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# Pfizer and BioNTech Announce Topline Data Demonstrating Robust Immune Response With Their LP.8.1-Adapted COVID-19 Vaccine 2025-2026 Formula

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- *Phase 3 clinical trial cohort of adults 65+ and 18-64 with at least one underlying risk condition shows at least a 4-fold increase in LP.8.1-neutralizing antibody titers after receiving the LP.8.1-adapted COVID-19 vaccine 2025-2026 Formula*
- *First LP.8.1 sublineage clinical findings reinforce pre-clinical data supporting recent FDA approval of 2025-2026 Formula of Pfizer-BioNTech COVID-19 Vaccine*
- *Companies have submitted these data to the FDA*

NEW YORK & MAINZ, Germany--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE, “Pfizer”) and BioNTech SE (Nasdaq: BNTX, “BioNTech”) today announced positive topline results from an ongoing Phase 3 clinical trial cohort evaluating the safety, tolerability, and immunogenicity of a 30-µg dose of the LP.8.1-adapted monovalent COMIRNATY® (COVID-19 Vaccine, mRNA) 2025-2026 Formula in adults aged 65 and older and in adults aged 18 through 64 with at least one underlying risk condition for severe COVID-19. The preliminary data show a robust increase in neutralizing antibodies targeting the LP.8.1 sublineage of SARS-CoV-2 following vaccination. These clinical findings reinforce pre-clinical data that supported the recent U.S. Food and Drug Administration (FDA) approval of the LP.8.1-adapted COVID-19 vaccine, which demonstrated improved immune responses against multiple circulating SARS-CoV-2 sublineages.

A total of 100 participants were enrolled in the open-label Phase 3 trial cohort, 50 adults aged 65 and older and 50 adults aged 18-64 with at least one underlying risk condition for severe COVID-19. Prior to receiving the LP.8.1-adapted COVID-19 vaccine 2025-2026 Formula, all participants had received the KP.2-adapted COVID-19 vaccine at least six months prior to enrollment and had not received any other COVID-19 vaccine or had COVID-19 disease since the KP.2 vaccination through enrollment in the study. Data from evaluable participants showed that the LP.8.1-adapted COVID-19 vaccine elicited a robust immune response against the LP.8.1 sublineage. In both age groups, 14 days following vaccination, LP.8.1-neutralizing antibody titers exceeded pre-vaccination levels, on average, by at least 4-fold. The safety profile of the vaccine was consistent with previous studies, with no new safety concerns identified.

The favorable neutralizing antibody responses and consistent safety profile of the LP.8.1-adapted vaccine for individuals with higher risk and who had been previously exposed to SARS-CoV-2 provide early information for prescribers for this year’s vaccination period. This study was conducted to provide additional information about immunological effects of the vaccine and is not intended to replace the post marketing commitments requested by the FDA.

To date, 5 billion doses have been distributed globally of the Pfizer-BioNTech COVID-19 vaccine, which continues to demonstrate a favorable safety and efficacy profile supported by extensive real-world evidence as well as by clinical, non-clinical, pharmacovigilance, and manufacturing data. 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 other countries.

## U.S. INDICATION AND IMPORTANT SAFETY INFORMATION

### INDICATION

COMIRNATY (COVID-19 VACCINE, mRNA) is a vaccine to protect against coronavirus disease 2019 (COVID-19).

COMIRNATY is for people who are:

- 65 years of age and older, or
- 5 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.

### IMPORTANT SAFETY INFORMATION

- You or your child should **NOT** get COMIRNATY ®(COVID-19 Vaccine, mRNA) if you or your child had a severe allergic reaction after 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, the vaccination provider may ask you or your child to stay at the place where you or your child 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
- 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 COMIRNATY, 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
    - Additional symptoms, particularly in children, may include:
        - Fainting
        - 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 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
- Vaccination with COMIRNATY may not protect all people who receive the vaccine

**Before getting COMIRNATY, tell your vaccination provider about all of your or your child's medical conditions, including if you or your child:**

- 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
- Febrile seizures (convulsions during a fever) in children 5 through 11 years of age

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

You may report side effects to 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.

**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 September 8, 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 positive topline results from an ongoing, non-pivotal Phase 3 clinical trial cohort evaluating the safety, tolerability, and immunogenicity of a 30-µg dose of the LP.8.1-adapted monovalent COMIRNATY® (COVID-19 Vaccine, mRNA) 2025-2026 Formula in adults ages 65 years and older and in adults ages 18 through 64 years with at least one underlying risk condition for severe COVID-19, qualitative assessments of available data, potential benefits, expectations for clinical trials, potential regulatory submissions 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), including the data discussed in this release for BNT162b2, 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 emergency use or conditional marketing authorizations), any monovalent or bivalent vaccine candidates (including the submissions to regulatory authorities for the COVID-19 vaccine tailored to the KP.2 sublineage of the SARS-CoV-2 Omicron JN.1 lineage), 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 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 or other unanticipated charges; 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 June 30, 2025, and in subsequent filings made by BioNTech with the SEC, which are available on the SEC's website at https://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.

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