UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

FOR THE MONTH OF JULY 2025

COMMISSION FILE NUMBER 001-39081

BioNTech SE
(Translation of registrant's name into English)

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(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F: Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

DOCUMENTS INCLUDED AS PART OF THIS FORM 6-K

On July 25, 2025, BioNTech SE and Pfizer Inc. announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has recommended marketing authorization for the companies' LP.8.1-adapted monovalent COVID-19 vaccine (COMIRNATY® LP.8.1) for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 6 months of age and older. The press release is attached hereto as Exhibit 99.1.

SIGNATURE

Pursuant to the requirements of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BioNTech SE

By: /s/ Ramón Zapata-Gomez
Name: Ramón Zapata-Gomez
Title: Chief Financial Officer

By: /s/ Dr. Sierk Poetting
Name: Dr. Sierk Poetting
Title: Chief Operating Officer

Date: July 25, 2025

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	Pfizer and BioNTech Receive Positive CHMP Opinion for LP.8.1-Adapted COVID-19 Vaccine in the European Union

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

- *Data indicate that the LP.8.1-adapted COVID-19 vaccine confers improved immune response against currently dominant and emerging sublineages – including the XFG and NB.1.8.1 variants[1] – compared to 2024-2025 COVID-19 vaccine formulations*
- *Upon authorization by the European Commission (EC), the LP.8.1-adapted COVID-19 vaccine will be available for individuals 6 months of age and older*
- *To date, over a billion adults and children around the world have received the Pfizer-BioNTech COVID-19 vaccine, which continues to demonstrate a favorable safety and efficacy profile supported by extensive real-world evidence, clinical, non-clinical, pharmacovigilance and manufacturing data*
- *Doses will be ready to ship to applicable EU member states immediately upon authorization by the European Commission*

NEW YORK and MAINZ, GERMANY, July 25, 2025 — Pfizer Inc. (NYSE: PFE, "Pfizer") and BioNTech SE (Nasdaq: BNTX, "BioNTech") announced today that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has recommended marketing authorization for the companies' LP.8.1-adapted monovalent COVID-19 vaccine (COMIRNATY® LP.8.1) for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 6 months of age and older. The adaptation is based on the recommendation from the EMA's Emergency Task Force (ETF) to update COVID-19 vaccines to target the LP.8.1 variant for the 2025-2026 season. The ETF stated that "targeting LP.8.1 will help maintain the effectiveness of the vaccines as SARS-CoV-2 continues to evolve."[2]

The CHMP's recommendation will be reviewed by the European Commission (EC), which is expected to make its final decision soon. Pfizer and BioNTech have already initiated manufacturing of the LP.8.1-adapted monovalent COVID-19 vaccine at risk to ensure supply readiness ahead of the upcoming fall and winter season when the demand for COVID-19 vaccination is expected to increase. The updated vaccine will be available to ship to applicable EU member states immediately following the EC decision.

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

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

The COVID-19 vaccines by Pfizer and BioNTech are based on BioNTech's proprietary mRNA technology and were developed by both companies. BioNTech is the Marketing Authorization Holder for

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[1] Vaccines and Related Biological Products Advisory Committee. 22 May 2025. Meeting Presentation- 2025-2026 COVID-19 Vaccine Formula: Pfizer/BioNTech Supportive Data. Available at: https://www.fda.gov/media/186597/download. Accessed 13 June 2025.

[2] European Medicines Agency (EMA) ETF recommends updating COVID-19 vaccines to target new LP.8.1. 16 May 2025. Available at: https://www.ema.europa.eu/en/news/etf-recommends-updating-covid-19-vaccines-target-new-lp81-variant. Accessed 13 June 2025.

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 people 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 completed a primary vaccination course and who have not had COVID-19 before, with the first two doses 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.

In addition, COMIRNATY has also been granted standard MA for three adapted vaccines: COMIRNATY Omicron XBB.1.5, which contains mRNA encoding for the spike protein of the Omicron XBB.1.5 subvariant of SARS-CoV-2, COMIRNATY JN.1, which contains mRNA encoding for the spike protein of the Omicron JN.1 subvariant of SARS-CoV-2 and COMIRNATY KP.2, which contains mRNA encoding for the spike protein of the Omicron KP.2 subvariant of SARS-CoV-2.

COMIRNATY Omicron XBB.1.5, COMIRNATY JN.1 and COMIRNATY KP.2 may 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 Omicron XBB.1.5, COMIRNATY JN.1 or COMIRNATY KP.2 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.
- 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 hemophilia) because bleeding or bruising may occur following an intramuscular administration in these individuals.

- Safety and immunogenicity of the vaccine have been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy. The efficacy of COMIRNATY Omicron XBB.1.5, COMIRNATY JN.1 and COMIRNATY KP.2 may be lower in immunosuppressed individuals.
- As with any vaccine, vaccination with COMIRNATY Omicron XBB.1.5, COMIRNATY JN.1 and COMIRNATY KP.2 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), Not known (cannot be estimated from the available data).
    - Very common side effects: Headache, diarrhea, arthralgia, myalgia, injection site pain, fatigue, chills, pyrexia, injection site swelling.
    - Common side effects: lymphadenopathy, injection site redness, nausea, vomiting.
    - Uncommon side effects: Hypersensitivity reactions (e.g. rash, pruritus, urticaria, angioedema), decreased appetite, insomnia, dizziness and lethargy, hyperhidrosis and night sweats, pain in extremity, asthenia, malaise, injection site pruritus.
    - Rare side effects: acute peripheral facial paralysis.
    - Very rare side effects: myocarditis, pericarditis.
    - Not known incidence: anaphylaxis, paresthesia and hypoesthesia, erythema multiforme, heavy menstrual bleeding, extensive swelling of vaccinated limbs, facial swelling.
- No data are available yet regarding the use of COMIRNATY Omicron XBB.1.5, COMIRNATY JN.1, and COMIRNATY KP.2 during pregnancy. However, there are limited clinical study data (approximately 300 pregnancy outcomes) from the use of COMIRNATY in pregnant participants. 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. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/fetal development, parturition or post-natal development. Based on data available with other vaccine variants, COMIRNATY Omicron XBB.1.5, COMIRNATY JN.1 and COMIRNATY KP.2 can be used during pregnancy.
- No data are available yet regarding the use of COMIRNATY Omicron XBB.1.5, COMIRNATY JN.1 and COMIRNATY KP.2 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 Omicron XBB.1.5, COMIRNATY JN.1 and COMIRNATY KP.2 can be used during breast-feeding.
- Animal studies with COMIRNATY do not indicate direct or indirect harmful effects with respect to reproductive toxicity.
- Comirnaty Omicron XBB.1.5, Comirnaty JN.1 and Comirnaty KP.2 (30 micrograms/dose dispersion for injection) may be administered concomitantly with seasonal influenza vaccine.
- In adults 18 years of age and older, Comirnaty Omicron XBB.1.5, Comirnaty JN.1 and Comirnaty KP.2 may be administered concomitantly with
    - a pneumococcal conjugated vaccine (PCV).
    - an unadjuvanted recombinant protein respiratory syncytial virus (RSV) vaccine.
- In individuals 65 years of age and older, Comirnaty Omicron XBB.1.5, Comirnaty JN.1 and Comirnaty KP.2 may be administered concomitantly with an unadjuvanted recombinant protein RSV vaccine and a high dose influenza vaccine.

- 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 diarrhea (> 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 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 (> 30%), decreased appetite (> 20%), drowsiness, tenderness at the injection site and fever (> 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 Omicron XBB.1.5, COMIRNATY JN.1 and COMIRNATY KP.2 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 Omicron XBB.1.5, COMIRNATY JN.1 and COMIRNATY KP.2 may not protect all vaccine recipients.
- For complete information on the safety of COMIRNATY Omicron XBB.1.5, COMIRNATY JN.1 and COMIRNATY KP.2 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.com

About Pfizer: Breakthroughs That Change Patients' Lives
At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For 175 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on X at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Pfizer Disclosure Notice
The information contained in this release is as of July 25, 2025. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about Pfizer's efforts to combat COVID-19, the collaboration between BioNTech and Pfizer to develop a COVID-19 vaccine, the BNT162b2 mRNA vaccine program, and the Pfizer-BioNTech COVID-19 Vaccine, also known as COMIRNATY® (COVID-19 Vaccine, mRNA) (BNT162b2) including an Omicron-adapted monovalent COVID-19 vaccine candidate, based on the LP.8.1 lineage, including the receipt of a positive CHMP opinion from the European Medicines Agency (EMA) for an Omicron-adapted monovalent COVID-19 vaccine, based on the LP.8.1 lineage, expectations regarding the demand for COVID-19 vaccines, planned regulatory submissions, qualitative assessments of available data, potential benefits, expectations for clinical trials, potential regulatory submissions, the anticipated timing of data readouts, regulatory submissions, regulatory approvals or authorizations and anticipated availability, manufacturing, distribution and supply involving substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preclinical and clinical data (including Phase 1/2/3 or Phase 4 data), any monovalent or bivalent vaccine candidates or any other vaccine candidate in the BNT162 program in any of our studies in pediatrics, adolescents, or adults or real world evidence, including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the ability to produce comparable clinical or other results, including the rate of vaccine effectiveness and safety and tolerability profile observed to date, in additional analyses of the Phase 3 trial and additional studies, in real world data studies or in larger, more diverse populations following commercialization; the ability of BNT162b2, any monovalent or bivalent vaccine candidates or any future vaccine to prevent COVID-19 caused by emerging virus variants; the risk that more widespread use of the vaccine will lead to new information about efficacy, safety, or other developments, including the risk of additional adverse reactions, some of which may be serious; the risk that preclinical and clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; whether and when additional data from the BNT162 mRNA vaccine program will be published in scientific journal publications and, if so, when and with what modifications and interpretations; whether regulatory authorities will be satisfied with the design of and results from these and any future preclinical and clinical studies; whether and when submissions to request emergency use or conditional marketing authorizations for BNT162b2 in additional populations, for a potential booster dose for BNT162b2, any monovalent or bivalent vaccine candidates or any potential future vaccines (including potential future annual boosters or re-vaccination), and/or other biologics license and/or emergency use authorization

applications or amendments to any such applications may be filed in particular jurisdictions for BNT162b2, any monovalent or bivalent vaccine candidates or any other potential vaccines that may arise from the BNT162 program, including a potential variant-based, higher dose, or bivalent vaccine, and if obtained, whether or when such emergency use authorizations or licenses will expire or terminate; whether and when any applications that may be pending or filed for BNT162b2 (including any requested amendments to the emergency use or conditional marketing authorizations), any monovalent or bivalent vaccine candidates, or other vaccines that may result from the BNT162 program may be approved by particular regulatory authorities, which will depend on myriad factors, including making a determination as to whether the vaccine's benefits outweigh its known risks and determination of the vaccine's efficacy and, if approved, whether it will be commercially successful; decisions by regulatory authorities impacting labeling or marketing, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of a vaccine, including development of products or therapies by other companies; disruptions in the relationships between us and our collaboration partners, clinical trial sites or third-party suppliers; risks and uncertainties related to potential changes to vaccine or other healthcare policy in the U.S.; the risk that demand for any products may be reduced or no longer exist or not meet expectations which may lead to reduced revenues or excess inventory on-hand and/or in the channel; uncertainties related to recommendations and coverage for, and the public's adherence to vaccines, boosters, treatments or combinations; risks related to our ability to accurately predict or achieve our revenue forecasts for our COVID-19 vaccine or any potential future COVID-19 vaccines; potential third-party royalties or other claims related to our COVID-19 vaccine; the risk that other companies may produce superior or competitive products; risks related to the availability of raw materials to manufacture or test a vaccine; challenges related to our vaccine's formulation, dosing schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery by Pfizer; the risk that we may not be able to successfully develop other vaccine formulations, booster doses or potential future annual boosters or re-vaccinations or new variant-based vaccines or combination vaccines; the risk that we may not be able to maintain or scale up manufacturing capacity on a timely basis or maintain access to logistics or supply channels commensurate with global demand for our vaccine, which would negatively impact our ability to supply the estimated numbers of doses of our vaccine within the projected time periods as previously indicated; whether and when additional supply agreements will be reached; uncertainties regarding the ability to obtain or maintain recommendations from vaccine advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations, including uncertainties related to the potential impact of narrowing recommended patient populations; challenges related to public vaccine confidence or awareness; risks and uncertainties related to issued or future executive orders or other new, or changes in, laws or regulations; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2024 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

About BioNTech

Biopharmaceutical New Technologies (BioNTech) is a global next generation immunotherapy company pioneering novel investigative therapies for cancer and other serious diseases. BioNTech exploits a wide array of computational discovery and therapeutic modalities with the intent of rapid development of novel biopharmaceuticals. Its diversified portfolio of oncology product candidates aiming to address the full continuum of cancer includes mRNA cancer immunotherapies, next-generation immunomodulators and targeted therapies such as antibody-drug conjugates (ADCs) and innovative chimeric antigen receptor (CAR) T cell therapies. Based on its deep expertise in mRNA development and in-house manufacturing capabilities, BioNTech and its collaborators are researching and developing multiple mRNA vaccine

candidates for a range of infectious diseases alongside its diverse oncology pipeline. BioNTech has established a broad set of relationships with multiple global and specialized pharmaceutical collaborators, including Bristol Myers Squibb, Duality Biologics, Fosun Pharma, Genentech, a member of the Roche Group, Genevant, Genmab, MediLink, OncoC4, Pfizer and Regeneron.
For more information, please visit www.BioNTech.com.

BioNTech Forward-looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not be limited to, statements concerning: BioNTech's efforts to combat COVID-19; the collaboration between BioNTech and Pfizer; the rate and degree of market acceptance of BioNTech's COVID-19 vaccine, including the LP.8.1-adapted monovalent COVID-19 vaccine; qualitative assessments of available data and expectations of potential benefits, including the adapted vaccine's response against multiple SARS-CoV-2 lineages, including NB.1.8.1 and other currently circulating sublineages; regulatory submissions and regulatory approvals or authorizations and expectations regarding manufacturing, distribution and supply; expectations regarding anticipated changes in COVID-19 vaccine demand, including changes to the ordering environment; and expected regulatory recommendations to adapt vaccines to address new variants or sublineages. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words.

The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond BioNTech's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to: the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preclinical and clinical data, including the data discussed in this release, and including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; BioNTech's pricing and coverage negotiations with governmental authorities, private health insurers and other third-party payors after BioNTech's initial sales to national governments; the future commercial demand and medical need for initial or booster doses of a COVID-19 vaccine; the impact of tariffs and escalations in trade policy; the availability of raw materials to manufacture a vaccine; our vaccine's formulation, dosing schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery; competition from other COVID-19 vaccines or related to BioNTech's other product candidates, including those with different mechanisms of action and different manufacturing and distribution constraints, on the basis of, among other things, efficacy, cost, convenience of storage and distribution, breadth of approved use, side-effect profile and durability of immune response; the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; the timing of and BioNTech's ability to obtain and maintain regulatory approval for BioNTech's product candidates; the ability of BioNTech's COVID-19 vaccines to prevent COVID-19 caused by emerging virus variants; BioNTech's and its counterparties' ability to manage and source necessary energy resources; BioNTech's ability to identify research opportunities and discover and develop investigational medicines; the ability and willingness of BioNTech's third-party collaborators to continue research and development activities relating to BioNTech's development candidates and investigational medicines; the impact of COVID-19 on BioNTech's development programs, supply chain, collaborators and financial performance; unforeseen safety issues and potential claims that are alleged to arise from the use of BioNTech's COVID-19 vaccine

and other products and product candidates developed or manufactured by BioNTech; BioNTech's and its collaborators' ability to commercialize and market BioNTech's COVID-19 vaccine and, if approved, its product candidates; BioNTech's ability to manage its development and related expenses; regulatory developments in the United States and other countries; BioNTech's ability to effectively scale BioNTech's production capabilities and manufacture BioNTech's products, including BioNTech's target COVID-19 vaccine production levels, and BioNTech's product candidates; risks relating to the global financial system and markets; and other factors not known to BioNTech at this time.

You should review the risks and uncertainties described under the heading "Risk Factors" in BioNTech's Report on Form 6-K for the period ended March 31, 2025, and in subsequent filings made by BioNTech with the SEC, which are available on the SEC's website at www.sec.gov. These forward-looking statements speak only as of the date hereof. Except as required by law, BioNTech disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise.

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