COVID-19 Vaccine Development Program
July 1, 2020
Disclaimer

• This presentation includes forward-looking statements about, among other things, Pfizer's efforts to combat COVID-19, Pfizer's Vaccine product candidates, including, among others, the BNT-162 COVID-19 vaccine program and its potential clinical benefits, planned clinical studies, manufacturing and distribution and the expected timing of clinical trials, that are subject to substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements.

• Additional information regarding these factors can be found in Pfizer’s Annual Report on form 10-K for the fiscal hear ended December 31, 2019 and in our 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 our subsequent reports on Form 8-K, all of which are filed with the US Securities and Exchange Commission (SEC) and available at www.sec.gov and www.pfizer.com, as well the joint press release of Pfizer and BioNTech, dated July 1, 2020.

• The forward-looking statements in this presentation speak only as of the original date of this presentation, and we undertake no obligation to update or revise any of these statements.
Mikael Dolsten, M.D., Ph.D.
Chief Scientific Officer and President, Worldwide Research, Development, and Medical
Pfizer and BioNTech began collaborating in 2018 to develop a vaccine for influenza and have now extended that collaboration to develop a vaccine for COVID-19.

BioNTech has one of the industry’s broadest technology toolkits including innovative mRNA technology and leading bioinformatics.

Pfizer is a proven, reliable multi-national vaccine producer, which has supplied vaccines to more than 165 countries and distributed more than 1 billion doses of vaccines with unprecedented reliability.

The collaboration combines BioNTech’s leading mRNA platform with Pfizer’s proven expertise across vaccine research and development, regulatory affairs, and global manufacturing and distribution.
mRNA Vaccines: A novel approach with promising vaccine characteristics

mRNA vaccine technology uses the cell’s own machinery to stimulate a potentially protective immune response through T cells and neutralizing antibodies

**Safety:** RNA vaccines are non-infectious and pose no known risk of insertional mutagenesis

**Efficacy:** RNA vaccines pose minimal risk of anti-vector immunity which permits boosting to help maximize the level and duration of immunity given protein-free lipid nanoparticles

**Speed:** BioNTech’s mRNA vaccine technology is designed to enable rapid development and quick production scaling

Please Note: The information contained in this document, including scientific approaches, assumptions regarding potential safety and efficacy, clinical trial and manufacturing plans and timing estimates, is subject to change based on emerging data, regulatory guidance, and manufacturing and technical developments, among other risks.
BNT162 mRNA vaccine program

SARS-COV-2 (3D Model)

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

Receptor Binding Domain (RBD)

Spike Protein

Spike-Antigen Whole Protein

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Kathrin Jansen, Ph.D.
Senior Vice President &
Head of Vaccine R&D
Rapid, ongoing vaccine development demonstrates strong clinical & regulatory expertise, necessary for potential Fall 2020 product availability.

**SARS-CoV-2 Genetic Sequence**
- Public January 12, 2020
- China

**COVID-19 mRNA Vaccine**
- Animal Studies
  - Started March 11, 2020
  - BioNTech

**PFE/BNT Letter of Intent**
- Signed March 17, 2020
- Pfizer-BioNTech

**Phase 1 / 2 Trial**
- Germany Started April 23, 2020
- Up to 200 subjects aged 18 – 55
- US Started May 4, 2020
- Up to 360 subjects aged 18 – 85

**Pivotal Phase 2b / 3 Trial**
- Goal: July 2020 Start
- Up to 30,000 subjects

**Potential Regulatory Approval or Authorization**
- Goal: 4Q 2020

Note: All future dates represented in graphic reflect anticipated timelines and are subject to clinical, technical, and regulatory success.
U.S. Phase 1/2 Study Design and Preliminary Results

BNT162b1 – Modified mRNA Vaccine
Twelve participants per dose level (10 μg and 30 μg), were vaccinated with BNT162b1 on Days 1 and 21 and 12 participants received a 100 μg dose on Day 1; 9 received placebo.

Between May 4, 2020 and June 19, 2020, 76 subjects were screened, and 45 participants were randomized and vaccinated.

U.S. Phase 1/2 randomized, placebo-controlled, observer-blinded study is evaluating the safety, tolerability, and immunogenicity of escalating dose levels of BNT162b1.

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In sera from the 30 µg and 100 µg dose level cohorts, RBD-Binding IgG GMCs were substantially higher than in the human convalescent serum panel.

RBD-Binding IgG GMCs after 1 or 2 doses

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Virus neutralizing GMTs after the 10 µg and 30 µg booster vaccinations (Dose 2) were higher than the neutralizing GMT of the human convalescent serum panel.

SARS CoV2 50% Neutralizing Titers after 1 or 2 doses

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Local reactions with BNT162b1 in healthy adults (18-55 yrs)

Reported within 7 days after Vaccinations 1 (10µg, 30µg, 100µg) and 2 (10µg, 30µg)

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Systemic Events with BNT162b1 in healthy adults (18-55 yrs)
Reported within 7 days after Vaccination 1

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Systemic Events with BNT162b1 in healthy adults (18-55 yrs)

Reported within 7 days after Vaccination 2: 10 µg & 30 µg

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

Fever  Fatigue  Headache  Chills  Vomiting  Diarrhea  Muscle pain  Joint pain  Medication

Mild  Moderate  Severe  Grade 4

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Investing in manufacturing at-risk with cumulative vaccine supply goal of up to 100MM doses in 2020 and potentially more than 1.2B doses in 2021

Kalamazoo, MI (USA)  Andover, MA (USA)  Puurs, Belgium  Mainz Region, Germany

St. Louis, MO (USA)  Idar Oberstein, Germany

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Key Takeaways SARS-CoV-2 mRNA Vaccine BNT162b1

Early positive data from ongoing phase 1/2 study

- Preliminary data demonstrated that **BNT162b1** could be administered in a dose that was **well tolerated**, and **generated dose dependent immunogenicity**, as measured by RBD-binding IgG concentrations and SARS-CoV-2 neutralizing antibody titers.

- Early positive data shows that BNT162b1 can be administered at a **low effective dose of 10µg** and provide **neutralizing titers at or above human convalescent plasma** as early as **4 weeks after vaccinations**.

- **Local reactions and systemic events** after immunization with 10 µg and 30 µg of BNT162b1 were dose-dependent, **generally mild to moderate, and transient**. **No serious adverse events** were reported.

- Data from the ongoing Phase 1/2 clinical trial are **expected to enable selection of a single lead candidate** and dose level for a potential large, global **Phase 2b/3 safety and efficacy study that may begin as early as July 2020**, subject to regulatory approval.

- **Efforts to manufacture the leading candidates, at risk, are gearing up.** If the safety and efficacy study is successful, and the vaccine receives regulatory approval, **the companies are currently expecting to manufacture up to 100 million doses by the end of 2020 and potentially more than 1.2 billion doses in 2021**.

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Q&A

Mikael Dolsten – Chief Scientific Officer and President, Pfizer Worldwide Research, Development, and Medical

Kathrin Jansen – Chief Scientific Officer and Senior Vice President, Vaccine R&D