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Pfizer and BioNTech Receive Positive CHMP Opinion for Omicron KP.2-adapted COVID-19 Vaccine in the European Union

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- *Upon authorization by the European Commission (EC), the Omicron KP.2-adapted COVID-19 vaccine will be available for individuals 6 months of age and older*
- *Data demonstrate that the Omicron KP.2-adapted COVID-19 vaccine generates a substantially improved response against multiple circulating Omicron JN.1 sublineages as did the Omicron JN.1-adapted COVID-19 vaccine authorized by the European Commission (EC) in July 2024*
- *Doses will be ready to ship to applicable European Union (EU) member states as soon as possible upon European Commission (EC) authorization*

NEW YORK & MAINZ, Germany--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE, "Pfizer") and BioNTech SE (Nasdaq: BNTX, "BioNTech") 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 KP.2-adapted monovalent COVID-19 vaccine (COMIRNATY ® KP.2) for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 6 months of age and older. The European Commission will review the CHMP's recommendation and is expected to make a final decision soon. Following the EC decision, Pfizer and BioNTech's Omicron KP.2-adapted COVID-19 vaccine will ship to European Union (EU) member states that have specifically ordered this formulation.

The CHMP recommendation dated September 19, 2024 is based on the non-clinical and manufacturing data of the Omicron KP.2-adapted vaccine and the clinical and real-world evidence supporting the safety and efficacy of prior formulas of the COVID-19 vaccines by Pfizer and BioNTech. The non-clinical data showed that the KP.2-adapted vaccine generates a substantially improved response against multiple currently circulating Omicron JN.1 sublineages, including KP.2, LB.1, KP.3 and KP.3.1.1, compared with the companies' Omicron XBB.1.5-adapted COVID-19 vaccine. [1]

In July 2024, the EC granted marketing authorization for Pfizer and BioNTech's Omicron JN.1-adapted COVID-19 vaccine. This authorization was based on evidence showing that the JN.1-adapted COVID-19 vaccine generates a substantially improved response against multiple Omicron JN.1 sublineages, including KP.2, LB.1, KP.3 and KP.3.1.1, as compared with the companies' Omicron XBB.1.5-adapted COVID-19 vaccine.

Pending authorization of the Omicron KP.2-adapted vaccine by the EC, both the Omicron KP.2-adapted vaccine and the Omicron JN.1-adapted vaccine will be available across the EU, though availability will vary based on individual country government requests and national recommendations.

In the United States, the U.S. Food and Drug Administration approved the companies' Omicron KP.2-adapted COVID-19 vaccine for individuals 12 years of age and older and granted emergency use authorization for individuals 6 months through 11 years of age on August 22, 2024. Pfizer and BioNTech will continue to monitor the evolving epidemiology of COVID-19 and remain prepared to develop modified vaccine formulas, as the data support and as regulatory agencies recommend.

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 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.

INDICATION, AUTHORIZED USE AND IMPORTANT SAFETY INFORMATION

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 COMIRNATY have occurred most commonly in adolescent males 12 through 17 years of age. In most of these individuals, symptoms began within a few days following vaccination. The chance of having this occur is very low. 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, 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. If it is not currently available via these links, it will be visible as soon as possible as we work to finalize the documents. Please check back for the full information shortly.

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. Myocarditis and pericarditis following Pfizer-BioNTech COVID-19 vaccines have occurred most commonly in adolescent males 12 through 17 years of age. In most of these individuals, symptoms began within a few days following vaccination. The chance of having this occur is very low. **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
    - Arm pain
    - Fainting in association with injection of the vaccine
    - Chills
    - Joint pain
    - Fever
    - Injection site swelling
    - Injection site redness
    - Nausea
    - Feeling unwell
    - Swollen lymph nodes (lymphadenopathy)
    - Decreased appetite
    - Diarrhea
    - Vomiting
    - 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 (2024-2025 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 . If it is not currently available via these links, it will be visible as soon as possible as we work to finalize the documents. Please check back for the full information shortly.

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 19, 2024. 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 KP.2 strain of the JN.1 lineage, including a positive Committee for Medicinal Products for Human Use (CHMP) opinion for an Omicron KP.2-adapted COVID-19 vaccine in the European Union, 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), 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 the emergency use or conditional marketing authorizations), any monovalent or bivalent vaccine candidates (including any submissions to regulatory authorities for the COVID-19 vaccine tailored to the KP.2 strain 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; 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 which, for our COVID-19 vaccine, resulted in significant inventory write-offs in 2023 and could continue to result in inventory write-offs, or other unanticipated charges; challenges related to the transition to the commercial market for our COVID-19 vaccine; uncertainties related to 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 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, 2023 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 therapies for cancer and other serious diseases. BioNTech 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) therapeutics, 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 and specialized pharmaceutical collaborators, including Biotheus, DualityBio, 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 Omicron KP.2-adapted monovalent COVID-19 vaccine; qualitative assessments of available data and expectations of potential benefits, including the adapted vaccine's response against multiple currently circulating Omicron JN.1 sublineages, including KP.2, LB.1, KP.3 and KP.3.1.1; 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, 2024, 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.

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[1] Vaccines and Related Biological Products Advisory Committee June 5, 2024 Meeting Presentation-Pfizer/BioNTech Clinical and Preclinical Supportive Data 2024-2025 COVID19 Vaccine Formula. https://www.fda.gov/media/179144/download . Accessed 23 August 2024.

Pfizer:
Media Relations
+1 (212) 733-1226
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
Victoria Meissner, M.D.
Investors@biontech.de

Source: Pfizer Inc.