

BioNTech

BNT162 COVID-19 Vaccine

Update on Clinical
Development Program

April 2020



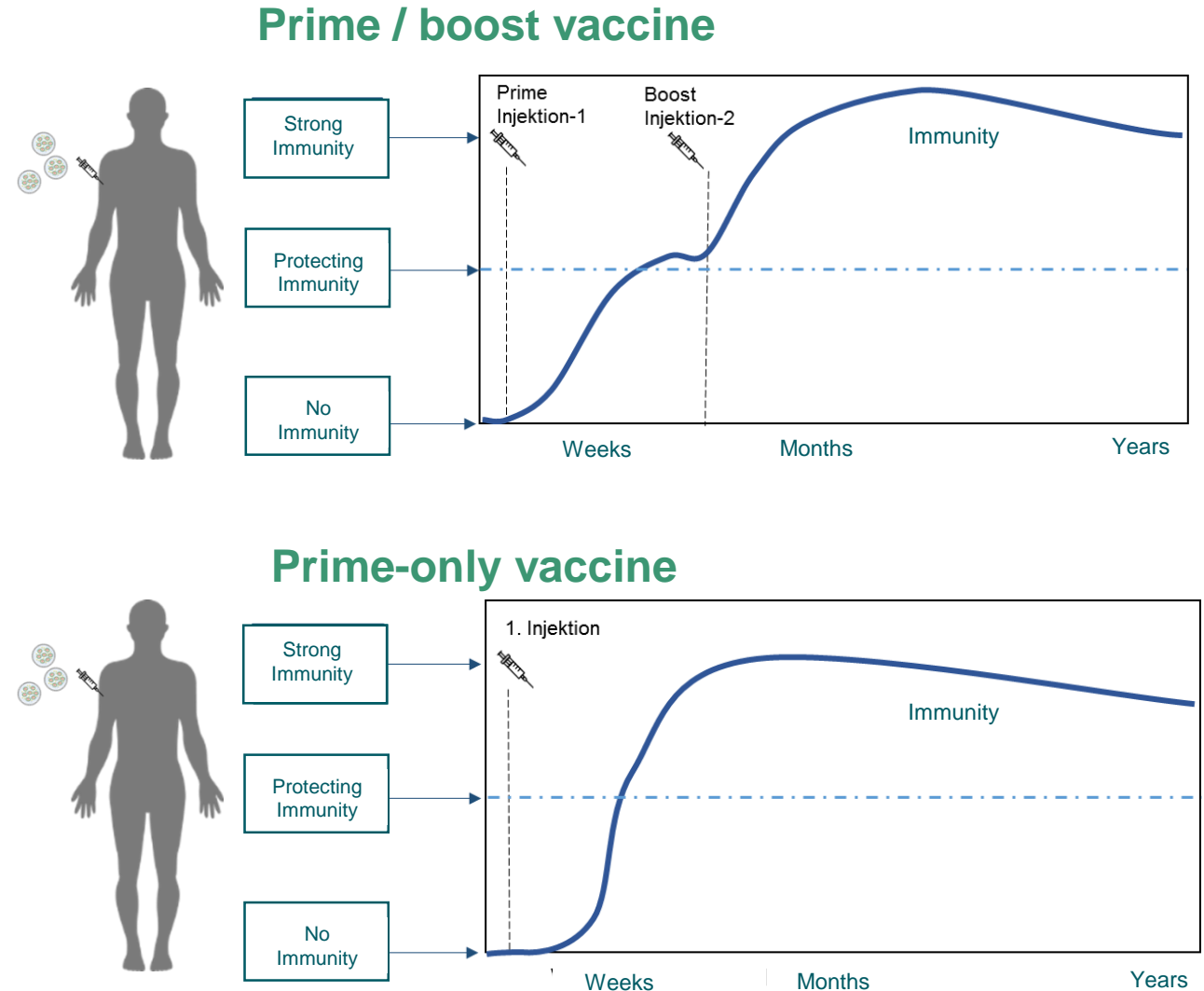
This slide presentation includes forward-looking statements

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.

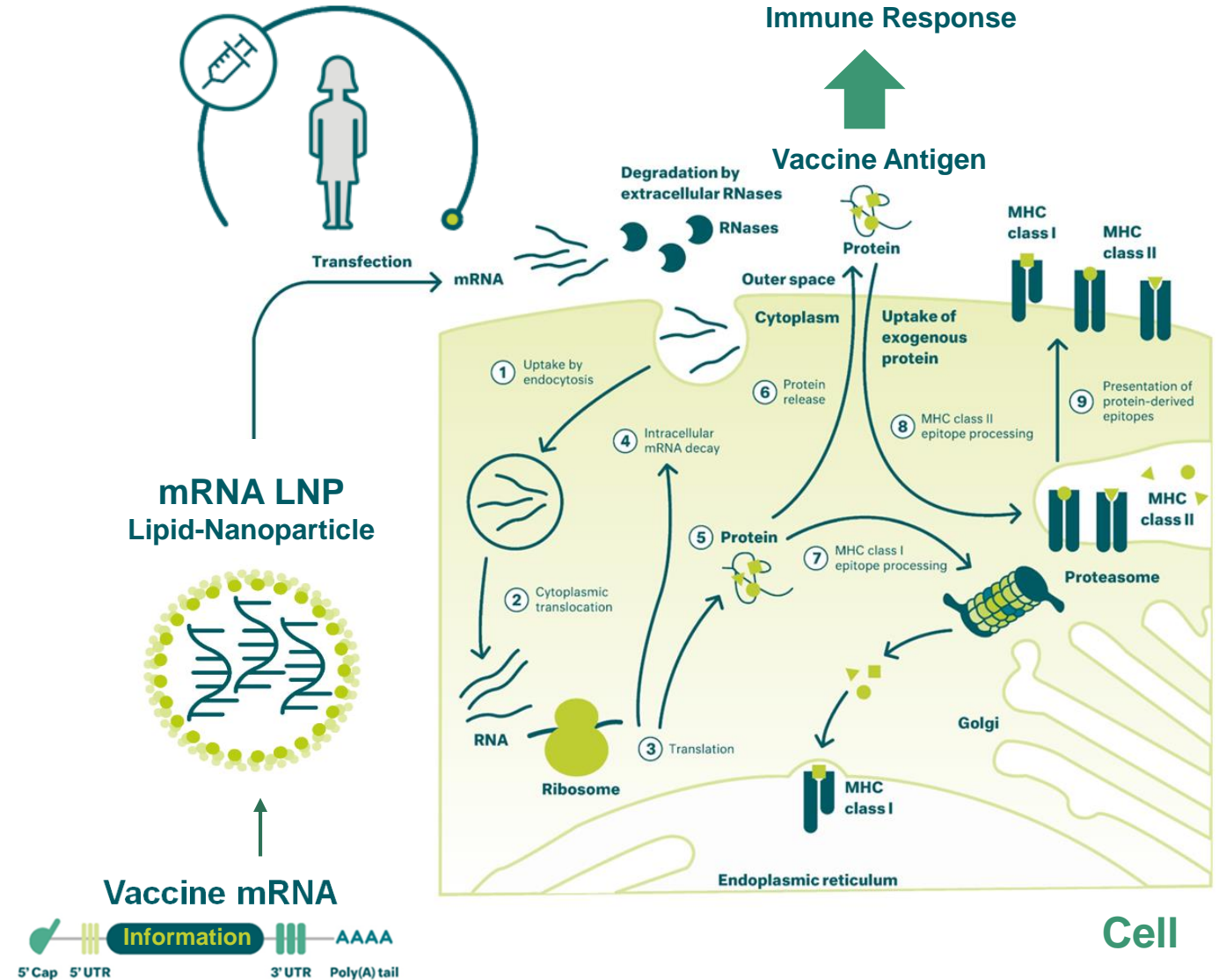
Vaccines represent the only long-term solution to the COVID-19 pandemic

- 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)



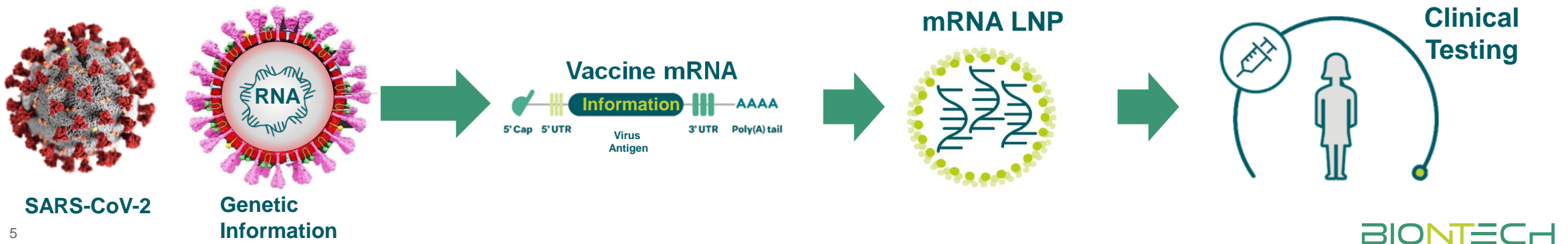
mRNA vaccines

- 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

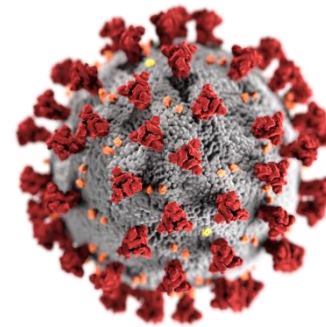
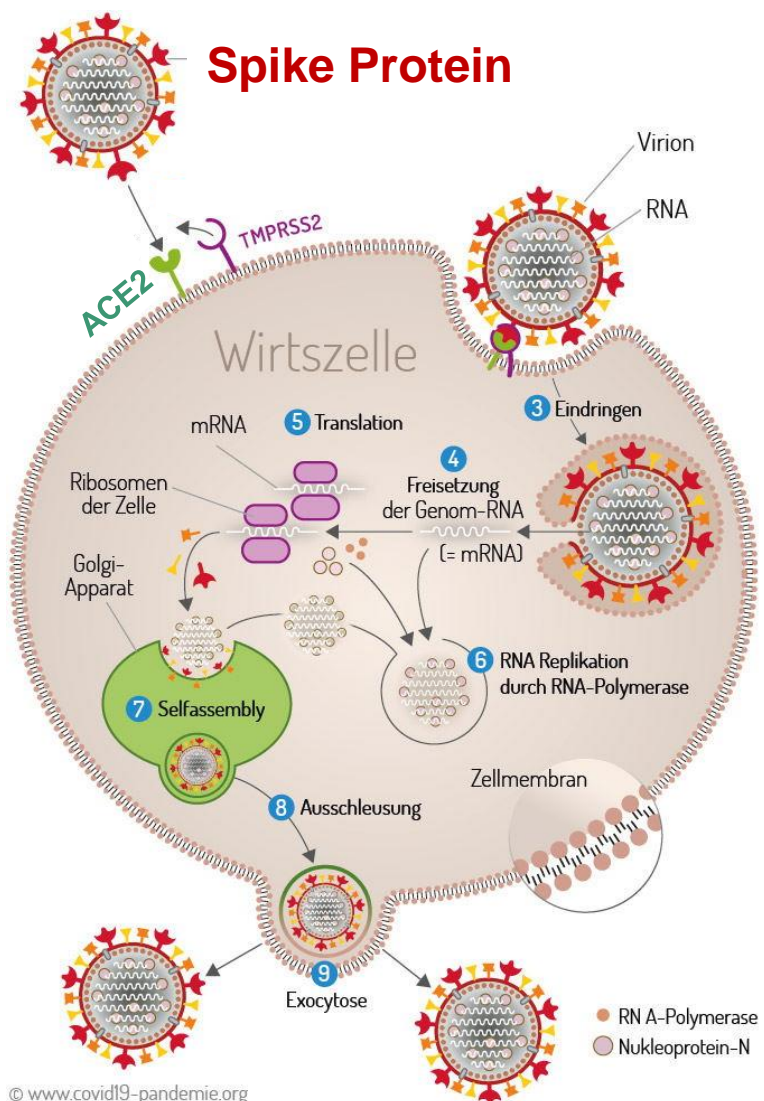


mRNA pharmaceuticals as pandemic vaccines

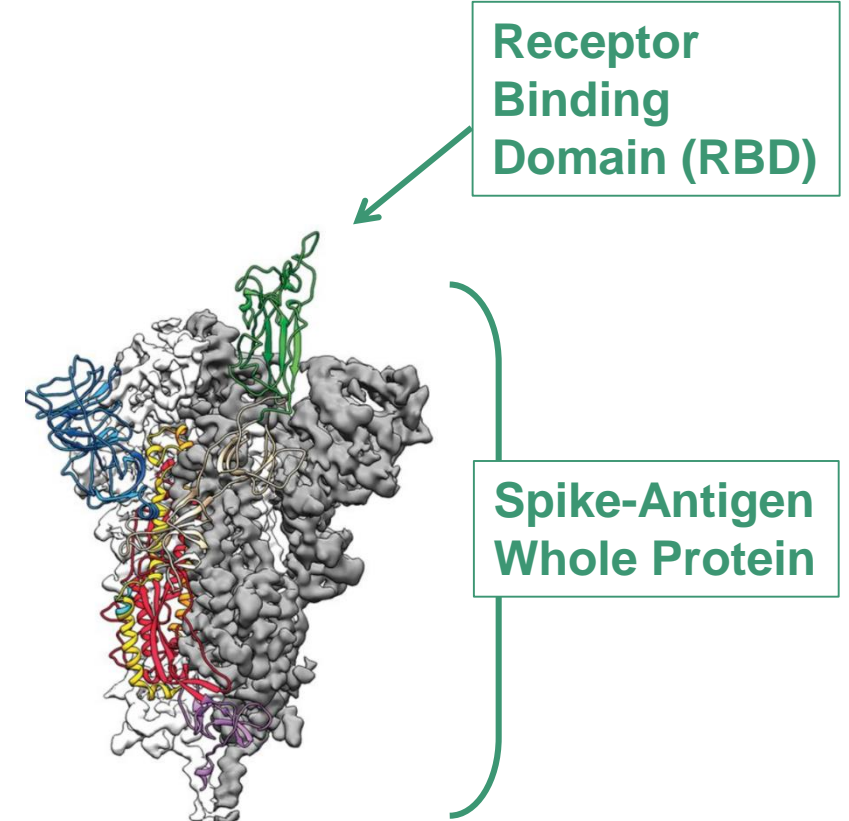
- Synthetic variants of naturally occurring genetic molecules
- Biochemically defined biopharmaceuticals
- High purity and free of animal product
- Inherent immune-activating qualities with no need for additional adjuvant
- Stimulates both antibody and T-cell immune response at low doses
- More than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



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



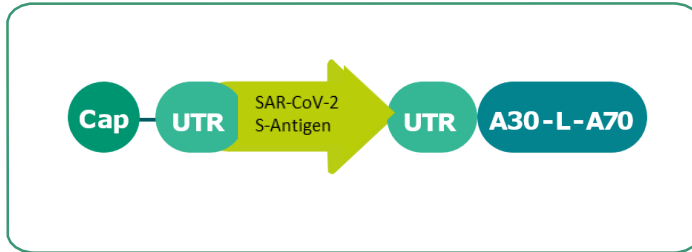
**SARS-COV-2
(3D Model)**



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

BNT162 mRNA vaccine technologies

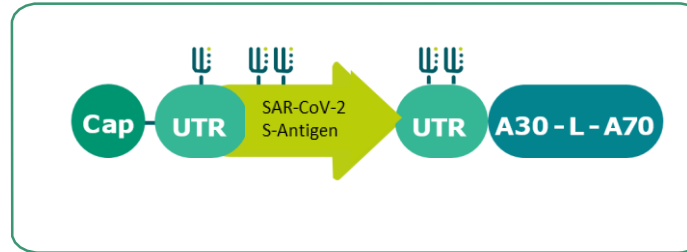
Uridine mRNA (uRNA)¹



Rationale

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

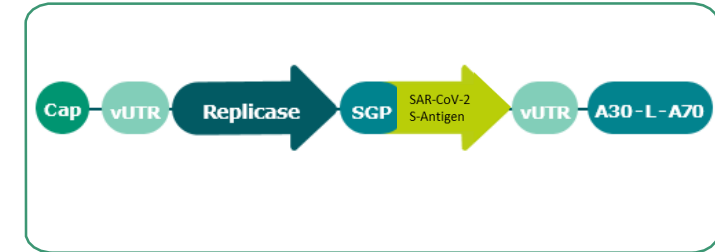
Nucleoside-modified mRNA (modRNA)²



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

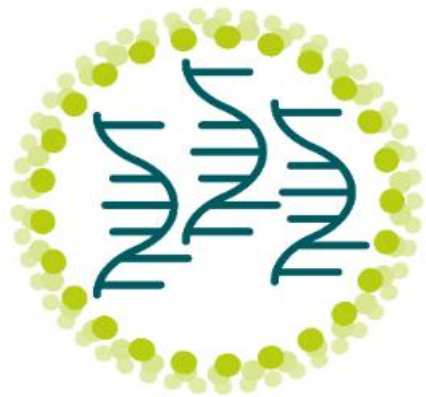
Project Lightspeed: BioNTech's COVID-19 Program

- 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
- 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)

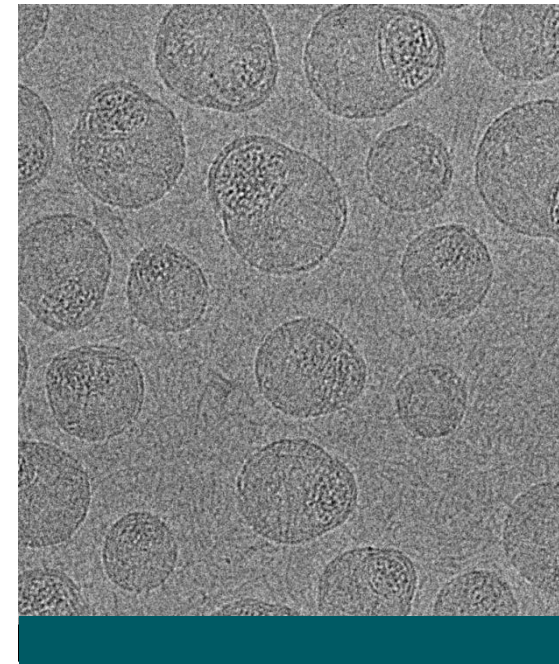
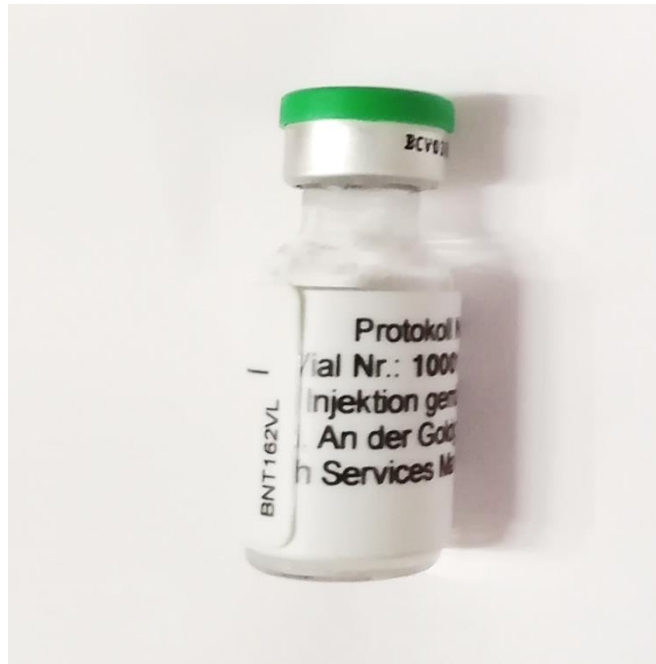
< 3 Months

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)

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

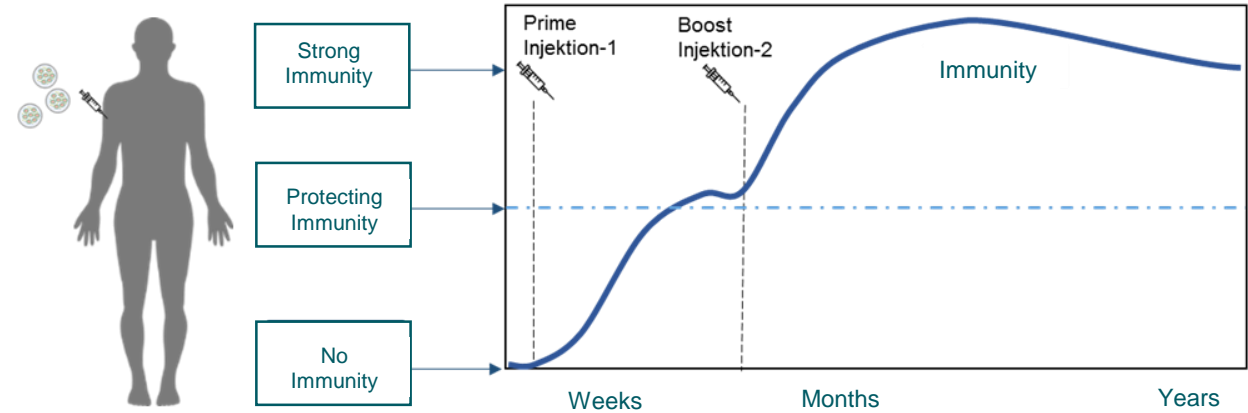
Target Population

- ~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 Impfstoff

