Pfizer and BioNTech Receive Positive CHMP Opinion for COMIRNATY® in Children 6 Months to less than 5 Years in the European Union

October 19, 2022

NEW YORK and MAINZ, Germany, October 19, 2022 —Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has recommended marketing authorization (MA) for a 3-µg dose of COMIRNATY® (COVID-19 vaccine, mRNA), which is based on the wild-type spike protein of SARS-CoV-2, as a three-dose series for children ages 6 months to less than 5 years (also referred to as 6 months through 4 years of age). The European Commission will review the CHMP recommendation and is expected to make a final decision soon.

Today's recommendation is based on data from a Phase 2/3 randomized, controlled trial that included 4,526 children aged 6 months to less than 5 years. In the trial, children received a third 3-µg dose of the original Pfizer-BioNTech COVID-19 Vaccine at least two months after the second dose at a time when Omicron BA.2 was the predominant variant. Following the third dose in this age group, the companies' original COVID-19 vaccine was found to be 73.2% (2-sided 95% CI: 43.8%, 87.6%) effective at preventing COVID-19, with a favorable safety profile similar to placebo. The 3-µg dose was carefully selected as the preferred dose for children under 5 years of age based on safety, tolerability, and immunogenicity.

The U.S. Food and Drug Administration (FDA) granted emergency use authorization (EUA) of the original Pfizer-BioNTech COVID-19 Vaccine as a three 3-µg dose series in this age group in June 2022. Submissions to other regulatory agencies around the world are ongoing.

Pfizer and BioNTech are also in discussions with health authorities regarding a regulatory pathway for potential authorization of their Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine for use in children under 5 years of age. A Phase 1/2/3 pediatric study was initiated in September 2022 to evaluate different dosing regimens and dose levels of the Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine across age groups.

COMIRNATY® and its adapted vaccine variations (COMIRNATY® Original/Omicron BA.1 and COMIRNATY® Original/Omicron BA.4-5) are based on BioNTech's proprietary mRNA technology and were developed by both BioNTech and Pfizer. BioNTech is the Marketing Authorization Holder in the United States, the European Union, the United Kingdom, Canada and the holder of emergency use authorizations or equivalents in the United States (jointly with Pfizer) and other countries. Submissions to pursue regulatory approvals in those countries where emergency use authorizations or equivalent were initially granted are planned.

About the Phase 1/2/3 Trial in Children for the Original Pfizer-BioNTech COVID-19 Vaccine

The Phase 1/2/3 trial (NCT04816643) has enrolled more than 10,000 children ages 6 months to under 12 years of age in the United States, Finland, Poland, Spain and Brazil from more than 90 clinical trial sites. The trial evaluated the safety, tolerability, and immunogenicity of the original Pfizer-BioNTech COVID-19 Vaccine in three age groups: ages 5 to less than12 years; ages 2 to less than 5 years; and ages 6 months to less than 2 years. Based on the Phase 1 dose-escalation portion of the trial, children ages 5 to less than 12 years received a two-dose schedule of 10 µg each while children under age 5 received three lower 3-µg doses in the Phase 2/3 study. The trial enrolled children with or without prior evidence of SARS-CoV-2 infection.

AUTHORIZED USE IN THE EU:

COMIRNATY® ▼ (the Pfizer-BioNTech COVID-19 vaccine) has been granted standard marketing authorization (MA) by the European Commission to prevent coronavirus disease 2019 (COVID-19) in people aged 5 years and older. The vaccine is administered as a 2-dose series, 3 weeks apart. 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. In addition, the MA has been expanded to include a booster dose (third dose) at least 3 months after the second dose in individuals 12 years of age and older. A third primary course dose may be administered at least 28 days after the second dose to people aged 5 years and older with a severely weakened immune system. 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 now available.

In addition, COMIRNATY has also been granted standard MA for two adapted vaccines: COMIRNATY Original/Omicron BA.1, which contains mRNA encoding for the spike protein of the wild-type and of the Omicron BA.1 subvariant of SARS-CoV-2; and COMIRNATY Original/Omicron BA.4-5, which contains mRNA encoding for the spike protein of the wild-type and of the Omicron BA.4/BA.5 subvariant of SARS-CoV-2. COMIRNATY Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 may be administered as a booster in people aged 12 years and older who have received at least a primary vaccination course against COVID-19. There should be an interval of at least 3 months between administration of COMIRNATY Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 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 suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis or pericarditis in general. The risk of myocarditis after a booster dose of COMIRNATY, COMIRNATY Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 has not yet been characterized.
- Rare cases of acute peripheral facial paralysis; uncommon incidence of insomnia, hyperhidrosis and night sweats; and unknown incidence of paraesthesia, hypoaesthesia and erythema multiforme have been identified in post-marketing experience.

- Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions (e. g. dizziness, palpitations, increases in heart rate, alterations in blood pressure, tingling sensations 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, COMIRNATY Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 may be lower in immunosuppressed individuals.
- As with any vaccine, vaccination with COMIRNATY, COMIRNATY Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 may not protect all vaccine recipients. Individuals may not be fully protected until 7 days after their second dose of the vaccine.
- Adverse reactions observed during clinical studies 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, tiredness, headache, muscle pain, chills, joint pain, diarrhea, fever
    - Common side effects: injection site redness, nausea, vomiting
    - Uncommon side effects: enlarged lymph nodes (more frequently observed after the booster dose), feeling unwell, arm pain, insomnia, injection site itching, allergic reactions such as rash or 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, 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
- 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. COMIRNATY can be used during pregnancy. No effects on the breast-fed newborn/infant are anticipated since the systemic exposure of breast-feeding woman to the initially approved COMIRNATY vaccine is negligible. Observational data from women who were breast-feeding after vaccination have not shown a risk for adverse effects in breast-fed newborns/infants. COMIRNATY can be used during breast-feeding.
- No data are available yet regarding the use of COMIRNATY Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 during pregnancy. Since differences between products are confined to the spike protein sequence, and there are no clinically meaningful differences in reactogenicity between those COMIRNATY variant-adapted vaccines that have been clinically evaluated, COMIRNATY Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 can be used during pregnancy.
- No data are available yet regarding the use of COMIRNATY Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 during 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 Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 can be used during breast-feeding
- Interactions with other medicinal products or concomitant administration of COMIRNATY, COMIRNATY Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 with other vaccines has not been studied.
- Animal studies with COMIRNATY Original do not indicate direct or indirect harmful effects with respect to reproductive toxicity.
- The safety of a COMIRNATY Original/Omicron BA.1 booster dose in individuals from 18 to ≤ 55 years of age is extrapolated from safety data from a subset of 315 adults 18 to ≤ 55 years of age who received a booster (fourth dose) of Omicron BA.1 30 µg (monovalent) after completing 3 doses of COMIRNATY. The most frequent adverse reactions in these participants 18 to ≤ 55 years of age were injection site pain (> 70%), fatigue (> 60%), headache (> 40%), myalgia (> 30%), chills (> 30%) and arthralgia (> 20%).
- In a subset from the Phase 3 study, 305 adults > 55 years of age who had completed 3 doses of COMIRNATY, received a booster of COMIRNATY Original/Omicron BA.1 after receiving Dose 3. The overall safety profile for the COMIRNATY Original/Omicron BA.1 booster (fourth dose) was similar to that seen after the COMIRNATY booster (third dose). The most frequent adverse reactions in participants greater than 55 years of age were injection site pain (> 50%), fatigue (> 40%),

headache 69 (> 30%), myalgia (> 20%), chills and arthralgia (> 10%). No new adverse reactions were identified for COMIRNATY Original/Omicron BA.1.

- The safety of a booster dose of COMIRNATY Original/Omicron BA.4-5 is inferred from safety data for a booster dose of COMIRNATY Original/Omicron BA.1, as well as for a booster dose of COMIRNATY Original.
- 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 Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 may not protect all vaccine recipients
- For complete information on the safety of COMIRNATY, COMIRNATY Original/Omicron BA.1 and COMIRNATY Original/Omicron BA.4-5, 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 medinfo@biontech.de, www.biontech.com or directly to BioNTech using email, telephone +49 6131 9084 0, or via the website.

About Pfizer: Breakthroughs That Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on and follow us on Twitter at @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 October 19, 2022. 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 a submission pending with the EMA and a CHMP opinion for a 3-µg dose of COMIRNATY (COVID-19 vaccine, mRNA), which is based on the wild-type spike protein of SARS-CoV-2, as a three-dose series for children ages 6 months to less than 5 years (also referred to as 6 months through 4 years of age, a regulatory pathway for potential authorization of the companies' Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine for use in children under 5 years of age and a Phase 1/2/3 pediatric study of the Omicron BA.4/BA.5 adapted bivalent COVID-19 vaccine, 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 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, bivalent or variant-adapted 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, bivalent or variant-adapted 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 and the submission pending with the EMA for a 3-µg dose of COMIRNATY (COVID-19 vaccine, mRNA), which is based on the wild-type spike protein of SARS-CoV-2, as a three-dose series for children ages 6 months to less than 5 year), 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; the risk that demand for any products may be reduced or no longer exist which may lead to reduced revenues or excess inventory; risks related to the availability of raw materials to manufacture a vaccine; challenges related to our vaccine's formulation, dosing schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery by Pfizer; the risk that we may not be able to successfully develop other vaccine formulations, booster doses or potential future annual boosters or re-vaccinations or new variant-based or next generation vaccines; 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, 2021 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 is a next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. The Company exploits a wide array of computational discovery and therapeutic drug platforms for the rapid development of novel biopharmaceuticals. Its broad portfolio of oncology product candidates includes individualized and off-the-shelf mRNA-based therapies, innovative chimeric antigen receptor T cells, bispecific immune checkpoint modulators, targeted cancer antibodies and small molecules. Based on its deep expertise in mRNA vaccine development and in-house manufacturing capabilities, BioNTech and its collaborators are developing multiple mRNA vaccine candidates for a range of infectious diseases alongside its diverse oncology pipeline. BioNTech has established a broad set of relationships with multiple global pharmaceutical collaborators, including Genmab, Sanofi, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma, and Pfizer. For more information, please visit www.BioNTech.com.

BioNTech Forward-looking Statements
This press release contains "forward-looking statements" of BioNTech within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may include, but may not be limited to, statements concerning: BioNTech's efforts to combat COVID-19; the collaboration between BioNTech and Pfizer including the program to develop a COVID-19 vaccine and COMIRNATY (COVID-19 vaccine, mRNA) (BNT162b2) (including the potential in children 6 months to 5 years of age and a positive CHMP opinion on the administration in children 6 months to 5 years of age in the EU, clinical trials studying the use BNT162b2 and its adapted vaccine variations in children 6 months to 12 years of age, an EUA in the U.S. and a submission pending with the EMA for an Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine for children ages 5 to less than 12 years of age, qualitative assessments of available data, potential benefits, expectations for clinical trials, the anticipated timing of regulatory submissions, regulatory approvals or authorizations and anticipated manufacturing, distribution and supply); our expectations regarding the potential characteristics of BNT162b2 in our clinical trials, real world data studies, and/or in commercial use based on data observations to date; preclinical and clinical data (including Phase 1/2/3 or Phase 4 data), including the descriptive data discussed in this release, for BNT162b2 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, including the risk that final or formal results from the clinical trial could differ from the topline data; the ability of BNT162b2 or a future vaccine to prevent COVID-19 caused by emerging virus variants; the expected time point for additional readouts on efficacy data of BNT162b2 and its adapted vaccine variations in our clinical trials; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; widespread use of BNT162b2 and its adapted vaccine variations 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 timing for submission of data for BNT162, or any future vaccine, in additional populations, (including in children 6 months to less than 5 years of age, potential future annual boosters or re-vaccinations), or receipt of, any marketing approval or emergency use authorization or equivalent, including or amendments or variations to such authorizations, 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; the development of other vaccine formulations, booster doses or potential future annual boosters or re-vaccinations or new variant based vaccines; our contemplated shipping and storage plan, including our estimated product shelf life at various temperatures; the ability of BioNTech to supply the quantities of BNT162 and its adapted vaccine variations to support clinical development and market demand, including our production estimates for 2022; challenges related to public vaccine confidence or awareness; 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 which may lead to reduced revenues or excess inventory; the availability of raw material to manufacture BNT162 or other vaccine formulation; 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; and uncertainties regarding the impact of COVID-19 on BioNTech's trials, business and general operations. Any forward-looking statements in this press release are based on BioNTech current expectations and beliefs of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: the ability to meet the pre-defined endpoints in clinical trials; competition to create a vaccine for COVID-19; the ability to produce comparable clinical or other results, including our stated rate of vaccine effectiveness and safety and tolerability profile observed to date, in the remainder of the trial or in larger, more diverse populations upon commercialization; the ability to effectively scale our productions capabilities; and other potential difficulties.

For a discussion of these and other risks and uncertainties, see BioNTech's Quarterly Report as Form 6-K for the quarter ended June 30, 2022, filed with the SEC on August 8, 2022, which is available on the SEC's website at www.sec.gov. All information in this press release is as of the date of the release, and BioNTech undertakes no duty to update this information unless required by law.

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