BioNTech

BNT162 COVID-19 Vaccine

Program Update

April 23, 2020
This slide presentation includes forward-looking statements

BioNTech Forward-looking statements

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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 with in-house GMP manufacturing
- Industry-leading global collaborations
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

• 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

• 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
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

BioNTech mRNA vaccines
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
BNT162 COVID-19 Vaccine Development

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
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 Ethic Commission (April 9, April 18)
- 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
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 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
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
• Four vaccine candidates representing different mRNA formats and targeting different antigens to be studied
• 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
Q&A