

**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 2020

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 December 2, 2020, BioNTech SE (the “Company”) and Pfizer Inc. announced that the Medicines & Healthcare Products Regulatory Agency (MHRA) in the U.K. has granted a temporary authorization for emergency use for their COVID-19 mRNA vaccine (BNT162b2), against COVID-19. The press release is attached hereto as Exhibit 99.1.

The Company also participated in a press conference and video webcast at 06:30 am CET on December 2, 2020, to provide an update on the status of the COVID-19 vaccine development program of its lead vaccine candidate BNT162b2. The presentation materials are attached hereto as Exhibit 99.2.

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 Financial Officer

Date: December 2, 2020

EXHIBIT INDEX

<u>Exhibit</u>	<u>Description of Exhibit</u>
99.1	<u>Press Release dated December 2, 2020 – Pfizer and BioNTech Achieve First Authorization for a Vaccine to Combat COVID-19.</u>
99.2	<u>Update on our COVID-19 vaccine development program with BNT162b2.</u>



Pfizer and BioNTech Achieve First Authorization in the World for a Vaccine to Combat COVID-19

- U.K. regulator, MHRA, authorizes supply of COVID-19 mRNA vaccine for emergency supply under Regulation 174; Companies are ready to deliver the first doses to the U.K. immediately
- First authorization for a COVID-19 vaccine represents a breakthrough scientific achievement to help combat this devastating pandemic
- The companies previously signed an agreement to supply a total of 40 million doses to the U.K. with delivery in 2020 and 2021
- U.S. FDA and EU EMA decisions on authorization are expected in December

NEW YORK and MAINZ, GERMANY, December 2, 2020 — Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) announced today that the Medicines & Healthcare Products Regulatory Agency (MHRA) in the U.K. has granted a temporary authorization for emergency use for their COVID-19 mRNA vaccine (BNT162b2), against COVID-19. This constitutes the first Emergency Use Authorization following a worldwide Phase 3 trial of a vaccine to help fight the pandemic. Pfizer and BioNTech are anticipating further regulatory decisions across the globe in the coming days and weeks and are ready to deliver vaccine doses following potential regulatory authorizations or approvals. The distribution of the vaccine in the U.K. will be prioritized according to the populations identified in guidance from the Joint Committee on Vaccination and Immunisation (JCVI).

"Today's Emergency Use Authorization in the U.K. marks a historic moment in the fight against COVID-19. This authorization is a goal we have been working toward since we first declared that science will win, and we applaud the MHRA for their ability to conduct a careful assessment and take timely action to help protect the people of the U.K.," said **Albert Bourla, Chairman and Chief Executive Officer, Pfizer**. "As we anticipate further authorizations and approvals, we are focused on moving with the same level of urgency to safely supply a high-quality vaccine around the world. With thousands of people becoming infected, every day matters in the collective race to end this devastating pandemic."

"The Emergency Use Authorization in the U.K. will mark the first time citizens outside of the trials will have the opportunity to be immunized against COVID-19," said **Ugur Sahin, M.D., CEO and Co-founder of BioNTech**. "We believe that the roll-out of the vaccination program in the U.K. will reduce the number of people in the high-risk population being hospitalized. Our aim is to bring a safe and effective vaccine upon approval to the people who need it. The data submitted to regulatory agencies around the world are the result of a scientifically rigorous and highly ethical research and development program."

The MHRA's decision is based on a rolling submission, including data from the Phase 3 clinical study, which demonstrated a vaccine efficacy rate of 95% ($p < 0.0001$) in participants without prior SARS-CoV-2 infection (first primary objective) and also in participants with and without prior SARS-CoV-2 infection (second primary objective), in each case measured from 7 days after the second dose. The first primary objective analysis is based on 170 cases of COVID-19, as specified in the study protocol. Efficacy was consistent across age, gender, race and ethnicity demographics, with an observed efficacy in adults age 65 and over of more than 94%. In the trial, BNT162b2 was generally well tolerated with no serious safety concerns reported by the Data Monitoring Committee to date. Today's decision also is based on a review of Pfizer's and BioNTech's Chemistry, Manufacturing and Control (CMC) data for BNT162b2.

In July 2020, Pfizer and BioNTech announced an agreement with the U.K. to supply 30 million doses of the BNT162b2 mRNA-based vaccine, once authorized for emergency use. That agreement was increased to 40 million doses in early October. The delivery of the 40 million doses will occur throughout 2020 and 2021, in stages, to ensure an equitable allocation of vaccines across the geographies with executed contracts. Now that the vaccine is authorized in the U.K., the companies will take immediate action to begin the delivery of vaccine doses. The first doses are expected to arrive in the U.K. in the coming days, with complete delivery fulfillment expected in 2021.

The companies have filed a request for Emergency Use Authorization with the U.S. Food and Drug Administration (FDA) and have submitted the final Conditional Marketing Authorization Application (CA) following rolling submissions with the European Medicines Agency (EMA) and several other regulatory agencies around the world.

Manufacturing and Delivery Capabilities

Pfizer and BioNTech continue to work in collaboration with governments and Ministries of Health around the world that will distribute the vaccine, subject to country authorization or approval, to help ensure it can reach those most in need as quickly as possible. The companies are leveraging leading vaccine manufacturing and distribution capabilities to quickly scale, manufacture and distribute large quantities of the vaccine at high quality, complementing the mRNA manufacturing expertise of BioNTech gained over almost a decade. Pfizer has a 171-year track record of researching, developing, manufacturing and delivering innovative medicines and vaccines to patients in need. Pfizer and BioNTech are confident in their ability to safely and effectively deliver the vaccine to the people in the U.K. Based on current projections, Pfizer's and BioNTech's combined manufacturing network has the potential to supply globally up to 50 million vaccine doses in 2020 and up to 1.3 billion doses by the end of 2021 (subject to manufacturing capacity and regulatory approval or authorization).

Through its existing mRNA production sites in Mainz and Idar-Oberstein, Germany, BioNTech is able to produce mRNA for commercial supply after having already produced the vaccine candidate doses for the clinical trials. BioNTech will also increase its manufacturing capacity in 2021, once a third site in Germany will start manufacturing to provide further capacities for a global supply of the potential vaccine. Critical to distribution in the U.K. will be Pfizer's manufacturing site in Puurs, Belgium, one of Pfizer's largest sterile injectable sites. The Puurs site is being used primarily for European supply but will also serve as back up supply to Kalamazoo, Michigan, for the U.S. market.

Pfizer has vast experience and expertise in cold-chain shipping and has an established infrastructure to supply the vaccine worldwide, including distribution hubs that can store vaccine doses for up to six months. The company's distribution is built on a flexible just-in-time system that can ship the frozen vials quickly to designated points of vaccination at the time of need. So, this will minimize the need for long term storage anywhere. Vaccination in a pandemic situation is expected to be rapid, with high demand, and we do not expect that the product will need to be stored at any location for more than 30 days.

To assure product quality, the companies have developed specially designed, temperature-controlled shippers for the BNT162b2 vaccine candidate, which can maintain recommended storage conditions (-70°C ±10°C) for extended periods of time without any additional equipment but dry ice. The shipper can maintain temperature for 10 days unopened which allows for transportation to markets globally. Once open, a vaccination center may use the specially designed shippers as a temporary storage solution to maintain the recommended storage conditions (-70°C ±10°C) up to 30 days with re-icing every five days in accordance with the handling instructions. Each shipper contains a GPS-enabled thermal sensor to track the location and temperature of each vaccine shipment 24 hours a day, seven days a week. Once thawed, the vaccine vial can be stored for up to five days at refrigerated (2-8°C) conditions.

Pfizer Disclosure Notice

The information contained in this release is as of December 2, 2020. 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 potential COVID-19 vaccine, the BNT162 mRNA vaccine program and modRNA candidate BNT162b2 (including qualitative assessments of available data, potential benefits, expectations for clinical trials, a temporary authorization for emergency use in the U.K., regulatory submissions, including a pending request for Emergency Use Authorization in the U.S. and rolling submissions with the EMA and several other regulatory agencies around the world, the anticipated timing of regulatory submissions, regulatory approvals or authorizations and anticipated manufacturing, distribution and supply), that involves 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 clinical data (including the Phase 3 data), including the possibility of unfavorable new preclinical or clinical trial data and further analyses of existing preclinical or clinical trial 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 or in larger, more diverse populations upon commercialization; the risk that 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 data from the BNT162 mRNA vaccine program will be published in scientific journal publications and, if so, when and with what modifications; whether regulatory authorities will be satisfied with the design of and results from these and any future preclinical and clinical studies; whether and when any other biologics license and/or Emergency Use Authorization applications may be filed in any jurisdictions for BNT162b2 or any other potential vaccine candidates; whether and when any applications that may be pending or filed for BNT162b2 may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the vaccine candidate's benefits outweigh its known risks and determination of the vaccine candidate's efficacy and, if approved, whether it will be commercially successful; whether and when the U.K. temporary use authorization may be superseded by the grant of a Marketing Authorisation; decisions by regulatory authorities impacting labeling, 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 or third-party suppliers; risks related to the availability of raw materials to manufacture a vaccine; challenges related to our vaccine candidate's ultra-low temperature formulation and attendant storage, distribution and administration requirements, including risks related to handling after delivery by Pfizer; the risk that we may not be able to successfully develop non-frozen formulations; the risk that we may not be able to create or scale up manufacturing capacity on a timely basis or have access to logistics or supply channels commensurate with global demand for any potential approved vaccine, which would negatively impact our ability to supply the estimated numbers of doses of our vaccine candidate within the projected time periods indicated; whether and when additional supply agreements will be reached; uncertainties regarding the ability to obtain recommendations from vaccine technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; 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, 2019 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, bi-specific checkpoint immuno-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, Bayer Animal Health, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma, and Pfizer. For more information, please visit www.BioNTech.de.

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 to develop a potential COVID-19 vaccine; our expectations regarding the potential characteristics of BNT162b2 in our Phase 2/3 trial and/or in commercial use based on data observations to date; the expected timepoint for additional readouts on efficacy data of BNT162b2 in our Phase 2/3 trial; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; the timing for submission of data for, or receipt of, any marketing approval or Emergency Use Authorization; the timing for submission of manufacturing data to the FDA; our contemplated shipping and storage plan, including our estimated product shelf life at various temperatures; and the ability of BioNTech to supply the quantities of BNT162 to support clinical development and, if approved, market demand, including our production estimates for 2020 and 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. 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 production capabilities; and other potential difficulties. For a discussion of these and other risks and uncertainties, see BioNTech's Quarterly Report for the Three and Nine Months Ended September 30, 2020, filed as Exhibit 99.2 to its Current Report on Form 6-K filed with the SEC on November 10, 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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Update on our COVID-19 vaccine development program with BNT162b2

December 2, 2020



This slide presentation includes forward-looking statements

Forward-Looking Statements

Various statements in this slide presentation concerning the future expectations of BioNTech, its plans and prospects, including the Company's views with respect to its efforts to combat COVID-19; the collaboration between BioNTech and Pfizer to develop a potential COVID-19 vaccine; its expectations regarding the potential characteristics of BNT162b2 in its Phase 2/3 trial and/or in commercial use based on data observations to date; the expected timepoint for additional readouts on efficacy data of BNT162b2 in our Phase 2/3 trial; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; the timing for submission of data for, or receipt of, any marketing approval or additional Emergency Use Authorization; the timing for submission of manufacturing data to the FDA; its contemplated shipping and storage plan, including its estimated product shelflife at various temperatures; and the ability of BioNTech to manufacture and supply the quantities of BNT162 to support clinical development and, if approved, market demand, including our production estimates for 2020 and 2021, are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, as amended. Words such as "expects," "plans," "potential," "target," "continue" and variations of these words or similar expressions are intended to identify forward-looking statements. Such statements are based on the current beliefs and assumptions of the management team of BioNTech and on the information currently available to the management team of BioNTech, and are subject to change. The Company will not necessarily inform you of such changes. These forward looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors that could cause the Company's actual results, performance or achievements to be materially different than any future results, performance or achievements expressed or implied by the forward-looking statements. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including but are not limited to: our 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 production capabilities; and other potential difficulties. Any forward-looking statements represent the Company's views only as of today and should not be relied upon as representing its views as of any subsequent date. The Company explicitly disclaims any obligation to update any forward-looking statements. The mRNA vaccine discussed in this slide presentation is an investigational product being developed by BioNTech and its collaborators and are not currently approved by the FDA, EMA or any other regulatory authority.

First emergency use authorization in the world for a COVID-19 vaccine following a Phase 3 trial



Received **Approval for Emergency Supply in the UK** for our COVID-19 mRNA vaccine BNT162b2



Formal Conditional Marketing Authorization Application submitted following rolling review with the European Medicines Agency (EMA)



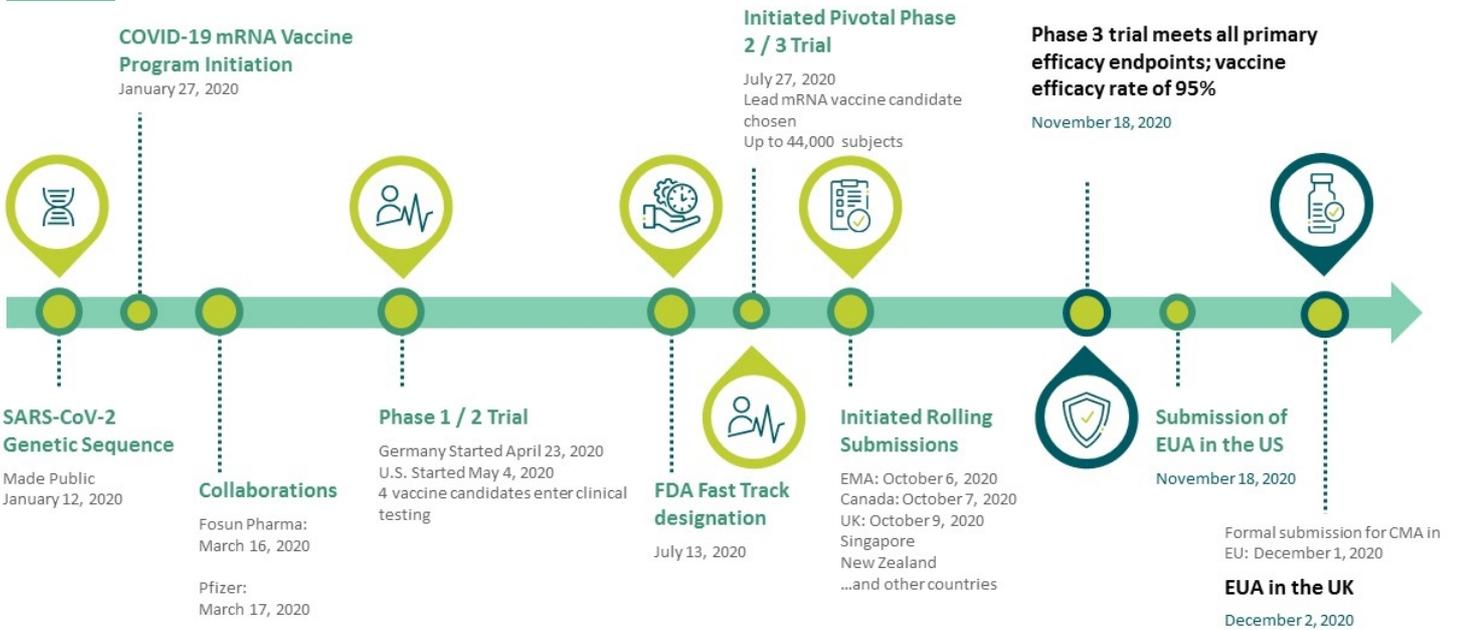
First deliveries in the U.K. expected **within days** based on existing supply agreement



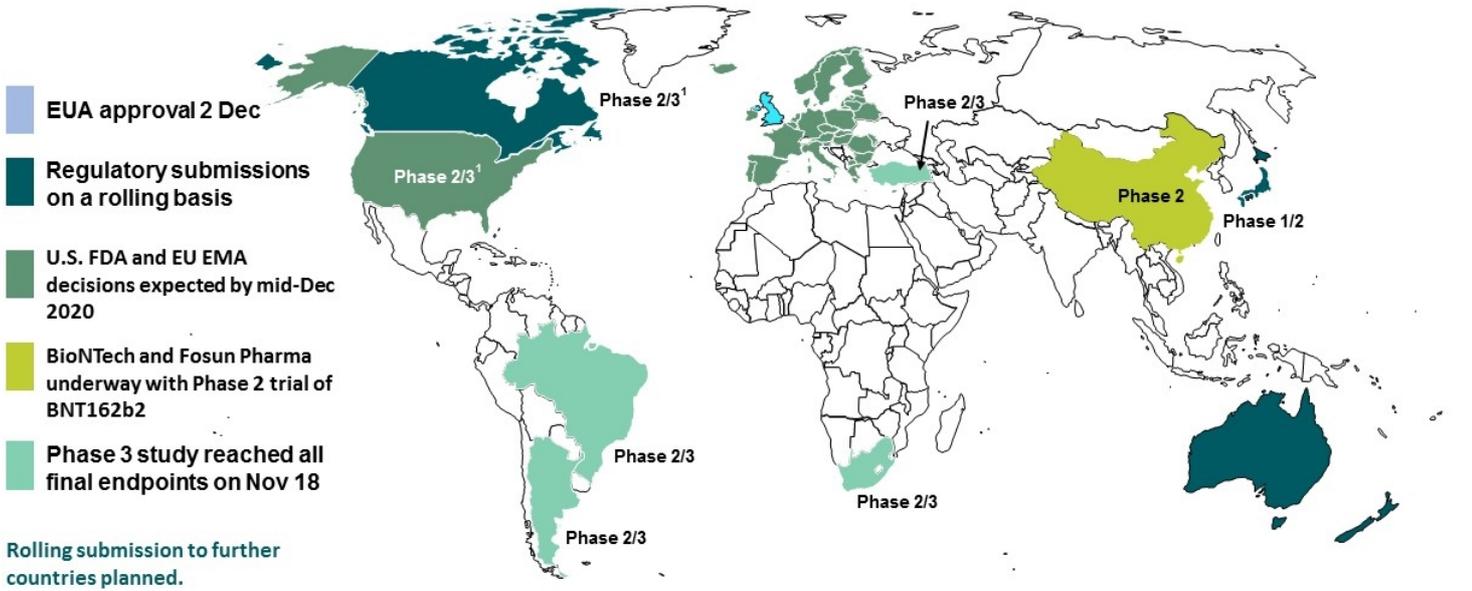
BioNTech will be the Marketing Authorization Holder in the U.K., the U.S., the EU and certain other countries.

Pfizer will market and distribute BNT162b2 in most countries

Project Lightspeed: circa 10-month path to develop an effective and well-tolerated vaccine following highly scientific and ethical standards

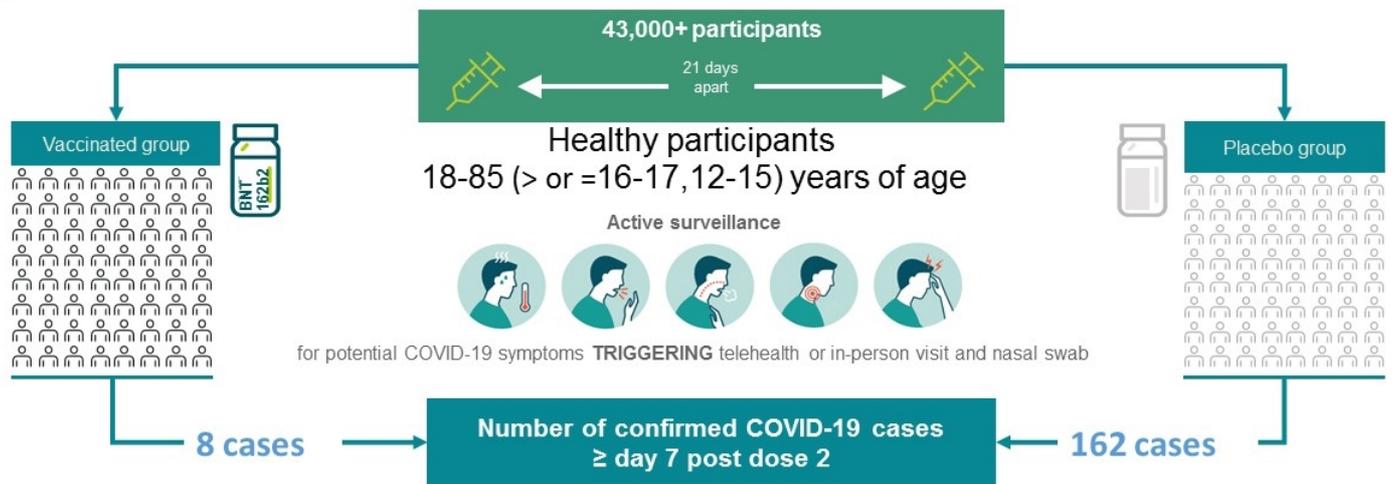


Project Lightspeed is a concerted and large-scale global effort



¹Phase 1/2 remains ongoing in U.S. and EU

BNT162b2: All primary endpoints met in Phase 3 final analysis



- Analysis indicates efficacy rate of 95% in participants with and without prior SARS-CoV-2 infection
- Final analysis of unblinded data by independent data monitoring committee conducted on Nov 18, 2020
- Vaccinated participants will continue to be monitored for efficacy and safety for up to 2 years

High efficacy and favorable safety profile for rapid and potent protection

Gold standard of clinical research – randomized large-scale clinical trial – to ensure safety and efficacy. We took important steps in parallel to accelerate the process together with the authorities – without shortcuts

Clinical Efficacy

95%

in all subjects

>94%

in subjects
>65 y/o

43,000+

participants in phase 3 trials
In U.S., Germany, Turkey, South Africa,
Brazil and Argentina

More than 40% between 65-85 years of age

No serious safety concerns

reported by the independent Data Monitoring Committee (DMC) to date

Generally well tolerated

Observed side-effects are common reactions to vaccination and transient¹. Adverse events were generally mild to moderate in intensity and resolved within a few days after vaccination.

Most frequently observed adverse events were injection site pain, fatigue, headache and muscle pain.

The only Grade 3 adverse events greater than 2% in frequency following dose 2 were:

Headache
2.0%

Fatigue
3.8%

7

¹Full safety assessment has been completed for ~38,000 study participants; BioNTech is also collecting safety data from adolescents and planning a pediatric study and a study on any effects on pregnancy

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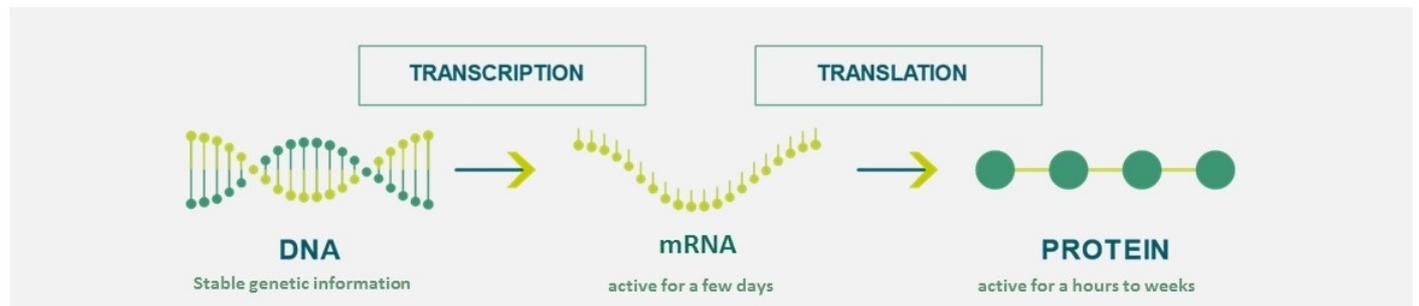


**COVID-19 vaccine
candidate:
BNT162b2**

A journey from
Scientific Discovery
to Drug Approval



What is messenger RNA?

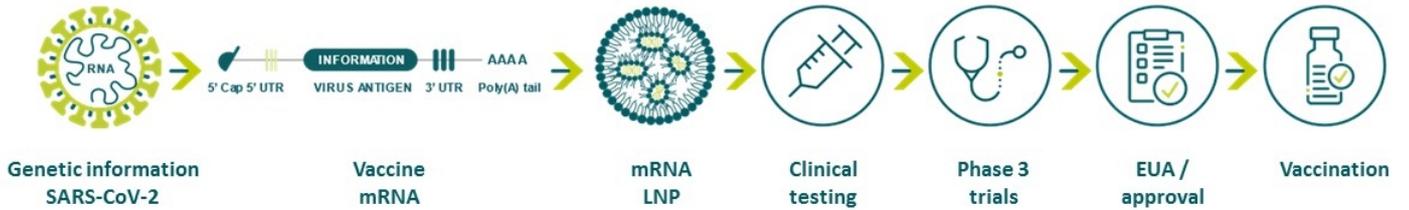


- **The first molecule of life**, involved in almost all aspects of cell biology
- Can be synthesized and engineered to resemble mRNA molecules as they occur **naturally in the cytoplasm of human cells** and transiently deliver proteins of interest
- mRNA has a **transient messenger function and is rapidly degraded** in the body

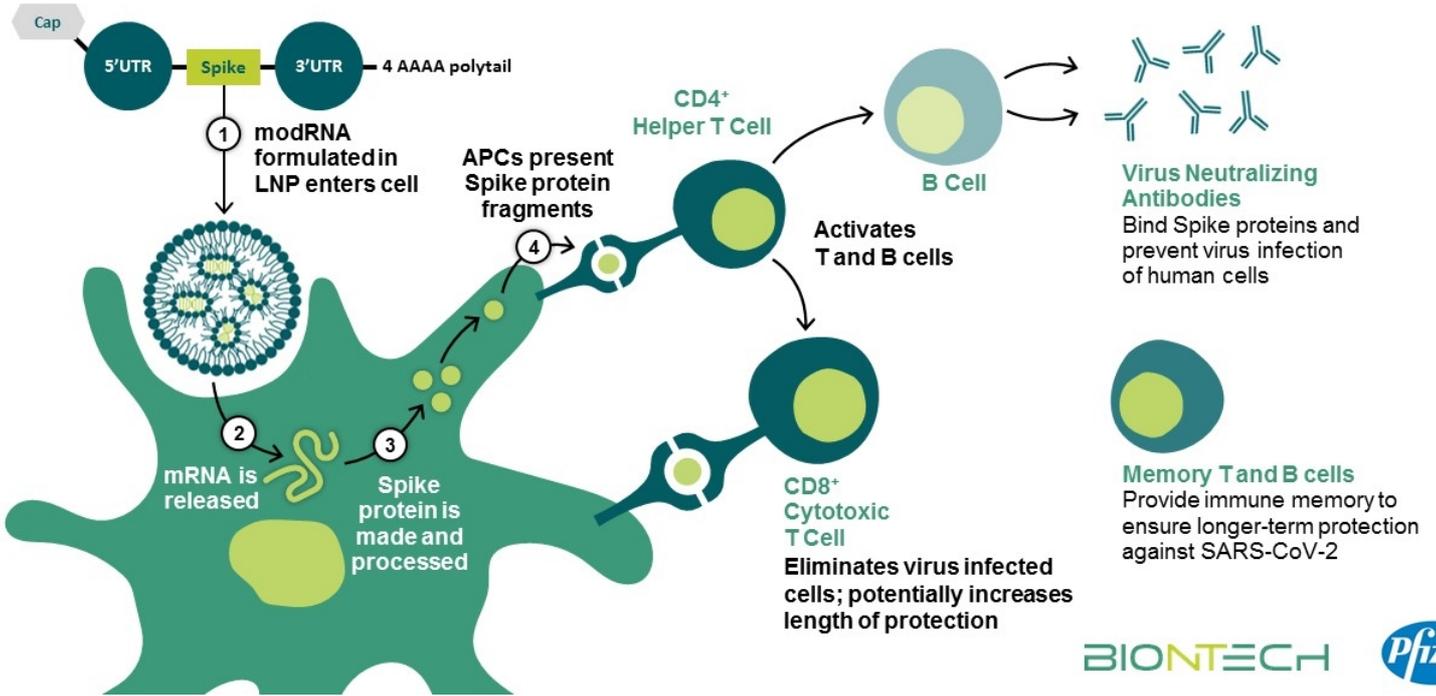
Characteristics:

mRNA is a natural solution for vaccines especially in a pandemic

Natural molecule studied for > 50 years with well-characterized bio-safety properties	Does not require addition of adjuvants or use of a viral vector for administration	Highly scalable production
	High purity and animal material free	Precision vaccine Virus-free Non-integrating into DNA Non-infectious



How mRNA vaccines work – training the immune system for a real infection: Both parts of the immune system activated against virus



Mechanism of action of BNT162b2 exploits multiple levers of immune response: Strong antibody and robust T-cell responses observed

Immunogenicity*³



No or only transient viral shedding in SARS-CoV-2 Virus Challenge

Tolerability*⁴



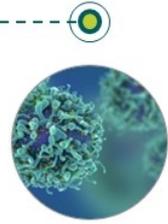
Local reactions and systemic events mostly mild to moderate and transient in effect

Antibody Responses*⁴



Strong SARS-CoV-2 neutralizing antibody responses in both younger and older adults

T Cell Responses*⁵



Expansion of multifunctional CD8+ and TH1-type CD4+ T cells

BioNTech Publications:

1. Holtkamp et al. Modification of antigen-encoding RNA increases stability, translational efficacy, and T-cell stimulatory capacity of dendritic cells. *Blood* 2006.
2. Orlandini von Niessen et al. Improving mRNA-based therapeutic gene delivery by expression-augmenting 3' UTRs identified by cellular library screening. *Molecular Therapy*, 2019.
3. Vogel et al. A prefusion SARS-CoV-2-spike RNA vaccine is highly immunogenic and prevents lung infection in non-human primates. *BioRxiv*, 2020.
4. Walsh et al. RNA-based Covid-19 vaccine BN162b2 selected for a pivotal efficacy study. *NEJM*, 2020.
5. Sahin et al. Concurrent human antibody and TH1-type cell responses elicited by a Covid-19 RNA vaccine. *Nature*, 2020

**Distribution of
BNT162b2 vaccine**



Effective global distribution of the BNT162b2 vaccine is only possible through effective partnerships



Worldwide 50:50 partnership (except Greater China)

- Global pharmaceutical leader with over 88,000 employees and a presence in more than 120 countries around the world
- Successful track record of building leading global vaccine franchises with numerous approved vaccines including leading franchises such as Prevnar
- Vast experience and expertise in cold-chain shipping and global logistics infrastructure to enable global supply worldwide
- BioNTech and Pfizer testing second generation clinical vaccine candidates and formulations

Partnership for China

- A leading pharmaceutical company in China with more than 28,000 employees; 2,200 in R&D
- End-to-end capabilities across R&D, product commercialization and distribution and healthcare services
- Broad reach across China with a presence in 33 of 34 provinces and ability to distribute to Tier 1-4 cities



BNT162: Global vaccine supply commitments*

- **Both BioNTech and Pfizer jointly scaling up manufacturing capacity to enable global supply:**
 - BioNTech already producing vaccine for clinical supply at 2 manufacturing sites in Germany
 - Pfizer will activate 3 manufacturing sites in the U.S. and 1 site in Europe
- **> 570 million doses committed*** for 2020 and 2021 in 13 countries and the EU with an option to purchase an **additional 600 million doses**
- Additional **commercial discussions ongoing** with multiple **countries** and supranational organizations including **COVAX**

Commercial supply commitments*		
Region	Number of Doses	Order value
Canada	Not disclosed	Not disclosed
EU	200 million with option for additional 100 million	Not disclosed
Japan	120 million	Not disclosed
United Kingdom	40 million	Not disclosed
United States	100 million with option for additional 500 million	\$1.95 billion for first 100 million doses
Multiple additional countries	Not disclosed	Not disclosed

* Subject to clinical success and regulatory approval
15



Minimal changes to pre-existing cold-chain supply: Ready for a robust UK rollout

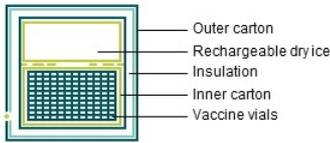
UK deployment models

- ✓ NHS Trusts
- ✓ Large scale vaccination sites
- ✓ Community/primary care led

Doses destined for the UK are manufactured in Belgium



Bespoke vaccine freezer boxes; each freezer box can host between approx. 1000 and 5000 doses



Pre-packed boxes are transported and distributed to vaccination centers



GPS trackers and thermo-sensors relay temperature data to ensure safe delivery



At vaccination centers, the vaccines can be stored in delivery boxes and regular fridges



There are over 1,500 immunization centers in England prepared to receive the vaccine vials



1

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Quick facts

One tray of vaccine vials is sufficient for almost 100 people

Each vial contains 5 doses (after dilution)

Diluted vials need to be used within 6 hours, per WHO regulations

This is more than enough time to vaccinate 5 people

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Ready to deliver – over 30 days storage in boxes and regular fridge: BNT162b2 will be administered like many other vaccines



Administration to vaccinees at **room temperature**

Injected intramuscular (arm); no additional equipment needed for administration at mass vaccination center



Storage in **delivery box** and **regular fridge** at vaccination centers for **20 days**

Up to 15 days with re-icing; up to 5 days in regular fridge (2-8°C)



Transport from manufacturing site/storage to vaccination centers and beyond, **based on governments' distribution strategies**

Storage at -70°C only necessary in case of long-term storage (for months), not necessary at vaccination centers; special warehouses already identified

Stability studies provide supporting evidence for transport of defrosted vials (2-8°C) for up to 6 hours, enabling vaccination centers to serve satellite facilities such as care homes



Next steps: roll-outs in other regions of the world upon regulatory approval

United Kingdom BioNTech MA Holder 1st Approval today	
United States BioNTech MA Holder Review on Dec 10	
European Union BioNTech MA Holder Review expected in Dec	
Canada BioNTech MA Holder	

+ other states will follow upon regulatory approval

Q&A



The Biontech logo is displayed in a light green, sans-serif font. The letters 'B', 'I', 'O', 'N', 'T', 'E', and 'C' are in a standard weight, while the 'H' is significantly bolder. The background of the top half of the page is a dark teal color with a pattern of faint, white, overlapping circular lines that create a grid-like effect.

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