Update on our COVID-19 vaccine

December 22, 2020

This slide presentation includes forward-looking statements

Forward-Looking Statements

Various statements in this slide presentation concerning the future expectations of BioNTech, its plans and prospects, including the Company's views with respect to its efforts to combat COVID-19; the collaboration between BioNTech and Pfizer to develop a potential COVID-19 vaccine; its expectations regarding the potential characteristics of BNT162b2 in its Phase 2/3 trial and/or in commercial use based on data observations to date; the expected time point for additional readouts on efficacy data of BNT162b2 in our Phase 2/3 trial; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; the timing for submission of data for, or receipt of, any marketing approval or Emergency Use Authorization; its contemplated shipping and storage plan, including its estimated product shelf life at various temperatures; and the ability of BioNTech to manufacture and supply the quantities of BNT162 to support clinical development and, if approved, market demand, including our production estimates for 2020 and 2021, are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, as amended. Words such as "expects," "plans," "potential," "target," "continue" and variations of these words or similar expressions are intended to identify forward-looking statements. Such statements are based on the current beliefs and assumptions of the management team of BioNTech and on the information currently available to the management team of BioNTech, and are subject to change. The Company will not necessarily inform you of such changes. These forward looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors that could cause the Company's actual results, performance or achievements to be materially different than any future results, performance or achievements expressed or implied by the forward-looking statements. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including but are not limited to: our ability to meet the pre-defined endpoints in clinical trials; competition to create a vaccine for COVID-19; the ability to produce comparable clinical or other results, including our stated rate of vaccine effectiveness and safety and tolerability profile observed to date, in the remainder of the trial or in larger, more diverse populations upon commercialization; the ability to effectively scale our productions capabilities; and other potential difficulties. Any forward-looking statements represent the Company's views only as of today and should not be relied upon as representing its views as of any subsequent date. The Company explicitly disclaims any obligation to update any forward-looking statements. The mRNA vaccine discussed in this slide presentation is an investigational product being developed by BioNTech and its collaborators and are not currently approved by the FDA, EMA or any other regulatory authority.

Safety information

Authorized use in the U.S.:

The Pfizer-BioNTech COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

Important safety information from U.S. FDA emergency use authorization prescribing information:

- Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine.
- Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine.
- Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine.
- The Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients.
- In clinical studies, adverse reactions in participants 16 years of age and older included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%).
- Severe allergic reactions have been reported following the Pfizer-BioNTech COVID-19 Vaccine during mass vaccination outside of clinical trials. Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine.
- Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.
- Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion.
- There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series.
- Vaccination providers must report Adverse Events in accordance with the Fact Sheet to VAERS at https://vaers.hhs.gov/reportevent.html or by calling 1-800-822-7967. The reports should include the words “Pfizer-BioNTech COVID-19 Vaccine EUA” in the description section of the report.
- Vaccination providers should review the Fact Sheet for mandatory requirements and Information to Provide to Vaccine Recipients/Caregivers and the Full EUA Prescribing Information for Requirements and Instructions for Reporting Adverse Events and Vaccine Administration Errors.

Conditional market authorization in 27 European States on 21 December for a COVID-19 vaccine

Received **first Conditional Marketing Authorizations worldwide** for use in the European Union, Switzerland & Norway

Received **Approval for Emergency Use / Temporary Use / Conditional Approval** in **more than 45 countries** worldwide (incl. the EU)

COMIRNATY®

is our official name of our mRNA vaccine in the EU and Switzerland

COMIRNATY® – The BioNTech-Pfizer COVID-19 vaccine

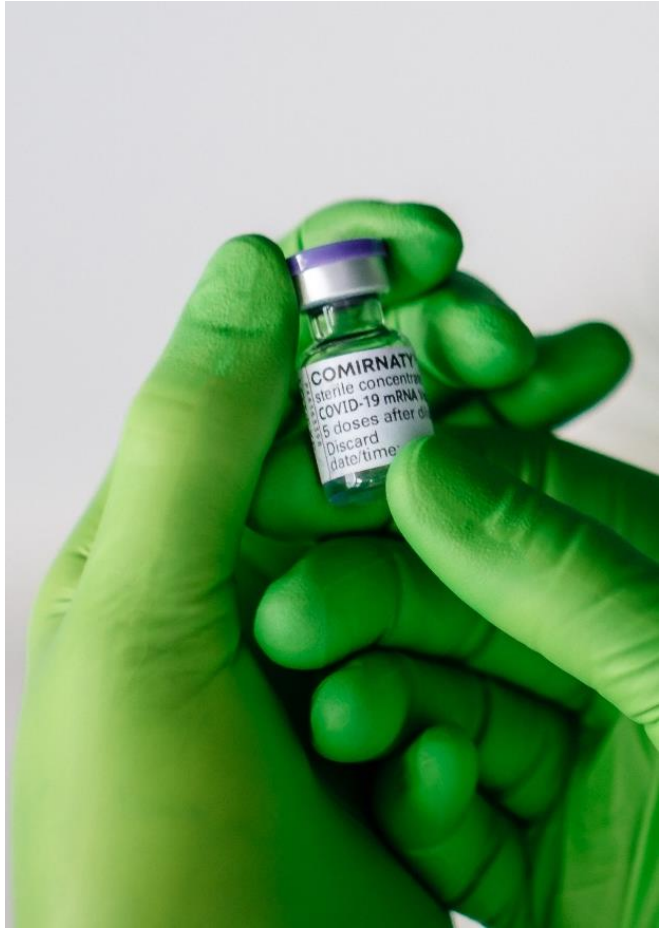
Developed 1,000 potential names in April

Recommended up to 3 names
(Primary + two backups)

COMIRNATY®
COVID-19 mRNA Vaccine

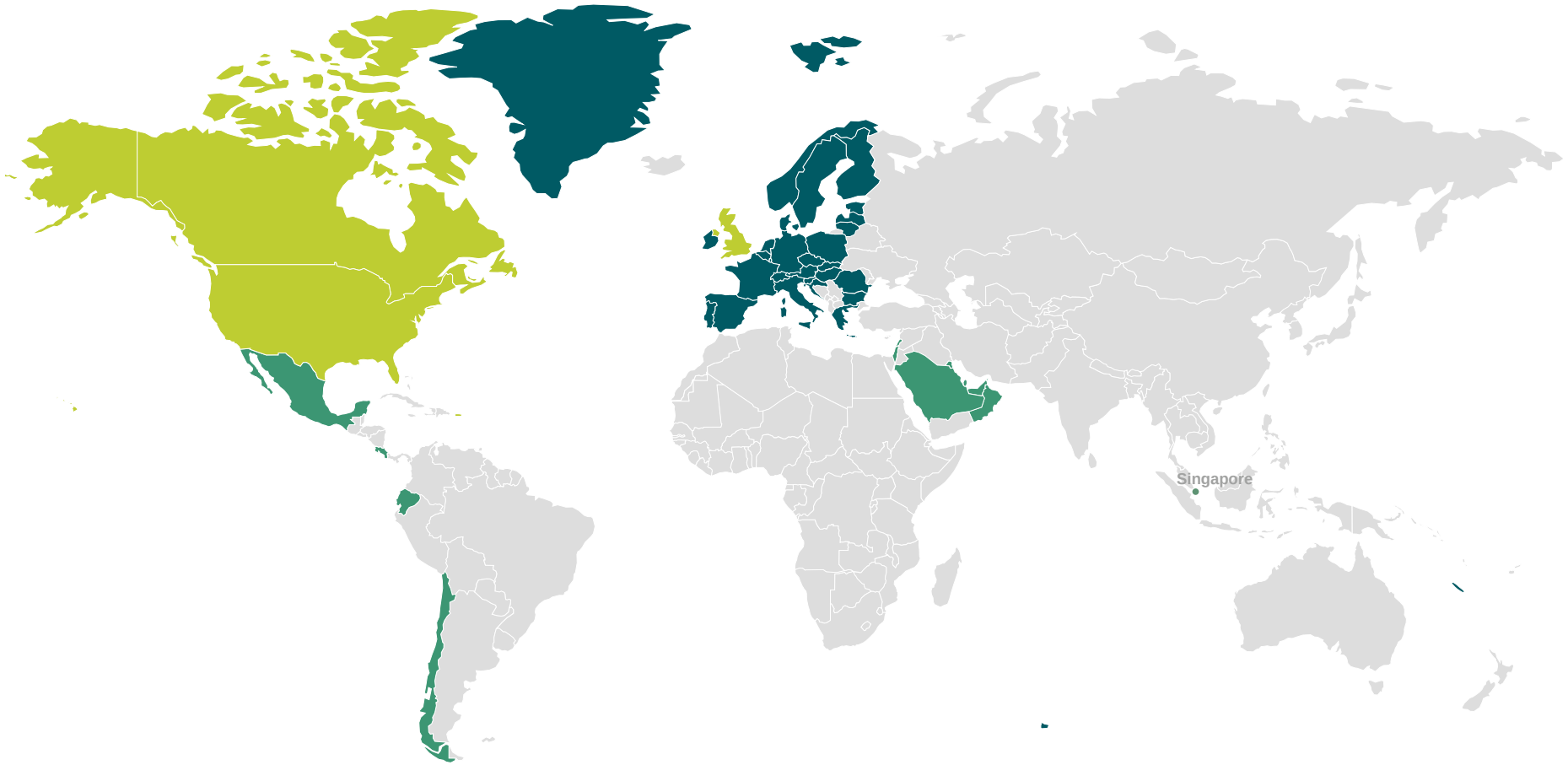
Creative rationale

COVID-19 + mRNA + Community + Immunity



A concerted and large-scale global effort

- **Conditional Marketing Authorization in the EU and Switzerland[1]**
- **Approved Emergency Use Authorization / Temporary Use Approval**
- **Vaccination with our COVID-19 vaccine already underway under Emergency Use Authorization/Temporary Use Approval**



Rolling application for emergency use authorization to further countries underway.

[1]The vaccine is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 16 years of age and older.

Commitment to equitable supply of vaccine globally

Target of 50 million supply doses by the end of 2020
Global allocation according to existing supply agreements

Up to 1.3 billion by end of 2021

North America

Europe

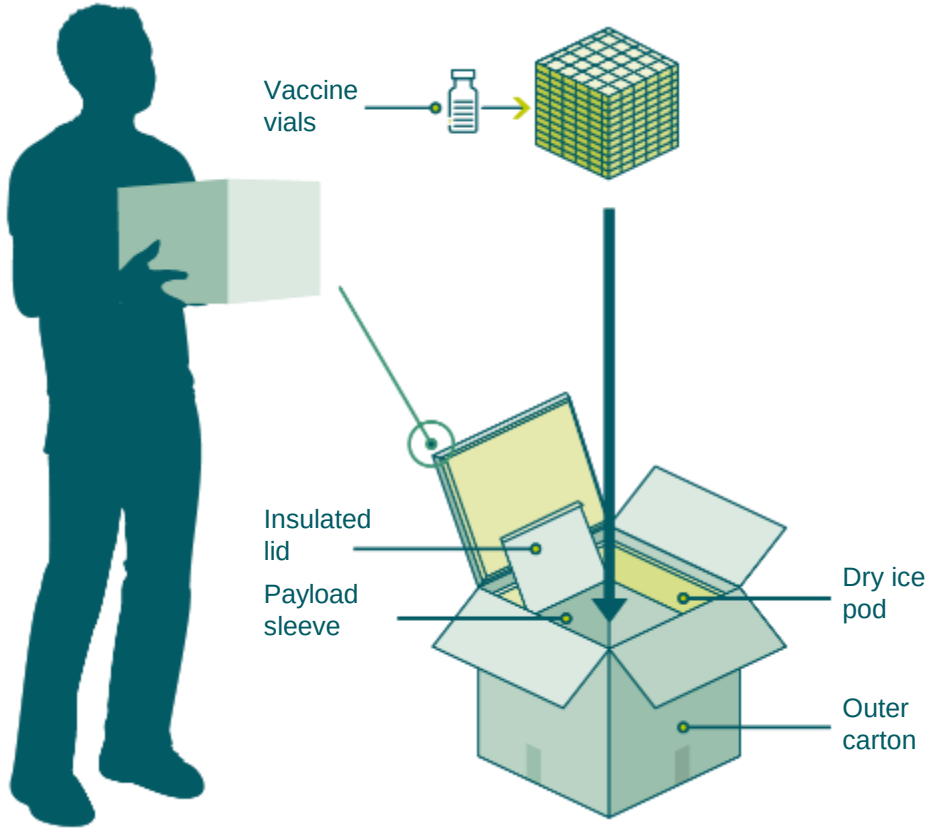
Other countries:

Based on **global supply agreements**

EU's dose allocation is based on the member states' population as agreed between the European Commission and its member states

- All countries across **the EU** that have **requested doses will receive them in the next 5 days**
- **Parallel vaccine shipments** to multiple EU countries **planned immediately** following completion of final paperwork (manufacturing batch release)

Vaccine transportation: minimal changes to pre-existing cold chain



Bespoke vaccine freezer boxes; each freezer box can host between approx. 1000 to 5000 doses

Pre-packed boxes are transported and **distributed to vaccination centers**

GPS trackers and **thermo-sensors relay temperature data** to ensure safe delivery

At vaccination centers, the vaccines **can be stored in delivery boxes and regular fridges**

Vaccine storage: administered like many other vaccines

Administration to vaccinees at room temperature

Injected intramuscular (arm); no additional equipment needed for administration at mass vaccination center

Once removed from the freezer, the unopened vaccine can be stored for up to 5 days at 2 °C to 8 °C

And up to 2 hours at temperatures up to 30 °C, prior to use

-70 °C Freezers Long-term storage not necessary at vaccination centers

Unless vaccination centers want to store for up to 6 months

Special warehouses already identified

Example: decentralized distribution in Germany: BioNTech delivers to 25 distribution centers, run by federal states

BioNTech delivers to

25
Distribution centers

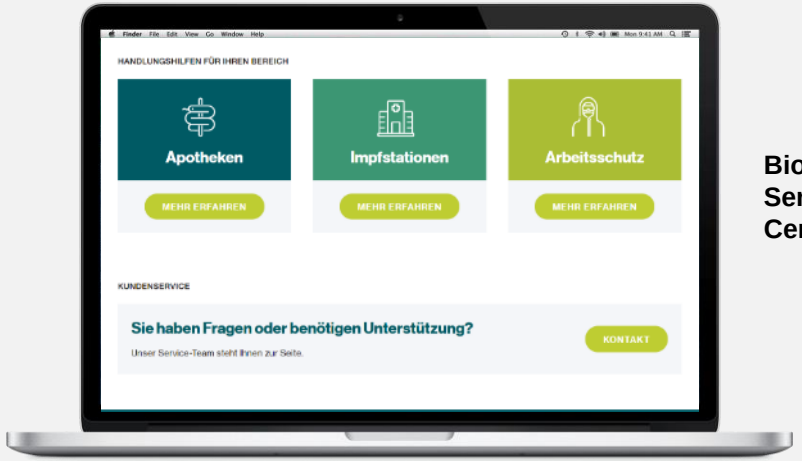
294
Districts

450
Vaccination centers

100
Mobile vaccination locations

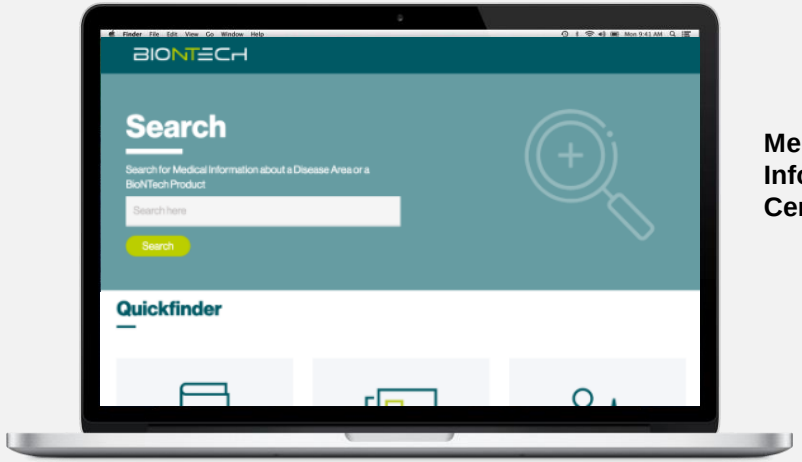
Accountability of the federal states

Example: comprehensive information provided to professionals and vaccination centers in Germany



BioNTech Service Center

Virtual Service Agent (AI chatbot)



Medical Information Center (HCP)

Vaccination Center Starter Kit

COMIRNATY®:

A journey from scientific discovery to approval

Project Lightspeed – a 10-month journey to an effective and safe vaccine

SARS-CoV-2 Genetic Sequence

Made Public
January 12, 2020

COVID-19 mRNA Vaccine Program Initiation

January 27, 2020

Collaborations

Fosun Pharma:
March 16, 2020

Pfizer:
March 17, 2020

Phase 1 / 2 Trial

Germany Started April 23, 2020
U.S. Started May 4, 2020
4 vaccine candidates enter clinical testing

FDA Fast Track designation

July 13, 2020

Initiated Pivotal Phase 2 / 3 Trial

July 27, 2020
Lead mRNA vaccine candidate chosen
Up to 44,000 subjects

Initiated Rolling Submissions

EMA: October 6, 2020
Canada: October 7, 2020
UK: October 9, 2020
Singapore
New Zealand
…and other countries

Phase 3 trial meets all primary efficacy endpoints; vaccine efficacy rate of 95%

November 18, 2020

Global roll-out has begun

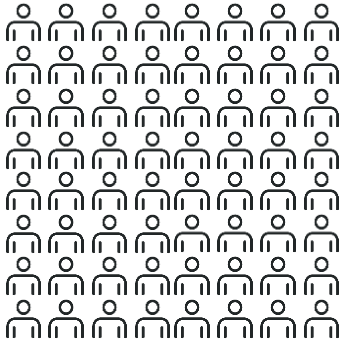
- Approval for emergency use / temporary supply or Conditional Marketing Authorization in more than 45 countries worldwide including the European Union

Data from Phase 3 study shows 95% efficacy

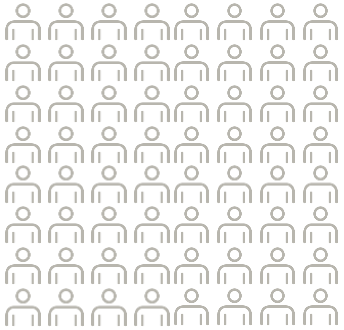
Approx. 44,000 participants

Healthy participants
18-85 (> or =16-17,12-15) years of age

Vaccinated group



Placebo group



Active surveillance

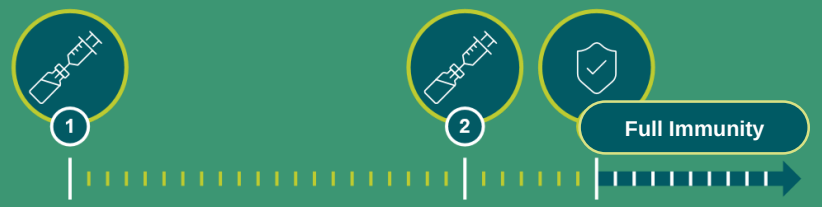
for potential COVID-19 symptoms **TRIGGERING** telehealth or in-person visit and nasal swab

8 cases → **Number of confirmed COVID-19 cases ≥ day 7 post dose 2** ← **162 cases**

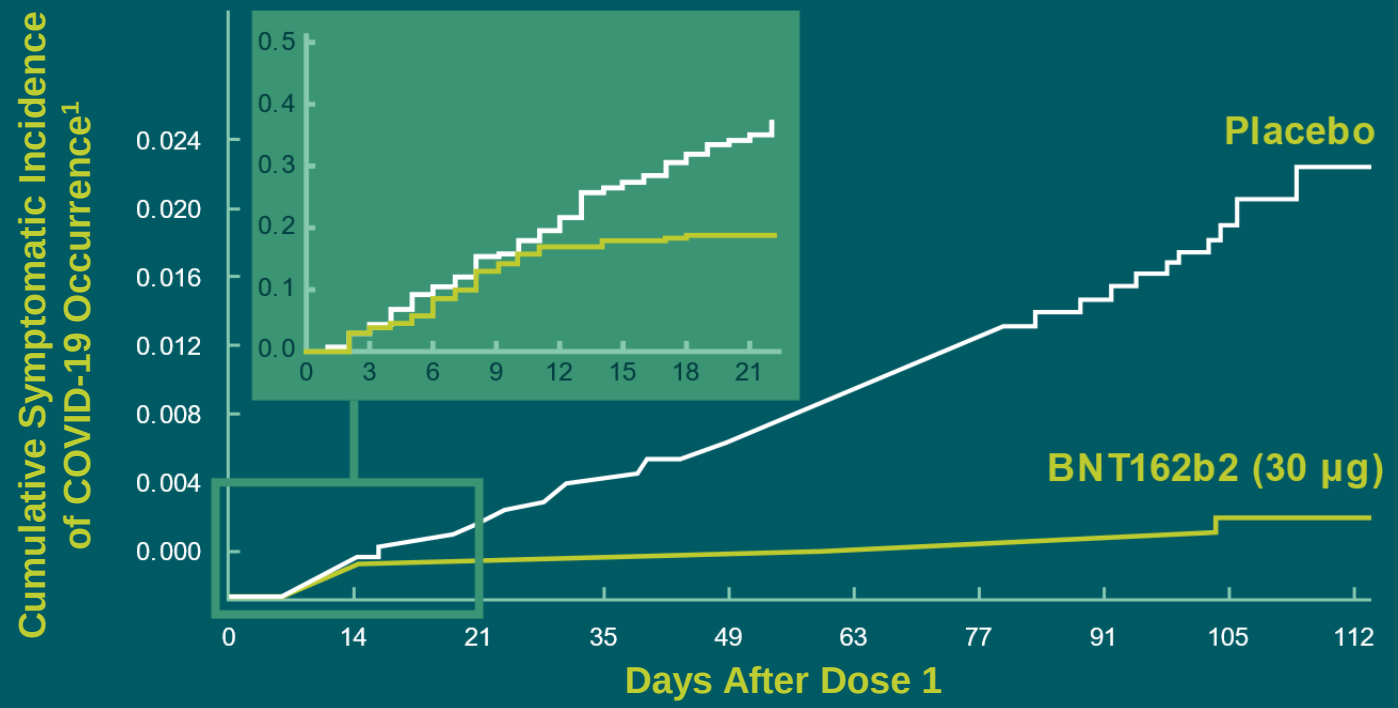
- Analysis indicates efficacy rate of 95% in participants with and without prior SARS-CoV-2 infection
- Final analysis of unblinded data by independent data monitoring committee conducted on Nov 18, 2020
- Vaccinated participants will continue to be monitored for efficacy and safety for up to 2 years

Phase 3 trial data suggest rapid onset of protection against COVID-19

People are vaccinated twice with 30 µg of mRNA, 21 days apart



95% protection against COVID-19 7 days after 2nd dose[2]



Onset of protection appears to begin as early as 12 days after the 1st dose

[1] https://www.nejm.org/doi/full/10.1056/NEJMoa2034577?query=featured_home
[2] Individuals may not be fully protected until 7 days after their second dose of vaccine.

Clinical data indicate COVID-19 Occurrence From 7 Days After Dose 2 by Comorbidity Status[1]

	BNT162b2 (30 µg) N=18,198		Placebo N=18,325			
	n	Surveillance Time (n)	n	Surveillance Time (n)	VE (%)	(95% CI)
Overall	8	2.214 (17,411)	162	2.222 (17,511)	95.0	(90.0, 97.9)
Comorbidity						
No comorbidity	4		76		94.7	(85.9, 98.6)
Any comorbidity	4		86		95.3	(87.7, 98.8)
Any malignancy	1		4		75.7	(-145.8, 99.5)
Cardiovascular	0		5		100.0	(-0.8, 100.0)
Chronic pulmonary disease	1		14		93.0	(54.1, 99.8)
Diabetes	1		19		94.7	(66.8, 99.9)
Obese (≥30.0 kg/m^2)	3		67		95.4	(86.0, 99.1)
Hypertension	2		44		95.4	(82.6, 99.5)
Diabetes (including gestational diabetes)	1		20		95.0	(68.7, 99.9)

[1]Subjects without evidence of infection prior to 7 days after dose 2

Clinical trial data indicates vaccine is highly efficacious with a favorable safety profile

Gold standard of clinical research – randomized large-scale clinical trial – to ensure safety and efficacy. We took important steps in parallel to accelerate the process together with the authorities – without shortcuts

Clinical Efficacy

95%

in all subjects

>94%

in subjects >65 y/o

~44,000

participants in phase 3 trials

in U.S., Germany, Turkey, South Africa, Brazil and Argentina

More than 40% between 65-85 years of age

No serious safety concerns

reported by the independent Data Monitoring Committee (DMC) to date

Generally well tolerated

Observed side-effects are common reactions to vaccination and transient.[1] Adverse events were usually mild to moderate in intensity and resolved within a few days after vaccination.

The only Grade 3 adverse events greater than 2% in frequency following dose 2 were:

Headache	Fatigue
2.0%	3.8%

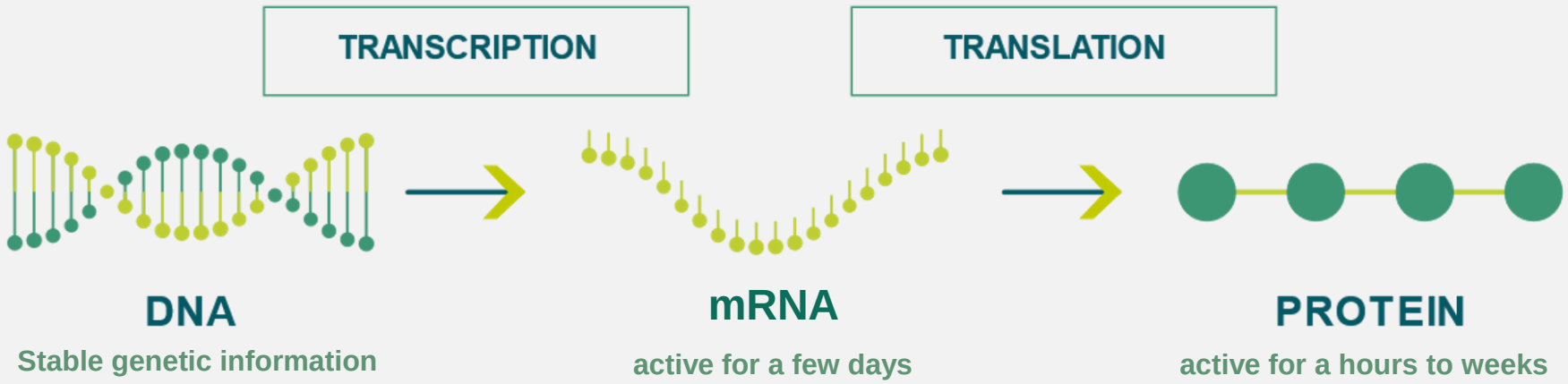
Most frequently observed adverse events were injection site pain and swelling, fatigue, headache, muscle pain, chills, joint pain and fever.

[1]Full safety assessment has been completed for ~38,000 study participants; BioNTech is also collecting safety data from adolescents and planning a pediatric study and a study on any effects on pregnancy.

How mRNA works:

A deep dive into the technology

What is messenger RNA?



- **The first molecule of life**, involved in almost all aspects of cell biology
- Can be synthesized and engineered to resemble mRNA molecules as they occur **naturally in the cytoplasm of human cells** and transiently deliver proteins of interest
- mRNA has a **transient messenger function and is rapidly degraded** in the body

mRNA vaccines are a natural solution that avoid the use of viruses

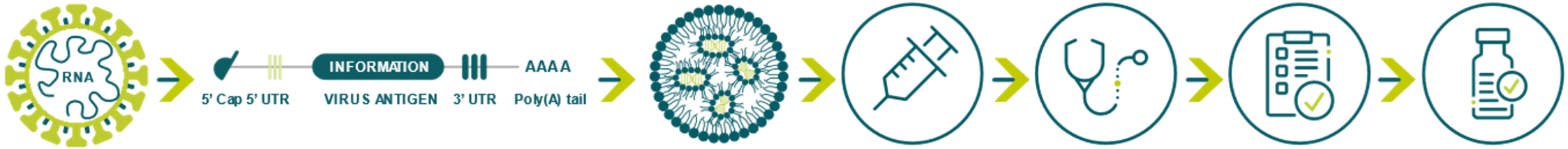
Natural molecule studied for > 50 years with well-characterized **bio-safety properties**

Does not require addition of adjuvants or use of a viral vector for administration

Highly scalable production

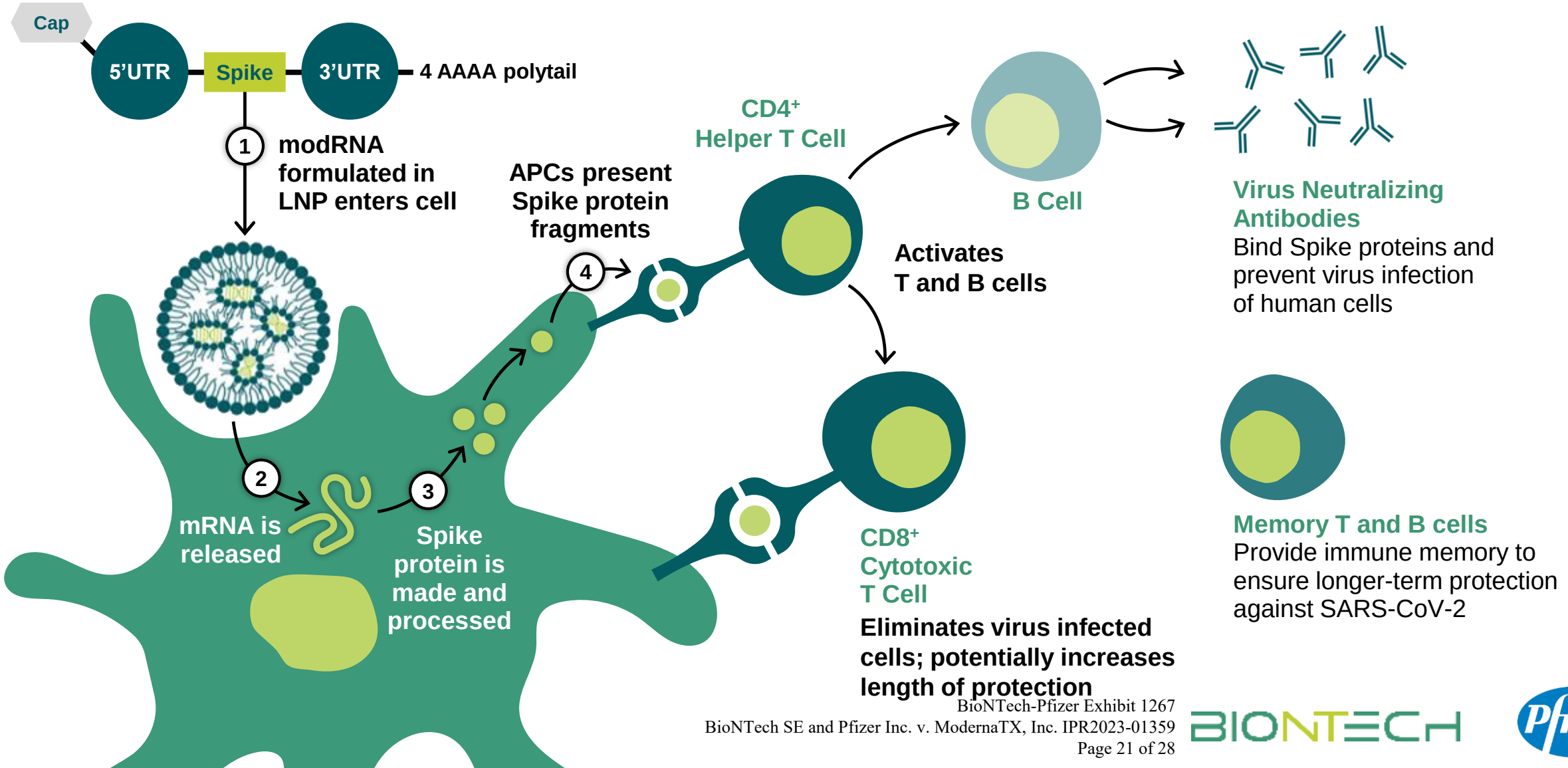
High purity and animal material free

Precision vaccine
Virus-free
Non-integrating into DNA
Non-infectious



Genetic information SARS-CoV-2 → **Vaccine mRNA** → **mRNA LNP** → **Clinical testing** → **Phase 3 trials** → **EUA / approval** → **Vaccination**

How mRNA vaccines work – training the immune system for a real infection



Multiple levers of immune response: Strong antibody and robust T cell responses observed

Immunogenicity*[3]

No or only transient viral shedding in SARS-CoV-2 Virus Challenge

Tolerability*[4]

Local reactions and systemic events mostly **mild to moderate** and transient in effect

Antibody Responses*[4]

Strong SARS-CoV-2 neutralizing antibody responses in **both younger and older adults.** Antibodies able to **neutralize pseudo-viruses representing 19 diverse SARS-CoV-2 variants*[6]**

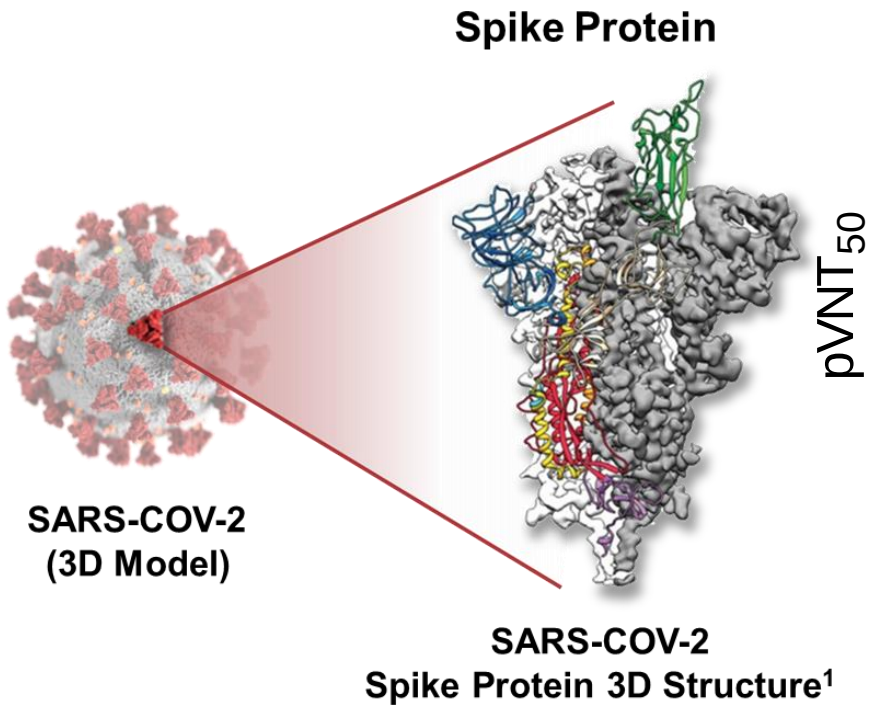
T Cell Responses*[5]

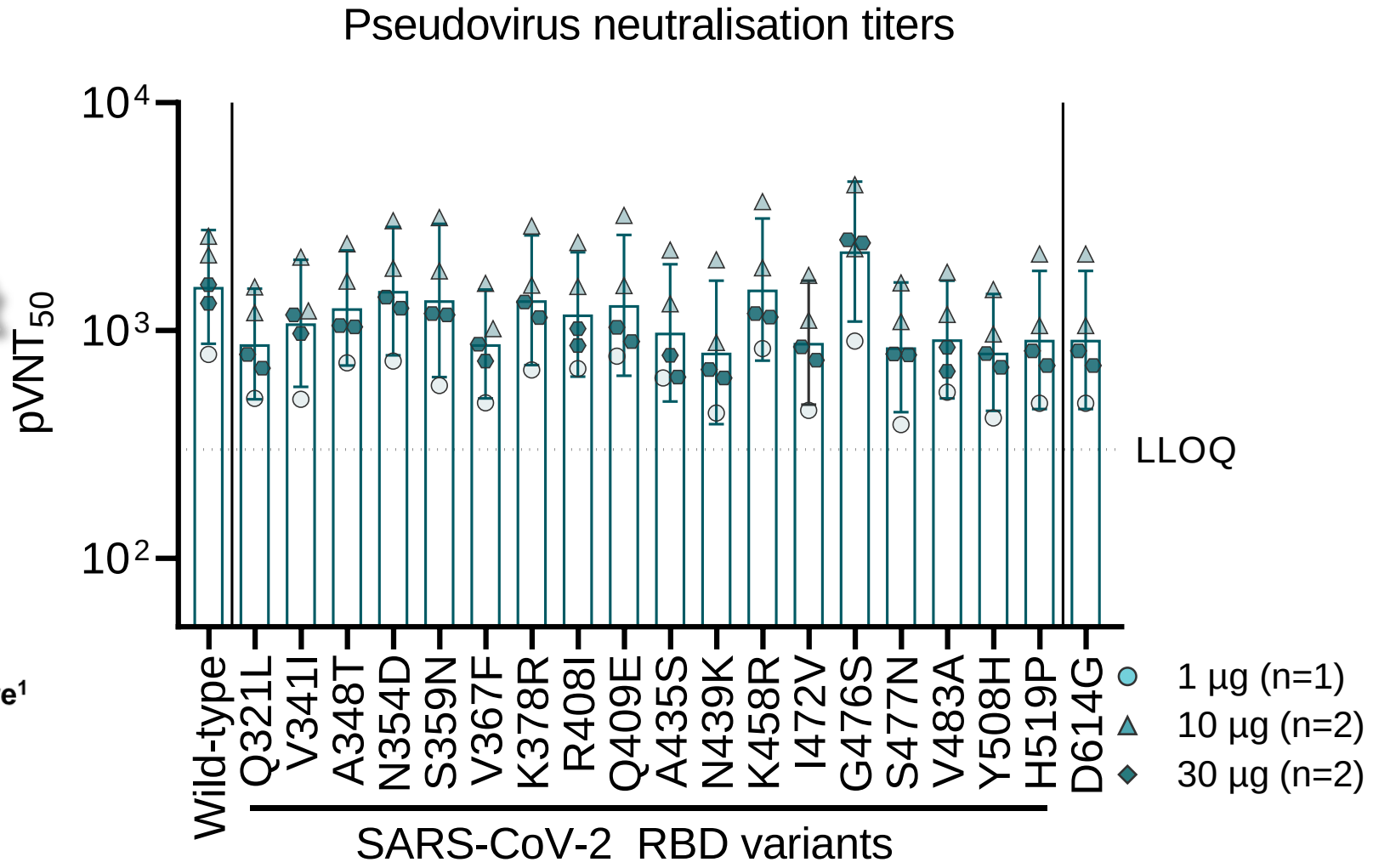
Strong expansion of multifunctional $CD8_+$ and **T_H1-type** $CD4_+$ T cells. T cell responses directed against multiple regions of the spike protein, including the RBD*[6]

BioNTech Publications:

1. Holtkamp et al. Modification of antigen-encoding RNA increases stability, translational efficacy, and T-cell stimulatory capacity of dendritic cells. Blood 2006.
2. Orlandini von Niessen et al. Improving mRNA-based therapeutic gene delivery by expression-augmenting 3' UTRs identified by cellular library screening. Molecular Therapy, 2019.
3. Vogel et al. A prefusion SARS-CoV-2-spike RNA vaccine is highly immunogenic and prevents lung infection in non-human primates. Nature 2020.
4. Walsh et al. Safety and immunogenicity of two RNA-based Covid-19 vaccine candidates: New England Journal of Medicine, 2020
5. Sahin et al. Concurrent human antibody and TH1-type cell responses elicited by a Covid-19 RNA vaccine. Nature, 2020.
6. Polack et al. Safety and efficacy of the BNT162b2 mRNA covid-19 vaccine: New England Journal of Medicine, 2020
7. Sahin et al. BNT162b2 induces SARS-CoV-2-neutralising antibodies and T cells in humans. Medrxiv, 2020.

BNT162b2 induced Antibodies cross-neutralize mutant SARS-COV-2 variants in pVNT assay





[1] Sahin U, et al. medRxiv 2020.12.09.20245175; doi: https://doi.org/10.1101/2020.12.09.20245175 [preprint]. Accessed December 2020.

What does COMIRNATY® contain – and why?

mRNA*

Active ingredient

This encodes the viral spike glycoprotein of the SARS-CoV-2 virus.

Salt

4 different salts

These buffer the vaccines to stabilize the pH, so that it matches the pH in our bodies.

Water for injection

Sugar

Sucrose

This is a cryoprotectant. It ensures the lipids don't get too sticky at cold storage temperatures.

Lipids

4 different molecules

They form a protective capsule around the RNA, aiding in the delivery of the RNA, and protect the RNA from degradation.

* Each dose: of 0.3 mL with 30 micrograms mRNA

What COMIRNATY® contains in detail – from the prescribers information

- **mRNA: Active Ingredient**
  - mRNA
- **Salt: 4 different salts**
  - potassium chloride
  - potassium dihydrogen phosphate
  - sodium chloride
  - disodium phosphate dihydrate
- **Sugar: Sucrose**
  - Sucrose
- **Lipids: 4 different molecules**
  - ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)
  - 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)
  - 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)
  - cholesterol

+ Water for injection

Q&A

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Thank you for your participation!

The press conference has now ended.