Pfizer Logo

Pfizer and BioNTech Receive Positive CHMP Opinion for Omicron XBB.1.5-adapted COVID-19 Vaccine in the European Union

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- *The updated COVID-19 vaccine is tailored to the Omicron XBB.1.5 sublineage of SARS-CoV-2 and is recommended for individuals 6 months of age and older*
- *Recommendation based on pre-clinical data showing that the Omicron XBB.1.5-adapted monovalent COVID-19 vaccine generates an improved response against multiple XBB-related sublineages, including XBB.1.5, XBB.1.16, XBB.2.3, and EG.5.1 (Eris), which continue to dominate globally*[1]
- *Doses will be ready to ship to applicable EU member states immediately upon authorization by the European Commission*

NEW YORK & MAINZ, Germany--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended marketing authorization for the companies' Omicron XBB.1.5-adapted monovalent COVID-19 vaccine (COMIRNATY® Omicron XBB.1.5) administered as a single dose for individuals 5 years of age and older, regardless of prior COVID-19 vaccination history. The Committee has also recommended the updated vaccine for children 6 months through 4 years of age as part or all of the primary three-dose vaccination series, depending on how many prior doses they received, or as single dose for those with a history of completion of a COVID-19 primary vaccination course or prior SARS-CoV-2 infection.

This press release features multimedia. View the full release here:
https://www.businesswire.com/news/home/20230829323192/en/

The European Commission (EC) will review the CHMP's recommendation and is expected to make a final decision soon. Following a decision from the EC, the updated vaccine will be ready to ship to applicable EU member states immediately. Pfizer and BioNTech have been manufacturing the Omicron XBB.1.5-adapted monovalent COVID-19 vaccine at risk to ensure supply readiness ahead of the upcoming fall and winter season when the demand for COVID-19 vaccination is expected to increase.[2]

"This season's vaccine is ready to ship as soon as the final regulatory decision is made, so that people across Europe can better help protect themselves against COVID-19 illness as the risk rises," said Albert Bourla, Chairman and Chief Executive Officer at Pfizer. "It's been nearly a year since many citizens in the European Union were vaccinated against COVID-19 and the updated formulation provides the opportunity for them to receive a vaccine more closely matched to current sublineages."

"As COVID-19 is expected to adopt a seasonal pattern, similar to other respiratory viruses, we remain committed to providing COVID-19 vaccines that are better matched to relevant circulating variants or

sublineages to people worldwide, to support vaccinations in the upcoming fall and winter season," said Prof. Ugur Sahin, M.D., CEO and Co-founder of BioNTech. "Omicron XBB-related sublineages are antigenically distant from prior Omicron strains and continue to account for the vast majority of COVID-19 cases globally. The updated COVID-19 vaccine aims to further improve protection against severe illness and hospitalization."

The CHMP's recommendation is based on the full body of previous clinical, non-clinical, and real-world evidence supporting the safety and efficacy of the COVID-19 vaccines by Pfizer and BioNTech. Further, the application included pre-clinical data showing that the Omicron XBB.1.5-adapted monovalent COVID-19 vaccine generates a substantially improved response against multiple XBB sublineages, including XBB.1.5, XBB.1.16, and XBB.2.3, compared to the Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine. Additional pre-clinical data demonstrate that serum antibodies induced by the updated COVID-19 vaccine, when compared to the Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine, also effectively neutralize the globally dominant and recently WHO-designated variant of interest EG.5.1 (Eris).[3]

Pfizer and BioNTech have also filed an application with the U.S. Food and Drug Administration (FDA) requesting approval of their Omicron XBB.1.5-adapted monovalent COVID-19 vaccine for individuals 6 months of age and older. A decision is expected in the coming days. The companies have submitted data for the updated COVID-19 vaccine to other regulatory authorities around the world.

The COVID-19 vaccines (COMIRNATY®) by Pfizer and BioNTech are based on BioNTech's proprietary mRNA technology and were developed by both companies. BioNTech is the Marketing Authorization Holder for COMIRNATY and its adapted vaccines (COMIRNATY Original/Omicron BA.1; COMIRNATY 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.

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 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 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

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 X (twitter.com) and Pfizer Inc. (@pfizer_news) / X (twitter.com), Pfizer | LinkedIn, youtube.com/pfizer and like us on Facebook at Pfizer - Home | Facebook.

Pfizer Disclosure Notice

The information contained in this release is as of August 30, 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 Pfizer and –BioNTech's COVID-19 vaccines, defined collectively herein as COMIRNATY (including regulatory applications pending with the European Commission and the U.S. Food and Drug Administration (FDA) for an Omicron XBB.1.5-adapted monovalent COVID-19 vaccine, data submitted for an Omicron XBB.1.5-adapted monovalent COVID-19 vaccine to other regulatory authorities, qualitative assessments of available data, potential benefits, expectations regarding demand for COVID-19 vaccination, 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 or pre-clinical data for COMIRNATY, or any 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 vaccine candidate or any 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 vaccine candidate 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 vaccine candidate 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 vaccine candidates or any other potential vaccines that may arise from the BNT162 program, 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 and including the applications pending with the FDA and the European Commission for the Omicron XBB.1.5-adapted monovalent COVID-19 vaccine), any vaccine candidates 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; challenges related to and uncertainties regarding the timing of a transition to the commercial market for any of our products; uncertainties related to the public's adherence to vaccines and boosters; risks related to our ability to achieve our revenue forecasts for COMIRNATY or any potential future COVID-19 vaccines; 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 or potential combination respiratory 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 or purchase 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; pricing and access challenges; challenges related to public confidence in, or awareness of COMIRNATY; uncertainties around future changes to applicable healthcare policies and guidelines issued by the U.S. federal government in connection with the declared termination of the federal government's COVID-19 public health emergency as of May 11, 2023; trade restrictions; potential third party royalties or other claims; 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 (BioNTech) 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 CAR) T cells, several protein-based therapeutics, including bispecific immune checkpoint modulators, targeted cancer antibodies and antibody-drug conjugate (ADC) therapies, as well as 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, Fosun Pharma, Genentech, a member of the Roche Group, Genevant, Genmab, OncoC4, Regeneron, Sanofi, and Pfizer.

For more information, please visit www.BioNTech.com.

BioNTech Forward-looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not be limited to, statements concerning: BioNTech's efforts to combat COVID-19; the collaboration between BioNTech and Pfizer; the rate and degree of market acceptance of BioNTech's COVID-19 vaccine, including the Omicron XBB.1.5-adapted monovalent COVID-19 vaccine; qualitative assessments of available data and expectations of potential benefits; regulatory submissions and regulatory approvals or authorizations and expectations regarding manufacturing, distribution and supply; expectations regarding anticipated changes in COVID-19 vaccine demand, including changes to the ordering environment; and expected regulatory recommendations to adapt vaccines to address new variants or sublineages. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond BioNTech's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to: 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 data discussed in this release, and including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; BioNTech's pricing and coverage negotiations with governmental authorities, private health insurers and other third-party payors after BioNTech's initial sales to national governments; the future commercial demand and medical need for initial or booster doses of a COVID-19 vaccine; 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; competition from other COVID-19 vaccines or related to BioNTech's other product candidates, including those with different mechanisms of action and different manufacturing and distribution constraints, on the basis of, among other things, efficacy, cost, convenience of storage and distribution, breadth of approved use, side-effect profile and durability of immune response; 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; the timing of and BioNTech's ability to obtain and maintain regulatory approval for BioNTech's product candidates; the ability of BioNTech's COVID-19 vaccines to prevent COVID-19 caused by

emerging virus variants; BioNTech's and its counterparties' ability to manage and source necessary energy resources; BioNTech's ability to identify research opportunities and discover and develop investigational medicines; the ability and willingness of BioNTech's third-party collaborators to continue research and development activities relating to BioNTech's development candidates and investigational medicines; the impact of the COVID-19 pandemic on BioNTech's development programs, supply chain, collaborators and financial performance; unforeseen safety issues and potential claims that are alleged to arise from the use of BioNTech's COVID-19 vaccine and other products and product candidates developed or manufactured by BioNTech; BioNTech's and its collaborators' ability to commercialize and market BioNTech's COVID-19 vaccine and, if approved, its product candidates; BioNTech's ability to manage its development and expansion; regulatory developments in the United States and other countries; BioNTech's ability to effectively scale BioNTech's production capabilities and manufacture BioNTech's products, including BioNTech's target COVID-19 vaccine production levels, and BioNTech's product candidates; risks relating to the global financial system and markets; and other factors not known to BioNTech at this time.

You should review the risks and uncertainties described under the heading "Risk Factors" in BioNTech's Report on Form 6-K for the period ended June 30, 2023 and in subsequent filings made by BioNTech with the U.S. Securities and Exchange Commission ("SEC"), which are available on the SEC's website at www.sec.gov. Except as required by law, BioNTech disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on BioNTech's current expectations and speak only as of the date hereof.

[1] World Health Organization. COVID-19 Weekly Epidemiological Update. Available at: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports

[2] Wiemken TL, Khan F, Nguyen JL, Jodar L, McLaughlin JM. Is COVID-19 seasonal? A time series modeling approach. *medRxiv*. 2022:2022.06.17.22276570.

[3] World Health Organization. EG.5 Initial Risk Evaluation. Available at: https://www.who.int/docs/default-source/coronaviruse/09082023eg.5_ire_final.pdf?sfvrsn=2aa2daee_1

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