

Update on our COVID-19 vaccine development program with BNT162b2

December 2, 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 timepoint 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 additional Emergency Use Authorization; the timing for submission of manufacturing data to the FDA; its contemplated shipping and storage plan, including its estimated product shelflife 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.

First emergency use authorization in the world for a COVID-19 vaccine following a Phase 3 trial



Received Approval for Emergency Supply in the UK for our COVID-19 mRNA vaccine BNT162b2



Formal Conditional Marketing Authorization Application submitted following rolling review with the European Medicines Agency (EMA)



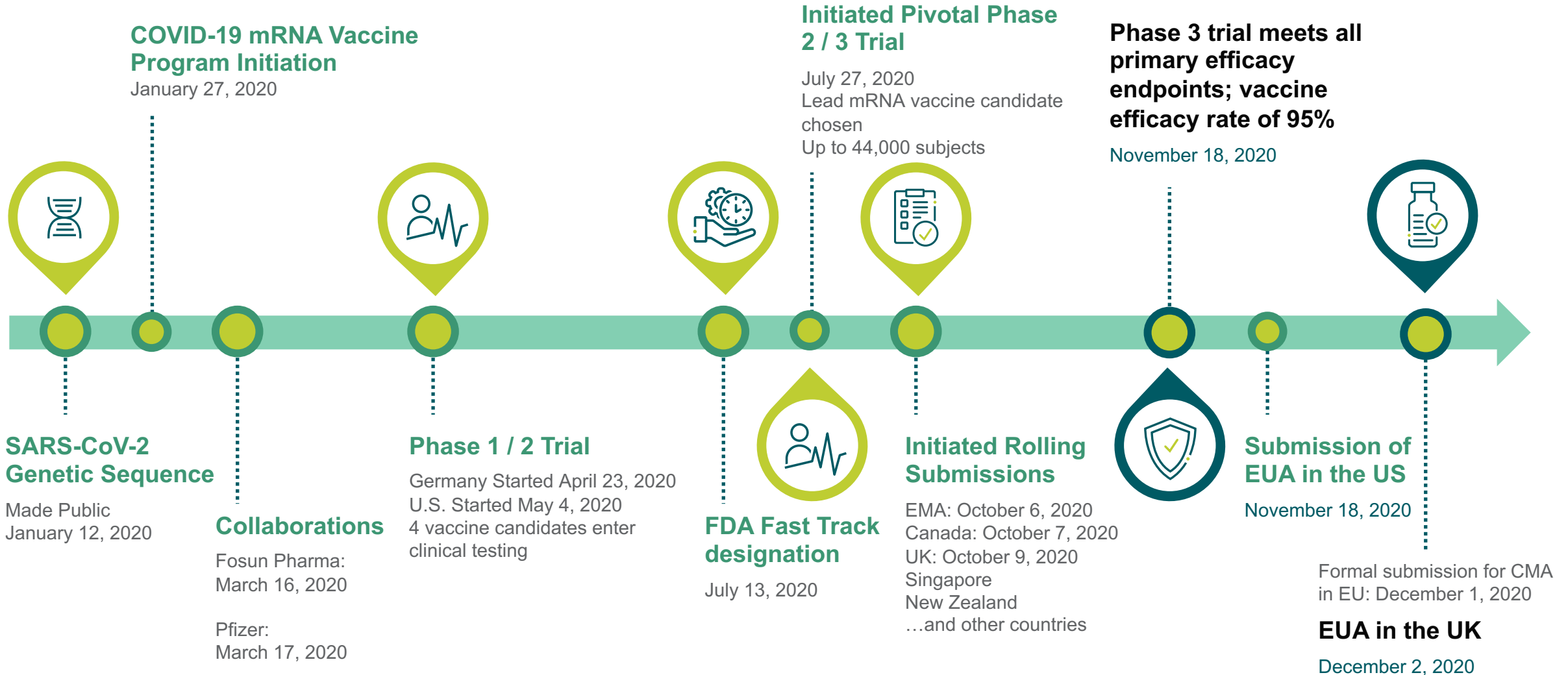
First deliveries in the U.K. expected **within days** based on existing supply agreement



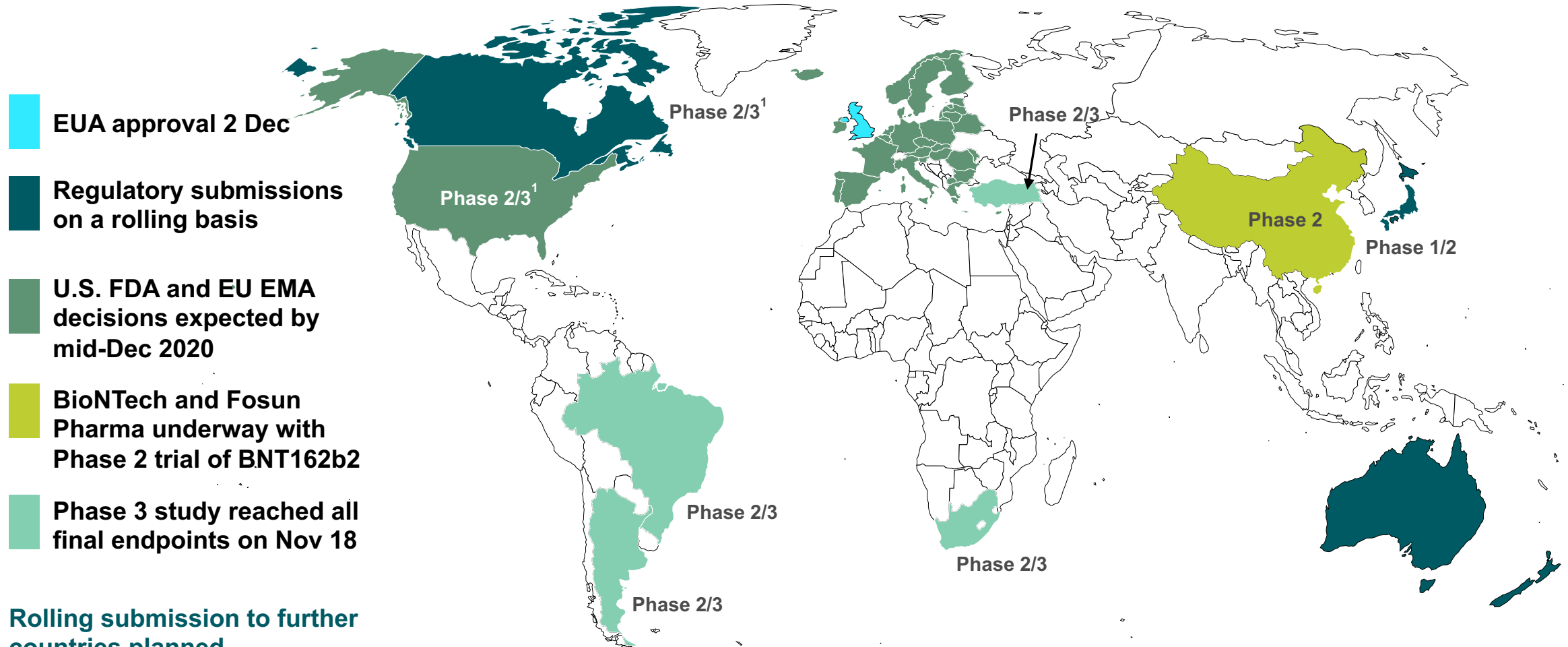
BioNTech will be the Marketing Authorization Holder in the U.K., the U.S., the EU and certain other countries.

Pfizer will market and distribute BNT162b2 in most countries

Project Lightspeed: circa 10-month path to develop an effective and well-tolerated vaccine following highly scientific and ethical standards

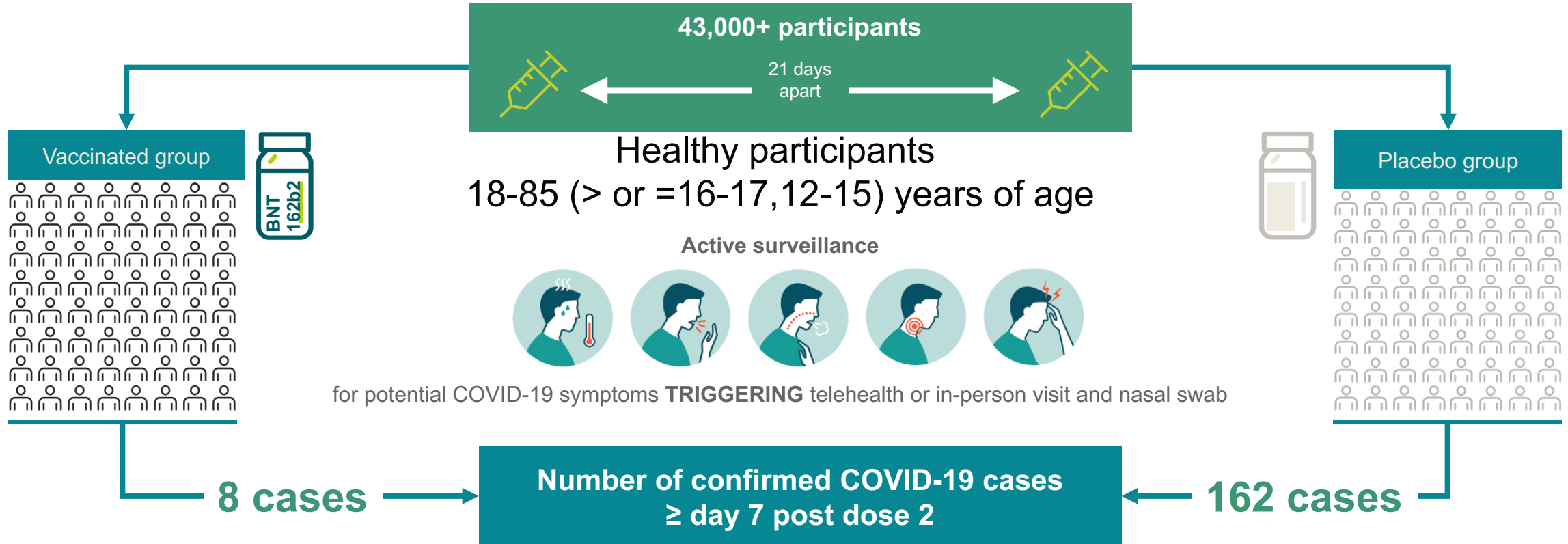


Project Lightspeed is a concerted and large-scale global effort



¹Phase 1/2 remains ongoing in U.S. and EU

BNT162b2: All primary endpoints met in Phase 3 final analysis



- 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

High efficacy and favorable safety profile for rapid and potent protection

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

43,000+

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 transient¹. Adverse events were generally mild to moderate in intensity and resolved within a few days after vaccination.

Most frequently observed adverse events were injection site pain, fatigue, headache and muscle pain.

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

Headache
2.0%

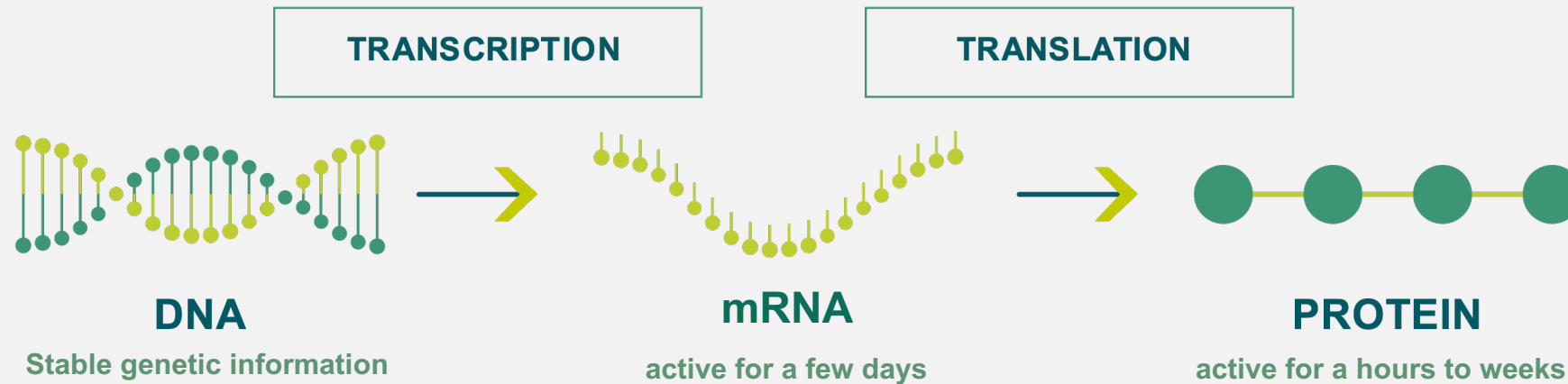
Fatigue
3.8%

**COVID-19 vaccine
candidate:
BNT162b2**

**A journey from
Scientific Discovery
to Drug Approval**



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

Characteristics: mRNA is a natural solution for vaccines especially in a pandemic

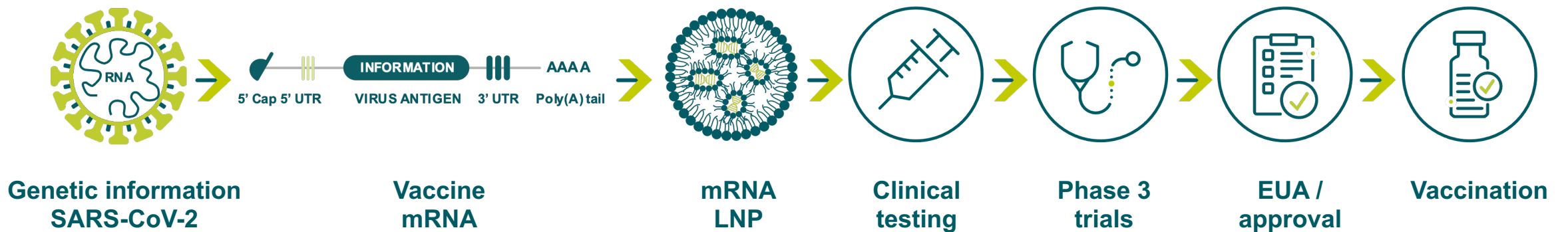
Natural molecule studied for > 50 years with well-characterized **bio-safety properties**

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

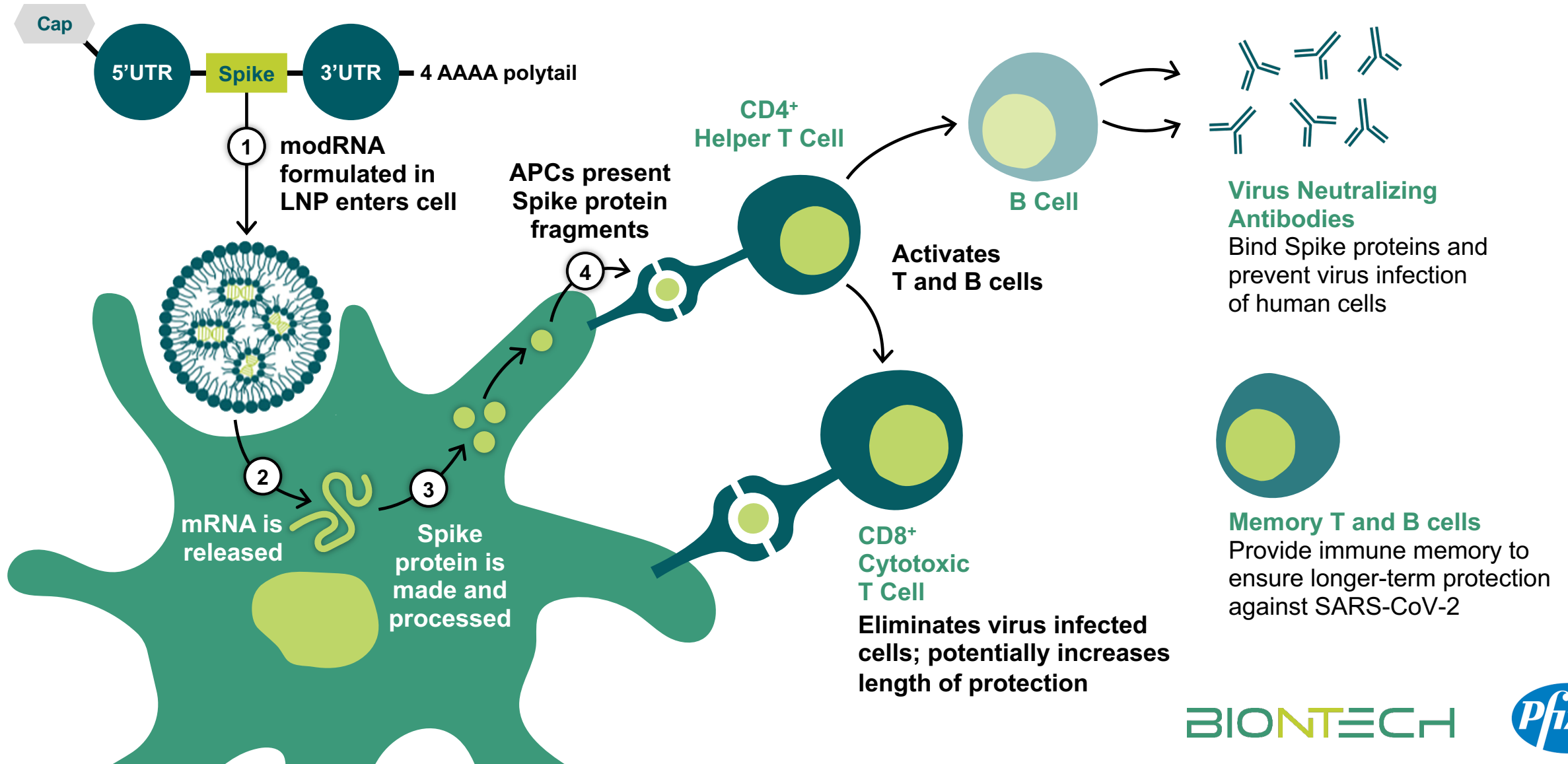
Highly scalable production

High purity and animal material free

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



How mRNA vaccines work – training the immune system for a real infection: Both parts of the immune system activated against virus



Mechanism of action of BNT162b2 exploits multiple levers of immune response: Strong antibody and robust T-cell responses observed

Immunogenicity*³



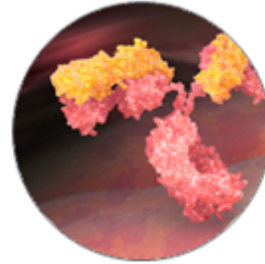
No or only transient viral shedding in SARS-CoV-2 Virus Challenge

Tolerability*⁴



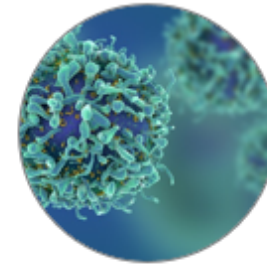
Local reactions and systemic events mostly mild to moderate and transient in effect

Antibody Responses*⁴



Strong SARS-CoV-2 neutralizing antibody responses in both younger and older adults

T Cell Responses*⁵



Expansion of multifunctional CD8+ and TH1-type CD4+ T cells

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. BioRxiv, 2020.
4. Walsh et al. RNA-based Covid-19 vaccine BN162b2 selected for a pivotal efficacy study. NEJM, 2020.
5. Sahin et al. Concurrent human antibody and TH1-type cell responses elicited by a Covid-19 RNA vaccine. Nature, 2020

Distribution of BNT162b2 vaccine



Effective global distribution of the BNT162b2 vaccine is only possible through effective partnerships



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FOSUN PHARMA

Worldwide 50:50 partnership (except Greater China)

- Global pharmaceutical leader with over 88,000 employees and a presence in more than 120 countries around the world
- Successful track record of building leading global vaccine franchises with numerous approved vaccines including leading franchises such as Prevnar
- Vast experience and expertise in cold-chain shipping and global logistics infrastructure to enable global supply worldwide
- BioNTech and Pfizer testing second generation clinical vaccine candidates and formulations

Partnership for China

- Fosun Pharma is a leading healthcare group in China with 31,370 employees worldwide, of which 2,200 staff work in the R&D team, accounting for 7% of all employees.
- Fosun strategically covers the entire value chain of pharmaceutical and healthcare industry with pharmaceutical manufacturing and R&D being the largest and core segment, together with strong presences in medical devices and diagnostic products, and healthcare services.
- 264 pipeline projects, including innovative drugs, generic drugs, biosimilars and consistency evaluation projects for generic drugs as at 31 December 2019.

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BNT162: Global vaccine supply commitments*

- **Both BioNTech and Pfizer jointly scaling up manufacturing capacity to enable global supply:**
 - BioNTech already producing vaccine for clinical supply at 2 manufacturing sites in Germany
 - Pfizer will activate 3 manufacturing sites in the U.S. and 1 site in Europe
- **> 570 million doses** committed* for 2020 and 2021 in 13 countries and the EU with an option to purchase an **additional 600 million doses**
- Additional **commercial discussions ongoing** with multiple **countries** and supranational organizations including **COVAX**

Commercial supply commitments*		
Region	Number of Doses	Order value
Canada	Not disclosed	Not disclosed
EU	200 million with option for additional 100 million	Not disclosed
Japan	120 million	Not disclosed
United Kingdom	40 million	Not disclosed
United States	100 million with option for additional 500 million	\$1.95 billion for first 100 million doses
Multiple additional countries	Not disclosed	Not disclosed

* Subject to clinical success and regulatory approval

Minimal changes to pre-existing cold-chain supply: Ready for a robust UK rollout

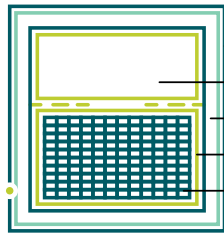
UK deployment models

- ✓ NHS Trusts
- ✓ Large scale vaccination sites
- ✓ Community/primary care led

Doses destined for the UK are manufactured in Belgium



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



- Outer carton
- Rechargeable dry ice
- Insulation
- Inner carton
- Vaccine vials

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



There are over 1,500 immunization centers in England prepared to receive the vaccine vials



1

2

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Quick facts

One tray of vaccine vials is sufficient for almost 100 people

Each vial contains 5 doses (after dilution)

Diluted vials need to be used within 6 hours, per WHO regulations

This is more than enough time to vaccinate 5 people

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Ready to deliver – over 30 days storage in boxes and regular fridge: BNT162b2 will be administered like many other vaccines



Administration to vaccinees at **room temperature**

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



Storage in **delivery box** and **regular fridge** at vaccination centers for **20 days**

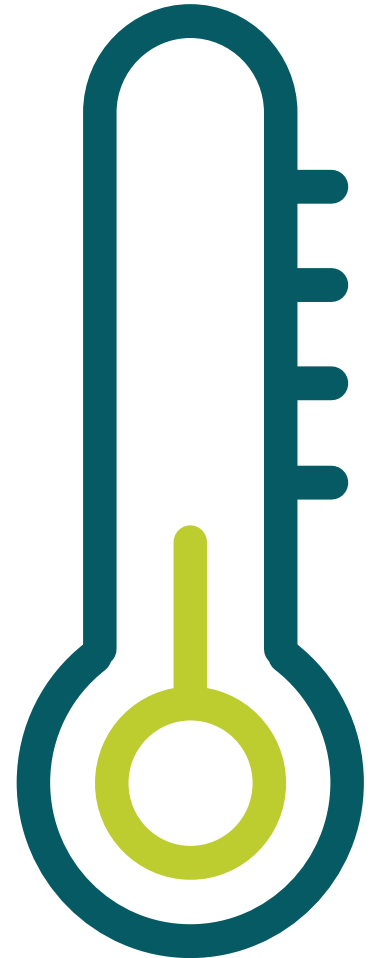
Up to 15 days with re-icing; up to 5 days in regular fridge (2-8°C)



Transport from manufacturing site/storage to vaccination centers and beyond, **based on governments' distribution strategies**

Storage at -70°C only necessary in case of long-term storage (for months), not necessary at vaccination centers; special warehouses already identified

Stability studies provide supporting evidence for transport of defrosted vials (2-8°C) for up to 6 hours, enabling vaccination centers to serve satellite facilities such as care homes



Next steps: roll-outs in other regions of the world upon regulatory approval

United Kingdom
BioNTech MA Holder
1st Approval today



United States
BioNTech MA Holder
Review on Dec 10

European Union
BioNTech MA Holder
Review expected in Dec

Canada
BioNTech MA Holder

+ other states will follow
upon regulatory approval

Q&A



The Biontech logo is displayed in a bold, sans-serif font. The letters 'B', 'I', 'O', 'N', 'T', 'E', and 'C' are in a light blue color, while the letters 'H' and 'H' are in a yellow color. The logo is positioned in the upper left quadrant of the page.

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