Update

OMICRON VARIANT
(B.1.1.529)

December 8, 2021

This Slide Presentation Includes 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 of a Omicron-specific COVID-19 vaccine candidate, the potential timing for the development of a Omicron-specific COVID-19 vaccine candidate, the testing of BNT162b2 against the Omicron variant, the effectiveness of a third booster dose of BNT162b2 to induce protection against Omicron-induced COVID-19 disease, and the timing for assessment of the effectiveness of a variant-specific COVID-19 vaccine, 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 or variant-specific COVID-19 vaccine candidates in our clinical trials and/or in commercial use based on data observations to date; the ability of BNT162b2 to prevent COVID-19 caused by the Omicron and other emerging virus variants; the expected time point for additional readouts on efficacy data of BNT162b2 in our clinical trials; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; the risk of further widespread use of our 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; decisions by regulatory authorities that may impact labeling or marketing, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of our vaccine, including development of products or therapies by other companies; the timing for submission of data for, or receipt of, any marketing authorization or Emergency Use Authorization; our contemplated shipping and storage plan, including our estimated product shelf life at various temperatures; disruptions in the relationships between us and our collaboration partners, clinical trial sites or other third-parties; risks related to the availability of raw materials to manufacture a vaccine; challenges related to our vaccine's formulation, two-dose and booster schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery by BioNTech and third-party providers; and the ability of BioNTech to supply the quantities of BNT162 or variant-specific COVID-19 vaccine candidates to support clinical development and market demand, including our production estimates for 2021. 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.

For a discussion of these and other risks and uncertainties, see BioNTech's Annual Report as Form 20-F for the Year Ended December 31, 2020, filed with the SEC on March 30, 2021, 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.

Safety Information

AUTHORIZED USE IN THE U.S.:
The Pfizer-BioNTech COVID19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 5 years of age and older.

IMPORTANT SAFETY INFORMATION FROM U.S. FDA EMERGENCY USE AUTHORIZATION PRESCRIBING INFORMATION:

- Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (eg, anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine
- Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine
- Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html)
- Reports of adverse events following use of the Pfizer-BioNTech COVID-19 Vaccine under EUA suggest increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The decision to administer the Pfizer-BioNTech COVID-19 Vaccine to an individual with a history of myocarditis or pericarditis should take into account the individual's clinical circumstances
- Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting
- Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine
- The Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients
- In clinical studies, adverse reactions in participants 16 years of age and older included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%), following administration of the primary series
- In a clinical study, adverse reactions in adolescents 12 through 15 years of age included pain at the injection site (90.5%), fatigue (77.5%), headache (75.5%), chills (49.2%), muscle pain (42.2%), fever (24.3%), joint pain (20.2%), injection site swelling (9.2%), injection site redness (8.6%), lymphadenopathy (0.8%), and nausea (0.4%), following administration of primary series
- In a clinical study, adverse reactions in adults 18 through 55 years of age following administration of a booster dose were pain at the injection site (83.0%), fatigue (63.7%), headache (48.4%), muscle pain (39.1%), chills (29.1%), joint pain (25.3%), lymphadenopathy (5.2%), nausea (0.7%), decreased appetite (0.3%), rash (0.3%), and pain in extremity (0.3%)
- Following administration of the Pfizer-BioNTech COVID-19 Vaccine, the following have been reported outside of clinical trials:
    - severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions, diarrhea, vomiting, and pain in extremity (arm) and syncope
    - myocarditis and pericarditis
- Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine
- Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy
- Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion
- There is no information on the co-administration of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.
- An overall review of adverse reactions reported in the study following the Pfizer-BioNTech COVID-19 Vaccine heterologous booster dose did not identify any new safety concerns, as compared with adverse reactions reported following a Pfizer-BioNTech COVID-19 Vaccine primary series doses or homologous booster dose
- Vaccination providers must report Adverse Events in accordance with the Fact Sheet to VAERS online at https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS call 1-800-822-7967. The reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report
- Vaccination providers should review the Fact Sheet for Information to Provide to Vaccine Recipients/Caregivers and Mandatory Requirements for Pfizer-BioNTech COVID-19 Vaccine Administration Under Emergency Use Authorization
- Before administration of Pfizer-BioNTech COVID-19 Vaccine, please see Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including Full EUA Prescribing Information available at www.cvdvaccine-us.com

Pfizer BIONTECH

Safety Information

COMIRNATY® ▼(COVID-19 mRNA Vaccine) has been granted conditional marketing authorisation by the European Medicines Agency to prevent coronavirus disease 2019 (COVID-19) in people from 5 years of age. EMA's human medicines committee (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.

Important safety information

Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with a known hypersensitivity to the active substance or to any of the excipients listed

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

Very rare cases of myocarditis and pericarditis have been observed following vaccination with Comirnaty. These cases have primarily occurred within 14 days following vaccination, more often after the second vaccination, and more often in younger men. Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis

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. 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® may be lower in immunosuppressed individuals.

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® may not protect all vaccine recipients. Individuals may not be fully protected until 7 days after their second dose of vaccine.

Comirnaty has no or negligible influence on the ability to drive and use machines. However, some of side effectsm mentioned below, may temporarily affect the ability to drive or use machines.

In clinical studies, 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

In clinical trials, the most frequent adverse reactions in participants 18 to 55 years of age who received a booster were injection site pain (> 80%), fatigue (> 60%), headache (> 40%), myalgia (> 30%), chills and arthralgia (> 20%).

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%)

There is limited experience with use of COMIRNATY® in pregnant women. Administration of COMIRNATY® in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and foetus.

It is unknown whether COMIRNATY® is excreted in human milk.

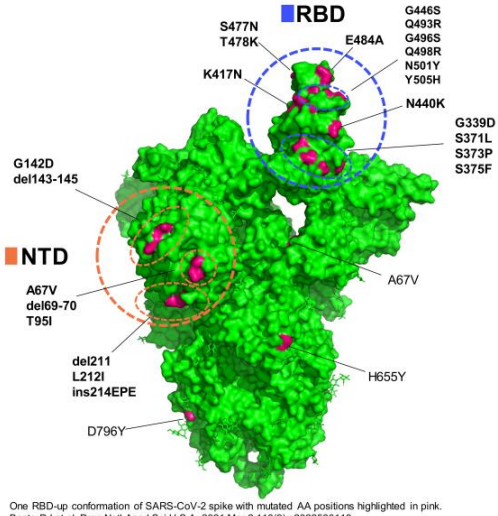
Interactions with other medicinal products or concomitant administration of COMIRNATY® with other vaccines has not been studied.

Very rare cases of myocarditis and pericarditis have been observed following vaccination with COMIRNATY® primarily in younger males, after the second dose, within 14 days following vaccination

The black equilateral triangle denotes that additional monitoring is required to capture any adverse reactions. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. Side effects can be reported to EudraVigilance [http://www.adrreports.eu/] or directly to BioNTech using email medinfo@biontech.de, telephone +49 6131 9084 0, or our website https://medicalinformation.biontech.de/

Pfizer BIONTECH

Omicron (B.1.1.529) has multiple mutations at sites which are known to be relevant for binding of neutralizing antibodies



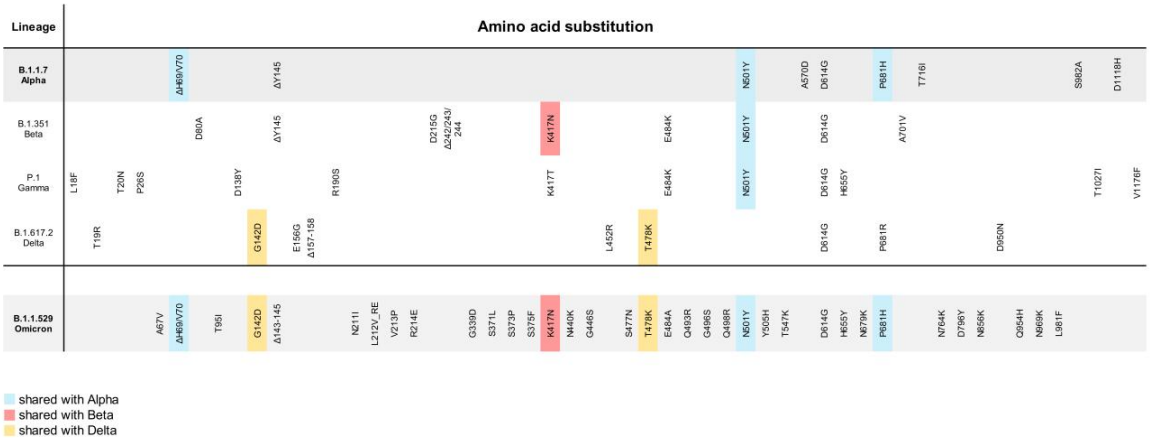
One RBD-up conformation of SARS-CoV-2 spike with mutated AA positions highlighted in pink.
Bento DJ et al. Proc Natl Acad Sci U S A. 2021 Mar 2;118(9):e2022586118

Both the receptor-binding domain (RBD) and the N-terminal domain (NTD) as immunodominant targets are affected

RBD directed mutations (15):
G339D, S371L, S373P, S375F, K417N, N440K, G446S, S477N, T478K, E484A, Q493R, G496S, Q498R, N501Y, Y505H

NTD directed mutations (8):
A67V, del69-70, T95I, G142D, del143-145, del211, L212I, ins214EPE

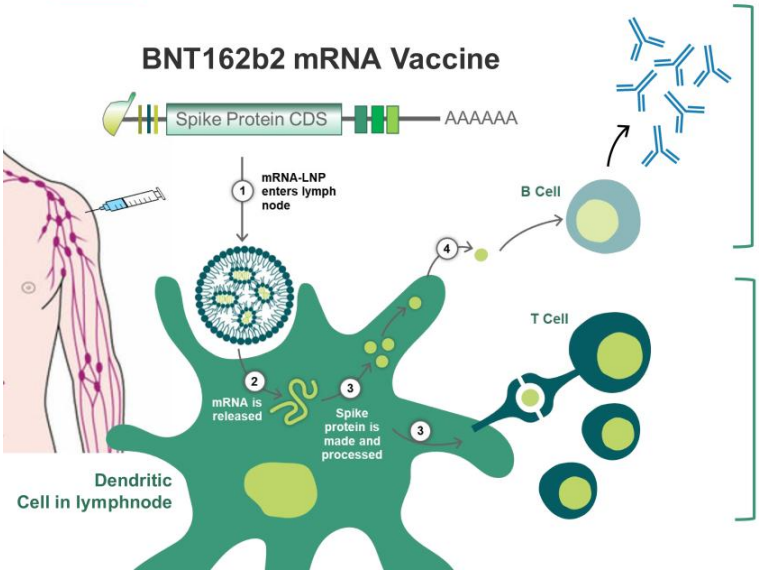
Omicron (B.1.1.529) shares multiple mutations with other SARS-CoV-2 variants



shared with Alpha
shared with Beta
shared with Delta

Pfizer BIONTECH

mRNA vaccines induce two layers of immune defense



1st Layer of Immune Defense:

Virus Neutralizing Antibodies

Considered to

- Prevent SARS-CoV-2 infection
- Prevent Covid-19

2nd Layer of Immune Defense:

Virus Specific CD4+ & CD8+ T cells

Considered to

- Kill virus-infected cells
- Prevent severe Covid-19

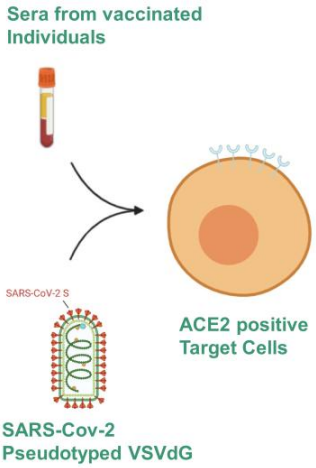
Pfizer BIONTECH

Laboratory *in vitro* pseudo-virus neutralization assay

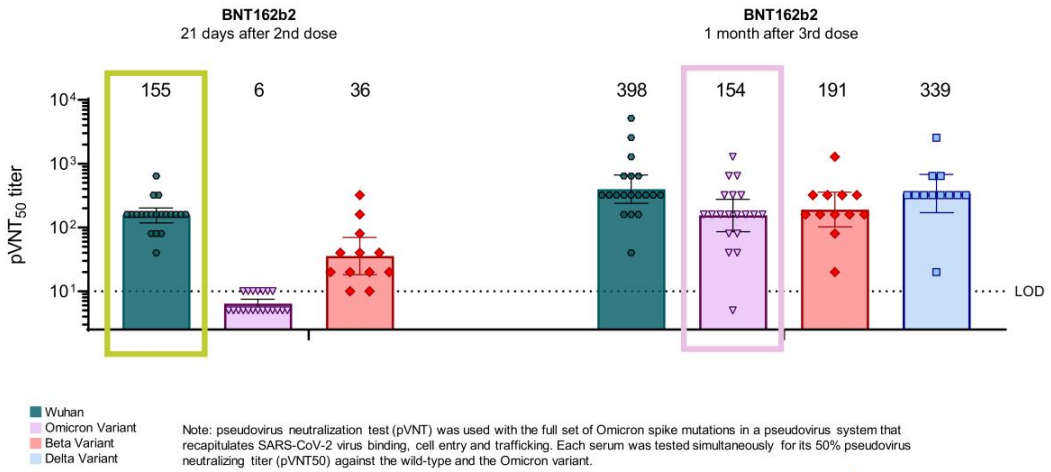
To evaluate the effectiveness of BNT162b2 against the Omicron variant, Pfizer and BioNTech tested a panel of human immune sera obtained from the blood of individuals that received **two** or **three** 30-µg doses of the current Pfizer-BioNTech COVID-19 vaccine, using a pseudovirus neutralization test (pVNT).

The sera (N=19-20) were collected from subjects **3 weeks after receiving the second dose** or **one month after receiving the third dose** of the Pfizer-BioNTech COVID-19 vaccine. Each serum was tested simultaneously for its neutralizing antibody titer against the **wild-type SARS-Cov-2 spike protein**, and the **Omicron spike** variant.

These results are **preliminary,** the companies will continue to collect more laboratory data and evaluate real-world effectiveness to assess and confirm protection against Omicron and inform the most effective path forward.



Three doses of BNT162b2 neutralize Omicron



Note: pseudovirus neutralization test (pVNT) was used with the full set of Omicron spike mutations in a pseudovirus system that recapitulates SARS-CoV-2 virus binding, cell entry and trafficking. Each serum was tested simultaneously for its 50% pseudovirus neutralizing titer (pVNT50) against the wild-type and the Omicron variant.

Pfizer BIONTECH

CD8+ T cell epitopes in BNT162b2 vaccine remain largely unaffected by omicron variant mutations

Approx. 80% of CD8+ epitopes identified by BNT / PFE are not affected by the mutations in the Omicron variant:

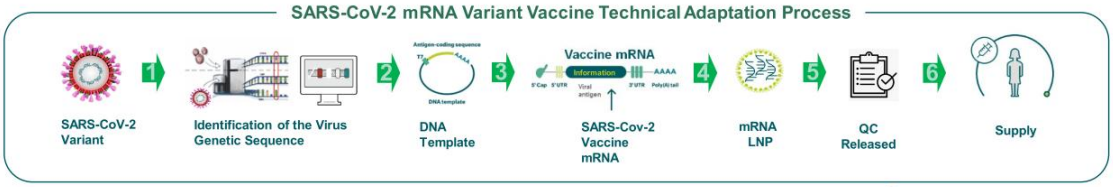
HLA-Allele	No of MHC-I epitopes*	No. of epitopes affected by mutations in different VOCs				
		Alpha	Beta	Gamma	Delta	Omicron
A*01:01	1	0	0	0	0	0
A*02:01	2	0	0	0	0	0
A*03:01	**2**	0	0	0	0	**1**
A*11:01	2	0	0	0	0	0
A*24:02	**5**	0	0	0	**1**	**1**
A*26:01	2	0	0	0	0	0
A*29:02	1	0	0	0	0	**1**
A*68:01	4	0	0	0	0	**1**
B*07:02	1	0	0	0	0	0
B*15:01	**3**	**1**	**2**	**1**	**1**	**2**
B*35:01	6	0	0	0	0	0
C*03:03	1	0	0	0	0	0
C*04:01	1	0	0	0	0	0
Total affected **Total unaffected**	**31**	**1 (4%)** **30 (96%)**	**2 (7%)** **26 (93%)**	**1 (4%)** **30 (96%)**	**2 (7%)** **26 (93%)**	**6 (22%)** **25 (78%)**

* identified as immunogenic in at least one subject. Data from 21 subjects from BNT162-01 study

Pfizer BIONTECH

Neutralization of Omicron after two doses of BNT162b2 and variant specific booster

Booster vaccine	Trial ID	Omicron neutralization by variant-specific booster compared to 3rd dose BNT162b2 [%]
BNT162b2	NCT04380701	100%
Alpha Variant	NCT05004181	466%
Beta Variant	NCT04949490	Pending
Delta Variant	NCT05004181	165%
Alpha/Delta Variant Mix	NCT05004181	155%



Summary

- Preliminary laboratory studies demonstrate that three doses of the Pfizer-BioNTech COVID-19 Vaccine neutralize the Omicron variant (B.1.1.529 lineage), while two doses show significantly reduced neutralization titers
- Data indicate that a third dose of BNT162b2 increases the neutralizing antibody titers by 25-fold compared to two doses against the Omicron variant; titers after the booster dose are comparable to titers observed after two doses against the wild-type virus, which are associated with high levels of protection
- Due to presence of B and T cell memory responses in vaccinated individuals, and as 80% of epitopes in the spike protein being recognized by CD8+ T cells are not affected by the mutations in the Omicron variant, two doses may still induce protection against **severe disease**
- These results are **preliminary,** the companies will continue to collect more laboratory data and evaluate **real-world effectiveness data** to assess protection against Omicron and inform the most effective path forward.

Pfizer BIONTECH

Next Steps: Boosters and development of a variant-specific vaccine

- **Broad booster campaigns** around the world could help to better protect people and to get through the winter season
- BNT/PFE continue development of a **variant-specific vaccine** against Omicron in case it is needed with the aim to induce high levels of protection against disease as well as a prolonged protection
- First batches of a potential Omicron-based vaccine are planned to be ready for **delivery by March pending regulatory authorization**
- **Several clinical trials with variant-specific vaccines** (alpha, beta, delta and alpha/delta mix) have been previously initiated to collect safety and tolerability data

Thank you

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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 DECEMBER 2021

COMMISSION FILE NUMBER 001-39081

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

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Germany
+49 6131-9084-0
(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 December 8, 2021, BioNTech SE (the "Company") held a press conference to provide an update on the Omicron variant of COVID-19. The presentation 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: December 8, 2021

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	BioNTech Press Conference Conference: Update on the Omicron Variant.