

**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 OCTOBER 2023

COMMISSION FILE NUMBER 001-39081

BioNTech SE

(Translation of registrant's name into English)

**An der Goldgrube 12
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Germany
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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 October 26, 2023, BioNTech SE and Pfizer Inc. announced positive topline results from a Phase 1/2 study (NCT05596734) evaluating the safety, tolerability and immunogenicity of mRNA-based combination vaccine candidates for influenza and COVID-19 among healthy adults 18 to 64 years of age. 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/ Dr. Sierk Poetting

Name: Dr. Sierk Poetting

Title: Chief Operating Officer

Date: October 26, 2023

EXHIBIT INDEX

<u>Exhibit</u>	<u>Description of Exhibit</u>
99.1	<u>Pfizer and BioNTech Announce Positive Topline Data for mRNA-based Combination Vaccine Program Against Influenza and COVID-19</u>



Pfizer and BioNTech Announce Positive Topline Data for mRNA-based Combination Vaccine Program Against Influenza and COVID-19

- *Lead formulations evaluated in the Phase 1/2 study demonstrated robust immune responses to influenza A, influenza B, and SARS-CoV-2 strains*
- *Safety profile of the mRNA-based combination vaccine candidates consistent with the companies' COVID-19 vaccine*
- *The companies plan to start a pivotal Phase 3 trial in the coming months*

NEW YORK and MAINZ, GERMANY, October 26, 2023 — Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today announced positive topline results from a Phase 1/2 study (NCT05596734) evaluating the safety, tolerability and immunogenicity of mRNA-based combination vaccine candidates for influenza and COVID-19 among healthy adults 18 to 64 years of age. In the clinical trial, the vaccine candidates were compared to a licensed influenza vaccine and the companies' Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine given at the same visit. The data from the trial showed that the companies' lead formulations demonstrated robust immune responses to influenza A, influenza B, and SARS-CoV-2 strains.

"We are encouraged by these early results in our Phase 1/2 study of our combination vaccine candidates against influenza and COVID-19. This vaccine has the potential to lessen the impact of two respiratory diseases with a single injection and may simplify immunization practices for providers, patients, and healthcare systems all over the world," said **Annaliesa Anderson, PhD, FAAM, Senior Vice President and Head, Vaccine Research and Development at Pfizer**. "mRNA-based vaccines have demonstrated their ability to induce robust antibody and T-cell responses, and we look forward to starting Phase 3 clinical development. Today's results are an important achievement towards our ambition of providing a broad portfolio of respiratory combination vaccines."

"Studies of confirmed viral infections suggest that COVID-19 adopts a seasonal pattern with peaks in fall and winter, similar to other respiratory diseases. Co-infections as well as consecutive respiratory infection during this period can further increase the risk of severe illness," said **Prof. Ugur Sahin, MD, CEO and Co-founder of BioNTech**. "Combination vaccines have the potential to become a mainstay of routine vaccination against respiratory diseases, especially for the vaccination of populations who have a higher risk of severe illness."

The topline results of the ongoing trial demonstrated that the combination formulations evaluated had a safety profile consistent with the safety profile of the companies' COVID-19 vaccine. Immunogenicity results induced by lead formulations in the companies' phase 1/2 trial showed point estimates for Geometric Mean Titer (GMT) ratios that were consistent with the criteria applied to regulatory approved vaccines against the respective influenza and SARS-CoV-2 strains. Point estimates for GMT ratios for all matched influenza vaccine strains with lead formulations were >1 relative to a licensed Quadrivalent Influenza Vaccine (QIV) given concomitantly with the Pfizer-BioNTech COVID-19 vaccine. A pivotal Phase 3 trial evaluating these lead formulations is expected to be initiated in the coming months. Data from the Phase 1/2 trial will be published in a peer-reviewed journal.

Pfizer and BioNTech previously announced that their mRNA-based combination vaccine candidate for influenza and COVID-19 received Fast Track Designation from the U.S. Food and Drug Administration (FDA).

About Respiratory Diseases

SARS-CoV-2 led to a global pandemic with more than 6.5 million deathsⁱ and a severe socio-economic burden worldwide.ⁱⁱ While vaccinations can help address the disease, COVID-19 is expected to remain a circulating, severe respiratory disease, requiring adjustments of vaccines to variants of concern. This is reminiscent of influenza, another respiratory disease that requires repeated vaccinations due to its genomic instability resulting in modifications of the surface protein hemagglutinin. Each year, influenza results in up to one billion infections, five million hospitalizations, and 650,000 deaths worldwide.ⁱⁱⁱ

INDICATION, AUTHORIZED USE AND IMPORTANT SAFETY INFORMATION

INDICATION

COMIRNATY[®] (COVID-19 Vaccine, mRNA) is a vaccine for use in people 12 years of age and older to protect against coronavirus disease 2019 (COVID-19).

IMPORTANT SAFETY INFORMATION

- You should **NOT** receive COMIRNATY[®] (COVID-19 Vaccine, mRNA) if you have had a severe allergic reaction to any ingredient of COMIRNATY or a previous dose of a Pfizer-BioNTech COVID-19 vaccine* or to any ingredient in these vaccines
 - *COMIRNATY (2023-2024 Formula) is made the same way as Pfizer-BioNTech COVID-19 Vaccine (Original monovalent) and Pfizer-BioNTech COVID-19 Vaccine, Bivalent, but it encodes the spike protein of SARS-CoV-2 Omicron variant lineage XBB.1.5 (Omicron XBB.1.5).
- There is a remote chance that COMIRNATY could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to 1 hour after getting a dose. For this reason, your vaccination provider may ask you to stay at the place where you received the vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:
 - Difficulty breathing
 - Swelling of the face and throat
 - A fast heartbeat
 - A bad rash all over the body
 - Dizziness and weakness
- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received mRNA COVID-19 vaccines, including COMIRNATY and Pfizer-BioNTech COVID-19 vaccines. Myocarditis and pericarditis following COMIRNATY have occurred most commonly in adolescent males 12 through 17 years of age. In most of these individuals, symptoms began within a few days following vaccination. The chance of having this occur is very low. You should seek medical attention right away if you or your child have any of the following symptoms after receiving the vaccine, particularly during the 2 weeks after receiving a dose of the vaccine:
 - Chest pain
 - Shortness of breath
 - Feelings of having a fast-beating, fluttering, or pounding heart
- Fainting can happen after getting injectable vaccines including COMIRNATY. Your vaccination provider may ask you to sit or lie down for 15 minutes after receiving the vaccine

- People with weakened immune systems may have a reduced immune response to COMIRNATY
- COMIRNATY may not protect all vaccine recipients
- **Before getting COMIRNATY, tell your vaccination provider about all of your medical conditions, including if you:**
 - have any allergies
 - had a severe allergic reaction after receiving a previous dose of any COVID-19 vaccine
 - have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
 - have a fever
 - have a bleeding disorder or are on a blood thinner
 - are immunocompromised or are on a medicine that affects the immune system
 - are pregnant, plan to become pregnant, or are breastfeeding
 - have received another COVID-19 vaccine
 - have ever fainted in association with an injection
- Additional side effects that have been reported with COMIRNATY or Pfizer-BioNTech COVID-19 vaccines include:
 - Non-severe allergic reactions such as rash, itching, hives, or swelling of the face
 - Injection Site reactions: pain, swelling, redness, arm pain
 - General side effects: tiredness, headache, muscle pain, chills, joint pain, fever, nausea, feeling unwell, lymph nodes (lymphadenopathy), decreased appetite, diarrhea, vomiting, dizziness.

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

You may report vaccine side effects to the FDA/CDC Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to www.vaers.hhs.gov/reportevent.html.

You can also report side effects to Pfizer Inc. at www.pfizersafetyreporting.com or by calling 1-800-438-1985.

Please click [here](#) for full Prescribing Information for COMIRNATY.

AUTHORIZED USE

Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula)* is FDA authorized under Emergency Use Authorization (EUA) to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 6 months through 11 years of age.

*Hereafter referred to as Pfizer-BioNTech COVID-19 Vaccine

EMERGENCY USE AUTHORIZATION

Pfizer-BioNTech COVID-19 Vaccine has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals aged 6 months through 11 years of age. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

IMPORTANT SAFETY INFORMATION

- A person should **NOT** get Pfizer-BioNTech COVID-19 Vaccine if they had a severe allergic reaction after a previous dose of any Pfizer-BioNTech COVID-19 vaccine or to any ingredients in these vaccines.
- There is a remote chance that the vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the vaccine. For this reason, the vaccination provider may ask you to stay at the place where you received the vaccine for monitoring after vaccination. **If your child experiences a severe allergic reaction, call 9-1-1, or go to the nearest hospital.** Signs of a severe allergic reaction can include:
 - o Difficulty breathing
 - o Swelling of the face and throat,
 - o A fast heartbeat
 - o A bad rash all over the body
 - o Dizziness and weakness
- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received mRNA COVID-19 vaccines. Myocarditis and pericarditis following Pfizer-BioNTech COVID-19 vaccines have occurred most commonly in adolescent males 12 through 17 years of age. In most of these individuals, symptoms began within a few days following vaccination. The chance of having this occur is very low. **Seek medical attention right away if your child has any of the following symptoms after receiving the vaccine, particularly during the 2 weeks after receiving a dose of the vaccine:**
 - o Chest pain
 - o Shortness of breath or difficulty breathing
 - o Feelings of having a fast-beating, fluttering, or pounding heart

Additional symptoms, particularly in children, may include:

- Fainting
 - Unusual and persistent irritability
 - Unusual and persistent poor feeding
 - Unusual and persistent fatigue or lack of energy
 - Persistent vomiting
 - Persistent pain in the abdomen
 - Unusual and persistent cool, pale skin
- Fainting can happen after getting injectable vaccines, including Pfizer-BioNTech COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received the vaccine for monitoring after vaccination

- People with weakened immune systems may have a reduced immune response to Pfizer-BioNTech COVID-19 Vaccine
- The Pfizer-BioNTech COVID-19 Vaccine may not protect everyone
- **Tell your vaccination provider about all of your medical conditions, including if you:**
 - have any allergies
 - has had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
 - has a fever
 - has a bleeding disorder or are on a blood thinner
 - is immunocompromised or are on a medicine that affects the immune system
 - is pregnant or is breastfeeding
 - has received another COVID-19 vaccine
 - has ever fainted in association with an injection
- Side effects that have been reported with Pfizer-BioNTech COVID-19 vaccines include:
 - Severe allergic reactions
 - Non-severe allergic reactions such as rash, itching, hives, or swelling of the face
 - Myocarditis (inflammation of the heart muscle)
 - Pericarditis (inflammation of the lining outside the heart)
 - Injection site pain/tenderness
 - Tiredness
 - Headache
 - Muscle pain
 - Arm pain
 - Fainting in association with injection of the vaccine
 - Chills
 - Joint pain
 - Fever
 - Injection site swelling
 - Injection site redness
 - Nausea
 - Feeling unwell
 - Swollen lymph nodes (lymphadenopathy)
 - Decreased appetite
 - Diarrhea
 - Vomiting
 - Dizziness
 - Irritability

These may not be all the possible side effects. Serious and unexpected side effects may occur. Call the vaccination provider or healthcare provider about bothersome side effects or side effects that do not go away.

Report vaccine side effects to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to www.vaers.hhs.gov/reportevent.html. Please include "Pfizer-BioNTech COVID-19 Vaccine(2023-2024 Formula) EUA" in the first line of box #18 of the report form.

In addition, individuals can report side effects to Pfizer Inc. at www.pfizersafetyreporting.com or by calling 1-800-438-1985.

Please click here for Pfizer-BioNTech COVID-19 Vaccine Healthcare Providers Fact Sheet and Vaccine Recipient and Caregiver EUA Fact Sheet.

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 www.Pfizer.com and follow us on Twitter at [@Pfizer](https://twitter.com/Pfizer) and [@Pfizer News](https://twitter.com/PfizerNews), [LinkedIn](https://www.linkedin.com/company/pfizer), [YouTube](https://www.youtube.com/channel/UCB3113R0QDk1v1n7111111111) and like us on Facebook at [Facebook.com/Pfizer](https://www.facebook.com/Pfizer).

Pfizer Disclosure Notice

The information contained in this release is as of October 26, 2023. 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 and BioNTech's mRNA-based combination vaccine candidate for influenza and COVID-19 among healthy adults 18 to 64 years of age, including its potential benefits, plans to initiate a pivotal Phase 3 trial, Pfizer's ambition of providing a broad portfolio of respiratory combination vaccines, Pfizer's efforts to combat COVID-19, the collaboration between BioNTech and Pfizer to develop a COVID-19 vaccine, the BNT162 mRNA vaccine program, and Pfizer and BioNTech's COVID-19 vaccines, defined collectively herein as COMIRNATY (including 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 pre-clinical and clinical data (including Phase 1/2/3 or Phase 4 or pre-clinical data for Pfizer's and BioNTech's mRNA-based combination vaccine candidate for

influenza and COVID-19, COMIRNATY or any of Pfizer's other respiratory vaccine candidates, including the data discussed in this release) in any of our studies in pediatrics, adolescents, or adults or real world evidence, including the possibility of unfavorable new pre-clinical, clinical or safety data and further analyses of existing pre-clinical, clinical or safety data or further information regarding the quality of pre-clinical, clinical or safety data, including the risk that additional data against newer Omicron sublineages could differ from previously reported data; the ability to produce comparable clinical or other results for Pfizer's and BioNTech's mRNA-based combination vaccine candidate for influenza and COVID-19, COMIRNATY or any of Pfizer's other respiratory vaccine candidates, including the rate of vaccine effectiveness and safety and tolerability profile observed to date and additional studies, in real world data studies or in larger, more diverse populations following commercialization; the ability of Pfizer's and BioNTech's mRNA-based combination vaccine candidate for influenza and COVID-19, COMIRNATY or any of Pfizer's other respiratory vaccine candidates to prevent COVID-19 caused by emerging virus variants; the risk that 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 pre-clinical 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 or other COVID-19 programs 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 existing or future pre-clinical and clinical studies; whether and when submissions to request emergency use or conditional marketing authorizations for Pfizer's and BioNTech's mRNA-based combination vaccine candidate for influenza and COVID-19, COMIRNATY or any of Pfizer's other respiratory vaccine candidates in additional populations, for a potential booster dose for COMIRNATY, any vaccine candidate or any potential future vaccines (including potential future annual boosters or re-vaccinations), and/or other biologics license and/or emergency use authorization applications or amendments to any such applications may be filed in particular jurisdictions for Pfizer's and BioNTech's mRNA-based combination vaccine candidate for influenza and COVID-19, COMIRNATY or any of Pfizer's other respiratory vaccine candidates, and if obtained, whether or when such emergency use authorizations or licenses, or existing emergency use authorizations, will expire or terminate; whether and when any applications that may be pending or filed for Pfizer's and BioNTech's mRNA-based combination vaccine candidate for influenza and COVID-19, COMIRNATY or any of Pfizer's other respiratory vaccine candidates (including any requested amendments to the emergency use or conditional marketing authorizations) 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 the authorization or approval of products or therapies developed by other companies; intellectual property and other litigation; disruptions in the relationships between us and our collaboration partners, clinical trial sites or third-party suppliers, including our relationship with BioNTech; the risk that demand for any products may be reduced, no longer exist or not meet expectations, which may lead to reduced revenues, excess inventory on-hand and/or in the channel which, for COMIRNATY, has resulted in inventory write-offs and other charges and could continue to result in inventory write-offs or other unanticipated changes; challenges related to and uncertainties regarding the timing of a transition to the commercial market for any of our products; uncertainties related to the public's adherence to vaccines and boosters; risks related to our ability to achieve our revenue forecasts for Pfizer's and BioNTech's mRNA-based combination vaccine candidate for influenza and COVID-19, COMIRNATY or any of Pfizer's other respiratory vaccine candidates; 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 or next generation vaccines or potential combination respiratory vaccines; the risk that we may not be able to maintain manufacturing capacity or access to logistics or supply channels commensurate with global demand for our vaccines, which would negatively impact our ability to supply our vaccines within the projected time periods; whether and when additional supply or purchase agreements will be reached or existing agreements will be completed or renegotiated; 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; pricing and access challenges; challenges related to public confidence in, or awareness of Pfizer's and BioNTech's mRNA-based combination vaccine candidate for influenza and COVID-19, COMIRNATY or any of Pfizer's other respiratory vaccine candidates; uncertainties around future changes to applicable healthcare policies and guidelines issued by the U.S. federal government in connection with the declared termination of the federal government's COVID-19 public health emergency as of May 11, 2023; trade restrictions; potential third party royalties or other claims; the uncertainties inherent in business and financial planning, including, without limitation, risks related to Pfizer's business and prospects, adverse developments in Pfizer's markets, or adverse developments in the U.S. or global capital markets, credit markets, regulatory environment or economies generally; 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, 2022 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 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 (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 pharmaceutical collaborators, including Duality Biologics, Fosun Pharma, Genentech, a member of the Roche Group, Genevant, Genmab, OncoC4, Regeneron, Sanofi and Pfizer.

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 limited to, statements concerning: the

initiation, timing, progress and results of BioNTech's research and development programs in infectious diseases, including the collaboration between BioNTech and Pfizer; current and future clinical trials of BioNTech and Pfizer's mRNA-based combination vaccine candidates for influenza and COVID-19, including statements regarding the timing of initiation and completion of studies or trials, including the planned initiation of a pivotal Phase 3 trial, related preparatory work and the availability of results; timing for any data readouts; the potential safety and efficacy of BioNTech's product candidates; BioNTech's anticipated market opportunity and size for its product candidates; qualitative assessments of available data and expectations of potential benefits, including top-line results from a Phase 1/2 trial evaluating the safety, tolerability and immunogenicity of BioNTech and Pfizer's mRNA-based combination vaccine candidates for influenza and COVID-19 among healthy adults 18 to 64 years of age; 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; future commercial demand and medical need; the availability of raw materials to manufacture a vaccine; the formulation, dosing schedule and attendant storage, distribution and administration requirements of BioNTech's vaccines, including risks related to storage and handling after delivery; competition from other products and 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, including Pfizer's and BioNTech's mRNA-based combination vaccine candidates for influenza and COVID-19, to prevent COVID-19 and/or influenza 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, including Pfizer's and BioNTech's mRNA-based combination vaccine candidates for influenza and COVID-19; BioNTech's and its collaborators' ability to commercialize and market BioNTech's COVID-19 vaccine and, if approved, its product candidates,

including Pfizer's and BioNTech's mRNA-based combination vaccine candidates for influenza and COVID-19; 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, 2023 and in subsequent filings made by BioNTech with the U.S. Securities and Exchange Commission ("SEC"), which are available on the SEC's website at www.sec.gov. 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. These forward-looking statements are based on BioNTech's current expectations and speak only as of the date hereof.

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ⁱ World Health Organization Coronavirus (COVID-19) Dashboard. Available at <https://covid19.who.int/>

ⁱⁱ Delardas O, Kechagias KS, Pontikos PN, Giannos P. Socio-Economic Impacts and Challenges of the Coronavirus Pandemic (COVID-19): An Updated Review. Sustainability. 2022; 14(15):9699. <https://doi.org/10.3390/su14159699>

ⁱⁱⁱ Influenza (Seasonal). World Health Organization. Available at [https://www.who.int/news-room/fact-sheets/detail/influenza-\(seasonal\)](https://www.who.int/news-room/fact-sheets/detail/influenza-(seasonal))