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

September 20, 2024

- *Upon authorization by the European Commission, 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 in July 2024*
- *Doses will be ready to ship to applicable European Union member states as soon as possible upon European Commission authorization*

NEW YORK and MAINZ, GERMANY, SEPTEMBER 20, 2024 —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 ("EC") 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.

AUTHORIZED USE IN THE EU:

COMIRNATY® ▼ has been granted standard marketing authorization (MA) by the European Commission to prevent coronavirus disease 2019 (COVID-19) in individuals from the age of 6 months. The vaccine is administered as a single dose in people 5 years of age and older, and as a three-dose series, in infants and children from 6 months to 4 years who have not had COVID-19 with the first two doses are given three weeks apart, followed by a third dose given at least 8 weeks after the second dose. Adults and adolescents from the age of 12 are given 30 micrograms per dose; children aged 5 to 11 years are given 10 micrograms per dose; infants and children aged 6 months to 4 years are given 3 micrograms per dose. Additional doses may be administered to individuals aged 5 years and older who are severely immunocompromised in accordance with national recommendations. The European Medicines Agency's (EMA's) Committee for Medicinal Products for Human Use (CHMP) has completed its rigorous evaluation of COMIRNATY, concluding by consensus that sufficiently robust data on the quality, safety and efficacy of the vaccine are available.

COMIRNATYJN.1 contains mRNA encoding for the spike protein of the JN.1 subvariant of SARS-CoV-2.

COMIRNATY JN.1may be administered as a single dose regardless of prior vaccination status in people aged 5 years and older. Children from 6 months to 4 years of age may have one or three doses depending on whether they have completed a primary vaccination course or have had COVID-19. There should be an interval of at least 3 months between administration of COMIRNATY JN.1 and the last prior dose of a COVID-19 vaccine.

IMPORTANT SAFETY INFORMATION

- Events of anaphylaxis have been reported. Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of the vaccine.
- There is an increased, but very rare risk (<1/10,000 cases) of myocarditis and pericarditis following vaccination with COMIRNATY. These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males. Available data

indicate that most cases recover. Some cases required intensive care support and fatal cases have been observed.

- From post-marketing experience very rare adverse reactions of myocarditis and pericarditis, uncommon incidence of dizziness; common incidence of vomiting, very common diarrhoea and unknown incidence (cannot be estimated from available data) of, paraesthesia, hypoaesthesia and erythema multiforme, extensive swelling of vaccinated limb, facial swelling (in vaccine recipients with a history of injection of dermatological fillers) have been identified.
- Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions (e.g. dizziness, palpitations, increases in heart rate, alterations in blood pressure, paresthesia, hypoesthesia and sweating) may occur in association with the vaccination process itself. Stress-related reactions are temporary and resolve on their own. Individuals should be advised to bring symptoms to the attention of the vaccination provider for evaluation. It is important that precautions are in place to avoid injury from fainting.
- Vaccination should be postponed in individuals suffering from acute severe febrile illness or acute infection. The presence of a minor infection and/or low-grade fever should not delay vaccination.
- As with other intramuscular injections, the vaccine should be given with caution in individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following an intramuscular administration in these individuals.
- The efficacy, safety and immunogenicity of the vaccine has not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy. The efficacy of COMIRNATY JN.1may be lower in immunosuppressed individuals.
- As with any vaccine, vaccination with COMIRNATY JN.1 may not protect all vaccine recipients. Individuals may not be fully protected until 7 days after their vaccination.
- Adverse reactions observed during clinical studies and identified after post authorization experience are listed below according to the following frequency categories: Very common (≥ 1/10), Common (≥ 1/100 to < 1/10), Uncommon (≥ 1/1,000 to < 1/100), Rare (≥ 1/10,000 to < 1/1,000), Very rare (< 1/10,000).
    - Very common side effects: injection site pain, injection site swelling, fever, chills, fatigue, headache, muscle pain, joint pain, diarrhea.
    - Common side effects: injection site redness, nausea, vomiting, enlarged lymph nodes (more frequently observed after a booster dose).
    - Uncommon side effects: feeling unwell, arm pain, insomnia, dizziness, injection site itching, allergic reactions such as rash, itching, feeling weak or lack of energy/sleepy, decreased appetite, excessive sweating, night sweats.
    - Rare side effects: temporary one-sided facial drooping, allergic reactions such as hives or swelling of the face.
    - Very rare side effects: inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis), which can result in breathlessness, palpitations or chest pain.
    - Not known incidence (cannot be estimated from the available data): anaphylaxis, extensive swelling of vaccinated limbs; facial swelling, pins and needles/tingling, reduced sense of touch or sensation, a skin reaction that causes red spots or patches on the skin, heavy menstrual bleeding.
- Overdose data is available from 52 study participants included in the clinical trial that due to an error in dilution received 58 micrograms of COMIRNATY. The vaccine recipients did not report an increase in reactogenicity or adverse reactions. In the event of overdose, monitoring of vital functions and possible symptomatic treatment is recommended.
- A large amount of observational data from pregnant women vaccinated with the initially approved COMIRNATY vaccine during the second and third trimester have not shown an increase in adverse pregnancy outcomes. While data on pregnancy outcomes following vaccination during the first trimester are presently limited, no increased risk for miscarriage has been seen. No data are available yet regarding the use of COMIRNATY JN.1during pregnancy. Based on data available with other vaccine variants, COMIRNATY JN.1can be used during pregnancy.
- No data are available yet regarding the use of COMIRNATY JN.1during breast-feeding. Observational data from women who were breast-feeding after vaccination with the initially approved COMIRNATY vaccine have not shown a risk for adverse effects in breast-fed newborns/infants. COMIRNATY JN.1can be used during breast-feeding.
- Interactions with other medicinal products or concomitant administration of COMIRNATY JN.1with other vaccines has not been studied in 3 mcg and 10 mcg dose. For 30 mcg dose, COMIRNATY JN.1may be administered concomitantly with seasonal influenza vaccine. Different injectable vaccines should be given at different injection sites.
- Animal studies with COMIRNATY Original do not indicate direct or indirect harmful effects with respect to reproductive toxicity.
- The most frequent adverse reactions in infants 6 to 23 months of age that received any primary course dose included irritability (> 60%), drowsiness (> 40%), decreased appetite (> 30%), tenderness at the injection site (> 20%), injection site redness and fever (> 10%).
- The most frequent adverse reactions in children 2 to 4 years of age that received any primary course dose included pain at injection site and fatigue (> 40%), injection site redness and fever (> 10%).
- The overall safety profile of COMIRNATY in participants 5 to 11 years of age was similar to that seen in participants 16 years of age and older. The most frequent adverse reactions in children 5 to 11 years of age that received 2 doses were injection site pain (> 80%), fatigue (> 50%), headache (> 30%), injection site redness and swelling (≥ 20%), myalgia, chills, and diarrhoea (> 10%).

- The overall safety profile for the booster dose was similar to that seen after the primary course. The most frequent adverse reactions in children 5 to 11 years of age were injection site pain (> 60%), fatigue (> 30%), headache (> 20%), myalgia, chills, injection site redness and swelling (> 10%)
- The overall safety profile of COMIRNATY in adolescents 12 to 15 years of age was similar to that seen in participants 16 years of age and older. The most frequent adverse reactions in adolescents 12 to 15 years of age that received 2 doses were injection site pain (> 90%), fatigue and headache (> 70%), myalgia and chills (> 40%), arthralgia and pyrexia (> 20%).
- The most frequent adverse reactions in participants 16 years of age and older that received 2 doses were injection site pain (> 80%), fatigue (> 60%), headache (> 50%), myalgia (> 40%), chills (> 30%), arthralgia (> 20%), pyrexia and injection site swelling (> 10%) and were usually mild or moderate in intensity and resolved within a few days after vaccination. A slightly lower frequency of reactogenicity events was associated with greater age.
- The safety profile for the booster dose (third dose) was similar to that seen after 2 doses. The most frequent adverse reactions in participants 18 to 55 years of age were injection site pain (> 80%), fatigue (> 60%), headache (> 40%), myalgia (> 30%), chills and arthralgia (> 20%).
- The safety profile for the COMIRNATY Original/Omicron BA.4-5 booster (fourth dose) was similar to that seen after 3 doses. The most frequent adverse reaction in participants 6 to 23 months of age was irritability (> 20%), decreased appetite (> 10%), and drowsiness (> 10%). The most frequent adverse reactions in participants 2 to 4 years of age were injection site pain (> 30%) and fatigue (> 20%). The most frequent adverse reactions in participants 5 to 11 years of age were injection site pain (> 60%), fatigue (> 40%), headache (> 20%), and muscle pain (> 10%). The most frequent adverse reactions in participants 12 years of age and older were injection site pain (> 60%), fatigue (> 50%), headache (> 40%), muscle pain (> 20%), chills (> 10%), and joint pain (> 10%).
- The safety of COMIRNATY JN.1 is inferred from safety data of the prior COMIRNATY vaccines.
- The duration of protection afforded by the vaccine is unknown as it is still being determined by ongoing clinical trials. As with any vaccine, vaccination with COMIRNATY JN.1may not protect all vaccine recipients.
- For complete information on the safety of COMIRNATY JN.1, always make reference to the approved Summary of Product Characteristics and Package Leaflet available in all the languages of the European Union on the EMA website.

The black equilateral triangle ▼ denotes that additional monitoring is required to capture any adverse reactions. This will allow quick identification of new safety information. Individuals can help by reporting any side effects they may get. Side effects can be reported to EudraVigilance or directly to BioNTech using email medinfo@biontech.de, telephone +49 6131 9084 0, or via the website www.biontech.de

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 20, 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.