by other companies; the timing for submission of data for, or receipt of, any marketing approval or Emergency Use Authorization; our contemplated shipping and storage plan, including our estimated product shelf life at various temperatures; disruptions in the relationships between us and our collaboration partners, clinical trial sites or other third-parties; risks related to the availability of raw materials to manufacture a vaccine; challenges related to our vaccine's formulation, two-dose schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery by BioNTech and third-party providers; the ability of BioNTech to supply the quantities of BNT162 to support clinical development and market demand, including our production estimates for 2021; whether and when additional supply agreements will be reached; challenges related to public vaccine confidence or awareness; and uncertainties regarding the impact of COVID-19 to 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, 2020, filed with the SEC on March 30, 2021, 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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[1] Ministry of Health of Israel. Division of Epidemiology. (December 15, 2021). Corona Vaccine Safety [PowerPoint presentation]. Vaccine Efficacy & Safety Follow-up Committee, Israel. https://www.gov.il/BlobFolder/reports/vaccine-efficacy-safety-follow-up-

committee/he/files_publications_corona_vaccine-safty-15122021.pdf

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

Source: Pfizer Inc.