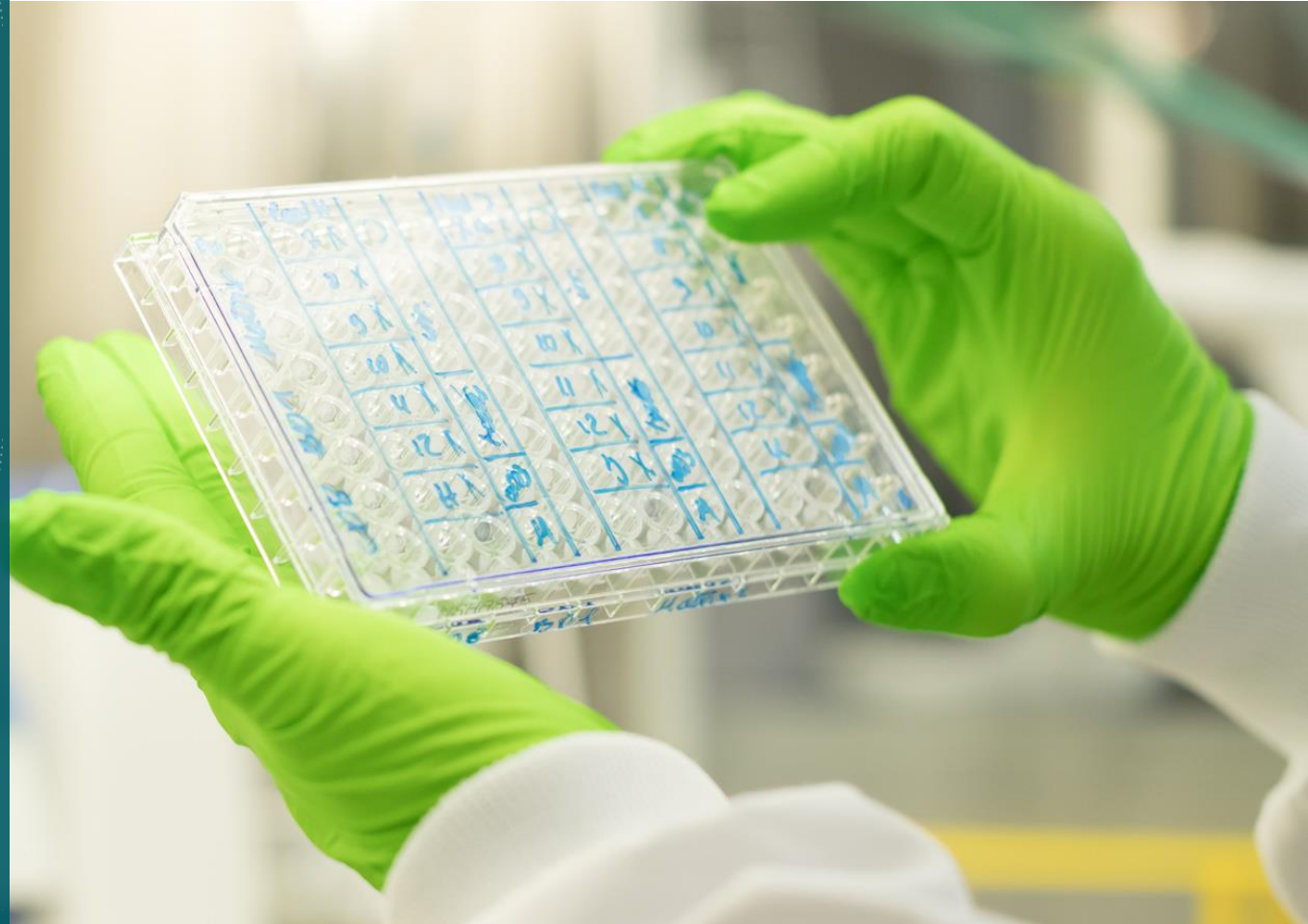


## Next Generation Immunotherapy

February 2021



# 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 the potential for mRNA therapeutics; the planned next steps in BioNTech's pipeline programs and specifically including, but not limited to, statements regarding plans to initiate clinical trials of BioNTech's product candidates and expectations for data announcements with respect to BioNTech's product candidates; the development of commercial capabilities and the transition of BioNTech to a fully integrated biopharmaceutical company; its expectations with respect to interactions with regulatory authorities such as FDA and EMA, including the potential approval of BioNTech's or its collaborators' current or future drug candidates; expected royalty and milestone payments in connection with BioNTech's collaborations; BioNTech's anticipated cash usage for fiscal year 2020 and beyond; the creation of long-term value for BioNTech shareholders; the ability of BioNTech to successfully develop and commercialize a vaccine for COVID-19 in partnership with Pfizer and Fosun Pharma; the timing for any potential emergency use authorizations or approvals for BNT162; and the ability of BioNTech to supply the quantities of BNT162 to support clinical development and, if approved, market demand, including its production estimates for 2021 and the impact of COVID-19 on our clinical trials and business operations, 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 the Company's ability to discover and develop its novel product candidates and successfully demonstrate the efficacy and safety of its product candidates; the pre-clinical and clinical results for its product candidates, which may not support further development of product candidates; actions of the Company's collaborators regarding continued product development and product commercialization; actions of regulatory authorities, which may affect the initiation, timing and progress of clinical trials or the ability of the Company to obtain marketing authorization for its product candidates; the Company's ability to obtain, maintain and protect its intellectual property; the Company's ability to enforce its patents against infringers and defend its patent portfolio against challenges from third parties; competition from others using technology similar to the Company's and others developing products for similar uses; the Company's ability to manage operating expenses; the Company's ability to obtain additional funding to support its business activities and establish and maintain its existing and future collaborations and new business initiatives; the Company's dependence on collaborators and other third parties for development, manufacture, marketing, sales and distribution of products; the outcome of litigation; and unexpected expenditures. 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 vaccines and other product candidates discussed in this slide presentation are investigational products 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.:

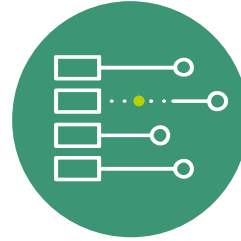
- The Pfizer-BioNTech COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

## 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
- **Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (<https://www.cdc.gov/vaccines/covid-19/>)**
- 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](tel: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 *Information to Provide to Vaccine Recipients/Caregivers* and *Mandatory Requirements for Pfizer-BioNTech COVID-19 Vaccine Administration Under Emergency Use Authorization*

# Next generation Immunotherapy

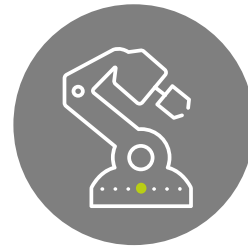
Harnessing the full  
potential of the  
immune system



**Building a fully integrated  
biopharmaceutical company**



**Immunotherapies for cancer &  
infectious diseases and beyond**

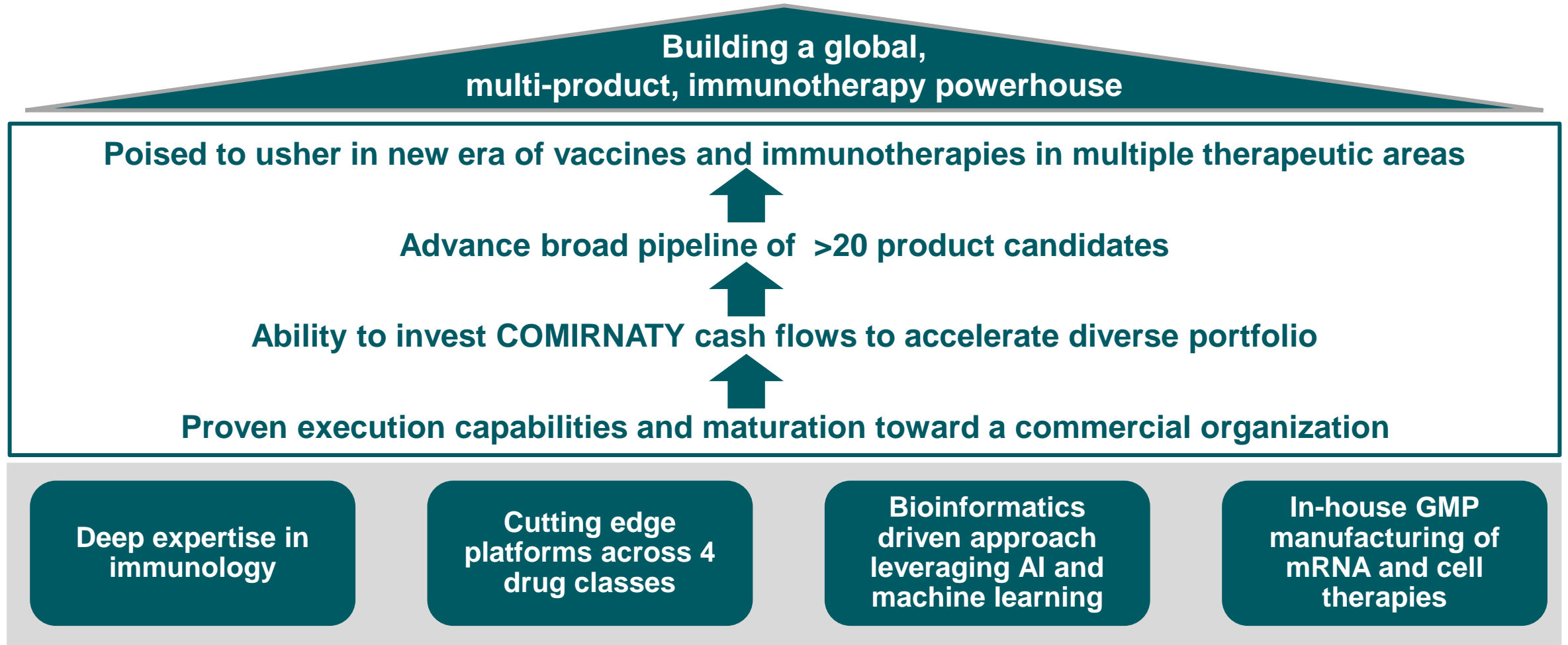


**Broad suite of novel  
technologies**



**Industry-leading global  
collaborations**

# Opportunity in 2021 and beyond



# We collaborate with global leaders in our industry

## Collaborations for clinical stage programs

### Covid-19 Vaccine

50:50 gross profit share<sup>1</sup>



### FixVac Melanoma

Each company to keep 100% of rights to own product

REGENERON

### iNeST

50:50 cost & profit share

Genentech

### Bispecific mABs

50:50 cost & profit share



### Intra-tumoral mRNA

cost & profit share



## Pre-clinical collaborations

### Seasonal Influenza

royalties & milestones



### Up to 10 Infectious Disease Indications

worldwide opt-in right

University of Pennsylvania

### HIV, Tuberculosis

developed world rights

BILL & MELINDA GATES foundation

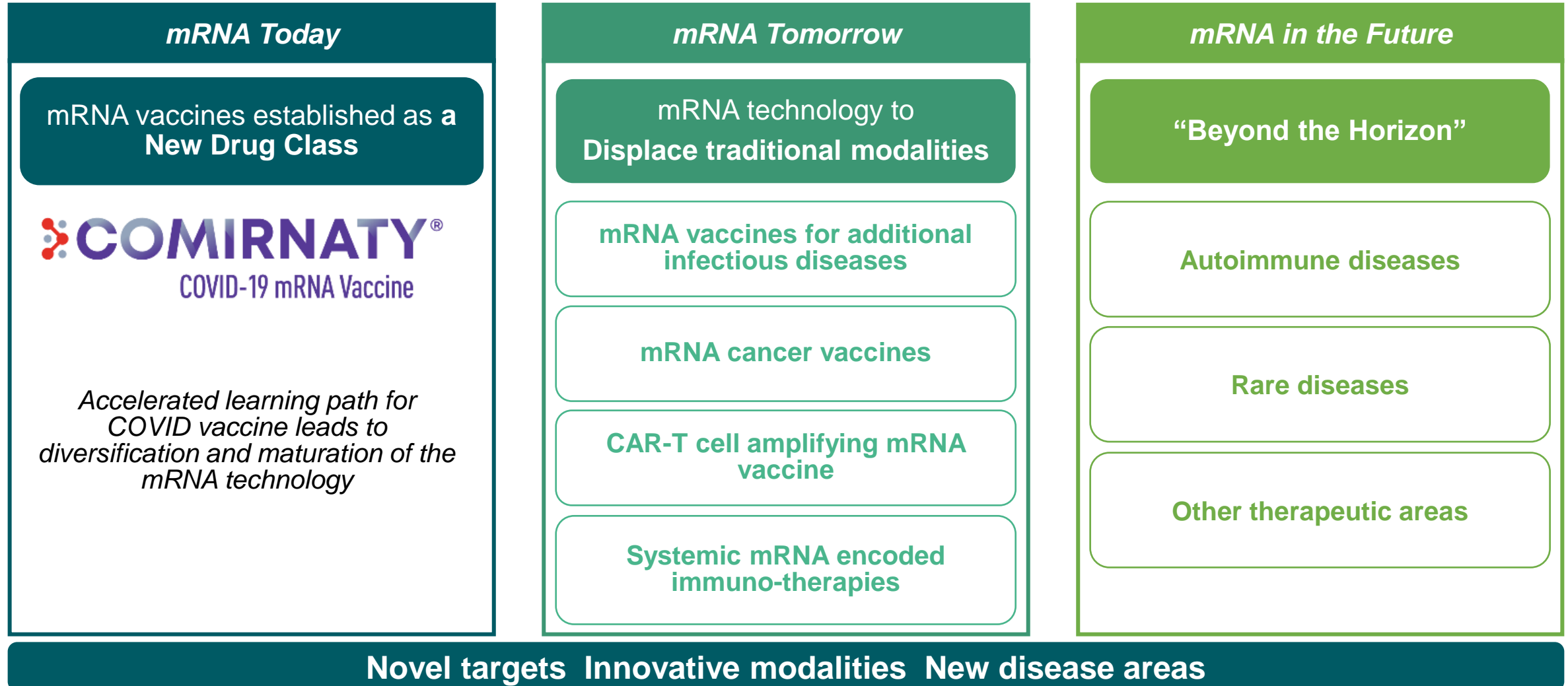
### 5 Rare Disease Indications

50:50 cost & profit share

GENEVANT

<sup>1</sup> 50:50 cost & profit share refers to terms of Pfizer collaboration only (world-wide ex-China)

# mRNA technology poised to revolutionize immunotherapy





# Infectious diseases represent a long-term growth pillar

## Unmet Medical Needs

- Increasing number of highly unaddressed indications
- Only 7 infectious disease vaccines approved by the FDA from 2017 to 2020
- Many high incident infections with no vaccine or therapy approved
- Efficacy of multiple approved vaccines is suboptimal

## BioNTech infectious diseases portfolio

**COMIRNATY**

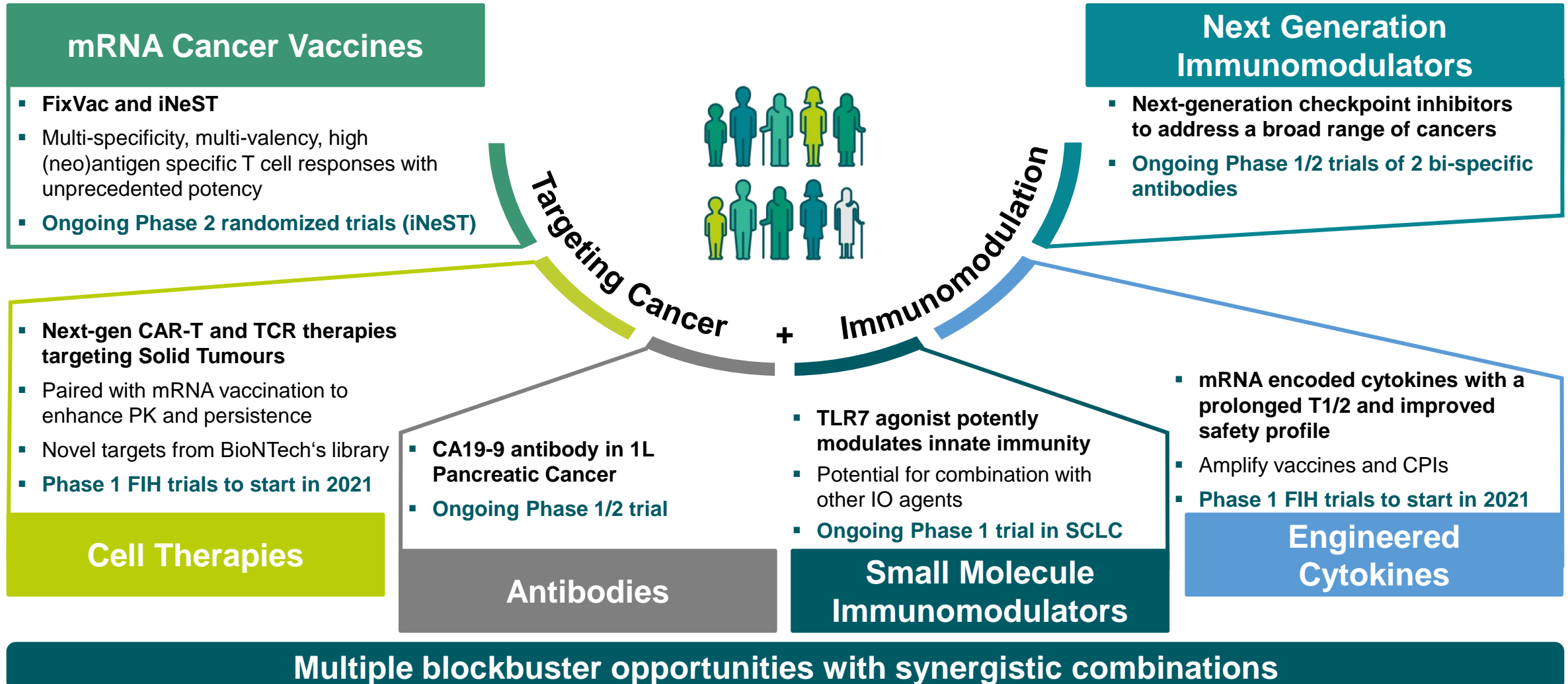
**Next generation COVID-19 vaccines**

**Influenza, HIV and TB vaccines**

**6 undisclosed programs**



# Rationally designed multi-platform immuno-oncology strategy

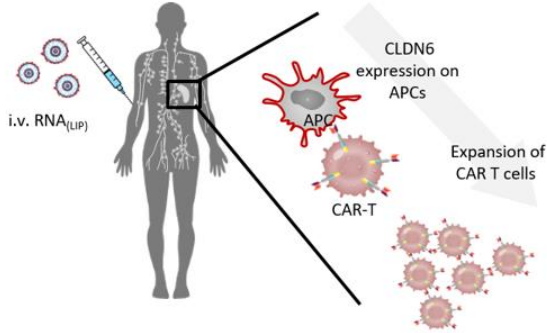
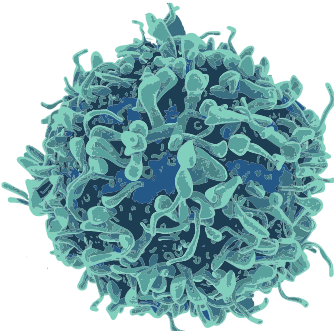
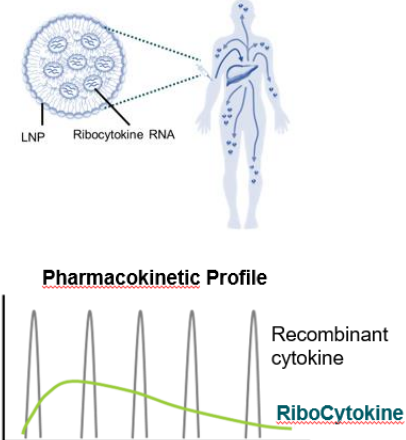
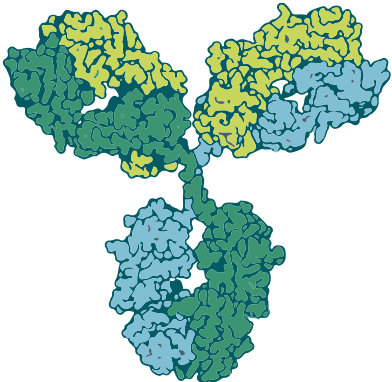


# A technology agnostic approach targets a broader addressable market

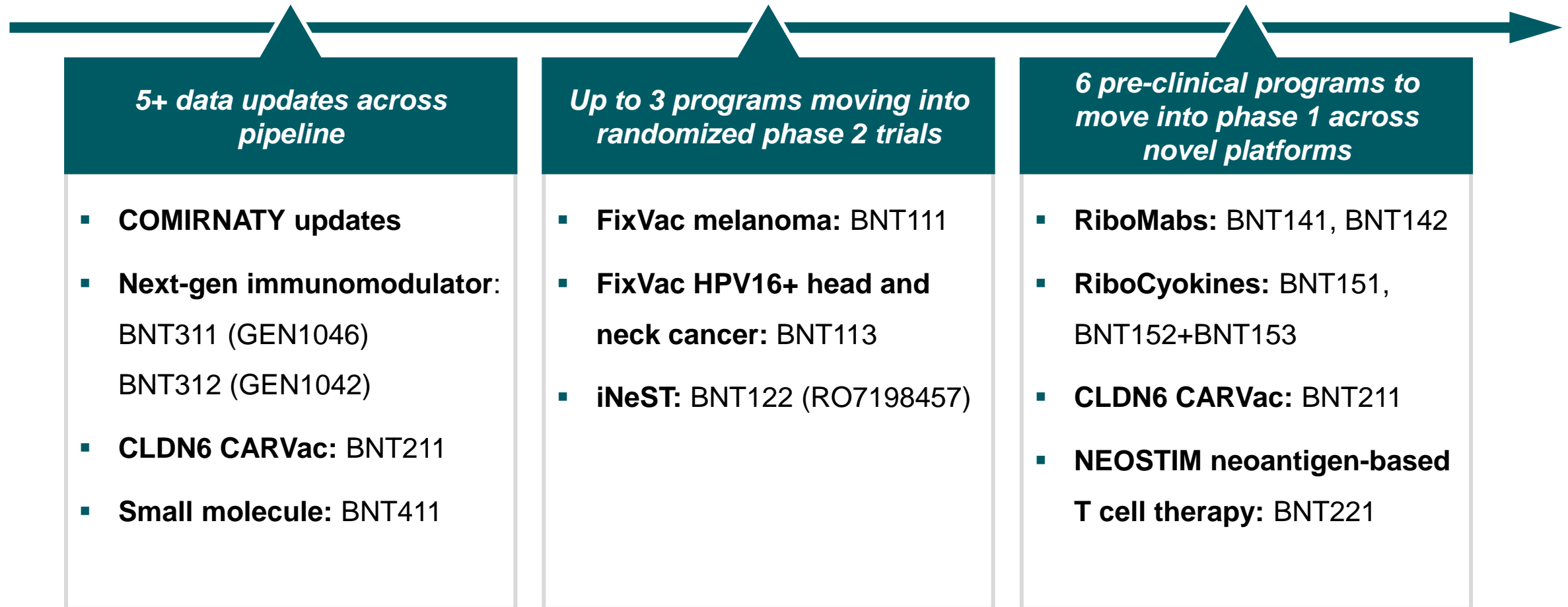
Cancer segment	Patient Population	Challenge	Our Therapeutic Strategies
High mutational burden/ adjuvant stage cancers	Significant portion of cancer patients	Poor risk-benefit profile of checkpoint inhibitors	<ul style="list-style-type: none"> <li>• <b>mRNA Neoantigen Immunotherapy (iNeST)</b></li> </ul>
Low mutational burden cancers	>60% of cancers	Poor response to checkpoint inhibitors	<ul style="list-style-type: none"> <li>• <b>Shared Antigens</b> (FixVac, CAR-T cells, Neoantigen-targeted T cells, Antibodies)</li> </ul>
“Immune desert” cancers	>40% of high-mutational cancers	Poor infiltration and activation of T-cells in TME <sup>1</sup>	<ul style="list-style-type: none"> <li>• <b>RNA Immunotherapy</b></li> <li>• <b>Immunostimulatory Compounds</b> (intratumoral, RiboCytokines)</li> </ul>
Cancers with MHC / B2M loss	20-30% of CPI-experienced advanced cancers	Failure of immune system to recognize tumor cells	<ul style="list-style-type: none"> <li>• <b>Antibodies</b></li> <li>• <b>CAR-Ts</b></li> </ul>
Refractory tumors	Patients with large tumors and multiple resistance mechanisms	Few treatment options	<ul style="list-style-type: none"> <li>• <b>Cell Therapies</b></li> <li>• <b>Combination Therapies</b></li> </ul>

<sup>1</sup>Tumor microenvironment

# Advancing innovation beyond current boundaries

<b>CARVac<sup>1</sup></b> <i>CAR-T cell amplifying mRNA therapy for solid tumors</i>	<b>NEOSTIM T cell therapy</b> <i>Individualized Neoantigen specific T cell therapy</i>	<b>RiboCytokines</b> <i>mRNA encoded Cytokines</i>	<b>RiboMabs<sup>2</sup></b> <i>mRNA encoded Antibodies</i>
 <ul style="list-style-type: none"> <li>▪ BNT 211 (CLDN 6 CAR)</li> </ul>	 <ul style="list-style-type: none"> <li>▪ BNT 221 (PBMC derived ex vivo T cell therapy)</li> </ul>	 <ul style="list-style-type: none"> <li>▪ BNT 151 (modified IL2)</li> <li>▪ BNT152 &amp; 153 (IL-2/IL-7)</li> </ul>	 <ul style="list-style-type: none"> <li>▪ BNT 141 (undisclosed)</li> <li>▪ BNT 142 (CD3xCLDN6)</li> </ul>
<b>Wholly owned</b> ✓	✓	✓	✓
<b>FIH start</b> <b>2021</b>	<b>2021</b>	<b>2021</b>	<b>2021</b>

# Key pipeline milestones expected in 2021



# Better placed than ever to bring innovation to patients

## 2021 Corporate Outlook

- Deliver COMIRNATY to up to 1 billion people globally
- Advance up to 3 oncology programs into randomized Phase 2 trials
- Initiate first trials in oncology with registrational potential
- Extend mRNA technology into new disease areas
- Expand global capabilities and footprint in the U.S., Europe, and Asia
- Continue to hire the best and brightest

## Long- term

- Usher in a new era of individualized cancer medicine
- Build a global business and commercialize our own products
- Become a 21st century immunotherapy powerhouse

# Agenda

## Overview and business outlook

Pipeline

## Deeper dive on our key programs



COVID-19 vaccine program (project “Lightspeed”)

mRNA vaccines – FixVac and iNeST













Antibodies

Small Molecule Immunomodulators

CARVac platform – CLDN6 CAR-T

RiboCytokines

# Oncology pipeline: 11 product candidates in 12 ongoing clinical trials

Drug class	Platform	Product Candidate	Indication (Targets)	Preclinical	Phase 1	Phase 2	Phase 3	Rights Collaborator	Milestones
mRNA	FixVac (fixed combination of shared cancer antigens)	BNT111	advanced melanoma					fully-owned	FPD <sup>4</sup> phase 2: 1H 2021
		BNT112	prostate cancer					fully-owned	
		BNT113	HPV16+ head and neck cancer <sup>1</sup>					fully-owned	FPD <sup>4</sup> phase 2: 1H 2021
		BNT114	triple negative breast cancer					fully-owned	
		BNT115	ovarian cancer <sup>1</sup>					fully-owned	
	iNeST (patient specific cancer antigen therapy)	RO7198457 (BNT122)	1L melanoma					Genentech (global 50:50 profit/loss)	Phase 2 trial planned in adjuvant CRC: FPD <sup>4</sup> in 1H 2021
			solid tumors						
	Intratumoral Immunotherapy	SAR441000 (BNT131)	solid tumors ( <i>IL-12sc</i> , <i>IL-15sushi</i> , <i>GM-CSF</i> , <i>IFNα</i> )					Sanofi (global profit/loss share)	
Antibodies	Next-Gen CP <sup>2</sup> Immunomodulators	GEN1046 (BNT311)	solid tumors ( <i>PD-L1</i> ×4-1BB)					Genmab (global 50:50 profit/loss)	Data update 2H 2021
		GEN1042 (BNT312)	solid tumors ( <i>CD40</i> ×4-1BB)						Data update 2H 2021
	Targeted Cancer Antibodies	BNT321 (MVT-5873)	pancreatic cancer (sLea)					fully-owned	
SMIM <sup>3</sup>	Toll-Like Receptor Binding	BNT411	solid tumors ( <i>TLR7</i> )					fully-owned	Data update 2H 2021

<sup>1</sup>BNT113 and BNT115 are currently being studied in investigator-initiated Phase 1 trials.

<sup>2</sup>Checkpoint Inhibitor.

<sup>3</sup>Small Molecule Immunomodulators.

<sup>4</sup>FPD = First Patient Dosed



# Early-stage oncology pipeline: 6 first-in-human trials to begin in 2021

Drug class	Platform	Product Candidate	Indication (Targets)	Rights Collaborator	Milestones
mRNA	FixVac	BNT116	NSCLC	fully-owned	
	RiboMabs (mRNA-encoded antibodies)	BNT141	solid tumors	fully-owned	Phase 1 start in 2H 2021
		BNT142	solid tumors ( <i>CD3+CLDN6</i> )	fully-owned	Phase 1 start in 2H 2021
	RiboCytokines (mRNA-encoded Cytokines)	BNT151	solid tumors ( <i>optimized IL-2</i> )	fully-owned	Phase 1 start in 1H 2021
		BNT152, BNT153	solid tumors ( <i>IL-7, IL-2</i> )	fully-owned	Phase 1 start in 1H 2021
Cell Therapies	CAR-T Cells	BNT211	solid tumors ( <i>CLDN6</i> )	fully-owned	Phase 1/2 start in 1H 2021 Data update in 2021
		BNT212	pancreatic, other cancers ( <i>CLDN18.2</i> )	fully-owned	
	Neoantigen-based T cell therapy	BNT221 (NEO-PTC-01)	solid tumors	fully-owned	Phase 1 start in 1H 2021
	TCRs	to be selected	all tumors	fully-owned	

# Broad infectious disease pipeline

Drug Class	Product Candidate	Indication (Targets)	Pre-clinical	Phase 1	Phase 2	Phase 3	Commercial	Rights / Collaborator
mRNA Vaccine	COMIRNATY	COVID-19						Pfizer/Fosun
	BNT162c2 (saRNA)	COVID-19						Pfizer/Fosun
	BNT162b3 (modRNA)	COVID-19						Pfizer/Fosun
	BNT161	Seasonal Influenza						Pfizer
	Un-named program	Tuberculosis						BMGF
	Un-named program	HIV						BMGF
	Undisclosed program	–						
	Undisclosed program	–						
	Undisclosed program	–						
	Undisclosed program	–						
	Undisclosed program	–						
Antibodies	Undisclosed program	COVID-19						Wholly-owned

BMGF= Bill & Melinda Gates Foundation

**Infectious Disease Pipeline Target: File 1-2 INDs per year for the next 3 years**

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COVID-19 vaccine program (project “Lightspeed”)

mRNA vaccines – FixVac and iNeST

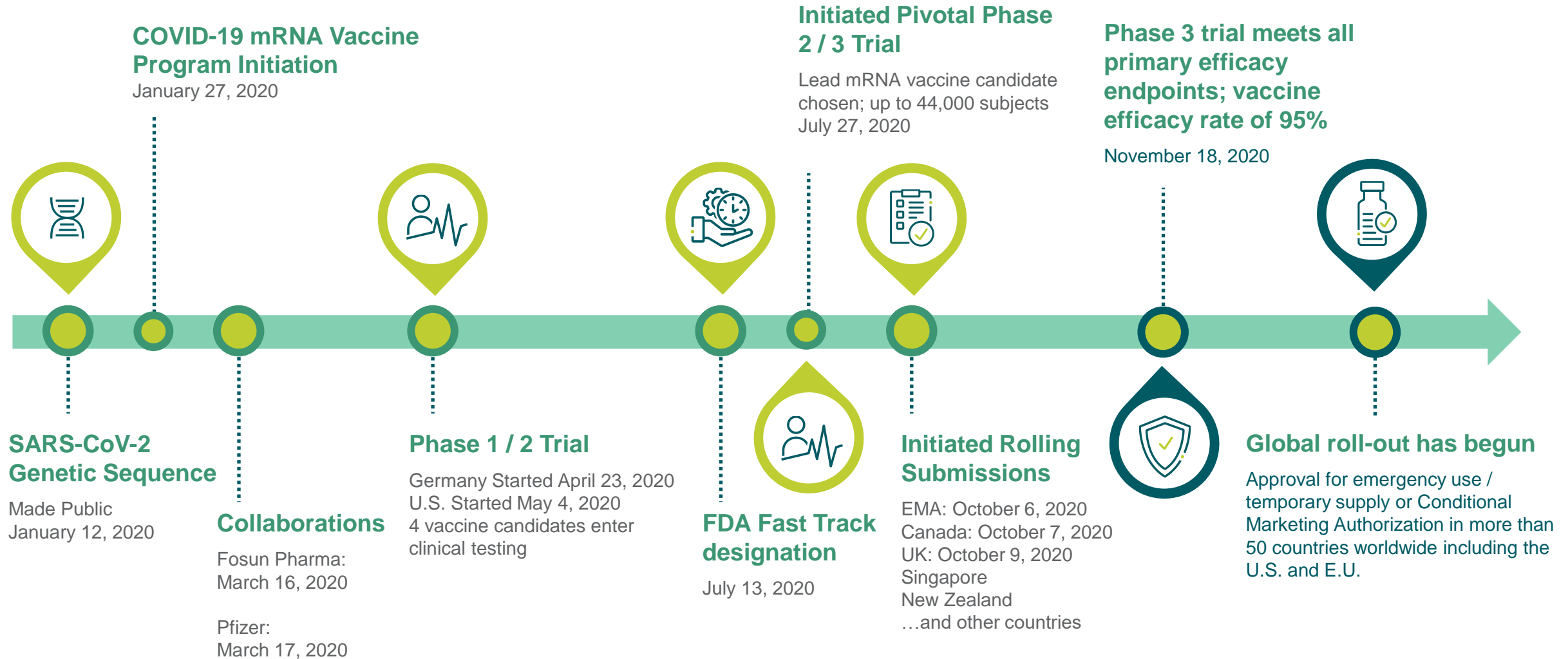
Antibodies

Small Molecule Immunomodulators

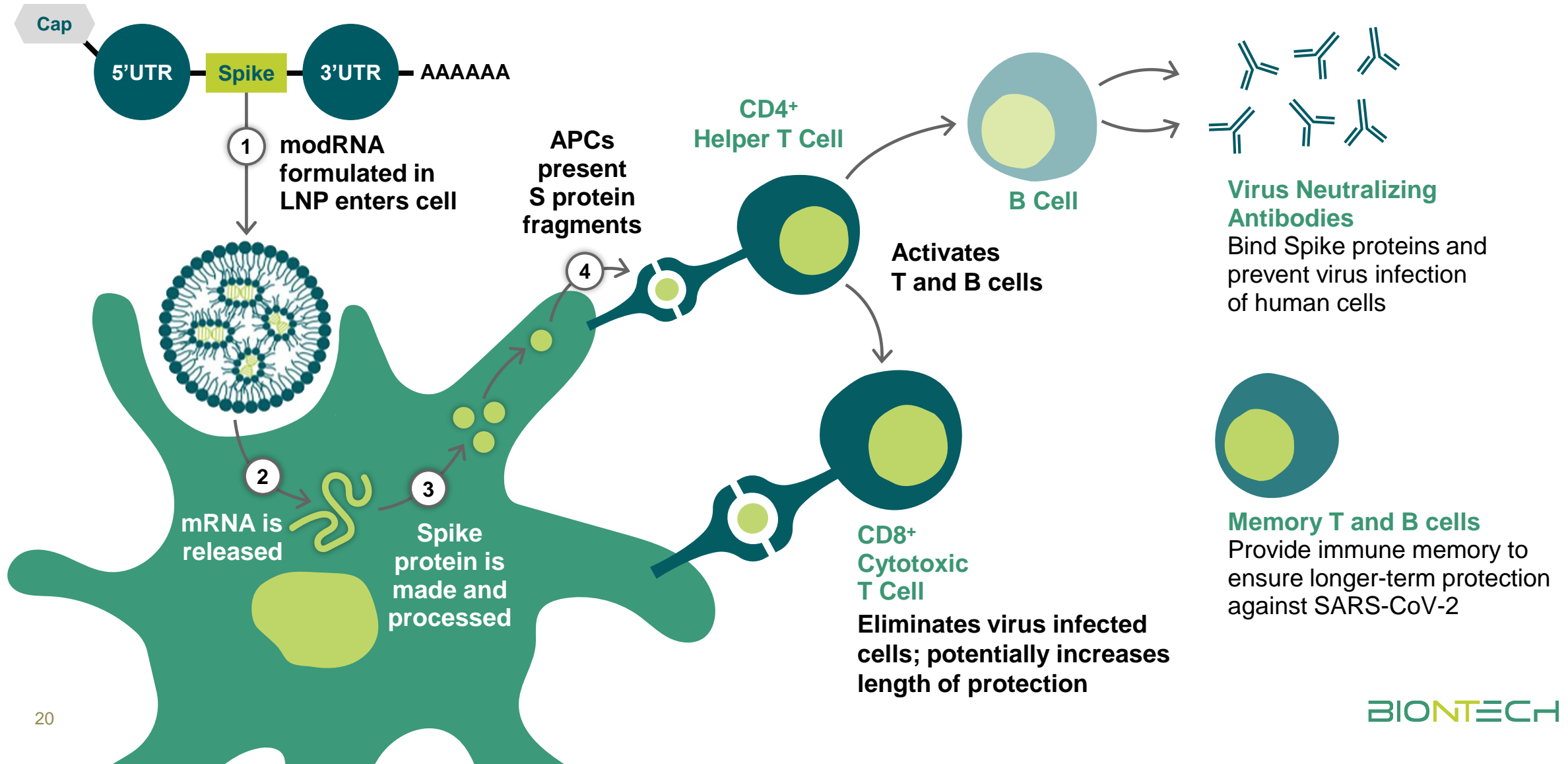
CARVac platform – CLDN6 CAR-T

RiboCytokines

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



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



# mRNA is a natural solution for vaccines especially in a pandemic

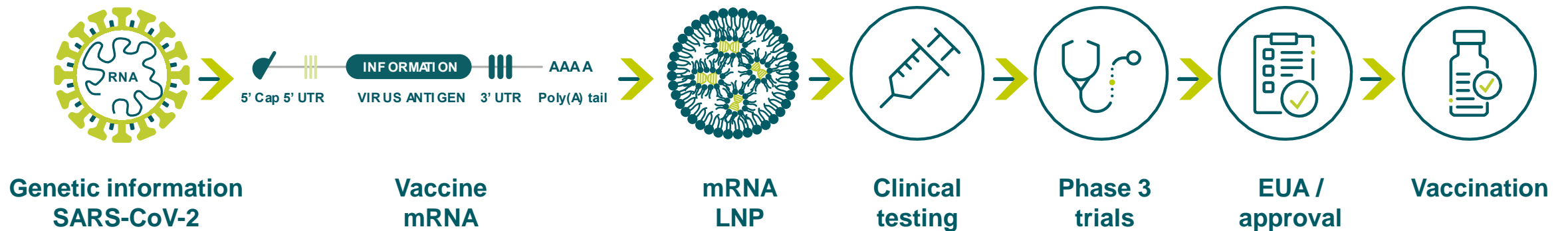
Natural molecule with  
well-characterized  
**bio-safety properties**

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

Highly scalable production

High purity and animal free

non-integrating into DNA and  
non-infectious  
unlike attenuated live virus and  
DNA based vaccines



# COVID-19 will likely become an endemic disease

## *Unmet Medical Needs*

## *Key Strengths*

<b>1</b>	<b>Safety &amp; Efficacy</b>	<b>Compelling efficacy &amp; safety in all tested age groups</b>
<b>2</b>	<b>Emergence of new viral variants</b>	<b>Ability to create re-engineered vaccine in 6 weeks<sup>1</sup></b>
<b>3</b>	<b>Naturally waning immune response</b>	<b>mRNA vaccine well-suited for re-vaccination</b>



# COMIRNATY: Leading the fight against COVID-19

- **First vaccine authorized for use in the US and the EU**
- **Authorization for Emergency Use / Temporary Use or Conditional Approval in > 50 countries**
- **32.9m million doses shipped<sup>1</sup>**
- Global phase 3 trial data indicates vaccine is **highly efficacious** and **generally well tolerated**
  - **95% vaccine efficacy** in 43,000+ participants
  - 94% efficacy in participants older than 65 years
  - Generally well tolerated with most **adverse events being mild to moderate in intensity and transient in effect**
  - Most common adverse events are fatigue, headache, pain at injection sites, chills, muscle and joint pain
- **Broad immunogenicity profile (poly-epitopic, multi-effector),** inducing high titer of neutralizing antibody and T cell responses

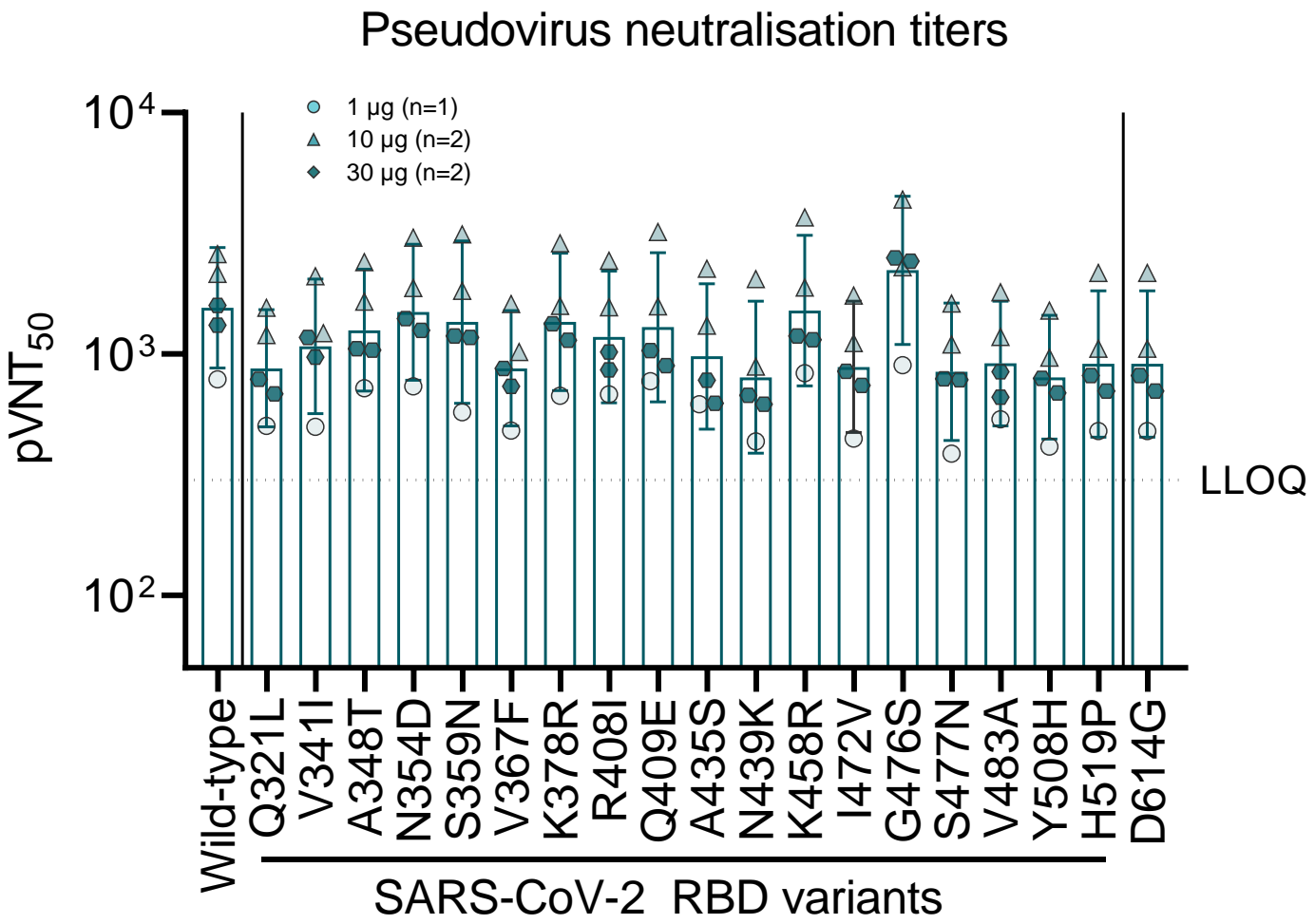
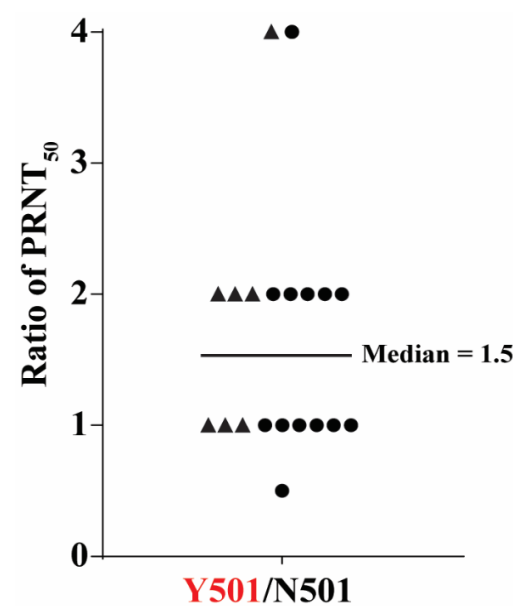
**COMIRNATY<sup>®</sup>**  
COVID-19 mRNA Vaccine



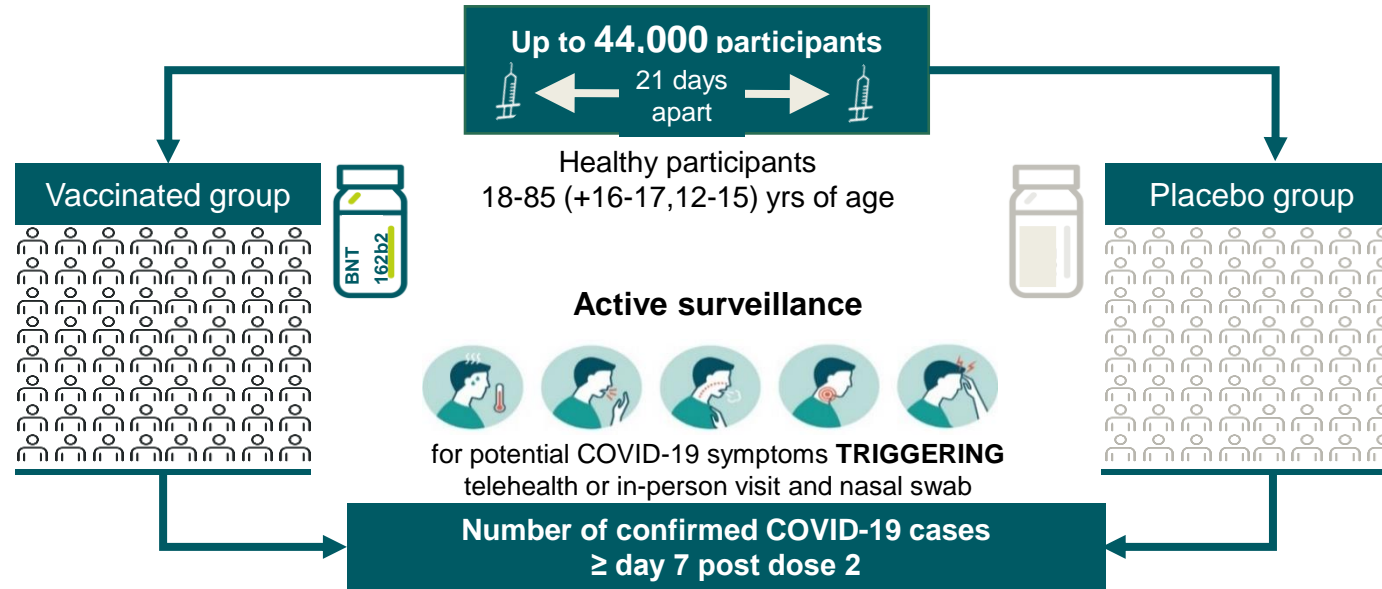
**For use in individuals  
16 years and older**

# BNT162b2 induced antibodies cross-neutralize SARS-COV-2 variants

- Sera of 20 Phase 3 trial participants contained equivalent **neutralizing activity against N501Y mutation** found in two highly transmissible strains as compared to the unmutated strain<sup>2</sup>



# BNT162 met all primary efficacy endpoints in global Phase 3 trial



## Primary Efficacy Objectives

Efficacy against confirmed COVID-19 in participants without evidence of infection before vaccination

Efficacy against confirmed COVID-19 in participants with and without evidence of infection before vaccination

**43,661 participants enrolled**  
**41,135 received 2nd dose**

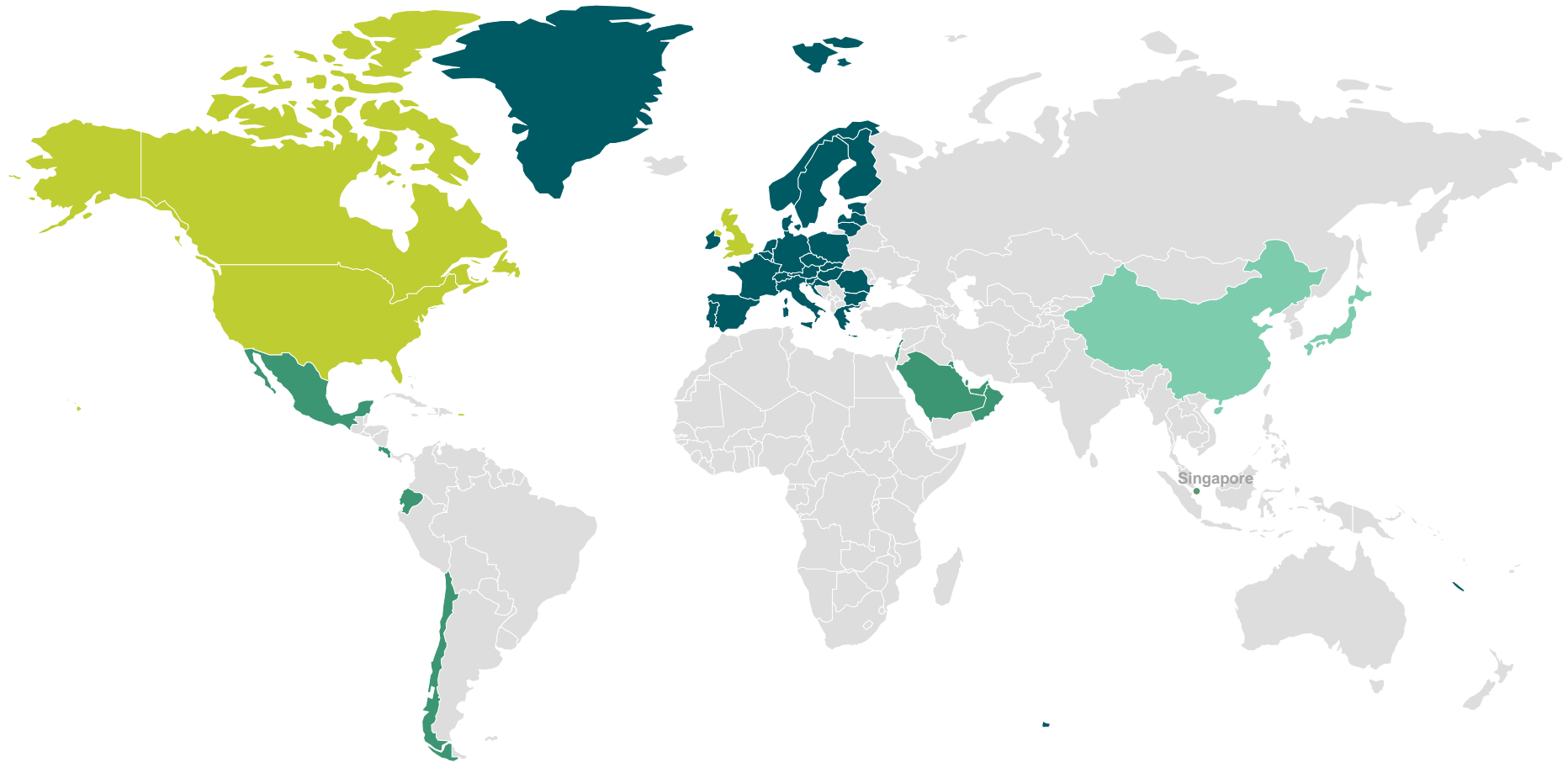
- Primary efficacy analysis demonstrated 95% vaccine efficacy beginning 28 days after first dose
- Observed >94% vaccine efficacy in adults over 65 years of age; 41% of global participants were 56-85 years old
- Primary efficacy analysis case split: 162 in placebo group vs. 8 in vaccine group
- Ten severe COVID-19 cases observed in the trial with 9 occurring in placebo group and 1 occurring in vaccine group
- Well tolerated across all populations

Race/Ethnicity	Overall Study
Asian	4.5%
Black	10%
Hispanic/Latinx	26%
Native American	0.8%

Data as of November 16<sup>th</sup>, 2020

# Project Lightspeed: A concerted and large-scale global effort

- Conditional Marketing Authorization in the EU and Switzerland<sup>1</sup>
- Approved Emergency Use Authorization / Temporary Use Approval
- Vaccination with our COVID-19 vaccine already underway under Emergency Use Authorization/Temporary Use Approval
- Ongoing Phase 2 trials in China and Japan



**Rolling application for emergency use authorization in further countries underway.**

# Supply up to two billion vaccine doses in 2021



- 3 Pfizer sites in the U.S. producing mRNA vaccine

- FY 2021 manufacturing capacity target: **2.0 billion doses\***
- Committed Doses for 2021: **>1 billion doses**
- **50:50** gross profit share with Pfizer (worldwide ex-China); **35-40%** gross profit share with Fosun Pharma in China
- **6 manufacturing sites** in Pfizer and BioNTech alliance
- **Additional external CMO sites** expanding LNP and fill-finish capacity



## Marburg: major inflection point

- up to 750m doses in annual capacity
- Expected to become operational by end of February 2021

# Multiple strategic levers to expand COMIRNATY access



## Increase Supply Capacity

- 6-dose vial
- Continuous process improvements
- New sites, suppliers and CMOs

## Broaden global distribution

- New country / regional authorizations
- BLA submission in U.S. and other regions
- Order book growth

## Expand label

- Pediatric indications
- Pregnant women
- Additional sub-populations

## Develop optimized formulations

- Further stability testing update for current formulation
- Improved thermostable formulation
- PEG-free formulation

## BNT162 global collaborations



- Co-development and co-commercialization worldwide (ex China) if approved
- Combined upfront payment and equity investment of \$185 million to BioNTech received in April
- Capital expenditures to be funded by each party independently
- Companies to share development expenses and gross profits on a 50:50 basis
- BioNTech eligible to receive further development & sales milestones up to \$563 million



- Co-development with Fosun Pharma to hold exclusive marketing rights in China if approved
- Combined upfront payment and equity investment of \$51 million to BioNTech received in April
- Fosun Pharma to fund development expenses in China
- BioNTech and Fosun to share gross profits on the sale of the vaccine in China
- BioNTech eligible to receive further China development & sales milestones up to \$84 million



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Antibodies

Small Molecule Immunomodulators

CARVac platform – CLDN6 CAR-T

RiboCytokines

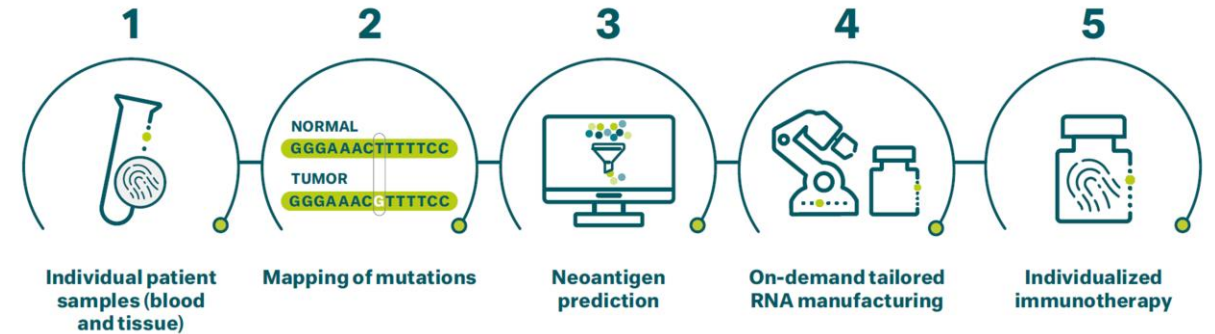
# Our mRNA vaccine platforms: FixVac and iNeST

## FixVac



- Off-the-shelf mRNA immunotherapy
- Targeting a fixed combination of shared antigens
  - Non-mutated shared antigens shared across patients
  - Applicable for almost all types of tumor antigens

## iNeST



- Fully individualized mRNA immunotherapy
- Targeting 20 neo-antigens unique to each patient
  - Vast majority of neo-antigens are unique to individual patients
  - Applicable across solid tumor types

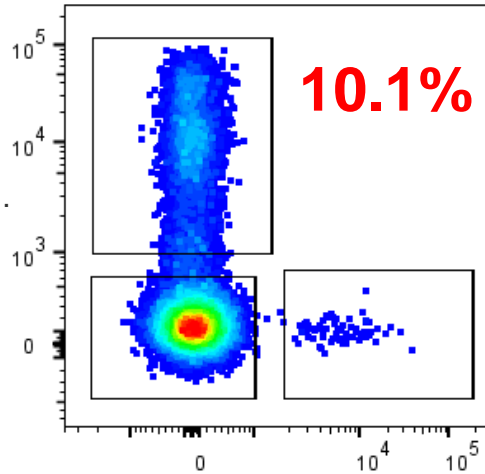
**Proprietary RNA-LPX formulation for systemic dendritic cell targeting**

**Strong immunogenicity observed *in vivo* via TLR7-driven adjuvant effect**

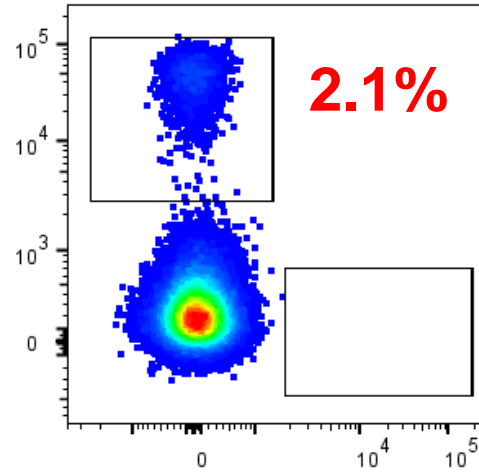
**Potent induction of strong *ex vivo* CD4+ and CD8+ T cell responses**

# Our RNA-LPX vaccine approach

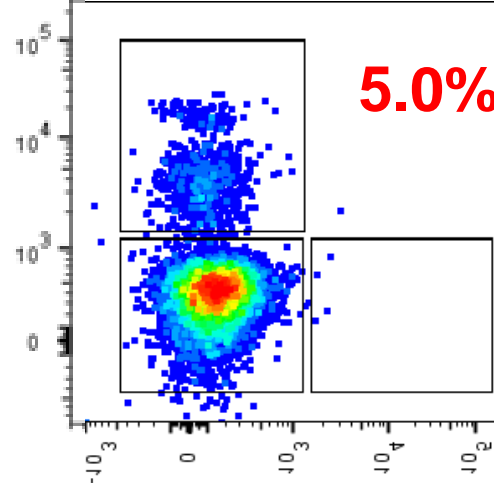
Strong vaccine-induced *ex vivo* CD8+ T cell responses<sup>1</sup> across different cancer types



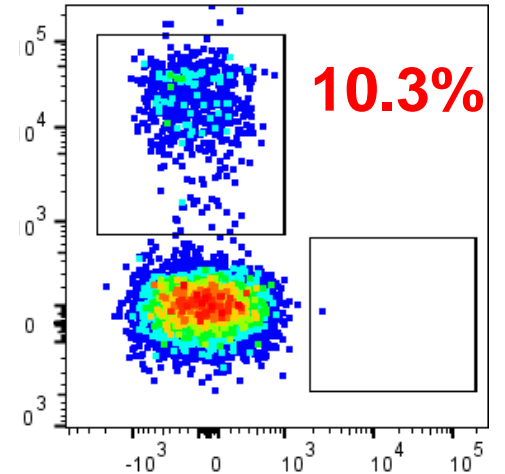
**NY-ESO-1**  
Melanoma  
BNT111, Lipo-MERIT trial



**MAGE-A3**  
Melanoma  
BNT111, Lipo-MERIT trial



**HPV16-E7**  
Head Neck Cancer  
BNT113, HARE40 trial



**Mutant Neoantigen**  
TNBC  
BNT114, TNBC MERIT trial

FixVac

iNeST

# BNT111 FixVac Melanoma: Planning to initiate randomized phase 2 trial

## Ongoing Phase 1 trial in Advanced Melanoma published in Nature

- Phase 1 trial data in CPI-experienced patients in monotherapy and in combination with anti-PD1 previously reported in July 2020 and published in Nature
- All patients showed tumor associated antigen (TAA) specific T cell responses with In vitro stimulation, and > 75% of patients showed immune responses against  $\geq 1$  TAA on an ex vivo basis
  - T cells responses ramped up over 4-8 weeks and increased or remained stable up to over one year with monthly maintenance therapy
- ***Reported durable clinical responses in monotherapy and in combination with anti-PD1 accompanied by high magnitude CD4+ and CD8+ response***

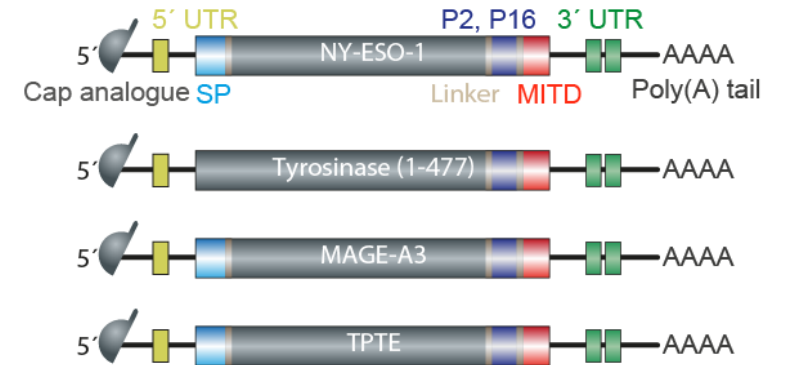
## Regeneron strategic collaboration and planned Phase 2 trial

- Signed strategic collaboration to jointly conduct randomized Phase 2 trial with BNT111 and Libtayo® (cemiplimab anti-PD-1 therapy)
- Targeting patients with anti-PD1-refractory/relapsed, unresectable Stage III or IV cutaneous melanoma
- Companies to share development costs equally and keep full commercial rights to own programs
- ***Plan to initiate randomized Phase 2 trial in the first half of 2021***

# BNT111 interim clinical activity data in advanced melanoma

## Summary

- Advanced melanoma patients (stage III, IV); dose range: 14µg -100µg
- Out of **74 patients** with available follow-up radiological imaging **42 patients** were assessed for preliminary analysis as of July 29, 2019
- of 25 patients** with metastatic melanoma who received **BNT111 monotherapy** following progression on CPI\* and in some cases other therapies
  - 3 patients with partial response (PR)
  - 1 patient with metabolic complete response<sup>1</sup>
  - 7 patients with stable disease (SD)
  - 14 progressive disease (PD)
- of 17 patients** with metastatic melanoma who received **BNT111 in combination** with CPI after progression on CPI monotherapy
  - 6 patients with partial response (PR)
  - 2 patients with stable disease (SD)
  - 9 progressive disease (PD)
- Adjuvant cohort of 32 patients still in study



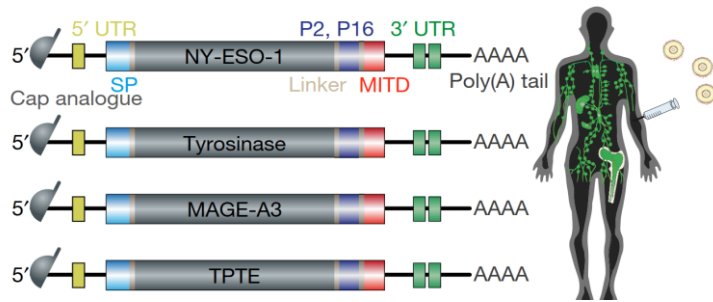
**Cumulative patient coverage of FixVac melanoma targets is over 90%**

**Report phase 1 data 1H 2020**

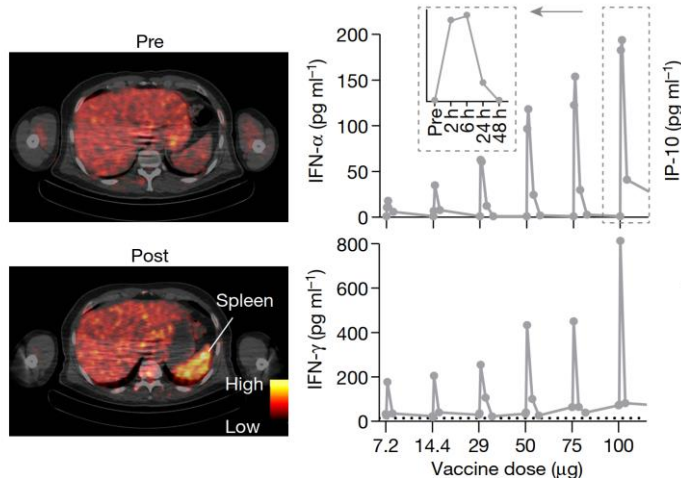
**Start randomized phase 2 trial in 1H 2021**

# BNT111 publication in Nature highlights

## Targeting of lymphoid DC for vaccine delivery & type I IFN activity



### Vaccine constructs

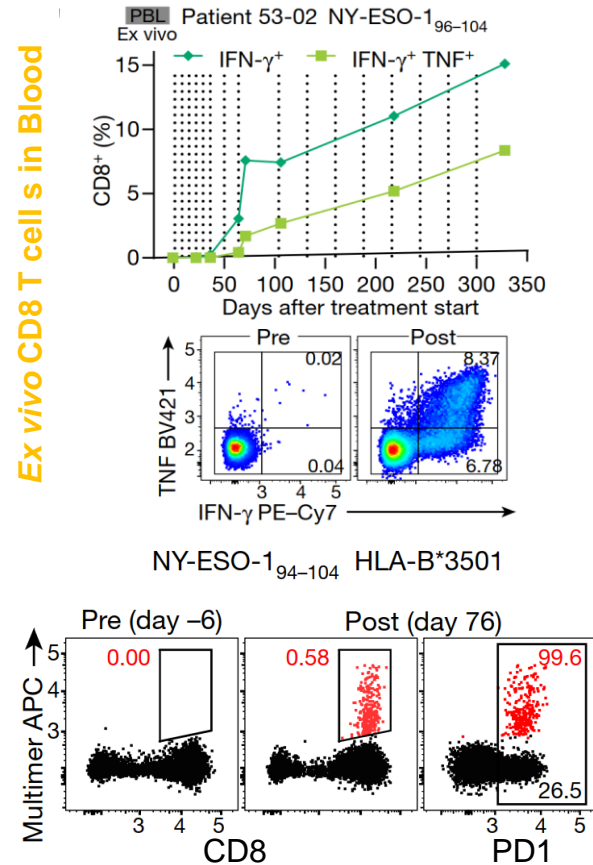


FDG PET

Blood Cytokines

## Strong CD4+, CD8+ T cell responses Multifunctional CD8+ PD1+ T cells

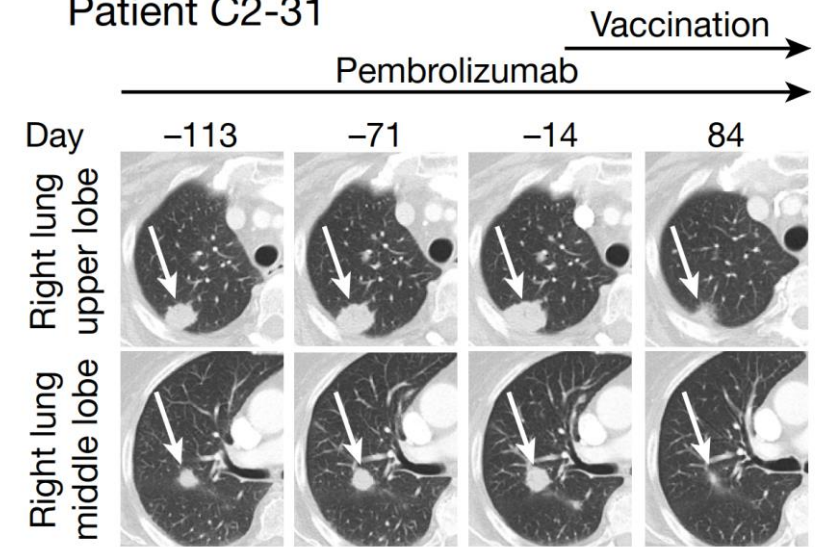
### Ex vivo CD8 T cells in Blood



## Objective responses in CPI-experienced melanoma patients with evaluable disease at baseline:

- ORR of BNT111 monotherapy: 4/25
- ORR of BNT111 + anti-PD1: 6/17 (35%) (CPI resensitizing activity of BNT111)

### Patient C2-31



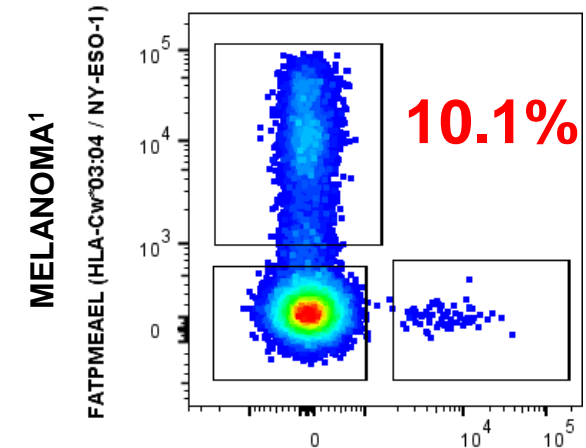
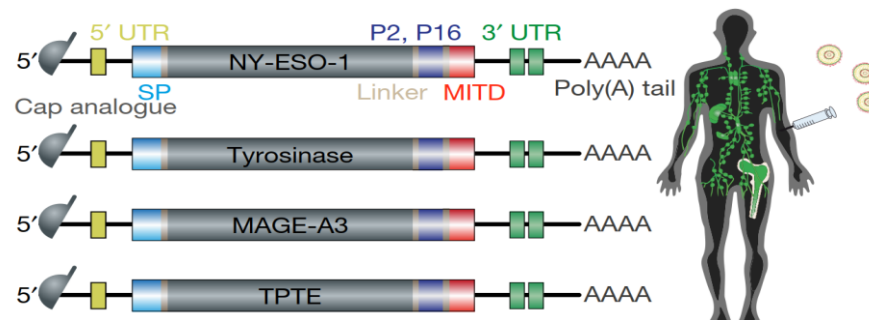
Lung CT scans before & after BNT111

# FixVac: Leveraging shared antigens to break immune tolerance

## Novel Structure

FixVac

- Multi-valency + Off-the-shelf
- Applicable for almost all types of tumor antigens



### Product candidate<sup>2</sup>

BNT111

BNT113

BNT112

BNT116

### Preclinical

**Advanced melanoma** *NY-ESO-1, MAGE-A3, Tyrosinase, TPTE*

**HPV+ head & neck cancer** *HPV E6 and E7 oncoproteins*

**Prostate cancer** *PSA, PAP, 3 addition undisclosed antigens*

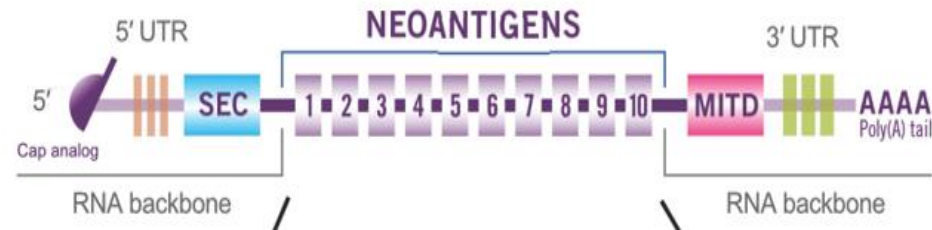
**NSCLC**

### Phase 1

### Phase 2

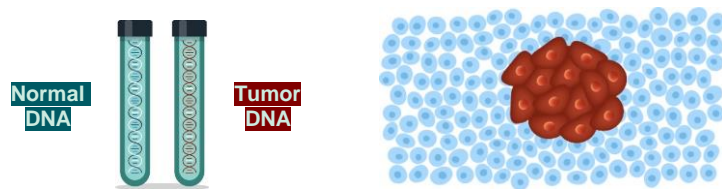


# iNeST<sup>1</sup>: Tailored treatment to exploit individual targets



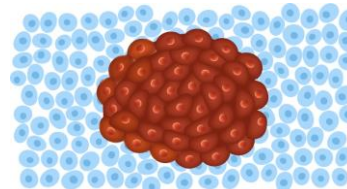
- Fully customized to the individual Patient
- Targeting 20 neo-antigens per patient

## ADJUVANT



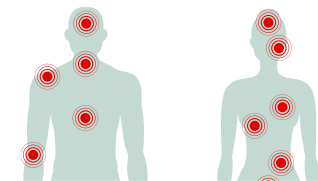
Residual cancer cells may remain – emphasis on recurrence free survival

## 1L METASTATIC



Rapidly growing but often still in early phase of metastases

## LATE-LINE METASTATIC



Bulky tumors with multiple organs involved

iNeST

- *Phase 2 trial planned*
- *8 of 8 stage III/IV melanoma patients with stable disease cancer free for **up to 60 months** (BNT121)<sup>1</sup>*

- *Ongoing Phase 2 trial in 1L melanoma*

- **Single agent activity** in melanoma<sup>2</sup> and gastric<sup>3</sup> Cancer
- **Encouraging efficacy signal validates iNeST potential in early settings**

# iNeST: Recent update from BNT122 reported at AACR

## Phase 1a dose escalation: Monotherapy in locally advanced or metastatic solid tumors

- **31 patients** enrolled, cohorts with **doses ranging from 25-100ug**
  - Most common tumor types were HR+/HER2+ breast, prostate, and ovarian cancer
  - **Median of 5 lines of prior therapies (range 1-17)**
  - Most patients enrolled had low **level of PD-L1 expression** in tumor
- Neoantigen-specific **T cell responses** observed in peripheral blood in **86%** of patients, significant T cell expansion and **both naïve and memory activated phenotype**
- Of 26 patients with at least one tumor assessment,
  - **1 patient with gastric cancer and metastatic liver lesions** had **confirmed CR** (ongoing for 10 months)
  - **12 patients** had **SD**

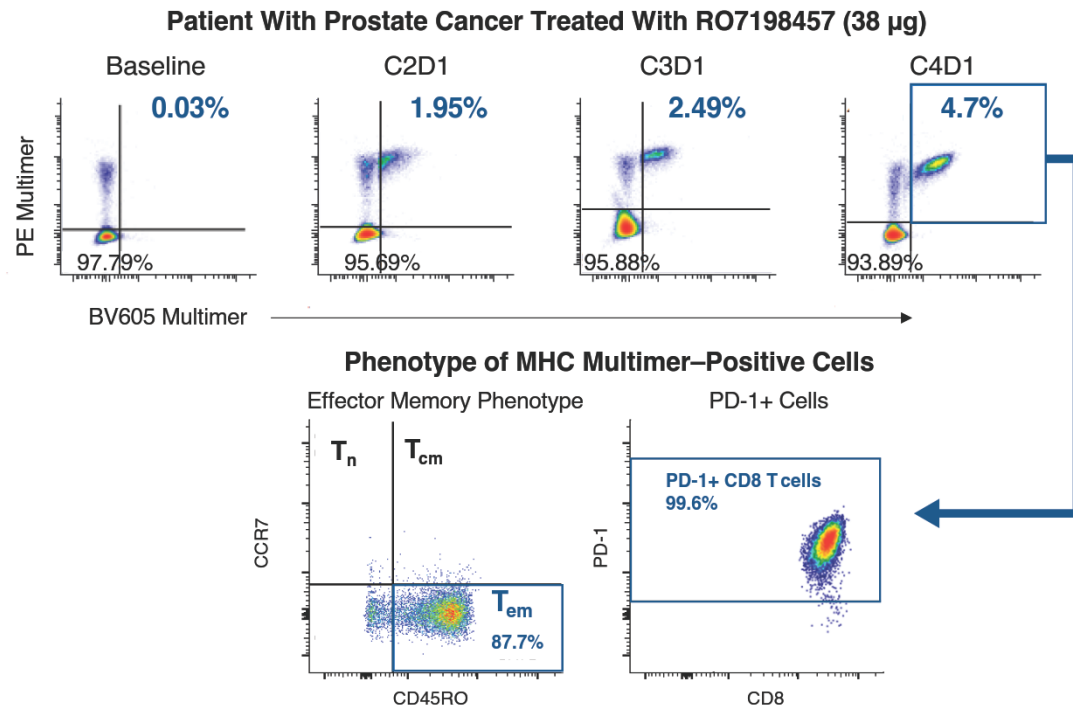
## Phase 1b combination with atezolizumab demonstrated clinical activity in heavily pretreated patients

- **132 patients** enrolled, cohorts with **doses ranging from 15-50µg**
- Heavily pre-treated patient population
  - Both CPI experienced and inexperienced
  - **Most patients with low PD-1**
- Clinical responses associated with T cell response, correlating immune profiling of patients' T cells to cancer-specific response
- Of 108 patients with at least one tumor assessment
  - **1 patient** had **CR as best response** (0.9%),
  - **8 patients** had **PR** (7.4%), and
  - **53 patients** had **SD** (49.1%)

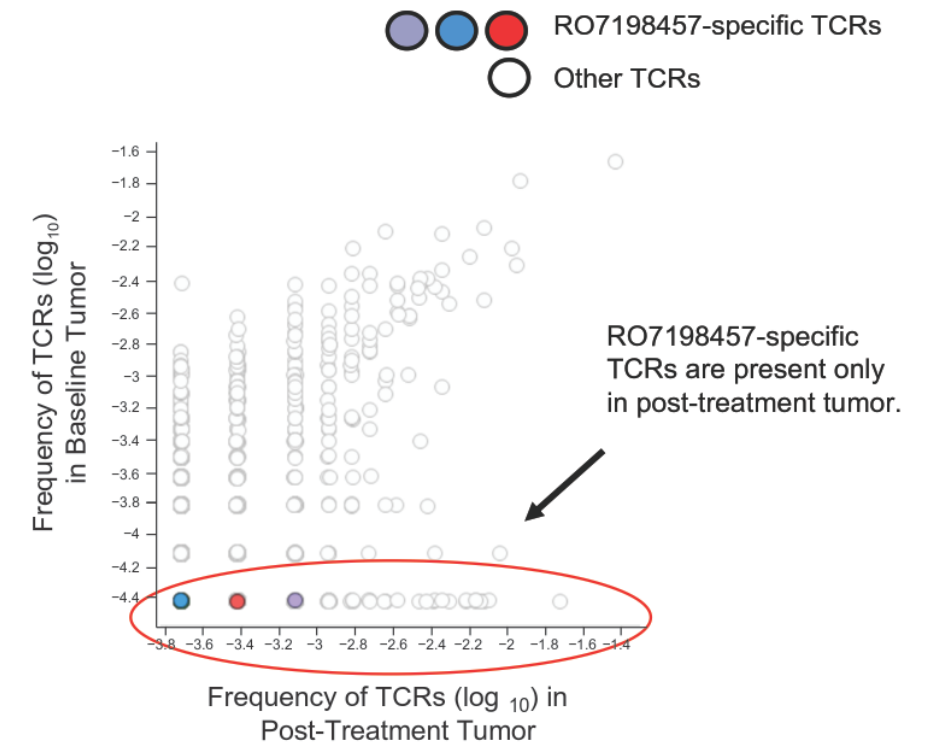
- **Demonstrates ability to elicit significant T cell responses of both effector and memory phenotype as monotherapy and in combination**
- **Treatment-related adverse events were primarily transient systemic reactions, manifesting as low grade CRS, IRR or flu-like symptoms**
- **Early evidence of clinical activity in highly refractory patient population**

# iNeST: Recent update from BNT122 reported at AACR (Cont'd)

## BNT122 induces CD8+ T cells in CPI-sensitive and CPI-insensitive tumor types



## BNT122 induces CD8+ T cell infiltrates in tumors



# BNT122 iNeST randomized Phase 2 trials ongoing and planned

	First-line advanced melanoma	Adjuvant colorectal cancer
Study design and patient population	A Phase 2, open-label, multicenter randomized trial of the efficacy and safety of BNT122 in combination with pembrolizumab vs. pembrolizumab in patients with previously untreated Advanced Melanoma	A Phase 2, open-label, multicenter randomized trial to compare the efficacy of BNT122 versus watchful waiting in patients with ctDNA positive, surgically resected Stage 2/3 rectal cancer, or Stage 2 high risk/stage 3 colon cancer
Rationale	<ul style="list-style-type: none"><li>▪ Evaluate added benefit of 1L BNT122 in an advanced CPI-sensitive tumor (PFS, ORR)</li><li>▪ Success ungates 1L use of iNeST in CPI-sensitive advanced cancers for combination therapy</li></ul>	<ul style="list-style-type: none"><li>▪ Evaluate added benefit of BNT122 in a micrometastatic CPI-insensitive tumor (RFS)</li><li>▪ Success ungates adjuvant use of iNeST for CPI-insensitive ctDNA+ cancer types</li></ul>
Status	Currently enrolling	To start in 1H 2021

# Digitalization and automation for neo-antigen vaccine manufacturing



**Paperless documentation**



**Semi-automatic manufacturing**

- 2 mRNA GMP production facilities: Idar-Oberstein (GMP since 2011) and Mainz (GMP since 2018)
- Construction and GMP licensure of new Mainz facility for iNeST expected in 2022/2023
- Partnered with Siemens to develop automated production processes

# Agenda

## Overview and business outlook

Pipeline

## Deeper dive on our key programs



COVID-19 vaccine program (project “Lightspeed”)

mRNA vaccines – FixVac and iNeST

Antibodies

Small Molecule Immunomodulators

CARVac platform – CLDN6 CAR-T

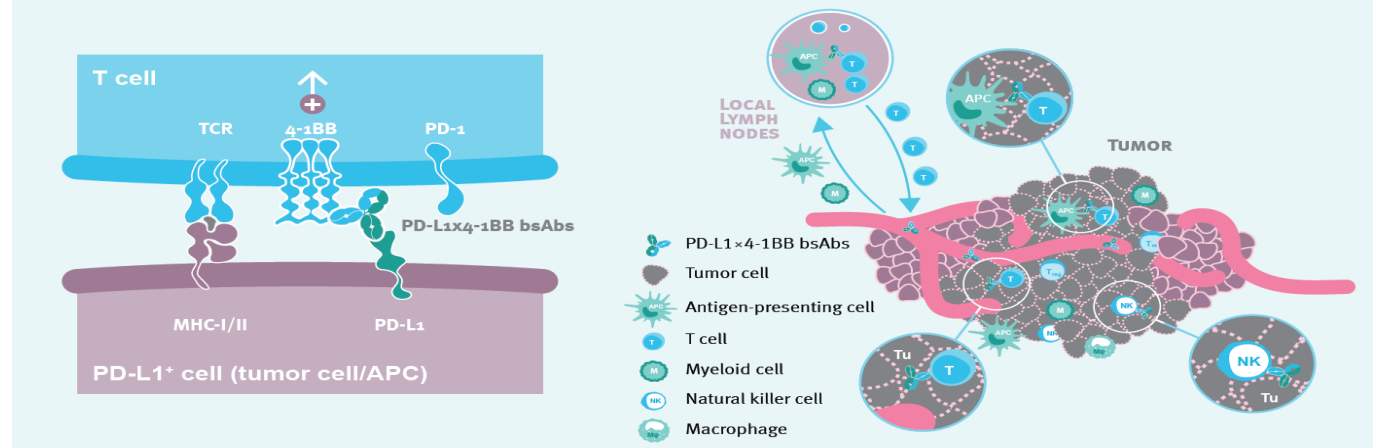
RiboCytokines



# BNT311: Next-generation bispecific antibody PD-L1x4-1BB

- **Next-generation immunotherapy** designed to enhance T cell and NK cell function through conditional 4-1BB co-stimulation while simultaneously blocking PD-L1 axis
- Bispecific antibody is 50:50 profit/loss share partnered with Genmab

MECHANISM OF ACTION OF FC-SILENCED PD-L1x4-1BB BSABS

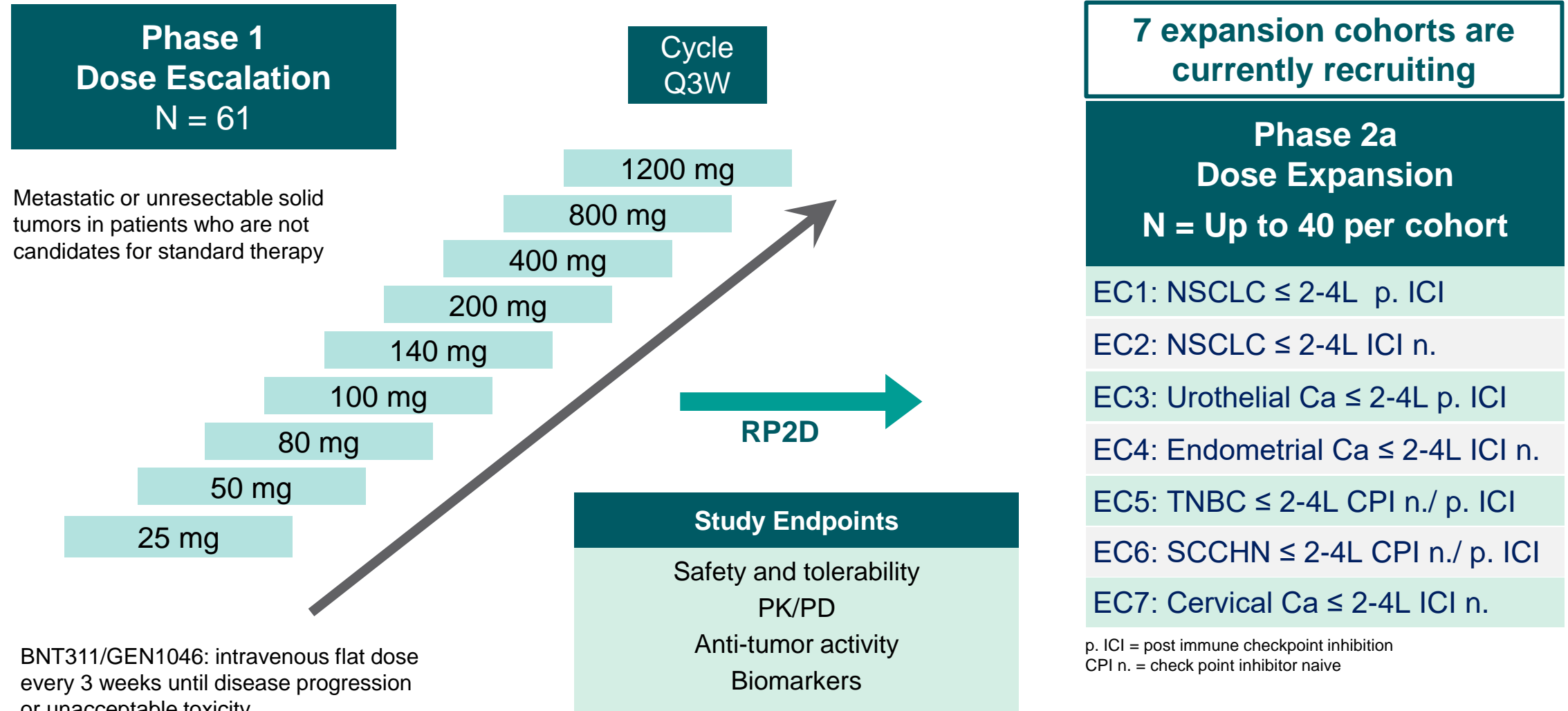


**Interim results  
of ongoing  
Phase 1/2a trial  
presented at  
SITC 2020**

Phase 1/2a dose escalation and expansion trial in heavily pretreated patients with advanced solid tumors to evaluate safety and initial anti-tumor activity

- Dose escalation (n=61) data demonstrated **manageable safety profile** and **preliminary clinical activity** across advanced solid tumors
- Expansion cohort (n=24) in NSCLC patients demonstrated **encouraging preliminary responses**

# BNT311: Safety trial in patients with malignant solid tumors (NCT03917381)





# BNT311: Interim results of ongoing Phase 1/2a trial

## Manageable safety profile and initial clinical activity in FIH trial

### Safety

- Most treatment-related AEs **mild to moderate**
- **No treatment-related bilirubin increases** or Grade-4 transaminase elevations
  - Grade-3 elevations resolved
  - 6 patients had DLTs
  - **MTD not reached**

### Dose escalation

- Clinical benefit **across different dose levels and solid tumor types**
- Disease control in **65.6% of patients**
- **4 partial responses:**
  - TNBC (1), ovarian cancer (1), CPI\* pre-treated NSCLC (2)
- Modulation of **circulating CD8+ T cells** and serum levels of interferon gamma and IP10 observed
  - Maximal induction 8-15 days after treatment

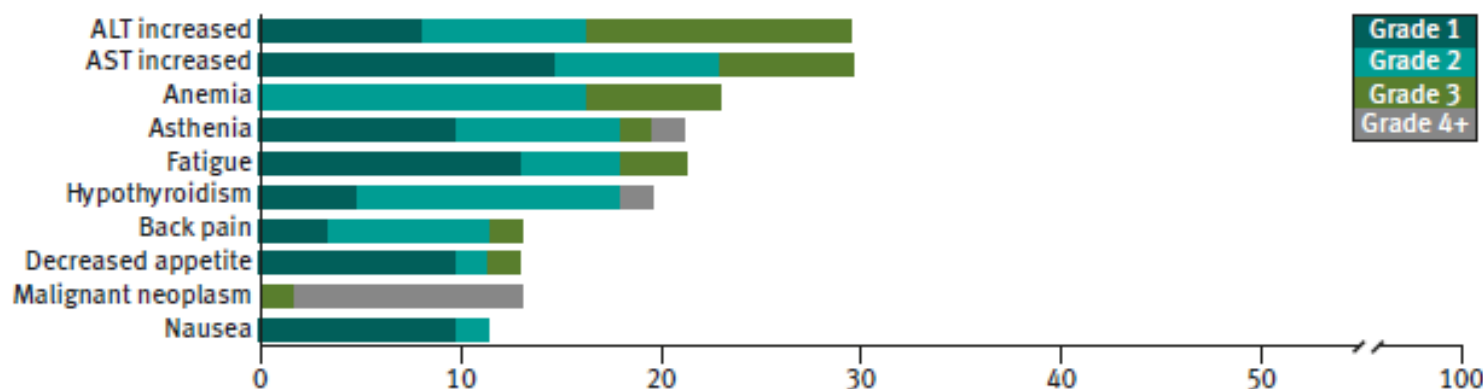
### Dose expansion

- **Encouraging preliminary efficacy** in 12 **PD-L1 relapsed/refractory NSCLC** patients
  - **2 confirmed partial responses**
  - **1 unconfirmed partial response**
  - **4 patients demonstrated stable disease**
- Enrollment ongoing in 6 additional cohorts

\*CPI – checkpoint inhibitor;  
SITC 2020, Garralda et al., Poster #412

# BNT311: Interim results of ongoing Phase 1/2a – safety profile

## TEAEs occurring in ≥10% of patients

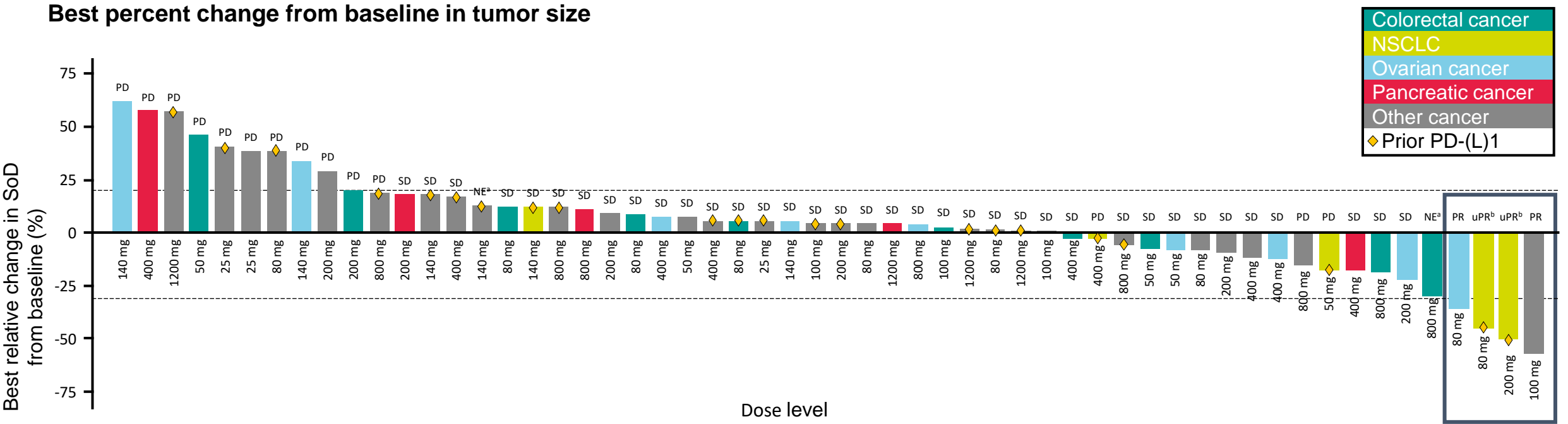


- The most common treatment-related adverse events were transaminase elevations, hypothyroidism and fatigue
- Treatment-related transaminase elevations occurred in 26.2% of patients (9.8% of patients had grade 3 transaminase elevations)
- There were no patients with Grade 4 transaminase, or treatment-related bilirubin increases
- MTD has not been reached

## TRAEs occurring in ≥10% of patients

Dose escalation cohort	All patients (N=61)		
	All grades, n (%)	Grade 3, n (%)	Grade 4, n (%)
Any TRAE	43 (70.5)	15 (24.6)	3 (4.9)
TRAEs in ≥10% of patients, by preferred term			
Transaminase elevation	16 (26.2)	6 (9.8)	0
Hypothyroidism	11 (18.0)	0	1 (1.6)
Fatigue	8 (13.1)	1 (1.6)	0

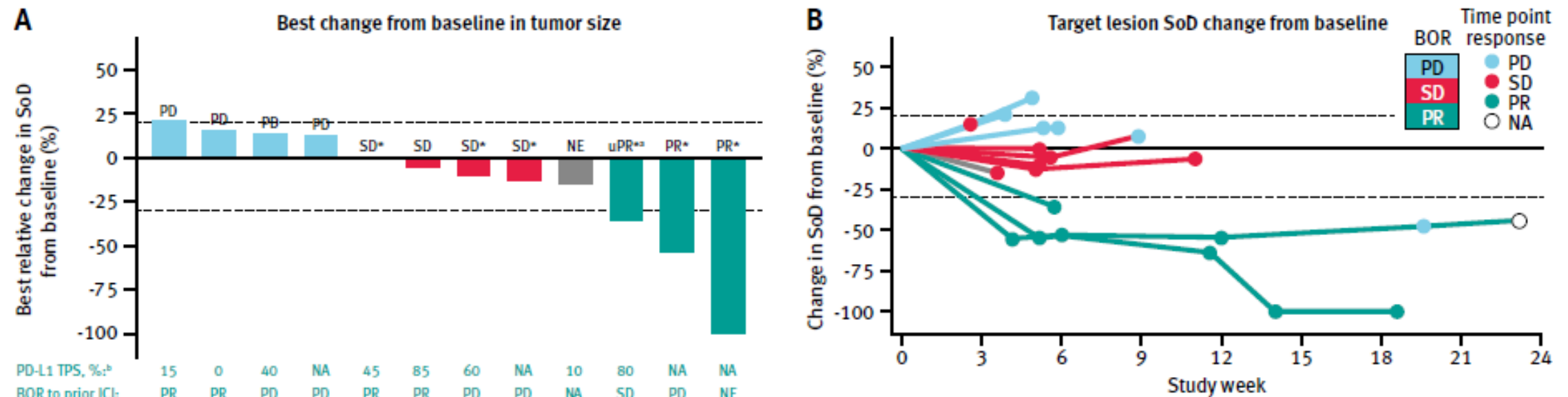
# BNT311: Interim results of ongoing phase 1/2a- anti-tumor activity dose escalation



**Disease control achieved in 65.6% of patients; four patients with PR**  
Includes 4 early partial responses in TNBC (1), ovarian cancer (1), and ICI-pre treated NSCLC (2) patients

Data cut-off: September 29, 2020. Post-baseline scans were not conducted for five patients.  
<sup>a</sup>Minimum duration of response (5 weeks) per RECIST v1.1 not reached.  
<sup>b</sup>PR was not confirmed on a subsequent scan.  
NE, non-evaluable; NSCLC, non-small cell lung cancer; PD, progressive disease; PD-(L)1, programmed death (ligand) 1; PR, partial response; SD, stable disease; SoD, sum of diameters; uPR, unconfirmed partial response.

# BNT311: Interim results of ongoing phase 1/2a – anti-tumor activity in CPI recurrent/refractory NSCLC expansion



As of October 12, 2020, 24 patients were enrolled in expansion cohort 1, which includes patients with NSCLC with progression on or after ICI therapy

- 12 patients had post-baseline scans; 6 patients were still on treatment with BNT311/GEN1046, 6 patients discontinued
- Preliminary efficacy in 12 patients who could be objectively assessed showed two patients who achieved confirmed PR, one with unconfirmed PR, and four patients with SD

Data cut-off: October 12, 2020.

\*Denotes patients with ongoing treatment.

aPR was not confirmed by a subsequent scan.

Includes all patients who had at least one post-baseline tumor assessment (schedule is every 6 weeks), and thus could be assessed for clinical benefit; 6 of 12 patients are still on treatment.

BOR, best overall response; ICI, immune checkpoint inhibitor; NA, not available; NE, non-evaluable; NSCLC, non-small cell lung cancer; PD, progressive disease; PD-(L)1, programmed death (ligand) 1; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumors; SD, stable disease; SoD, sum of diameters; TPS, tumor proportion score; uPR, unconfirmed partial response.

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Deeper dive on our key programs



COVID-19 vaccine program (project “Lightspeed”)

mRNA vaccines – FixVac and iNeST

Antibodies

Small Molecule Immunomodulators

CARVac platform – CLDN6 CAR-T

RiboCytokines

# BNT411: initiated FIH Phase 1 trial for our TLR7 agonist in July 2020

- BNT411 is an intravenously administered small molecule TLR7 (toll-like receptor 7) agonist
- Engineered for high potency and high TLR7 receptor-selectivity at the therapeutically active dose range
- Activation of both adaptive and innate immune system has been observed, in particular in combination with cytotoxic therapies and CPIs
- Type 1 interferon-dominated release of cytokines and chemokines and potent stimulation of antigen-specific CD8+ T cells, B cells and innate immune cells such as NK cells and macrophages
- Expected to have therapeutic potential across various solid tumor indications
- Phase 1/2a clinical trial as a mono and combination therapy initiated in July 2020

## Study design:

- Phase 1/2a, first-in-human, open-label, dose-escalation trial
- Evaluation of safety, pharmacokinetics, pharmacodynamics, and preliminary efficacy of BNT411 as a monotherapy in patients with solid tumors and in combination with atezolizumab, carboplatin and etoposide in patients with chemotherapy-naïve extensive-stage small cell lung cancer (ES-SCLC)
- Enrollment: ~60 participants

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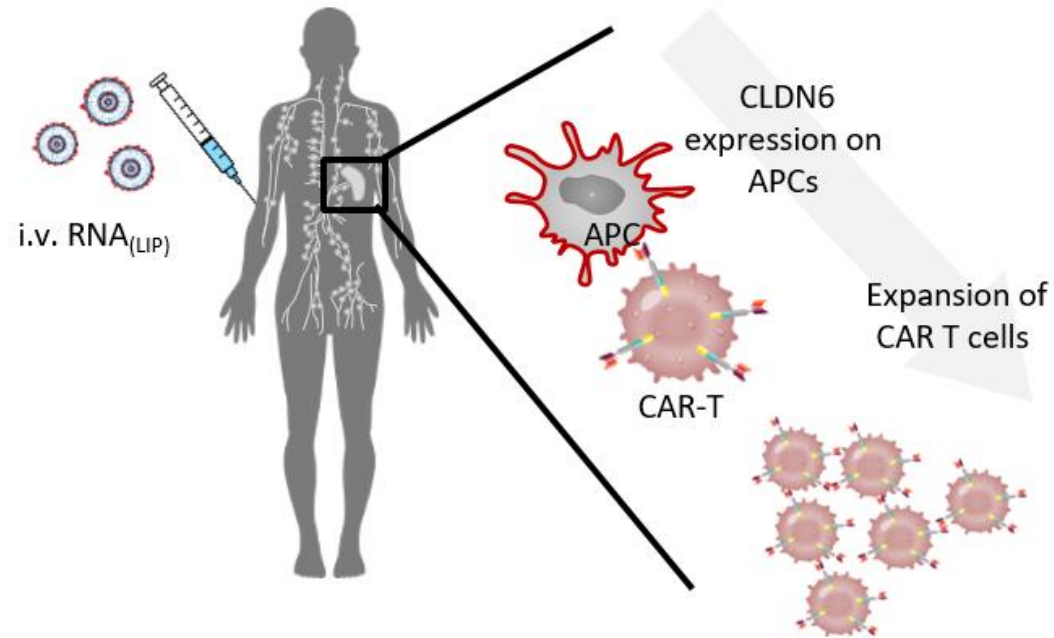
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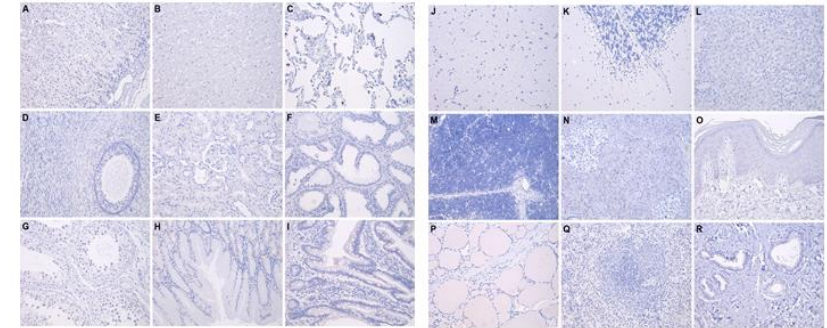
RiboCytokines

# BNT211: Next generation CAR-T targeting CLDN6 with CARVac “primer”

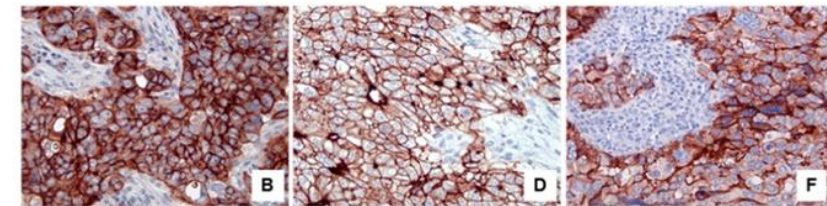


- CAR-T cell therapy + RNA Vaccine to amplify CAR-T cell *in vivo*

CLDN6 is not present in healthy tissues



CLDN6 is expressed in multiple cancers

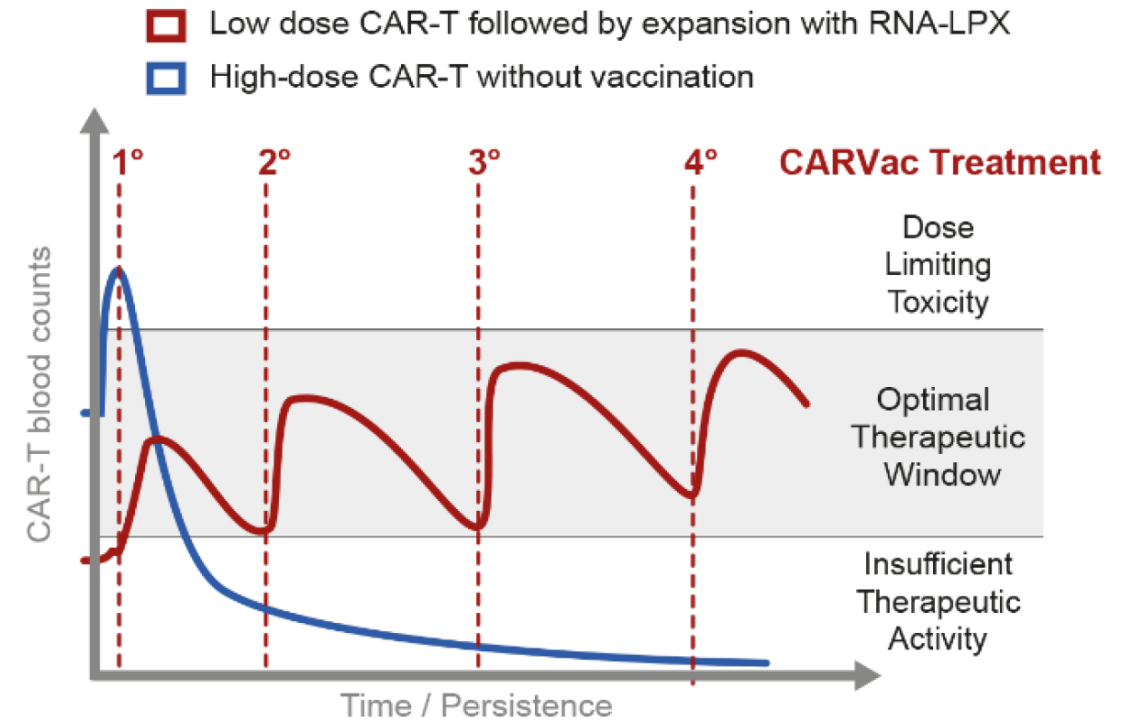
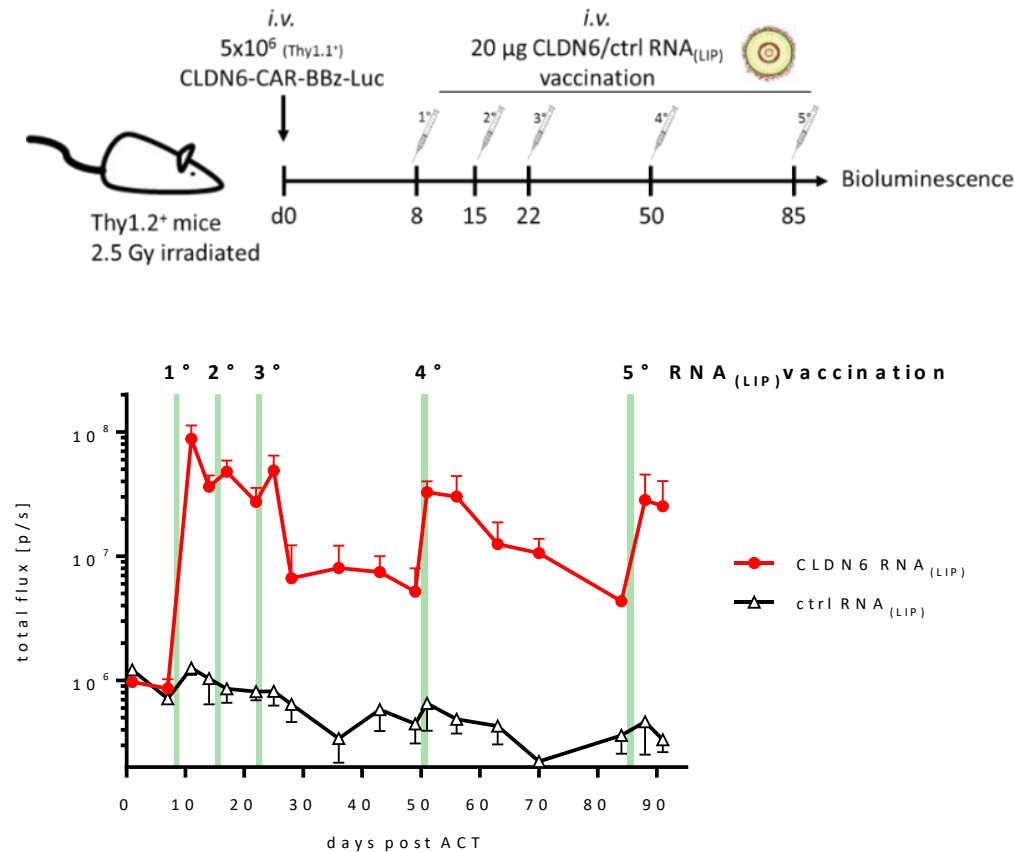


Ovarian cancer   Testicular tumor   Lung cancer

**Eradication of advanced tumors demonstrated in an ovarian carcinoma xenograft model**



# BNT211: Next generation CAR-T targeting CLDN6 with CARVac “primer”



Applicability shown for CLDN6, CLD18.2, CD19 CAR-T cells

**RNA-lipoplex vaccine shown to enhance expansion & persistence of CAR-T**

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Antibodies

Small Molecule Immunomodulators

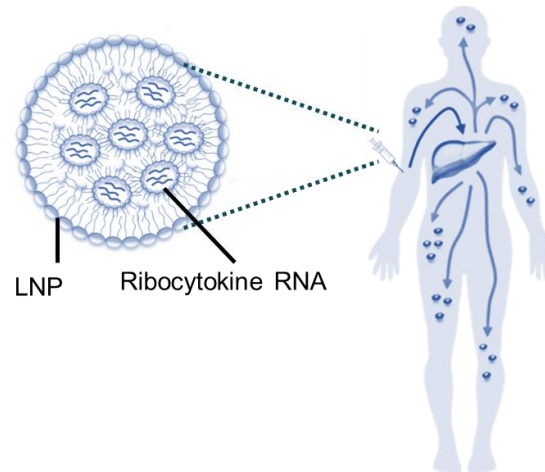
CARVac platform – CLDN6 CAR-T

RiboCytokines

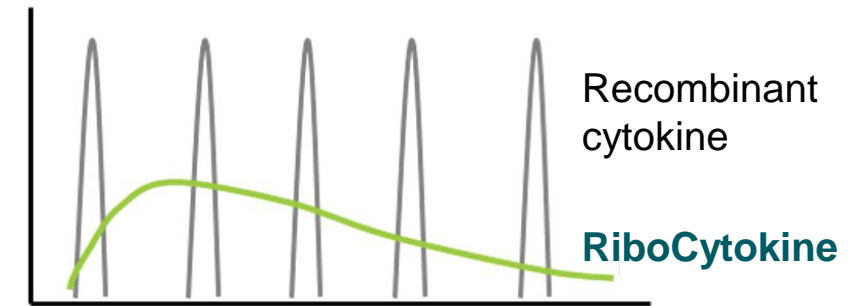
# RiboCytokines: a novel therapeutic platform

## The concept

- Cytokines encoded by mRNA and produced in the patient
- Improved PK properties to improve tolerability and activity
- Cytokine design to improve immunological properties and tolerability



## Pharmacokinetic profile



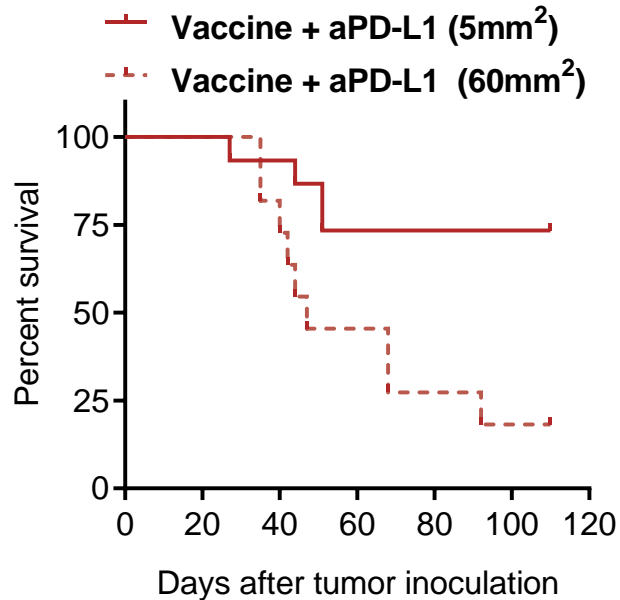
## Therapeutic goals

- Overcome resistance mechanisms by therapeutic synergy
- Improve activity of mRNA Vaccines

**Worldwide** rights; wholly owned

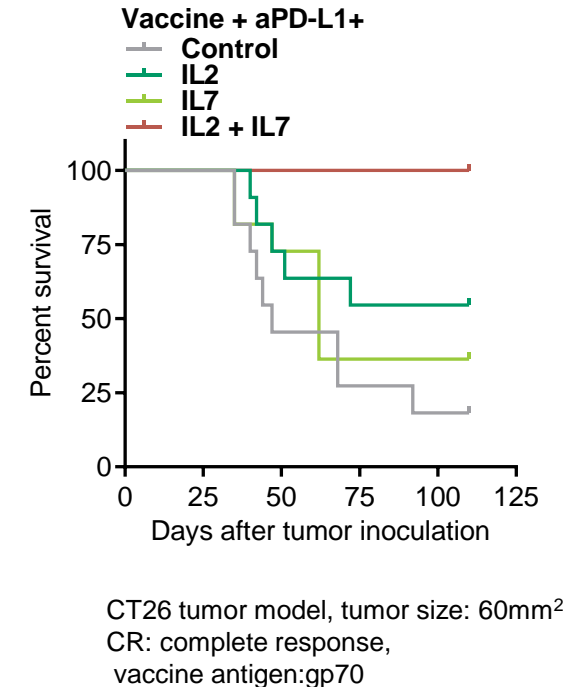
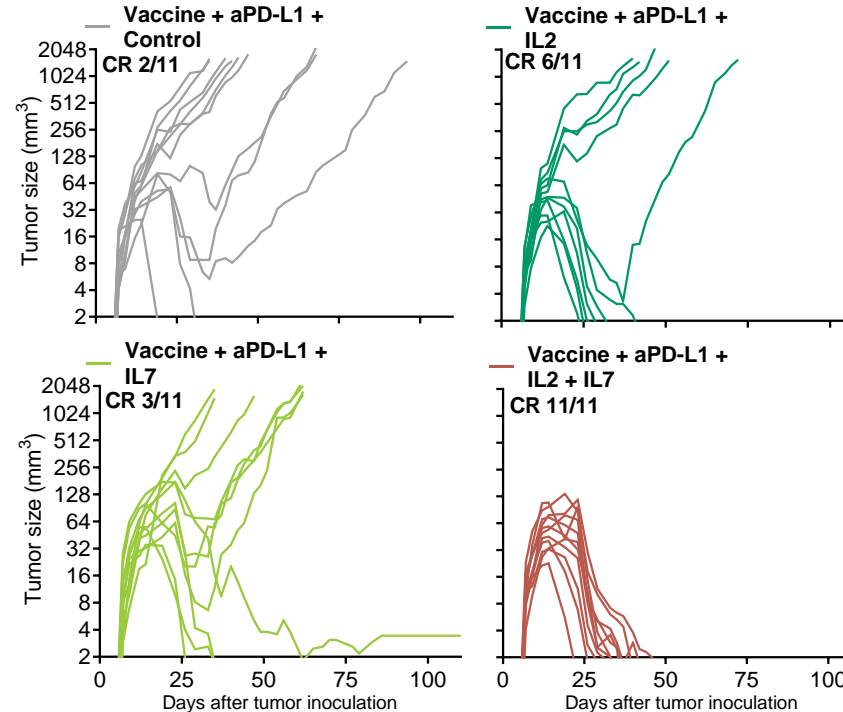
Product Candidate	Preclinical	Phase 1	Phase 2	
BNT151	Optimized IL-2			Expected to enter the clinic in 1H 2021 Expected to enter the clinic in 1H 2021
BNT152+BNT153	IL-7, IL-2			

# RiboCytokines boosted vaccination activity & PD-L1 blockade pre-clinically



CT26 tumor model, vaccine antigen: gp70

## Vaccine + aPD-L1 +



Effect of tumor size on treatment success of vaccination + aPD-L1

RiboCytokines boost the clinical activity of vaccination + aPD-L1 in large tumors



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