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 APRIL 2020

COMMISSION FILE NUMBER 001-39081

BioNTech SE

(Translation of registrant's name into English)

An der Goldgrube 12 D-55131 Mainz
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 April 22, 2020, BioNTech SE (the "Company") issued a press release, announcing regulatory approval to commence a first clinical trial of COVID-19 vaccine candidates from the German regulatory authority, Paul-Ehrlich-Institut, as well as details of a conference call and webcast to be held at 8:00 am EST on April 23, 2020. The press release is attached hereto as Exhibit 99.1.

The Company also participated in a press conference held by the Paul-Ehrlich-Institut at 11:00 am CET on April 22, 2020. The presentation materials from the press conference and for the conference call and webcast are attached hereto as Exhibit 99.2.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, 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: April 22, 2020

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	Press Release dated April 22, 2020 - BioNTech and Pfizer announce regulatory approval from German authority Paul-Ehrlich-Institut to commence first clinical trial of COVID-19 vaccine candidates.
99.2	Presentation: BNT162 COVID-19 Vaccine Update on Clinical Development Program April 2020.

Exhibit 99.1

BioNTech and Pfizer announce regulatory approval from German authority Paul-Ehrlich-Institut to commence first clinical trial of COVID-19 vaccine candidates

- **First COVID-19-related clinical trial to start in Germany**
- **Initial dose escalation phase to target dose range of 1µg to 100µg**
- **Clinical supply from BioNTech's GMP-certified mRNA production facilities in Europe**
- **Four vaccine candidates to enter clinical development**

MAINZ, Germany, and NEW YORK, USA, April 22, 2020 (GLOBE NEWSWIRE) – BioNTech SE (Nasdaq: BNTX, "BioNTech" or "the Company") and Pfizer Inc. (NYSE: PFE), have announced today that the German regulatory authority, the Paul-Ehrlich-Institut, has approved the Phase 1/2 clinical trial for BioNTech's BNT162 vaccine program to prevent COVID-19 infection. BioNTech and Pfizer are jointly developing BNT162. The trial is the first clinical trial of a COVID-19 vaccine candidate to start in Germany, and is part of a global development program. Pfizer and BioNTech will also conduct trials for BNT162 in the United States upon regulatory approval, which is expected shortly.

The four vaccine candidates are the first candidates from BioNTech's COVID-19-focused project "Lightspeed", each representing different mRNA formats and target antigens. Two of the four vaccine candidates include a nucleoside modified mRNA (modRNA), one includes a uridine containing mRNA (uRNA), and the fourth vaccine candidate utilizes self-amplifying mRNA (saRNA). Each mRNA format is combined with a lipid nanoparticle (LNP) formulation. The larger spike sequence is included in two of the vaccine candidates, and the smaller optimized receptor binding domain (RBD) from the spike protein is included in the other two candidates. The RBD-based candidates contain the piece of the spike that is thought to be most important for eliciting antibodies that can inactivate the virus.

The dose escalation portion of the Phase 1/2 trial will include approximately 200 healthy subjects between the ages of 18 to 55 and will target a dose range of 1 µg to 100 µg aiming to determine the optimal dose for further studies as well as evaluate the safety and immunogenicity of the vaccine. The study will also evaluate the effects of repeated immunization for three of the four vaccine candidates which utilize uRNA or modRNA. Subjects with a higher risk for a severe COVID-19 infection will be included in the second part of the study.

"We are pleased to have completed pre-clinical studies in Germany and will soon initiate this first-in-human trial ahead of our expectations. The speed with which we were able to move from the start of the program to trial initiation speaks to the high level of engagement from everyone involved," says **CEO and Co-founder of BioNTech, Ugur Sahin**.

"Pfizer and BioNTech's partnership has mobilized our collective resources with extraordinary speed in the face of this worldwide challenge," said **Albert Bourla, Pfizer Chairman and CEO**. "Now that the work in Germany can commence, we are looking forward to and actively preparing for the potential start of this unique and robust clinical study program in the United States in the near future."

During the clinical development stage, BioNTech will provide its partners clinical supply of the vaccine from its GMP-certified mRNA manufacturing facilities in Europe.

BioNTech is also collaborating with Fosun Pharma to develop BNT162 in China, where the companies expect to conduct trials.

During a press conference held by the Paul Ehrlich Institut today (April 22, 2020) at 11am CET, Ugur Sahin also stated that first data readouts from this Phase 1/2 clinical trial of the BNT162 product candidates could be expected as early as end of June 2020.

BioNTech Conference Call and Webcast
BioNTech will host a conference call and webcast Thursday, April 23, 2020 at 08:00 a.m. EDT (2:00 p.m. CET). The slide presentation and audio of the webcast will be available via the following link: https://edge.media-server.com/mmc/p/b9xow5kn
To participate in the conference call, please dial the following numbers 15-20 minutes prior to the start of the webcast and provide the Conference ID: 8534807

United States international: +1 (646) 741 3167

United States domestic (toll-free): +1 (877) 870 9135

Germany: +49 (0) 692 2222 625

Standard International: +44 (0) 2071 928338

The slide presentation and audio of the webcast will be available on BioNTech's website https://biontech.de/ in the "Events & Presentations" page of the Investor Relations section. A replay of the webcast will be available shortly after the conclusion of the call and archived in the same section of the BioNTech's website.

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 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 Eli Lilly and Company, Genmab, Sanofi, Bayer Animal Health, Genentech, a member of the Roche Group, 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 planned next steps in BioNTech's project Lightspeed; the timing to initiate clinical trials of BNT162 in Germany; collaborations between BioNTech and Pfizer, and BioNTech and Fosun Pharma, to develop a potential COVID-19 vaccine; the expected timing of clinical trials of BNT 162 in the United States and China; and the ability of BioNTech to supply the quantities of BNT162 to support clinical development. 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: competition to create a vaccine for Covid-19 and potential difficulties. For a discussion of these and other risks and uncertainties, see BioNTech's Annual Report on Form 20-F filed with the SEC on March 31, 2020, which has been filed with the SEC and 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.

About Pfizer Inc.: 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 150 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 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 April 22, 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, BioNTech's mRNA vaccine program, BNT162, a collaboration between BioNTech and Pfizer to develop a potential COVID-19 vaccine and the expected timing of clinical trials, including their potential benefits, 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 the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from the clinical studies; whether and when any biologics license applications may be filed in any jurisdictions for any potential vaccine candidates under the collaboration; whether and when any such applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether any such vaccine candidates will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of any such vaccine candidates, including development of products or therapies by other companies; manufacturing capabilities or capacity; uncertainties regarding the ability to obtain recommendations from vaccine technical committees and other public health authorities regarding any such vaccine candidates and uncertainties regarding the commercial impact of any such recommendations; 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 http://www.sec.gov/ and www.Pfizer.com.

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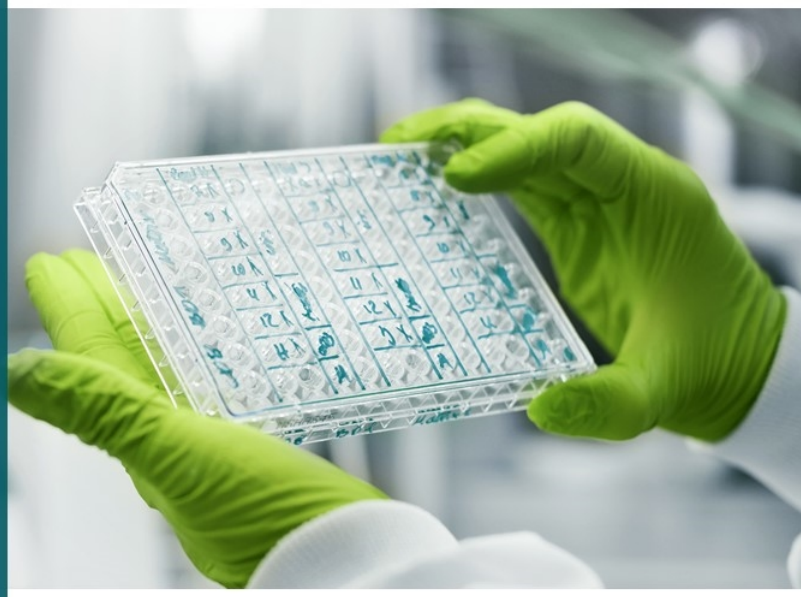
Exhibit 99.2

BioNTech

BNT162 COVID-19 Vaccine

Update on Clinical Development Program



April 2020

BIONTECH

This slide presentation includes forward-looking statements

BioNTech Forward-looking statements

This presentation 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 planned next steps in BioNTech's project Lightspeed; the timing to initiate clinical trials of BNT162 in Germany; collaborations between BioNTech and Pfizer, and BioNTech and Fosun Pharma, to develop a potential COVID-19 vaccine; the expected timing of clinical trials of BNT 162 in the United States and China; and the ability of BioNTech to supply the quantities of BNT162 to support clinical development. Any forward-looking statements in this presentation 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: competition to create a vaccine for Covid-19 and potential difficulties. For a discussion of these and other risks and uncertainties, see BioNTech's Annual Report on Form 20-F filed with the SEC on March 31, 2020, which has been filed with the SEC and 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.

Next generation immunotherapy

Harnessing the full potential of the immune system

Broad suite of novel technology platforms

Immunotherapies for cancer and infectious diseases

Fully integrated w/in-house GMP manufacturing

Industry-leading global collaborations

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COVID-19 vaccine program with global consortium

- "Lightspeed" program includes both vaccines and therapeutics
- BNT162: different mRNA-based vaccine candidates aimed at preventing COVID-19 infection
- Exploits highly potent Lipid-Nano-Particulate (LNP) mRNA vaccine platforms for the prevention of infectious diseases
- Preclinical activity demonstrated in multiple infectious disease models including Influenza, Ebola Virus, Zika Virus, HIV and others
- To be manufactured at state-of-the-art GMP certified mRNA manufacturing facilities in Europe

Pfizer

- Collaboration signed for co-development and distribution outside of China
- R&D sites from both companies
- Builds on previous R&D collaboration for mRNA-based vaccines for influenza

FOSUNPHARMA 复星医药

- Joint development in China and collaboration to conduct trials in China
- BNTX to receive up to $135m in upfront, investment and milestones
- Companies to share gross profits from sales in China

Demonstrated rapid progress for COVID-19 program

Paul-Ehrlich-Institut (PEI) has approved Phase 1/2 trial for BNT162

- First clinical trial of COVID-19 vaccine in Germany
- Fourth regulatory approval worldwide for vaccine candidate testing
- Additional trials expected in USA (Pfizer), Europe, and China (Fosun Pharma)
- Regulatory approval to conduct trials of BNT162 USA expected shortly

Vaccines developed with different mRNA formats and target antigens

- 2 with mod(RNA), 1 with u(RNA) and 1 with sa(RNA)
- All combined with lipid nanoparticle (LNP) formulation
- Targeting larger spike sequence and smaller optimized receptor binding domain (RBD) from spike protein
- Initial dose escalation phase to target dose range of 1µg to 100µg

Clinical trial materials from BioNTech's GMP-certified mRNA manufacturing facilities in Europe

Dr. Ugur Sahin,
Co-Founder and CEO

BNT162 Program Update

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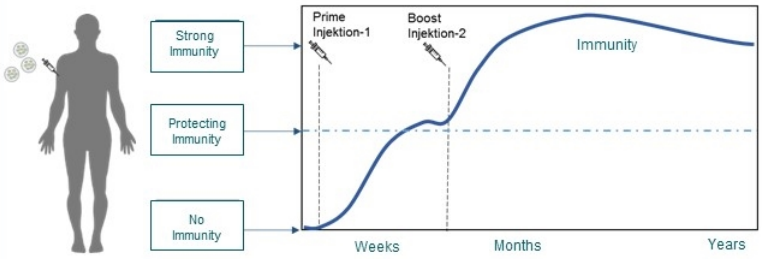
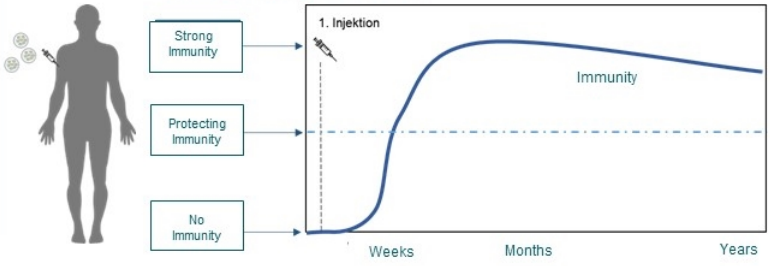
Vaccines represent the only long-term solution to the COVID-19 pandemic

- Goal: Rapid development, clinical testing and approval of well-tolerated and safe vaccines for prevention of COVID-19
- Based on our established mRNA technologies
- Induction of long-term memory immune response, protecting individuals from SARS-CoV-2 infections and COVID-19 illness
- Clinical testing of 4 vaccine candidates
- R&D collaborations with Pfizer (worldwide, outside of China) and Fosun (China)

Prime / boost vaccine

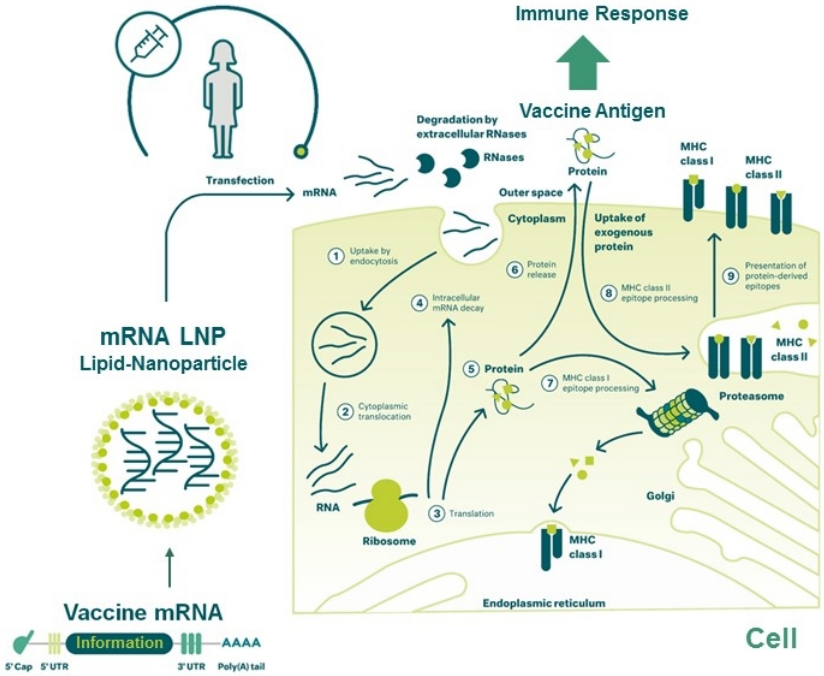


Prime-only vaccine



mRNA vaccines

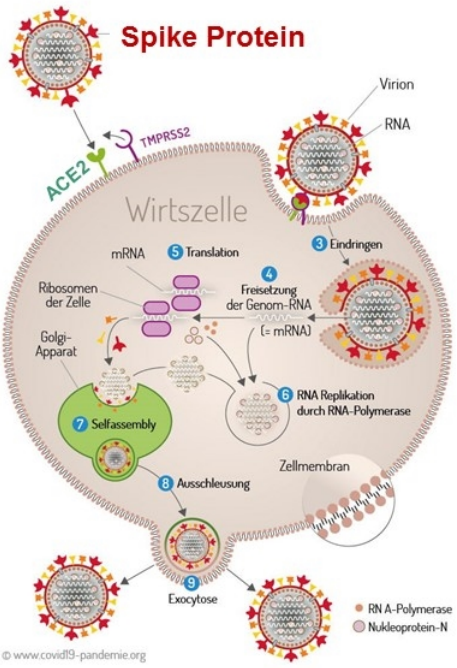
- Mechanism of action of mRNA vaccines: Delivery of mRNA-coded genetic information as blueprint for vaccine into cells of vaccinated individual
- mRNA uptake into cells results in vaccine antigen synthesis
- mRNA stimulates immune system of vaccinated individual, generating immune response to the vaccine antigen

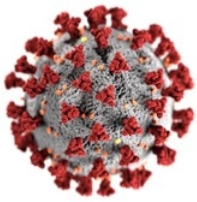


mRNA pharmaceuticals as pandemic vaccines

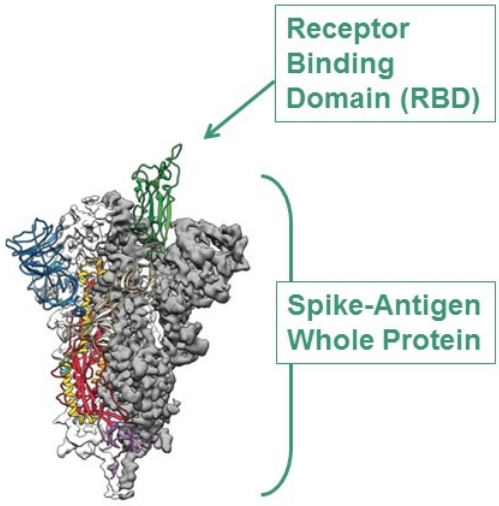
- Synthetic variants of naturally occuring genetic molecules
- Biochemically defined biopharmaceuticals
- High purity and free of animal product
- Inherent immune-activating qualities with no need for additional adjuvant
- Stimulates both antibody and T-cell immune response at low doses
- More than 400 patients does in cancer setting since 2013 (both safety and efficacy)
- Highy scalable production with potential to manufacture hundreds of millions of doses

BNT162 target structures: SARS-CoV-2 Spike-Protein and RBD





SARS-COV-2
(3D Model)



SARS-COV-2
Spike Protein 3D Structure
(Wrapp et al., 2020, Science)

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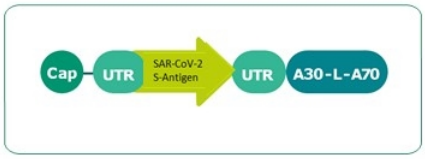
BNT162 mRNA vaccine technologies

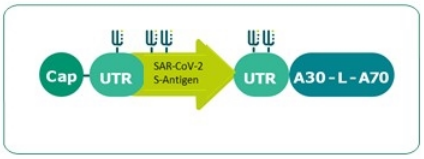
Uridine mRNA (uRNA)[1]



Rationale

- Prime / boost
- Strong adjuvant effect
- Active at low doses
- Strong antibody response
- CD8 T-Cells > CD4 T-Cells

Nucleoside-modified mRNA (modRNA) [2]



Rationale

- Prime / boost
- Moderate adjuvant effect
- Very strong antibody response
- CD4 T-Cells > CD8 T-Cells

Self-amplifying mRNA (saRNA) [3]

Rationale

- Prime (1x injection)
- Long-term activity
- Very strong antibody response
- Very strong T-Cell response (CD8 and CD4)
- Potent immune protection at low doses (approx. 60x lower dosages required to induce immunity vs. uRNA observed in preclinical models)

[1] Kreiter et al., Nature 2015, Kranz, Diken et al., Nature, 2016, Sahin et al., Nature 2017, Reinhard et al., Science 2020

[2] Pardi et al., Nature, 2017, Pardi et al., Mol Ther 2019, [3] Vogel et al., Mol. Ther 2018, Moyo et al., Mol Ther 2019

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Project Lightspeed: BioNTech`s COVID-19 Program

- Established R&D concept (January 16-29)
- Initiation of R&D activities (January 29)
- Advisory meetings with regulatory institution in Germany (PEI) (February 6, March 20, April 8)
- Development of assays for the analysis of SARS-CoV-2 immune response
- Pre-clinical testings of >20 mRNA vaccine candidates
- BNT162 vaccine candidates for clinical testing
  - GLP toxicology studies
  - Demonstration of strong vaccine efficacy in animal studies (antibodies and T-Cells)
  - Clinical grade GMP manufacturing of research vaccine candidates

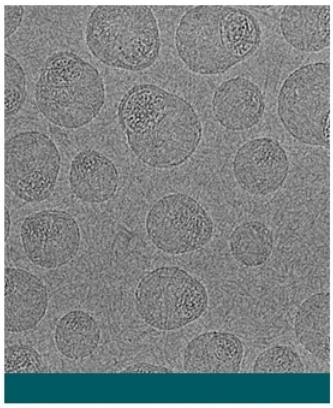
< 3 Months

- Application for clinical testing in Germany: PEI and EK Baden Württemberg (April 9, April 18)
  - Reports (preclinical data, manufacturing & quality control)
  - Study protocol, investigator brochure, additional documents
- Clinical trial approval for first vaccine candidate by PEI & Ethics Commission (April 21)
- Further regulatory applications in preparation for trials in USA (Pfizer) and China (Fosun Pharma)

BNT162b1

Nucleoside-modified mRNA against RBD subunit of SARS-CoV-2
mRNA nanoparticle-formulation*

mRNA LNP



EM imaging, Tom Madden, Acuitas

* Collaboration with Acuitas (Vancouver), Polymun (Austria)

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BNT162 Phase 1/2 clinical trial in Germany

Design

- Testing of 4 vaccine candidates in one clinical trial
- Concomitant approval of every vaccine candidate
- Separate evaluation of each candidate
- Testing via i.m. injection of 1µg -100µg doses
- Prime / boost or prime only

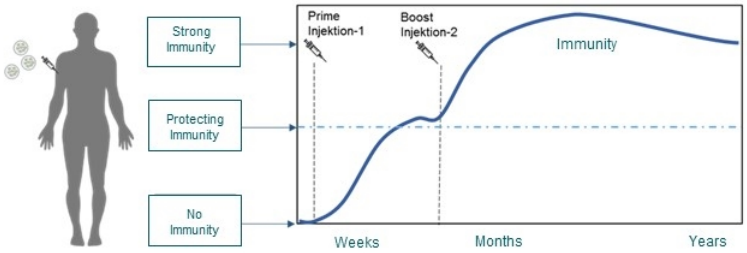
Target Population

- ~200 healthy subjects aged 18 to 55
- Subjects with higher risk of severe infection included in 2nd part

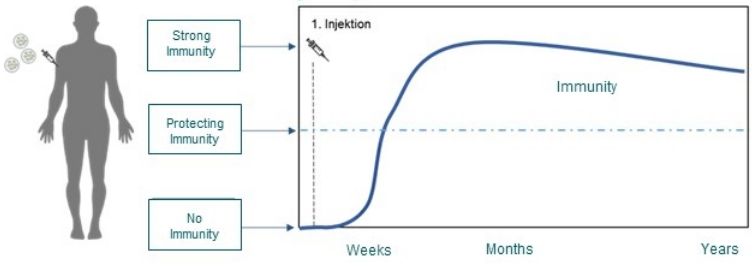
Objectives

- Safety and tolerability
- Immunogenicity (VNT = virus neutralization test)
- Determine optimal dose for further studies

Prime / Boost Impfstoff



Prime-only Impstoff



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Summary - Outlook

- Rapid progress from start to approval for FIH trials demonstrated
- Established international collaboration consortium to address pandemic (Pfizer, Fosun)
- Additional trials expected, including in the USA, Europe and China
  - Regulatory approval to begin clinical testing expected shortly in USA
- Four vaccine candidates representing different mRNA formats and targeting different antigens to be studied
  - All combined with LNP formulation
- Phase 1/2 dose escalation trial to determine optimal dose for further studies and evaluate both safety and immunogenicity
- BioNTech providing clinical trial material from GMP-certified mRNA manufacturing facilities in Europe