BioNTech

BNT162 COVID-19 Vaccine

Update on Clinical Development Program

April 2020
BioNTech Forward-looking statements

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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)
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 Spike Protein 3D Structure (Wrapp et al., 2020, Science)
**BNT162 mRNA vaccine technologies**

**Uridine mRNA (uRNA)**
- Prime / boost
- Strong adjuvant effect
- Active at low doses
- Strong antibody response
- CD8 T-Cells > CD4 T-Cells

**Nucleoside-modified mRNA (modRNA)**
- Prime / boost
- Moderate adjuvant effect
- Very strong antibody response
- CD4 T-Cells > CD8 T-Cells

**Self-amplifying mRNA (saRNA)**
- 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)

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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
- 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)
BNT162 COVID-19 Vaccine Development

**BNT162b1**

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

* Collaboration with Acuitas (Vancouver), Polymun (Austria)
BNT162 COVID-19 Vaccine Development

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