NEWS RELEASE

Pfizer and BioNTech Receive Positive CHMP Opinion for LP.8.1-adapted COVID-19 Vaccine in the European Union

2025-07-25

- Data indicate that the LP.8.1-adapted COVID-19 vaccine confers improved immune response against currently dominant and emerging sublineages – including the XFG and NB.1.8.1 variants1 – compared to 2024-2025 COVID-19 vaccine formulations
- Upon authorization by the European Commission (EC), the LP.8.1-adapted COVID-19 vaccine will be available for individuals 6 months of age and older
- To date, over a billion adults and children around the world have received the Pfizer-BioNTech COVID-19 vaccine, which continues to demonstrate a favorable safety and efficacy profile supported by extensive real-world evidence, clinical, non-clinical, pharmacovigilance and manufacturing data
- 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, "Pfizer") and **BioNTech SE** (Nasdaq: BNTX, "BioNTech") announced today that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has recommended marketing authorization for the companies' LP.8.1-adapted monovalent COVID-19 vaccine (COMIRNATY® LP.8.1) for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 6 months of age and older. The adaptation is based on the recommendation from the EMA's Emergency Task Force (ETF) to update COVID-19 vaccines to target the LP.8.1 variant for the 2025-2026 season. The ETF stated that "targeting LP.8.1 will help maintain the effectiveness of the vaccines as SARS-CoV-2 continues to evolve."2

The CHMP's recommendation will be reviewed by the European Commission (EC), which is expected to make its final decision soon. Pfizer and BioNTech have already initiated manufacturing of the LP.8.1-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. The updated vaccine will be available to ship to applicable EU member states immediately following the EC decision.

The CHMP's recommendation is based on the cumulative body of evidence previously submitted by Pfizer and BioNTech that includes clinical, non-clinical, and real-world data supporting the safety and efficacy of Pfizer and BioNTech COVID-19 vaccines. This application included non-clinical and manufacturing data showing that the LP.8.1-adapted monovalent COVID-19 vaccine generates overall improved immune responses against multiple circulating SARS-CoV-2 lineages, including XFG, NB.1.8.1, LF.7, and other currently circulating contemporary sublineages, compared to the companies' JN.1 and KP.2-adapted monovalent COVID-19 vaccines.1

The companies have also submitted data for the updated COVID-19 vaccine to regulatory authorities around the world. The companies are continuing to monitor the evolving epidemiology of COVID-19 in preparation to meet global public health needs.

The COVID-19 vaccines 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 in the United States, the European Union, the United Kingdom, and other countries, and the holder of emergency use authorizations or equivalents in the United States (jointly with Pfizer) and other countries.

US INDICATION, AUTHORIZED USE AND IMPORTANT SAFETY INFORMATION

US INDICATION

COMIRNATY® (COVID-19 Vaccine, mRNA) is a vaccine for use in people 12 years of age and older to protect against coronavirus disease 2019 (COVID-19).

IMPORTANT SAFETY INFORMATION

- You should NOT get COMIRNATY ®(COVID-19 Vaccine, mRNA) if you had a severe allergic reaction to a previous dose of COMIRNATY or any Pfizer-BioNTech COVID-19 vaccine or to any ingredient in these vaccines
- There is a remote chance that COMIRNATY could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to 1 hour after getting a dose. For this reason, your vaccination provider may ask you to stay at the place where you received the vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:
    - Difficulty breathing
    - Swelling of your 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 mRNA COVID-19 vaccines, including COMIRNATY and Pfizer-BioNTech COVID-19 vaccines. Myocarditis and pericarditis following administration of mRNA COVID-19 vaccines have occurred most commonly in males 12 years through 24 years of age. In most of these people, symptoms began within a week following vaccination. You should seek medical attention right away if you or your child have any of the following symptoms after receiving the vaccine, particularly during the 2 weeks after receiving a dose of 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 COMIRNATY. Your vaccination provider may ask you to sit or lie down
- People with weakened immune systems may have a reduced immune response to COMIRNATY
- COMIRNATY may not protect all people who receive the vaccine

Before getting COMIRNATY, tell your vaccination provider about all of your medical conditions, including if you:

- have any allergies
- had a severe allergic reaction after receiving a previous dose of any COVID-19 vaccine
- 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 your 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

Additional side effects that have been reported with COMIRNATY or Pfizer-BioNTech COVID-19 vaccines include:

- Non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- Injection site reactions: pain, swelling, redness, arm pain
- General side effects: tiredness, headache, muscle pain, chills, joint pain, fever, nausea, feeling unwell, swollen

lymph nodes (lymphadenopathy), decreased appetite, diarrhea, vomiting, dizziness

These may not be all the possible side effects of COMIRNATY. Ask your healthcare provider about any side effects that concern you.

You may report side effects to the FDA/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, you can report side effects to Pfizer Inc. at 1-800-438-1985 or **www.pfizersafetyreporting.com**

Please click here for full **Prescribing Information** and **Patient Information** for COMIRNATY

AUTHORIZED USE

Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula)* is FDA authorized under Emergency Use Authorization (EUA) to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 6 months through 11 years of age.

*Hereafter referred to as Pfizer-BioNTech COVID-19 Vaccine.

EMERGENCY USE AUTHORIZATION

Emergency uses of COVID-19 vaccines from BioNTech and Pfizer, including Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula), 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 6 months of age and older. Emergency uses are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical products 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

- Your child should NOT get Pfizer-BioNTech COVID-19 Vaccine if they had a severe allergic reaction after a previous dose of any Pfizer-BioNTech COVID-19 vaccine 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 one hour after getting a dose of the vaccine. For this reason, the vaccination provider may ask you to stay at the place where you received the vaccine for monitoring after vaccination. If your child experiences a severe allergic reaction, call 9-1-1, or go to the nearest hospital. 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, or 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 mRNA COVID-19 vaccines including Pfizer-BioNTech COVID-19 Vaccine. Myocarditis and pericarditis following administration of mRNA COVID-19 vaccines have occurred most commonly in males 12 years through 24 years of age. In most of these people, symptoms began within a week following vaccination. Seek medical attention right away if your child has any of the following symptoms after receiving the vaccine, particularly during the 2 weeks after receiving a dose of the vaccine:
    - 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. 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
- Pfizer-BioNTech COVID-19 Vaccine may not protect everyone
- Tell your vaccination provider about all of your child's medical conditions, including if your child:
    - has any allergies
    - has had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
    - has a fever
    - has a bleeding disorder or is on a blood thinner
    - is immunocompromised or is on a medicine that affects the immune system
    - is pregnant or is breastfeeding

    - has received another COVID-19 vaccine
    - has ever fainted in association with an injection
- Side effects that have been reported with Pfizer-BioNTech COVID-19 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/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
    - Febrile seizures (convulsions during a seizure)

These may not be all the possible side effects. Serious and unexpected side effects may occur. Call the vaccination provider or healthcare provider about bothersome side effects or side effects that do not go away.

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**. Please include "Pfizer-BioNTech COVID-19 Vaccine (2025-2026 Formula) EUA" in the first line of box #18 of the report form.

In addition, individuals can report side effects to Pfizer Inc. at **www.pfizersafetyreporting.com** or by calling 1-800-438-1985.

Please click here for **Pfizer-BioNTech COVID-19 Vaccine Healthcare Providers Fact Sheet** and **Vaccine Recipient and Caregiver EUA Fact Sheet**.

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 175 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 X 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 July 24, 2025. 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 Omicron-adapted monovalent COVID-19 vaccine candidate, based on the LP.8.1 lineage, including the receipt of a positive CHMP opinion from the European Medicines Agency (EMA) for an Omicron-adapted monovalent COVID-19 vaccine, based on the LP.8.1 lineage, expectations regarding the demand for COVID-19 vaccines, planned regulatory submissions, qualitative assessments of available data, potential benefits, expectations for clinical trials, potential regulatory submissions, the anticipated timing of data readouts, regulatory submissions, regulatory approvals or authorizations and anticipated availability, 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), any monovalent or bivalent

vaccine candidates or any other vaccine candidate in the BNT162 program in any of our studies in pediatrics, adolescents, or adults or real world evidence, including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the 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 or bivalent 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-vaccination), 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, 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; risks and uncertainties related to potential changes to vaccine or other healthcare policy in the U.S.; the risk that demand for any products may be reduced or no longer exist or not meet expectations which may lead to reduced revenues or excess inventory on-hand and/or in the channel; uncertainties related to recommendations and coverage for, and the public's adherence to vaccines, boosters, treatments or combinations; risks related to our ability to accurately predict or achieve our revenue forecasts for our COVID-19 vaccine or any potential future COVID-19 vaccines; potential third-party royalties or other claims related to our COVID-19 vaccine; 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 vaccines or combination 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 or maintain recommendations from vaccine advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations, including uncertainties related to the potential impact of narrowing recommended patient populations; challenges related to public vaccine confidence or awareness; risks and uncertainties related to issued or future executive orders or other new, or changes in, laws or regulations; 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, 2024 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 global next generation immunotherapy company pioneering novel investigative therapies for cancer and other serious diseases. BioNTech exploits a wide array of computational discovery and therapeutic modalities with the intent of rapid development of novel biopharmaceuticals. Its diversified portfolio of oncology product candidates aiming to address the full continuum of cancer includes mRNA cancer immunotherapies, next-generation immunomodulators and targeted therapies such as antibody-drug conjugates (ADCs) and innovative chimeric antigen receptor (CAR) T cell therapies. Based on its deep expertise in mRNA development and in-house manufacturing capabilities, BioNTech and its collaborators are researching and 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 and specialized pharmaceutical collaborators, including Bristol Myers Squibb, Duality Biologics, Fosun Pharma, Genentech, a member of the Roche Group, Genevant, Genmab, MediLink, OncoC4, Pfizer and Regeneron.
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 LP.8.1-adapted monovalent COVID-19 vaccine; qualitative assessments of available data and expectations of potential benefits, including the adapted vaccine's response against multiple SARS-CoV-2 lineages, including NB.1.8.1 and other currently circulating sublineages; 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 impact of tariffs and escalations in trade policy; 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 COVID-19 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 related expenses; 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 March 31, 2025, and in subsequent filings made by BioNTech with the SEC, which are available on the SEC's website at **www.sec.gov**. These forward-looking statements speak only as of the date hereof. 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.

[Category: Vaccines]

1 Vaccines and Related Biological Products Advisory Committee. 22 May 2025. Meeting Presentation- 2025-2026 COVID-19 Vaccine Formula: Pfizer/BioNTech Supportive Data. Available at: **https://www.fda.gov/media/186597/download**. Accessed 13 June 2025.
2 European Medicines Agency (EMA) ETF recommends updating COVID-19 vaccines to target new LP.8.1. 16 May 2025. Available at: **https://www.ema.europa.eu/en/news/etf-recommends-updating-covid-19-vaccines-target-new-lp81-variant**. Accessed 13 June 2025.

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