# BNT162 COVID-19 Vaccine Update Call

July 1, 2020

# This slide presentation includes forward-looking statements

**Forward-Looking Statements**

This slide 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 timing to initiate clinical trials of BNT162 and anticipated publication of data from these clinical trials; collaborations between BioNTech and Pfizer, and BioNTech and Fosun Pharma, to develop a potential COVID-19 vaccine; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; and the ability of BioNTech to supply the quantities of BNT162 to support clinical development and, if approved, market demand. 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, 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



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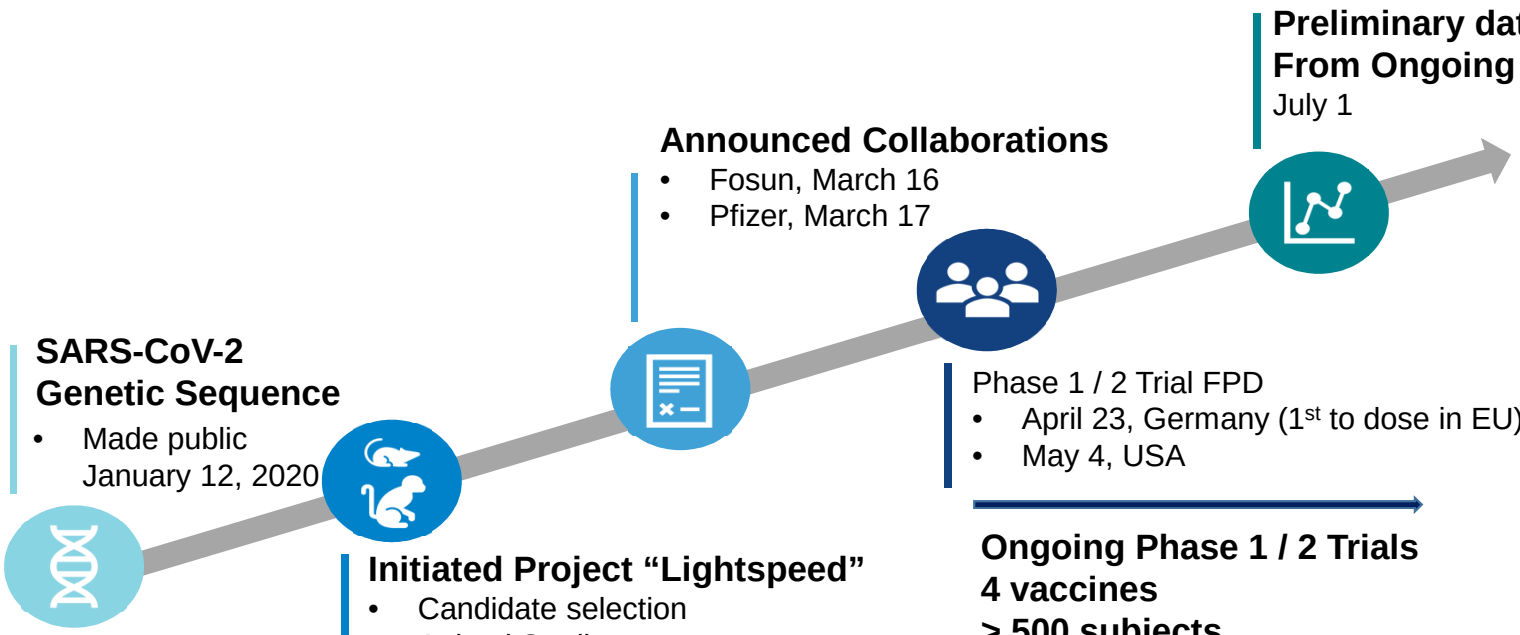
# Timeline for Project “Lightspeed”




***Approximately 5 months***



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# Principles of Virus Infection

Virus exposure

↓

Entry into cell

↓

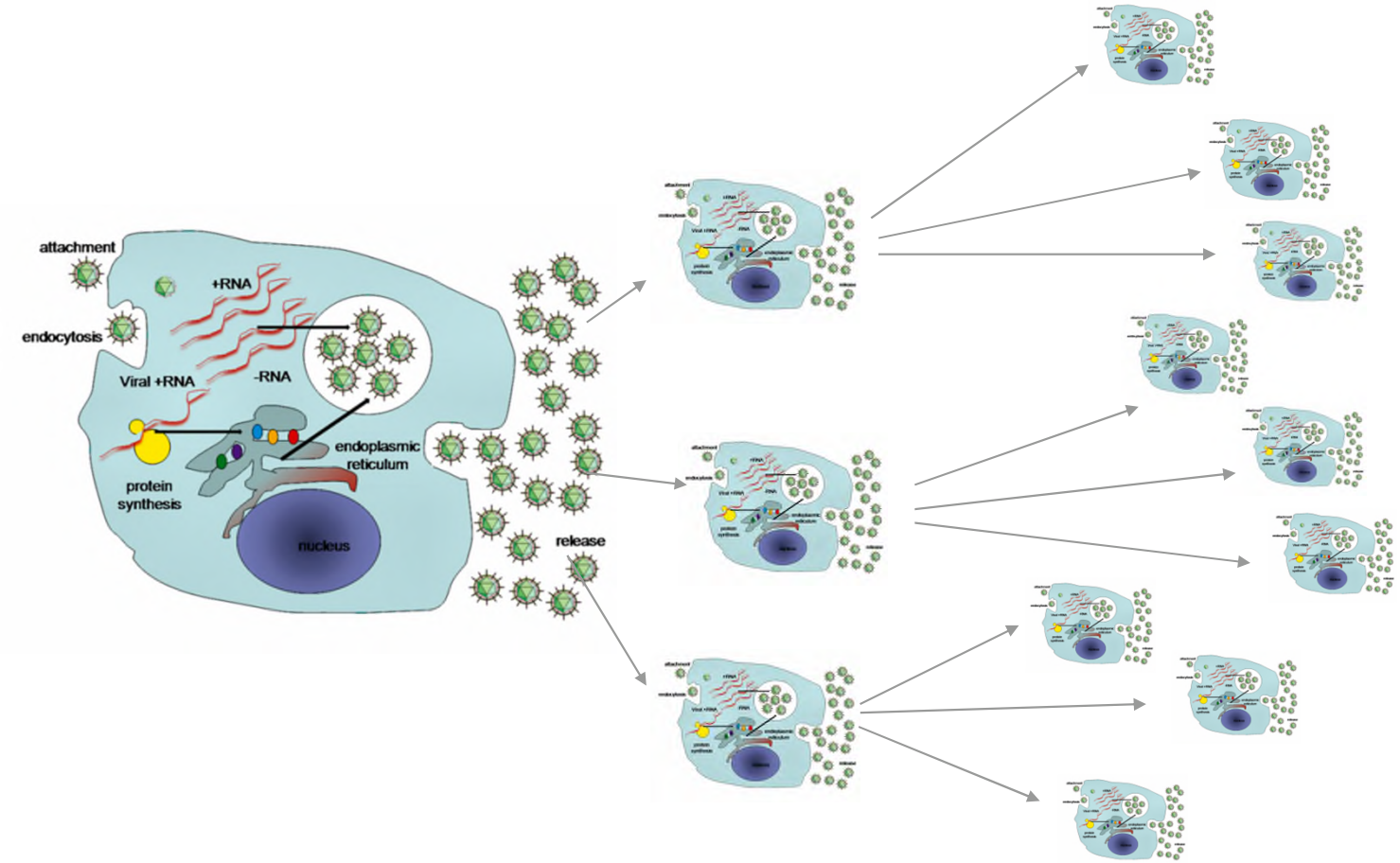
Replication

↓

New virus release

↓

Spread into new cells



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# Vaccine induced Immune control

## Antigen + Immune stimulus

**Immune Response**

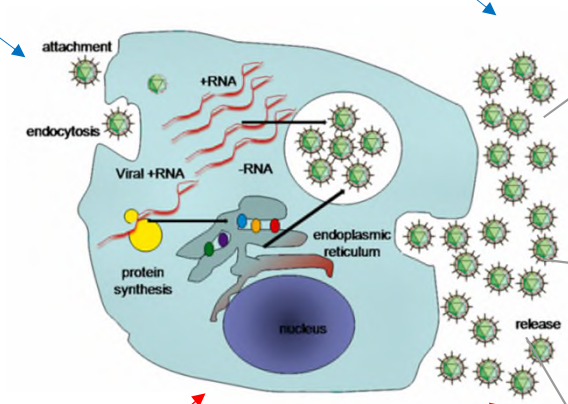
**Memory B cells**
Neutralising antibodies

**CD4 T cells**
Multiple functions

**CD8 T cells**
Killing infected cells

**Antibodies** inhibit spread from
- Cell to Cell
- Individual to another Individual

**T cells** reduce production of new virus



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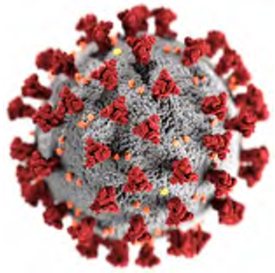
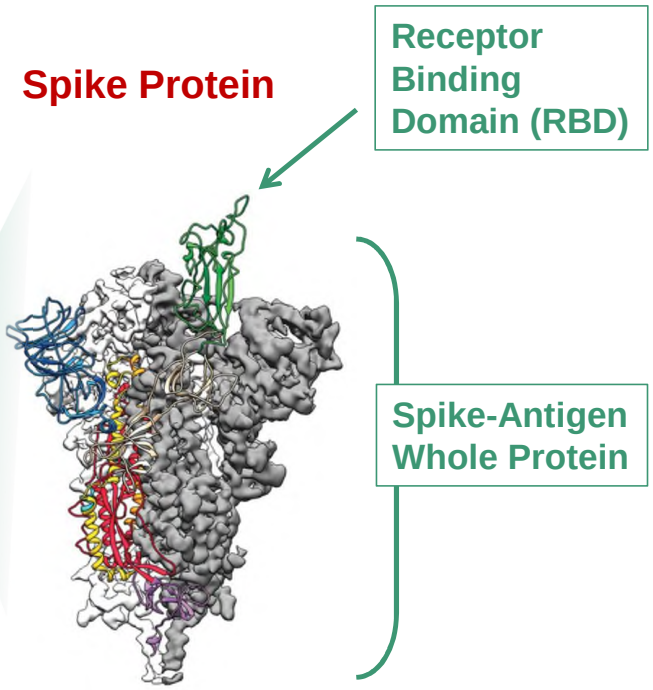
# BNT162 Variants: Targeting SARS-CoV-2 Spike-Protein and RBD



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




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

| Variant | Target | RNA construct | Immunization |
|---|---|---|---|
| **162a1** | RBD subunit | uRNA | prime/ boost |
| **162b1** | RBD subunit | modRNA | prime/ boost |
| **162b2** | 2P-mutated full spike protein | modRNA | prime/ boost |
| **162c2** | 2P-mutated full spike protein | saRNA | single injection |



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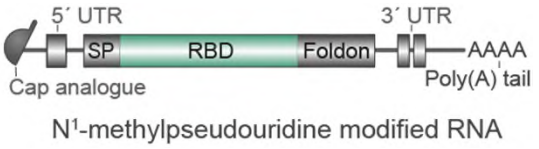
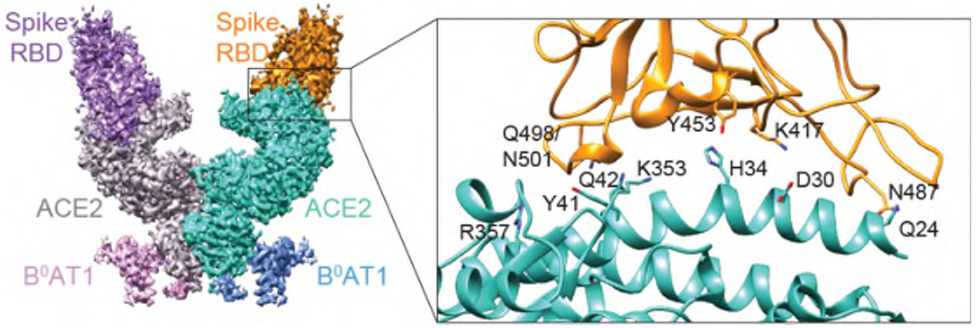
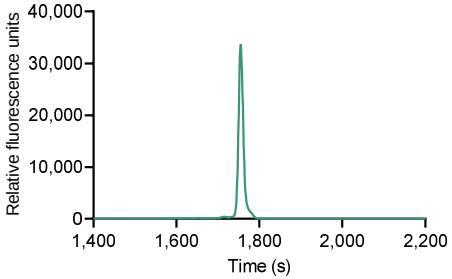
# BNT162b1 encodes a natively folded trimeric RBD



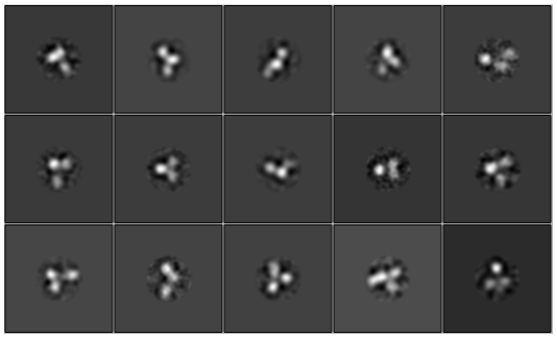

## RBD monomer (Cryo-EM)



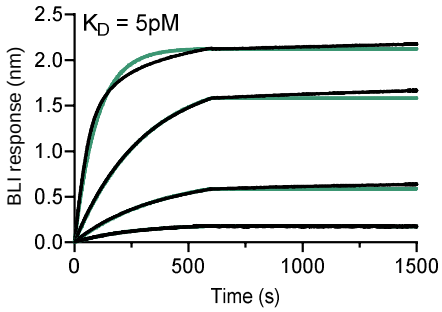

## RNA Drug Substance




## RBD-foldon Trimer (Neg. stain EM)



## RBD-Trimer binding to ACE2




**Kd = 5pm**

(Surface plasmon resonance)



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# Global BNT162 clinical development program ongoing

**Phase 1/2 trials ongoing in Europe and US**

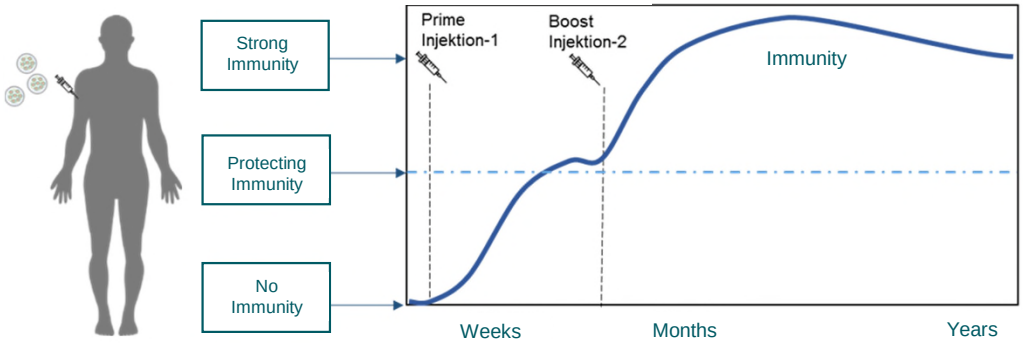
- Evaluating safety, efficacy and optimal dose of 4 vaccine candidates

**Designs**

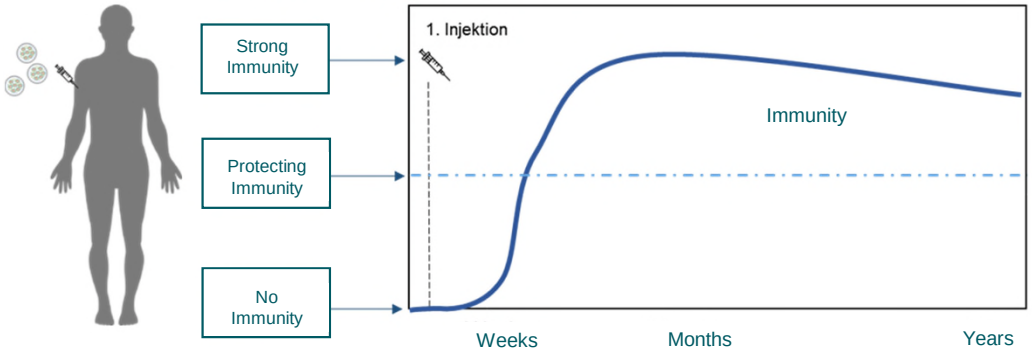
- Europe: Dose escalation part up to 200 healthy subjects aged 18 to 55
- US: Seamless study design with several thousand subjects; Initial dose-finding part up to 360 healthy subjects aged 18-85
- Dose range <1 µg to 100 µg
- Single-dose and 2-dose regimens to be tested in initial trial

Between May 4, 2020 and June 19, 2020;
45 participants randomized and vaccinated in US study

## Prime / boost vaccine




## Prime-only vaccine



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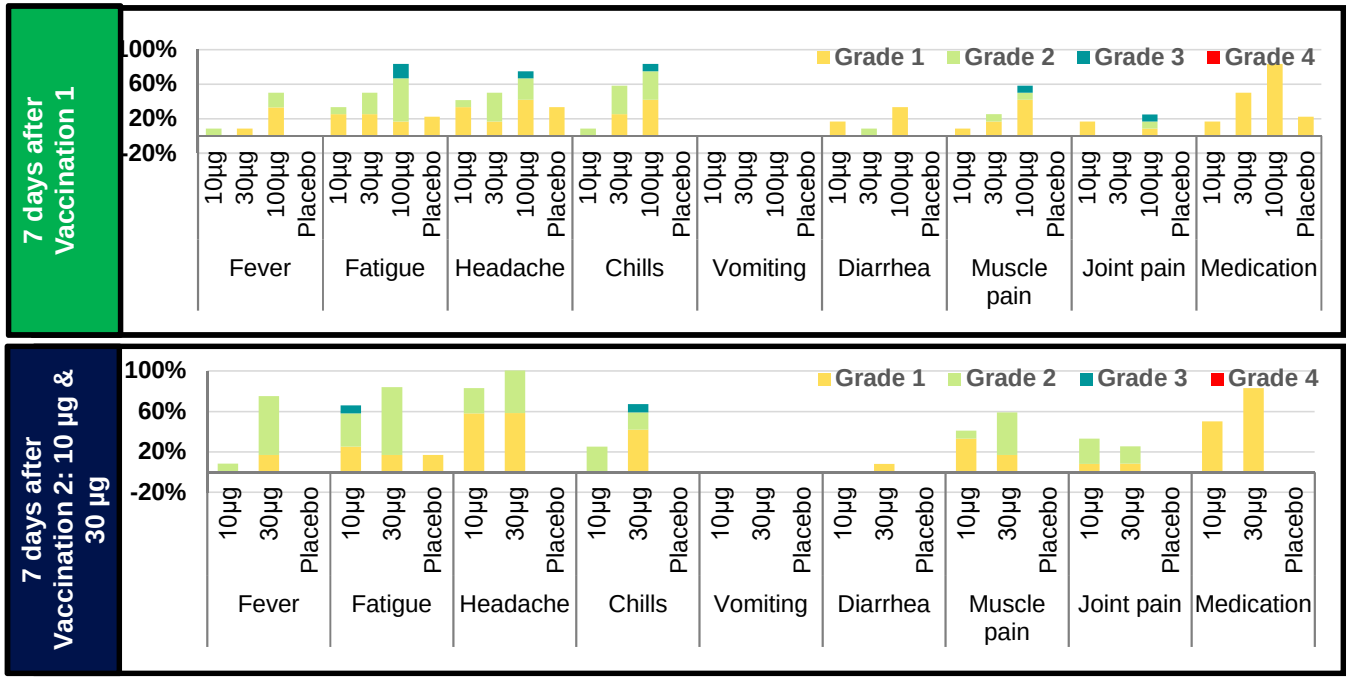
# BNT162b1: Interim safety and tolerability results in human

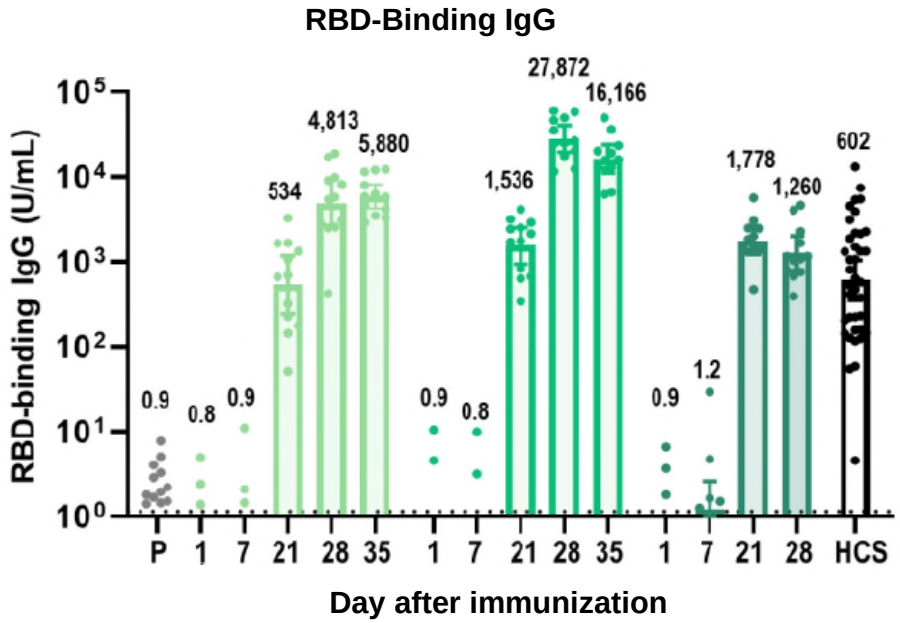
- Pain at injection site most frequent **local reaction**
  - All mild or moderate in severity except for one report of severe pain in 100 µg level
- **Systemic events**, including fever, more common after second dose than first dose in 10 µg and 30 µg groups
  - Following Dose 2, 8.3% of participants who received 10 µg and 75.0% of participants who received 30 µg reported fever ≥ 38.0°C
  - Most local reactions and systemic events peaked by Day 2 after vaccination and resolved by Day 7
- No Serious AEs (SAEs) reported

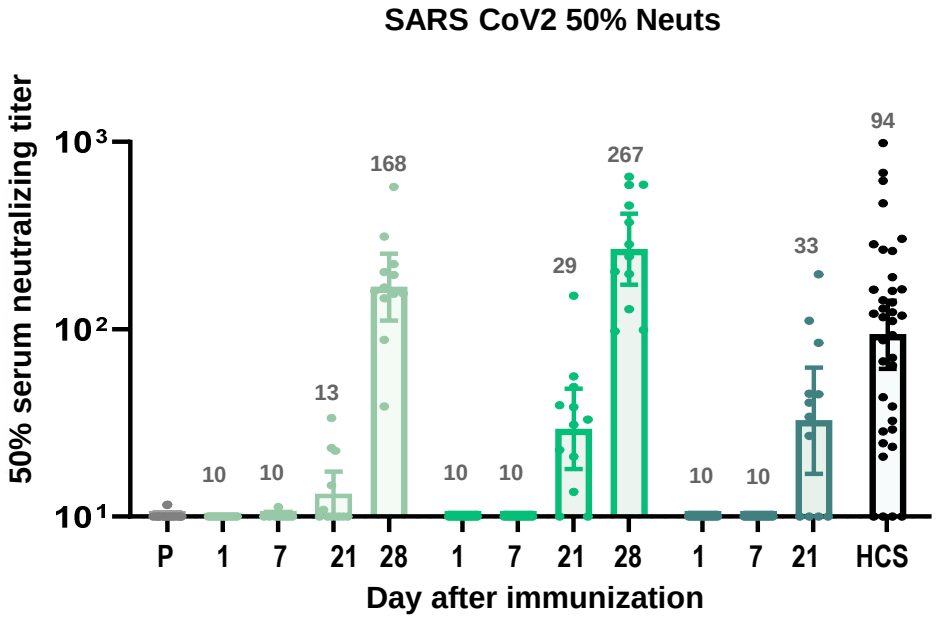


# BNT162b1: Interim immunogenicity results in human (US phase 1)

Placebo
10 µg dose level
30 µg dose level
100 µg dose level
HCS

## RBD-Binding IgG GMCs and SARS CoV2 50% Neutralizing Titers after 1 or 2 doses




- Highest neutralizing titers observed seven days after second dose of 10 µg or 30 µg on day 28 after vaccination
  - 1.8- and 2.8-times neutralizing GMT of 94 of convalescent serum panel
- Elevation of RBD-binding IgG concentrations in all subjects who received 2 vaccinations at 10 µg and 30 µg dose levels at day 28
  - 8- and 46.3-times GMC of 602 units/ml of convalescent serum panel
- Subjects who received 100 µg had 3-times and 0.35-times, respectively, the GMC and GMT of convalescent serum panel

# Key Open Questions

- Durability of safety and immune responses beyond Day 28 (6 month follow up for all participants)
- T-cell responses (CD4 & CD8)
- Level of immunity required for protection in humans
- Differences in specific patient populations (e.g., underlying health conditions, age, race/ethnicity)

## Next Steps

- Data submitted for potential publication in peer-reviewed journal – and now available as a pre-print at www.medrxiv.org
- Additional data from German trial for BNT162b1 expected to be released within next 2 weeks
- Preliminary data will be used, together with additional data being generated, to select lead candidate and dose for initiation of large-scale Phase 2b/3 trial anticipated by late July, subject to regulatory approval
- BioNTech and Pfizer working closely together on manufacturing scale-up, supply chain and network planning



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# Q&A