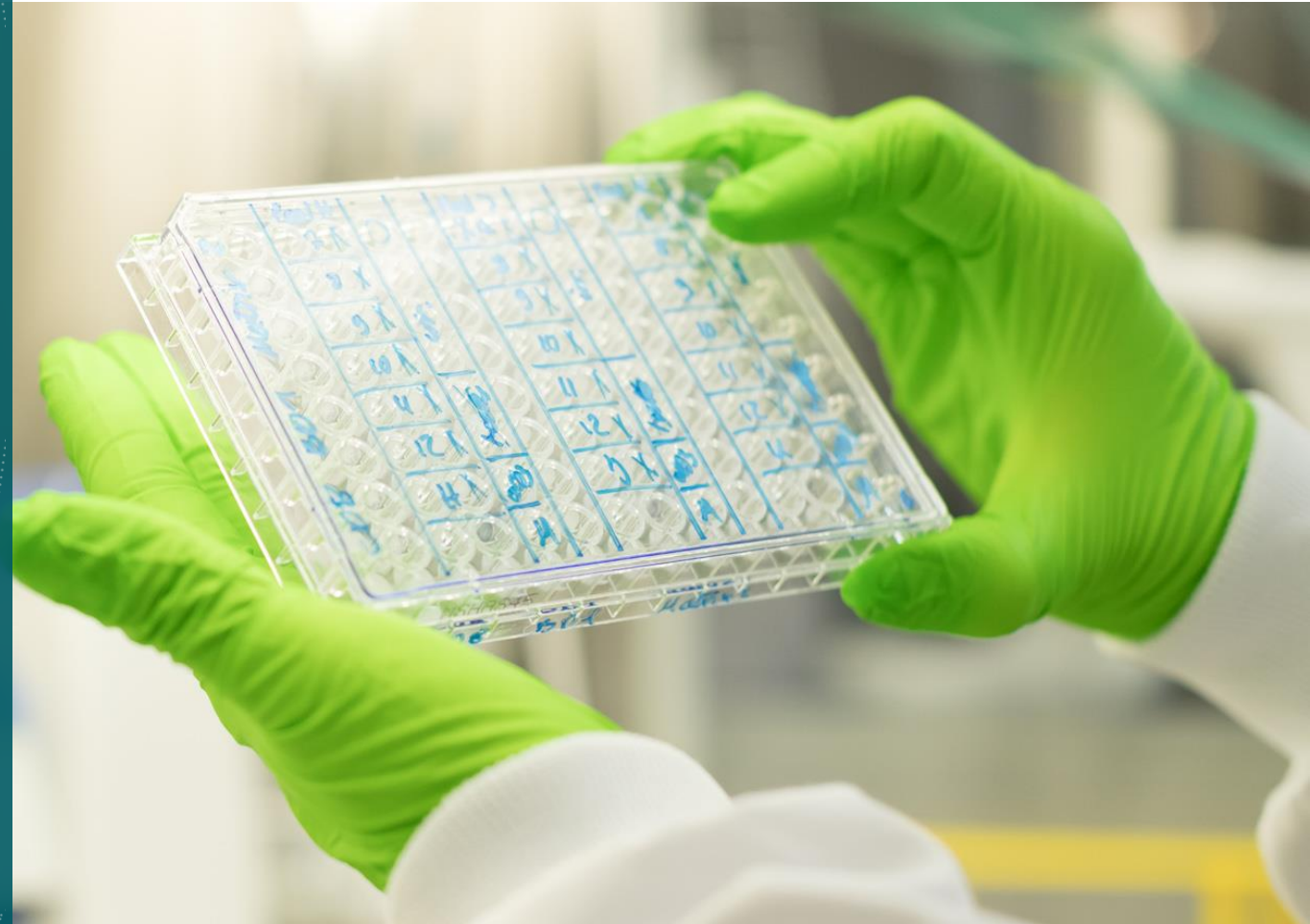


Next Generation Immunotherapy

December 2020



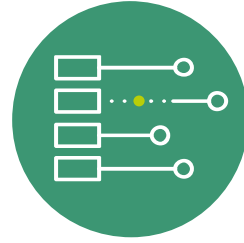
This slide presentation includes forward-looking statements

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 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 2020 and 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.

Next generation Immunotherapy

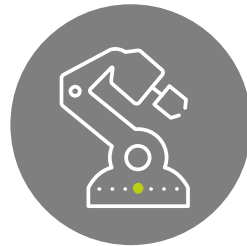
Harnessing the full
potential of the
immune system



**Broad suite of novel
technology platforms**



**Immunotherapies for cancer
and infectious diseases**



**Fully integrated with in-house
GMP manufacturing**



**Industry-leading global
collaborations**

We collaborate with global leaders in our industry

Collaborations for clinical stage programs

Covid-19 Vaccine
50:50 gross profit share¹

FixVac Melanoma
Each company to keep 100%
of rights to own product

iNeST
50:50 cost & profit share

Bispecific mABs
50:50 cost & profit share

Intra-tumoral mRNA
cost & profit share



REGENERON

Genentech



SANOFI

Pre-clinical collaborations

Seasonal Influenza
royalties & milestones

**Up to 10 Infectious
Disease Indications**
worldwide opt-in right

HIV, Tuberculosis
developed world rights

**5 Rare Disease
Indications**
50:50 cost & profit share



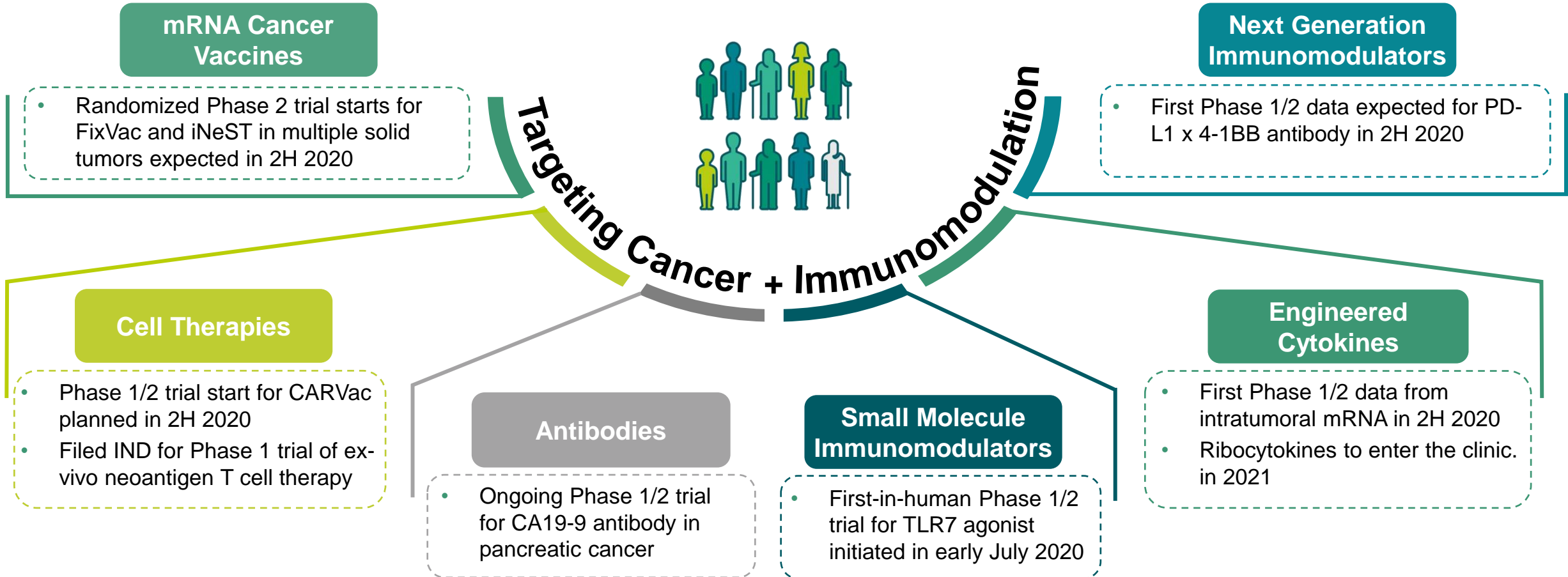
University of
Pennsylvania

BILL & MELINDA
GATES foundation

GENEVANT

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

Broad progress in executing our multi-platform IO strategy



Potential for multiple blockbuster opportunities with powerful combinations

Compelling data generated from innovative immunotherapy approaches

Approved PD1-/PD-L1
Inhibitors

+

mRNA Cancer
Vaccines

- **FixVac Melanoma (BNT111):** Induces objective responses in CPI-experienced patients
- **iNeST (BNT122):** Currently in Phase 2 in combination with CPI in 1L Melanoma. 2 adjuvant trials planned in 2020

mRNA Cancer
Vaccines

+

Engineered
Cytokines

- **Ribocytokine IL-2 (BNT151):** Amplification of vaccine induced T cell response in pre-clinical studies

Cell Therapies

+

mRNA Cancer
Vaccines

- **BNT211:** Novel CLDN-6 CAR-T approach utilizing CAR-T Amplifying RNA Vaccine (**CARVac**)
- Significant amplification of CAR-T cells in preclinical studies (published in Science, 2020)

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"> • mRNA Neoantigen Immunotherapy (iNeST)
Low mutational burden cancers	>60% of cancers	Poor response to checkpoint inhibitors	<ul style="list-style-type: none"> • Shared Antigens (FixVac, CAR-T cells, Neoantigen-targeted T cells, Antibodies)
“Immune desert” cancers	>40% of high-mutational cancers	Poor infiltration and activation of T-cells in TME ¹	<ul style="list-style-type: none"> • RNA Immunotherapy • Immunostimulatory Compounds (intratumoral, RiboCytokines)
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"> • Antibodies • CAR-Ts
Refractory tumors	Patients with large tumors and multiple resistance mechanisms	Few treatment options	<ul style="list-style-type: none"> • Cell Therapies • Combination Therapies

¹Tumor microenvironment

Oncology pipeline: Expanded to 11 product candidates in 12 clinical trials

Drug class	Platform	Product Candidate	Indication (Targets)	Pre-clinical	Phase 1	Phase 2	Rights / Collaborator		
mRNA	FixVac (fixed combination of shared cancer antigens)	BNT111	advanced melanoma		▶		fully-owned (Regeneron)	▶ BNT111: Clinical data published in <i>Nature</i> (July 2020); subsequent announcement of Regeneron collaboration	
		BNT112	prostate cancer		▶		fully-owned		
		BNT113	HPV16+ head and neck cancer ¹		▶		fully-owned		
		BNT114	triple negative breast cancer		▶		fully-owned	▶ BNT114 data update for TNBC-MERIT trial at ESMO Virtual Congress 2020	
		BNT115	ovarian cancer ¹		▶		fully-owned		
	iNeST (patient specific cancer antigen therapy)	RO7198457 (BNT122)	1L melanoma			▶		Genentech (global 50:50 profit/loss)	
			multiple solid tumors		▶				
Antibodies	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)	▶ BNT131 data update from Phase 1 presented at SITC	
		Next-Gen CP ² Immunomodulators	GEN1046 (BNT311)	multiple solid tumors (<i>PD-L1</i> × <i>4-1BB</i>)		▶		Genmab (global 50:50 profit/loss)	▶ BNT311 Interim update from Phase 1 presented at SITC
			GEN1042 (BNT312)	multiple solid tumors (<i>CD40</i> × <i>4-1BB</i>)		▶			
	Targeted Cancer Antibodies	BNT321 (MVT-5873)	pancreatic cancer (sLea)		▶		fully-owned		
SMIM ³	Toll-Like Receptor Binding	BNT411	solid tumors (<i>TLR7</i>)		▶		fully-owned	▶ BNT411 FPD in Phase 1/2 trial in ES-SCLC	

¹BNT113 and BNT115 are currently being studied in investigator-initiated Phase 1 trials.

²Checkpoint Inhibitor.

³Small Molecule Immunomodulators.

We plan to initiate multiple FIH¹ trials for our preclinical product candidates in 2021

Drug class	Platform	Product Candidate	Indication (Targets)	Rights Collaborator	Milestones
Oncology					
mRNA	FixVac	BNT116	NSCLC	fully-owned	
	RiboMabs (mRNA-encoded antibodies)	BNT141	multiple solid tumors	fully-owned	Phase 1 start in 1H 2021
		BNT142	multiple solid tumors (<i>CD3+CLDN6</i>)	fully-owned	Phase 1 start in 2H 2021
	RiboCytokines (mRNA-encoded Cytokines)	BNT151	multiple solid tumors (<i>optimized IL-2</i>)	fully-owned	Phase 1 start in 1H 2021
		BNT152, BNT153	multiple solid tumors (<i>IL-7, IL-2</i>)	fully-owned	Phase 1 start in 1H 2021
Cell Therapies	CAR-T Cells	BNT211	multiple solid tumors (<i>CLDN6</i>)	fully-owned	Phase 1/2a start in 2H 2020
		BNT212	pancreatic, other cancers (<i>CLDN18.2</i>)	fully-owned	
	Neoantigen-based T cell therapy	BNT221 (NEO-PTC-01)	multiple solid tumors	fully-owned	Phase 1 start in 1H 2021
	TCRs	to be selected	all tumors	fully-owned	
mRNA	Infectious Disease Immunotherapies	BNT161	influenza	Pfizer	
		undisclosed	up to 10 indications	Penn ³	
		undisclosed	HIV and tuberculosis	Bill & Melinda Gates Foundation	
	Rare Disease PRT ²	BNT171	not disclosed	Genevant	
		undisclosed	4 additional rare disease indications	(global 50:50 profit/loss)	

We expect to initiate multiple phase 1 trials in 2021

¹ FIH = First in Human; ² PRT = Protein Replacement Therapy; ³ We are eligible to receive worldwide licenses

Positioned for transformative 2021

- Focused on executing **ongoing global regulatory submissions** for BNT162 COVID-19 vaccine on the heels of positive Phase 3 data demonstrating 95% vaccine efficacy rate beginning 28 days after first dose
- **Commercial preparation activities** for manufacturing and global distribution progressing for BNT162 with partners Pfizer and Fosun
- Advancing **oncology** pipeline towards **multiple late-stage clinical trial initiations**
- **Additional first-in-human trials** of novel product candidates expected **across proprietary platforms**
- **Well capitalized** to deliver on key **commercial, operational and pipeline milestones**
- **Transformational opportunity** ahead to positively impact the world – and **accelerate our long-term vision** to build a next generation immunotherapy leader

Agenda

Overview and business outlook

Deeper dive on our key programs

COVID-19 vaccine program (project “Lightspeed”)

mRNA vaccines – FixVac and iNeST

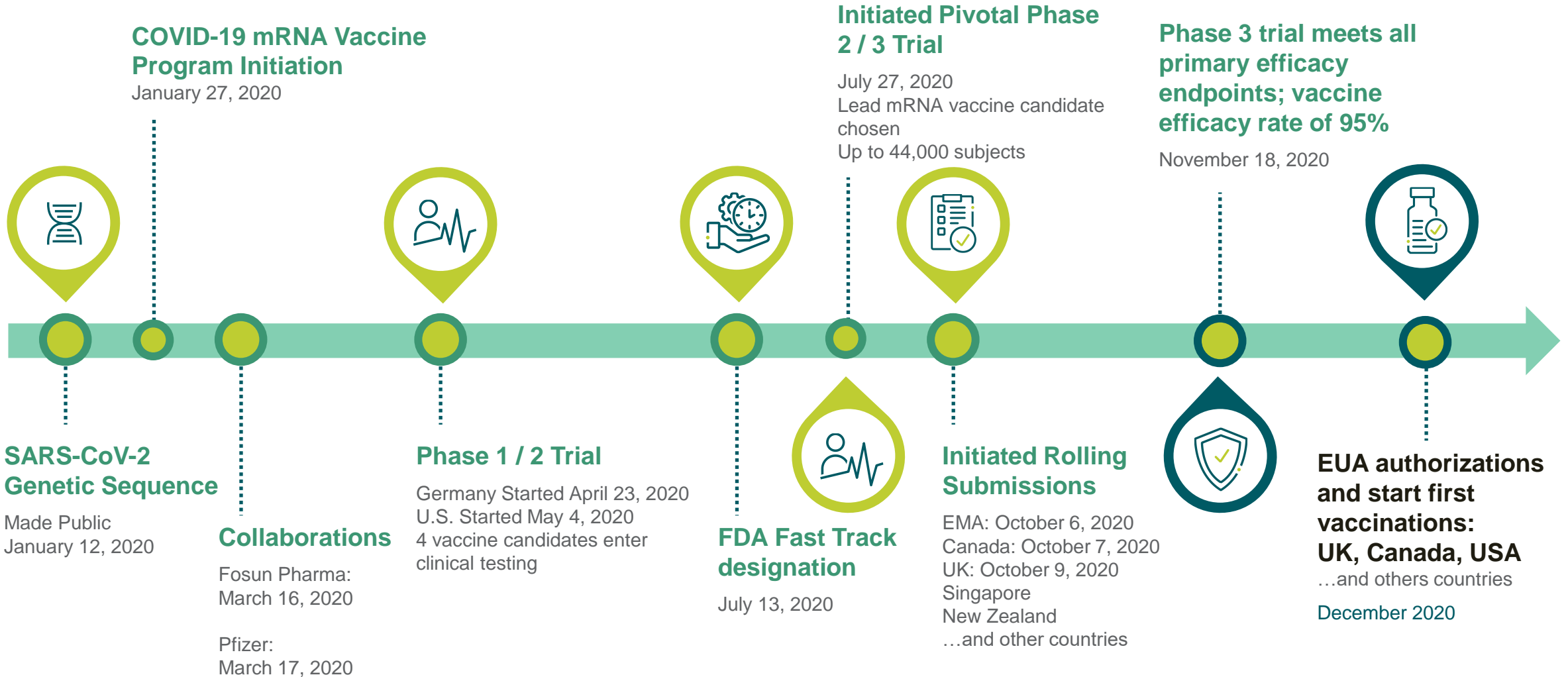
Antibodies

Small Molecule Immunomodulators

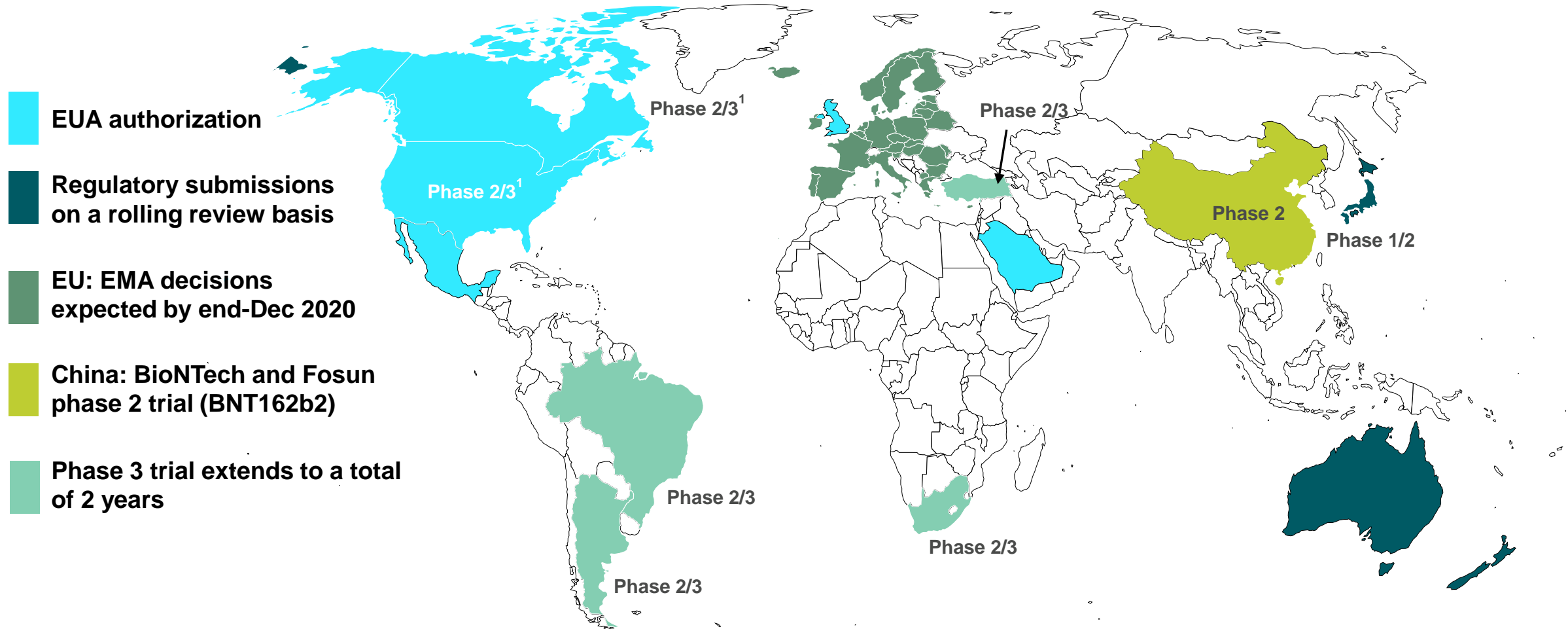
CARVac platform – CLDN6 CAR-T

RiboCytokines

BNT162 Project Lightspeed: 11-months from discovery to authorization

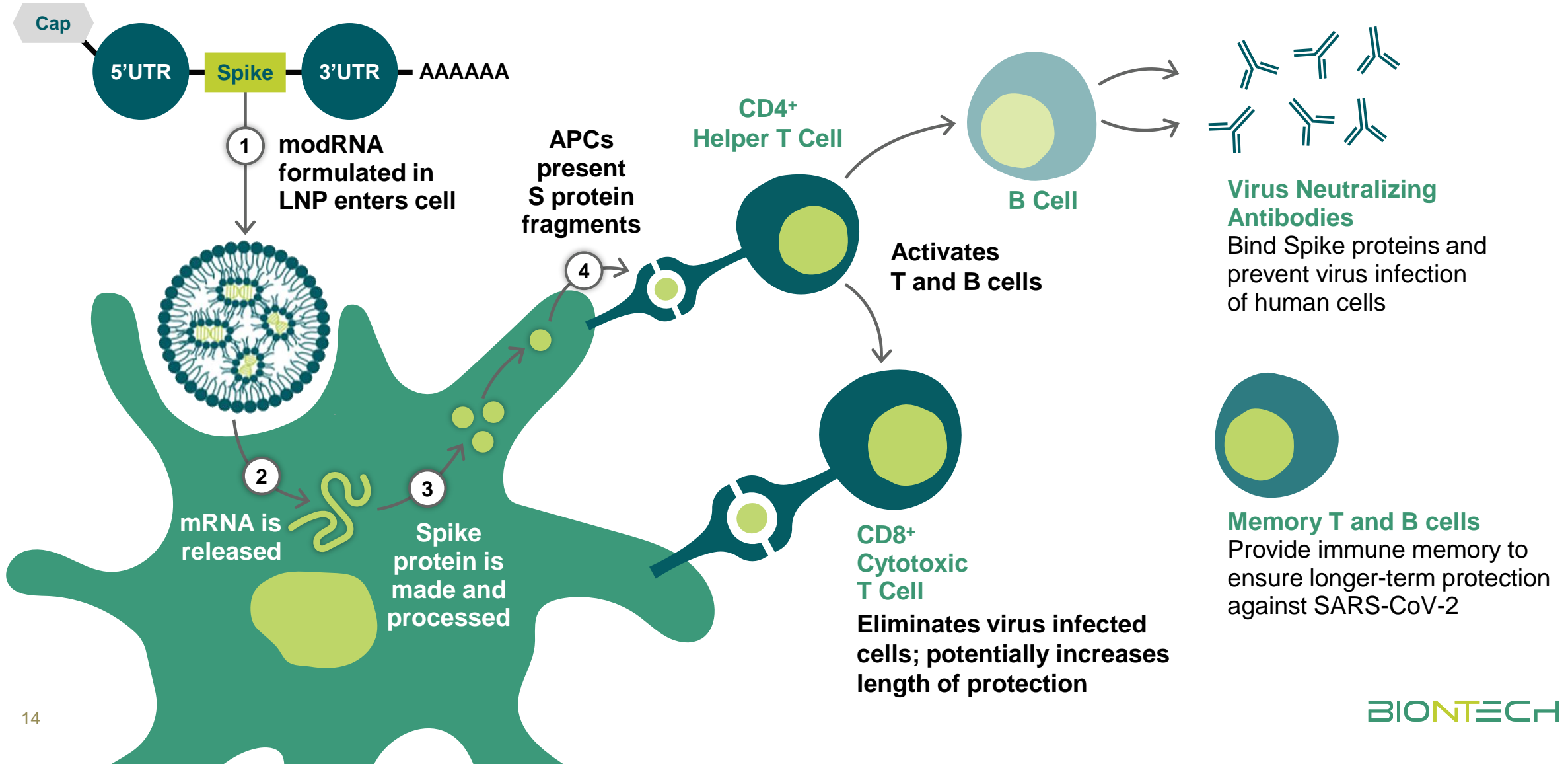


BNT162 Project Lightspeed: a concerted and large-scale global effort



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

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



mRNA is a natural solution for vaccines especially in a pandemic

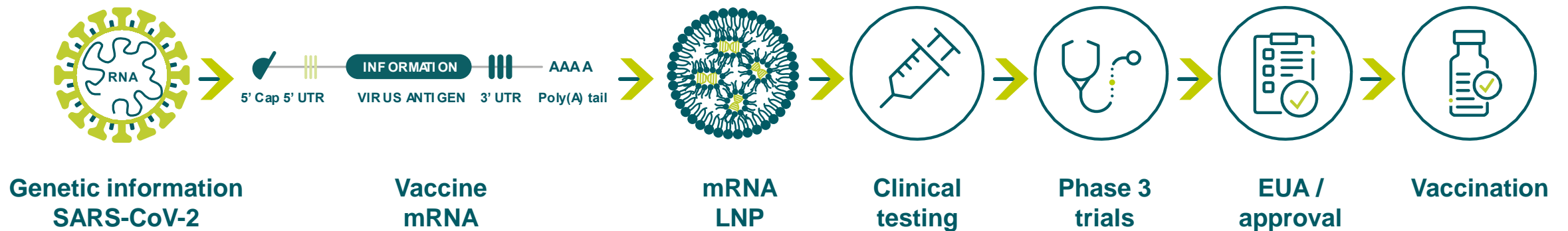
Natural molecule with well-characterized **bio-safety properties**

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

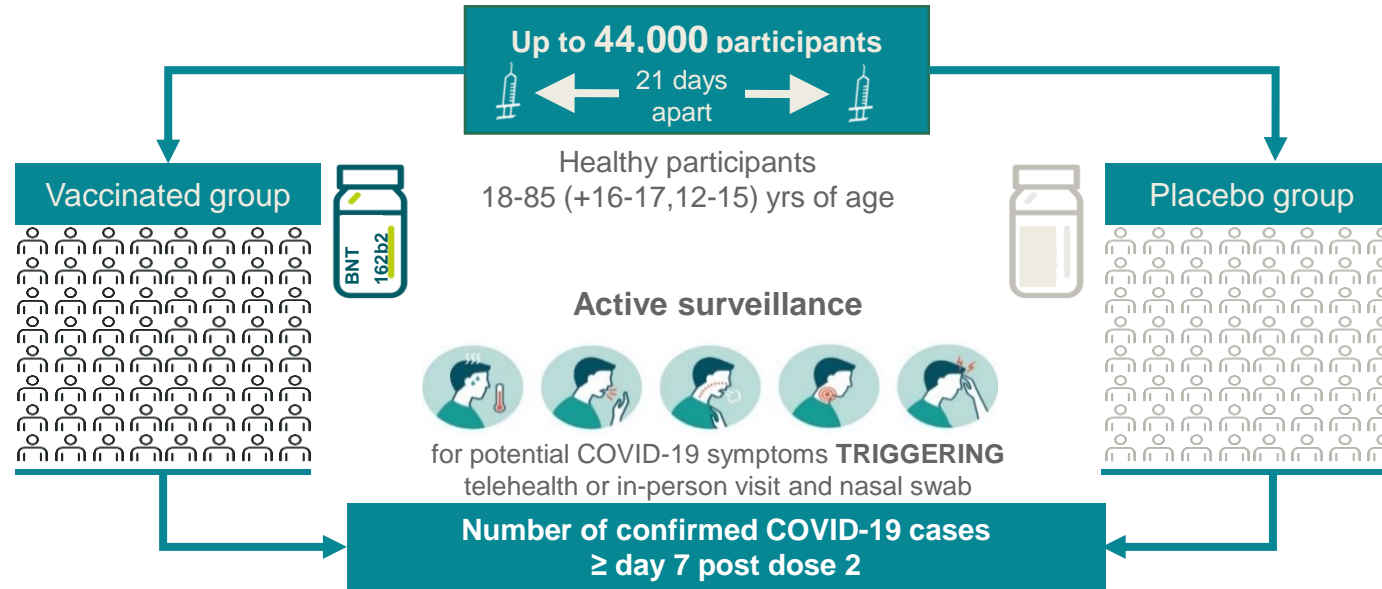
Highly scalable production

High purity and animal free

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



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

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

Data as of November 16th, 2020

- 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 with no serious safety concerns

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

No serious safety concerns

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

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

Generally well tolerated

Headache

2 in 100 people

Fatigue

Less than 4 in 100 people

Most frequently observed adverse events were injection site pain, fatigue, headache and muscle pain. These are common and transient reactions to vaccination¹. Adverse events were mild to moderate in intensity in general and resolved within a few days after vaccination.

BNT162 exploits multiple levers of immune response

Immunogenicity*³



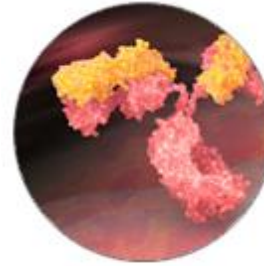
No or only transient viral shedding in SARS-CoV-2 Virus Challenge

Tolerability*⁴



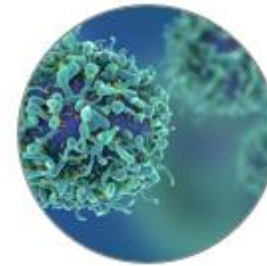
Local reactions and systemic events mostly mild to moderate and transient in effect

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 T_H1-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

BNT162: Global commercial supply commitments*

- **Both BioNTech and Pfizer jointly scaling up manufacturing capacity to enable global supply**
 - BioNTech already producing vaccine at 2 manufacturing sites in Germany
 - Pfizer has activated 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	30 million	Not disclosed
United States	100 million with option for additional 500 million	\$1.95 billion for first 100 million doses
Additional countries	Not disclosed	Not disclosed

* Subject to clinical success and regulatory approval

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

Agenda

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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

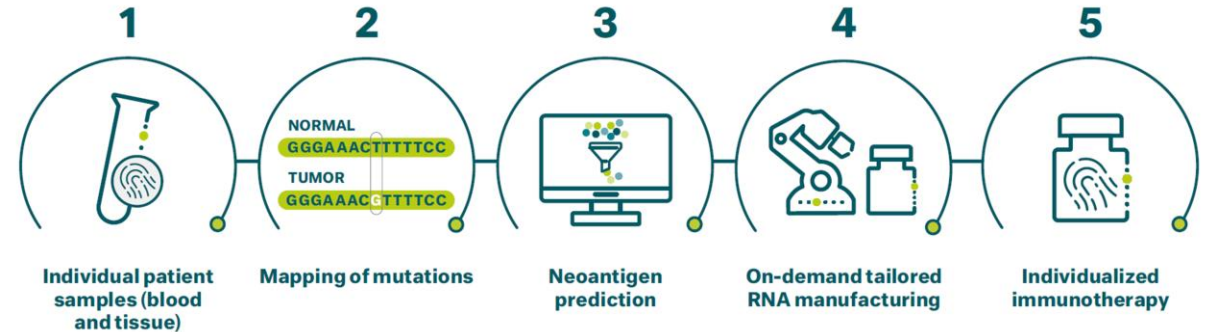
Our mRNA vaccine platforms: FixVac and iNeST

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

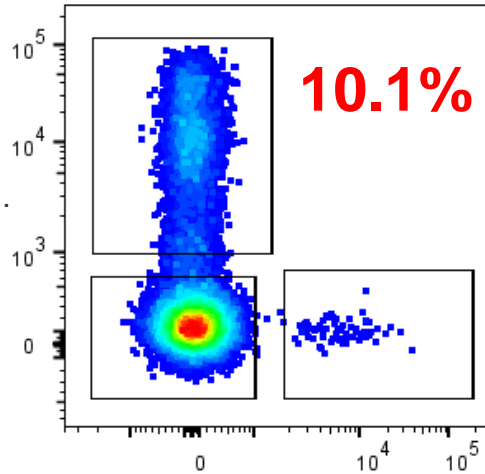
Proprietary RNA-LPX formulation for systemic dendritic cell targeting

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

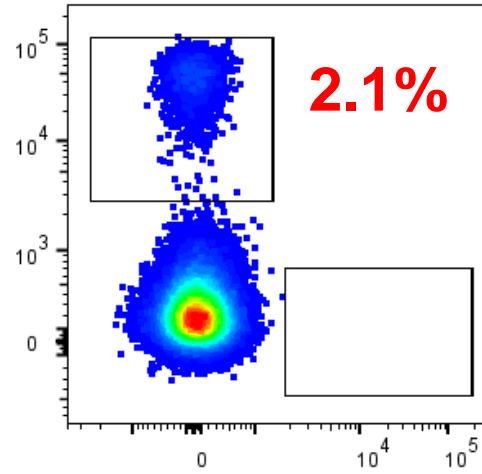
Potent induction of strong *ex vivo* CD4+ and CD8+ T cell responses

Our RNA-LPX vaccine approach

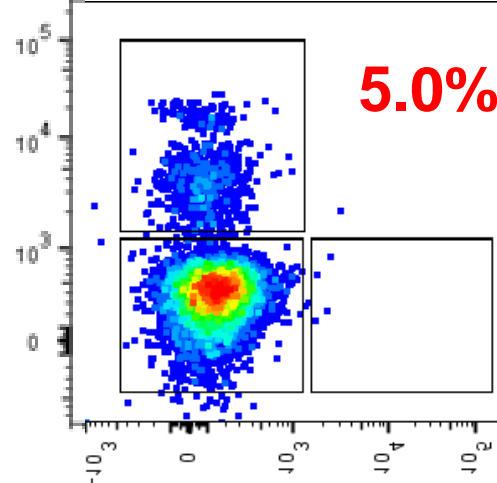
Strong vaccine-induced *ex vivo* CD8+ T cell responses¹ across different cancer types



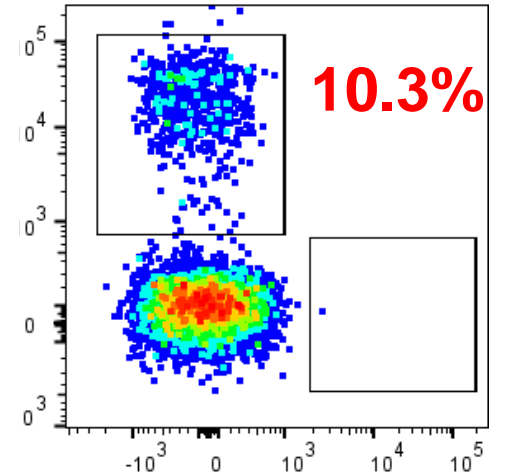
NY-ESO-1
Melanoma
BNT111, Lipo-MERIT trial



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 ≥ 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***

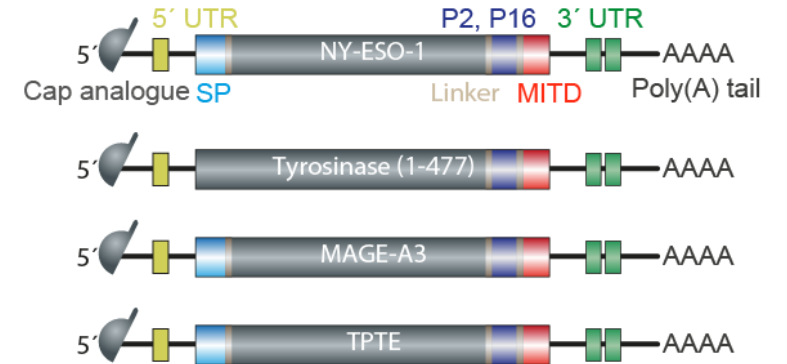
Regeneron strategic collaboration and planned Phase 2 trial

- 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 response¹
 - 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



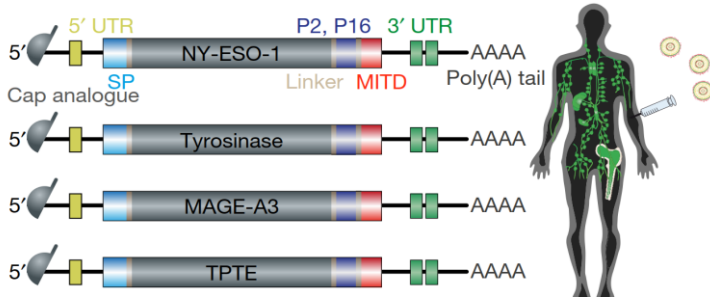
Cumulative patient coverage of FixVac melanoma targets is over 90%

Report phase 1 data 1H 2020

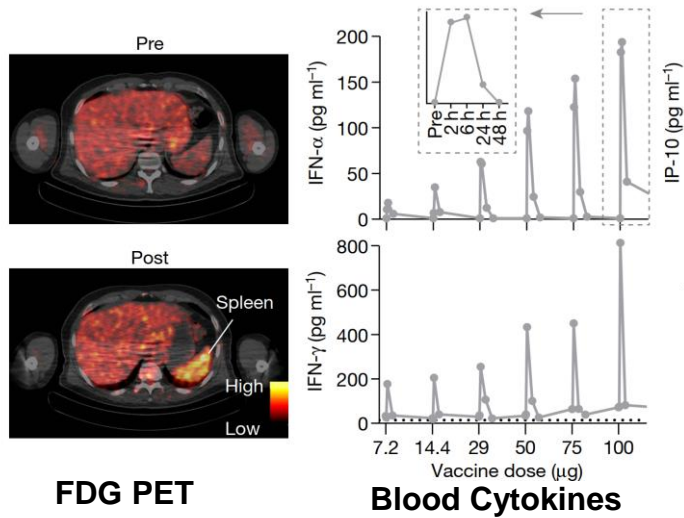
Start randomized phase 2 trial in 1H 2021

BNT111 publication in Nature highlights

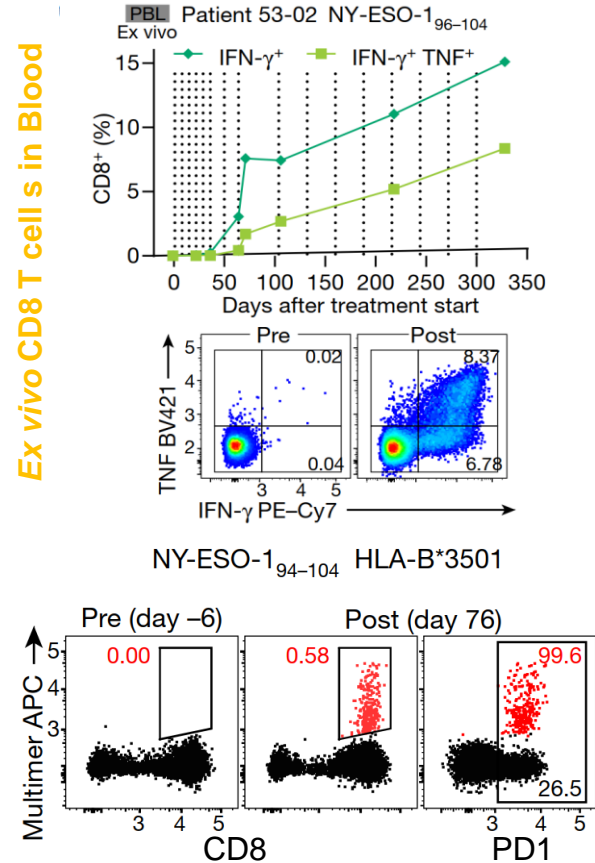
Targeting of lymphoid DC for vaccine delivery & type I IFN activity



Vaccine constructs



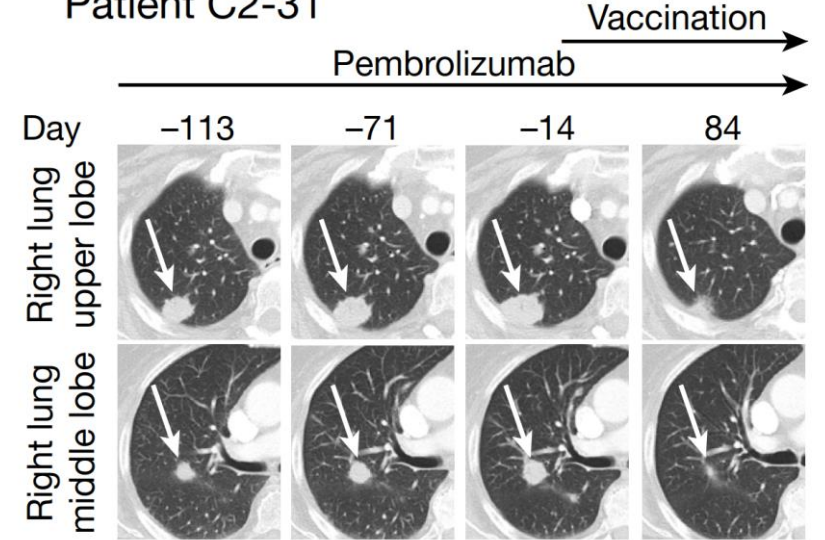
Strong CD4+, CD8+ T cell responses Multifunctional CD8+ PD1+ T cells



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

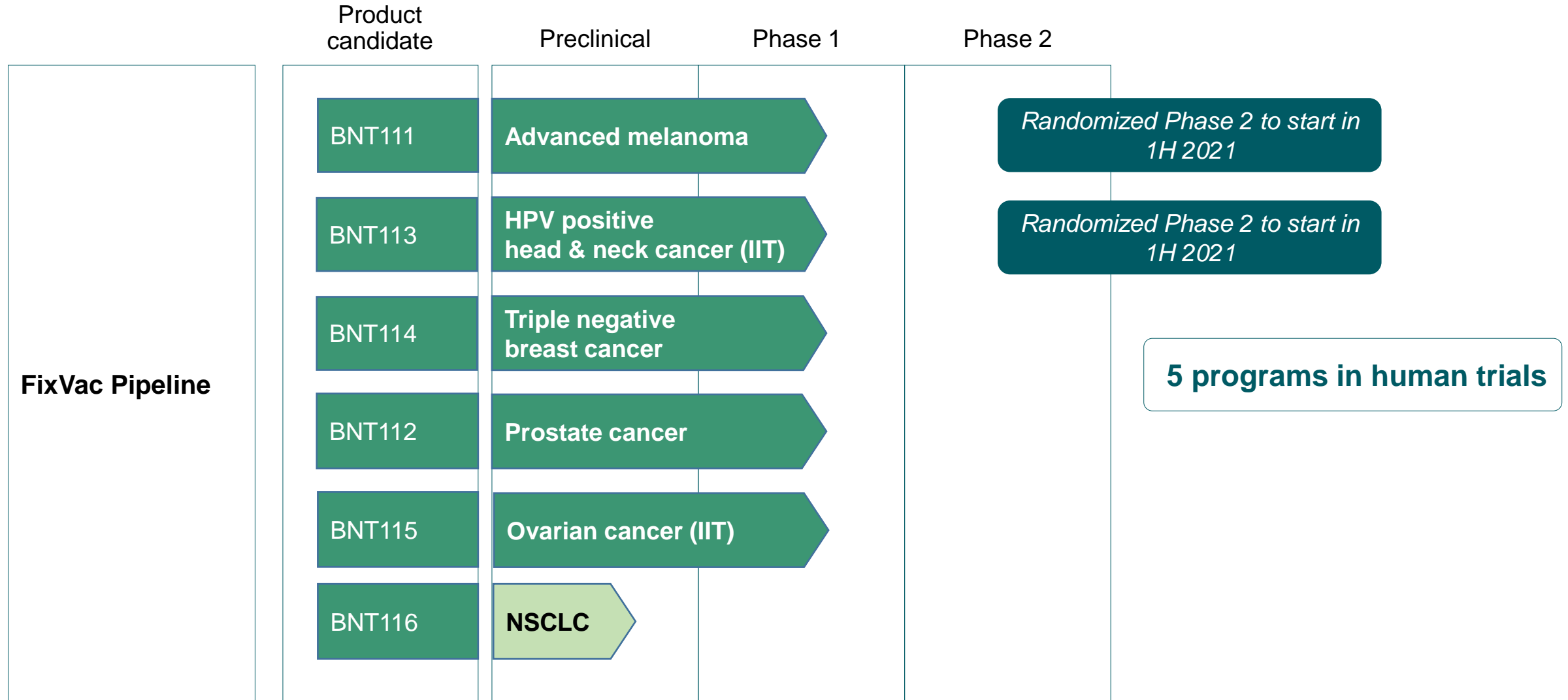
- ORR of BNT111 monotherapy: 4/25
- ORR of BNT111 + anti-PD1: 6/17 (35%) (CPI resensitizing activity of BNT111)

Patient C2-31

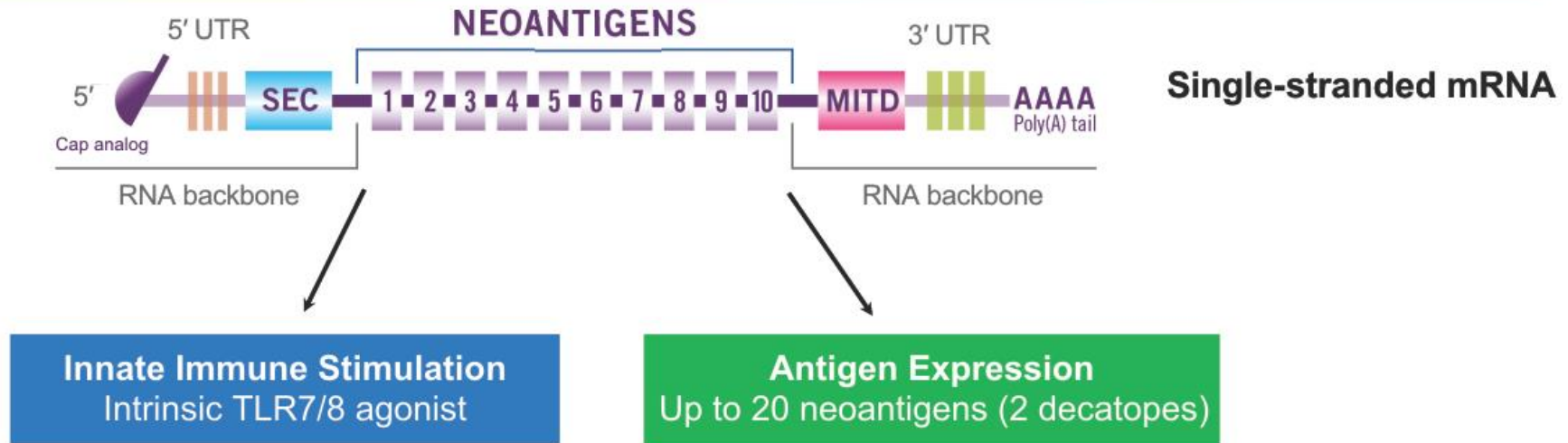
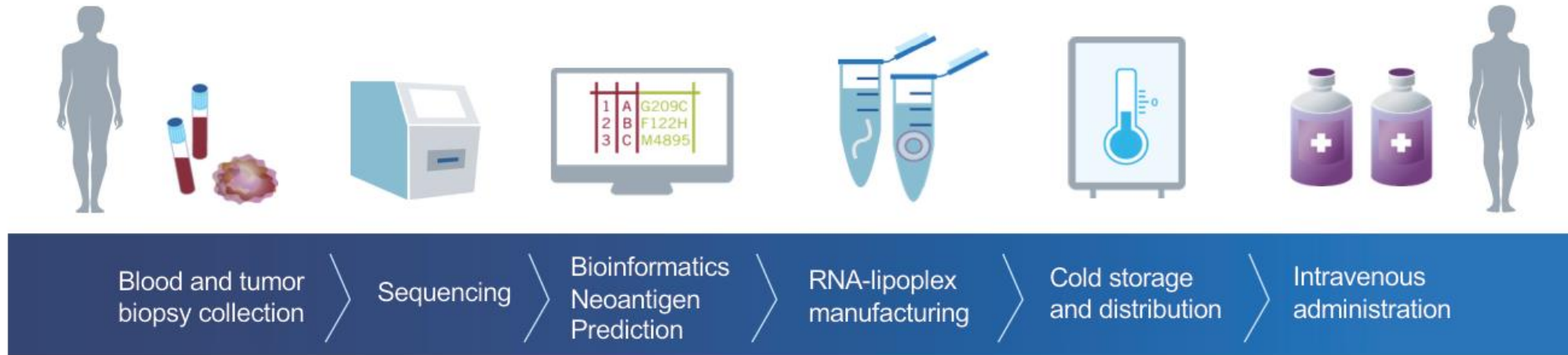


Lung CT scans before & after BNT111

FixVac: A flexible format designed to be rapidly adapted for different tumors



iNeST: Individualized neoantigen specific immunotherapy



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**

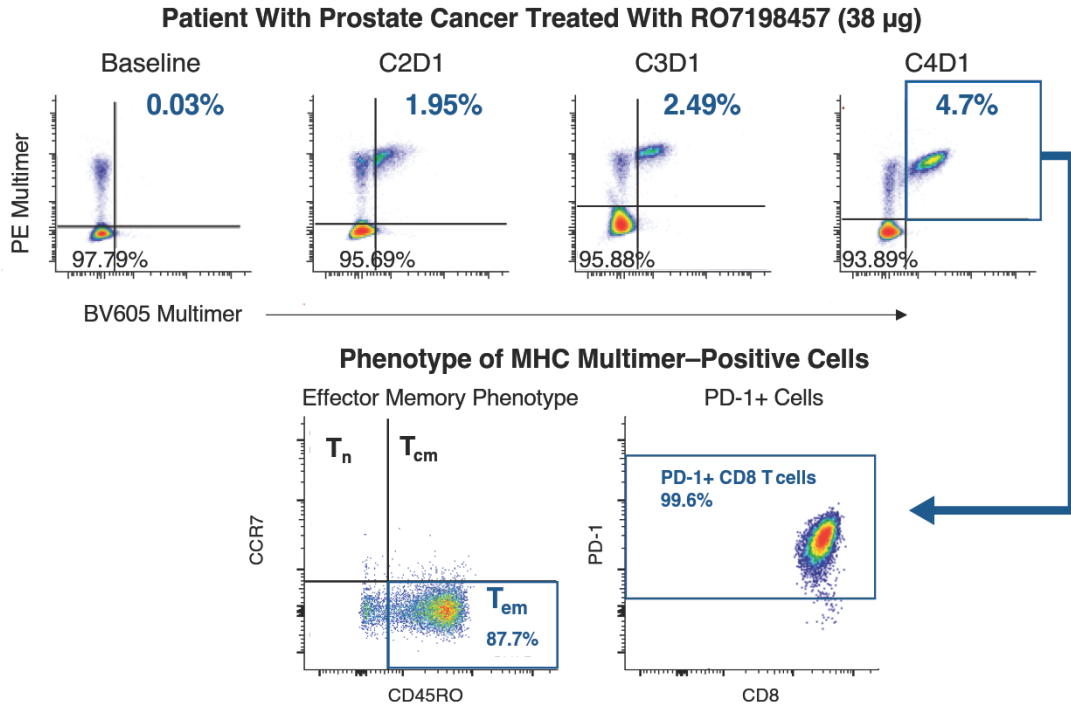
Phase 1b combination with atezolizumab demonstrated clinical activity in heavily pretreated patients

- **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%)

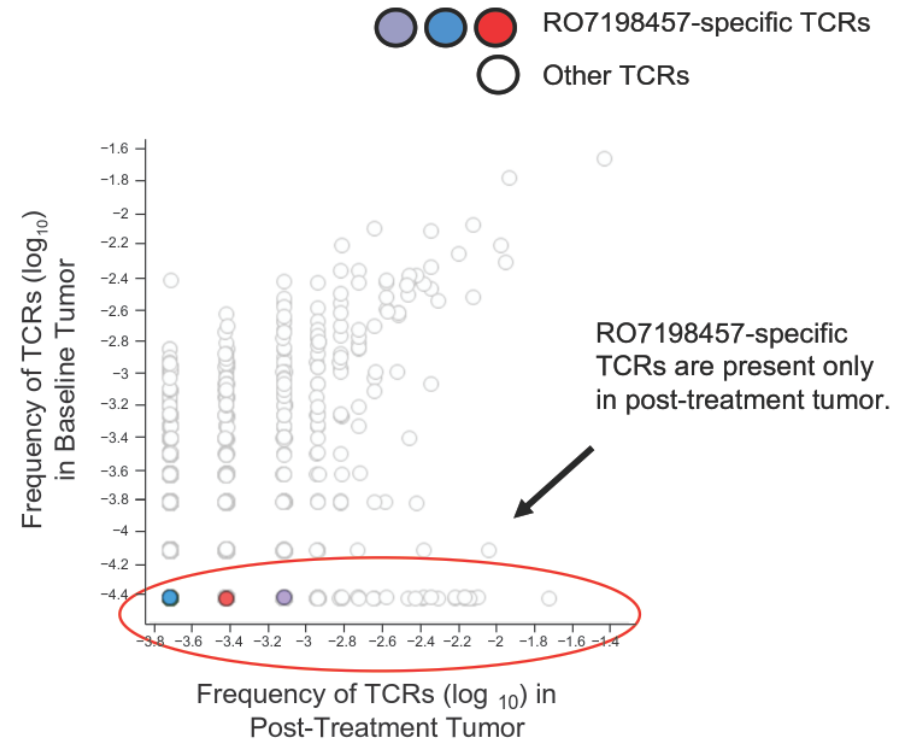
- **Demonstrates ability to elicit significant T cell responses of both effector and memory phenotype as monotherapy and in combination**
- **Treatment-related adverse events were primarily transient systemic reactions, manifesting as low grade CRS, IRR or flu-like symptoms**
- **Early evidence of clinical 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 non-small cell lung cancer	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 of the efficacy and safety of BNT122 in combination with atezolizumab vs. atezolizumab alone following adjuvant platinum-doublet chemotherapy in patients who are ctDNA positive after surgical resection of Stage II-III NSCLC	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"> Evaluate added benefit of 1L BNT122 in an advanced CPI-sensitive tumor (PFS, ORR) Success un gates 1L use of iNeST in CPI-sensitive advanced cancers for combination therapy 	<ul style="list-style-type: none"> Evaluate added benefit of BNT122 in a micrometastatic CPI-sensitive tumor (RFS) Success un gates adjuvant use of iNeST in CPI-sensitive ctDNA+ cancer types 	<ul style="list-style-type: none"> Evaluate added benefit of BNT122 in a micrometastatic CPI-insensitive tumor (RFS) Success un gates adjuvant use of iNeST for CPI-insensitive ctDNA+ cancer types
Status	<i>Currently enrolling</i>	<i>To start in 1H 2021</i>	<i>To start in 1H 2021</i>

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

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Small Molecule Immunomodulators

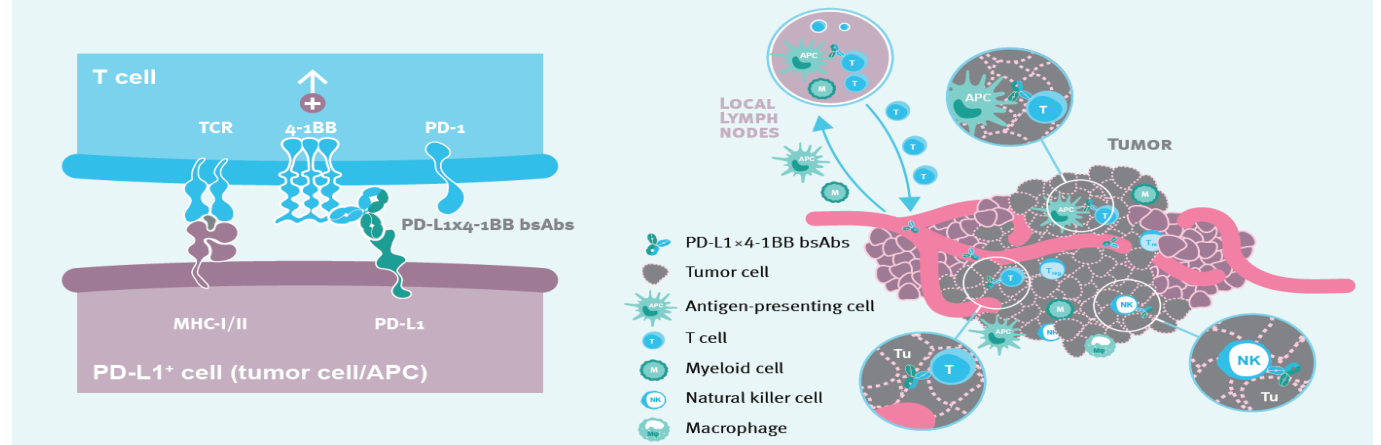
CARVac platform – CLDN6 CAR-T

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

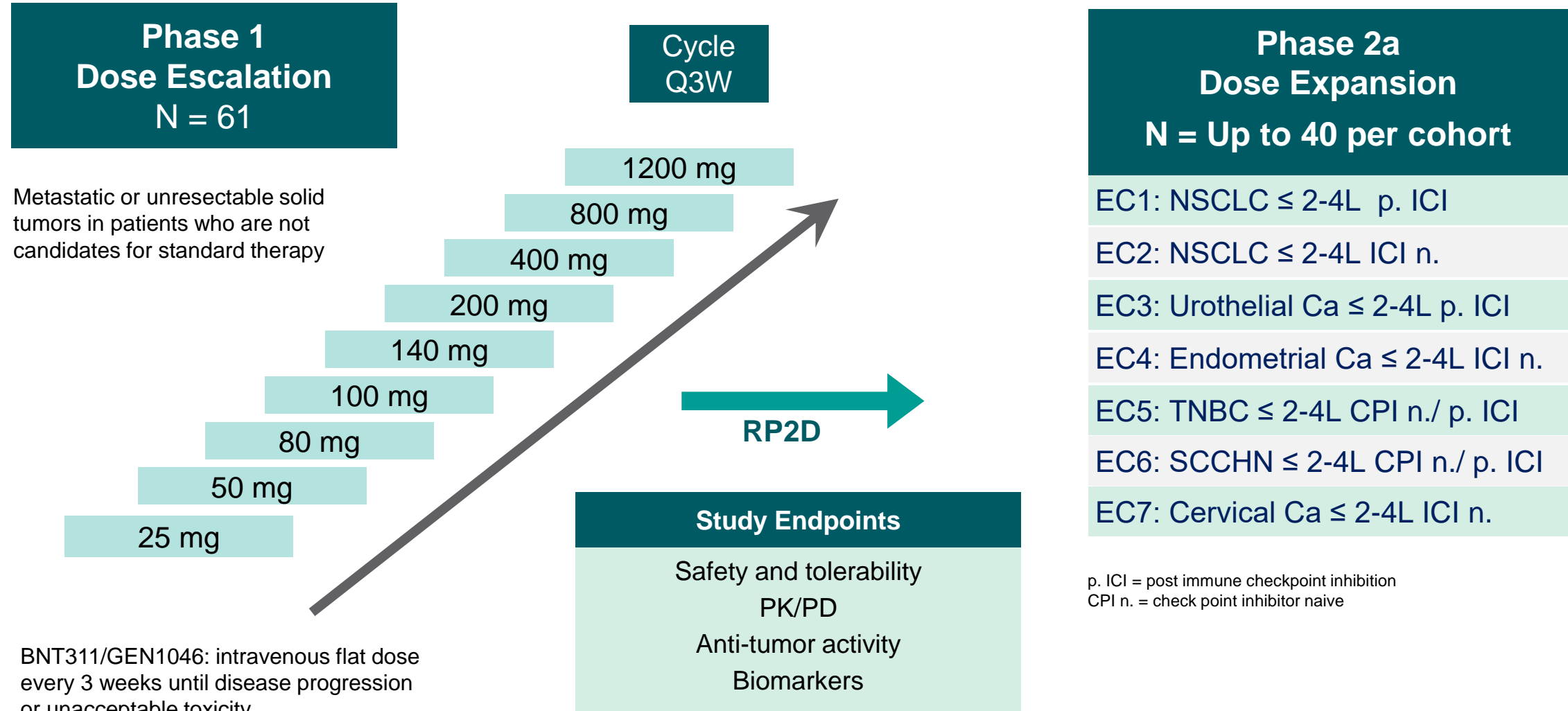


**Interim results
of ongoing
Phase 1/2a trial
presented at
SITC 2020**

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)



p. ICI = post immune checkpoint inhibition
CPI n. = check point inhibitor naive

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

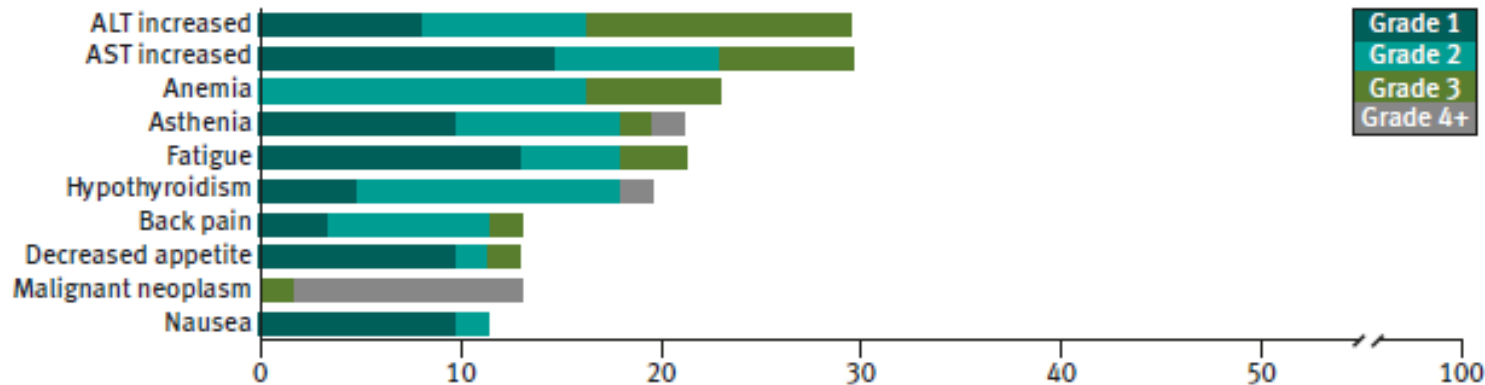
Dose expansion

- **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



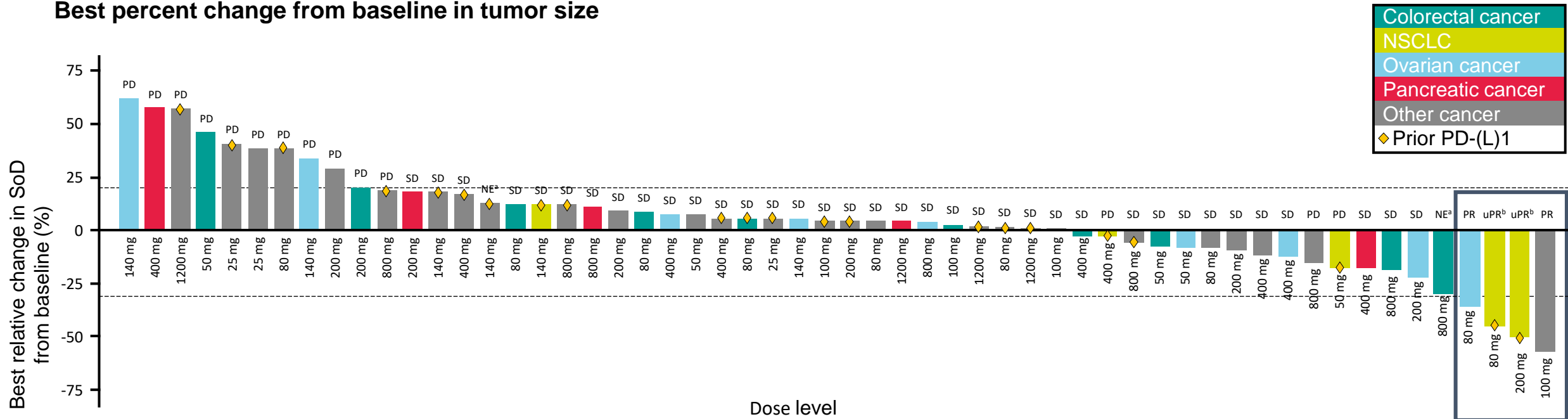
- The most common treatment-related adverse events were transaminase elevations, hypothyroidism and fatigue
- Treatment-related transaminase elevations occurred in 26.2% of patients (9.8% of patients had grade 3 transaminase elevations)
- There were no patients with Grade 4 transaminase, or treatment-related 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

Best percent change from baseline in tumor size



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

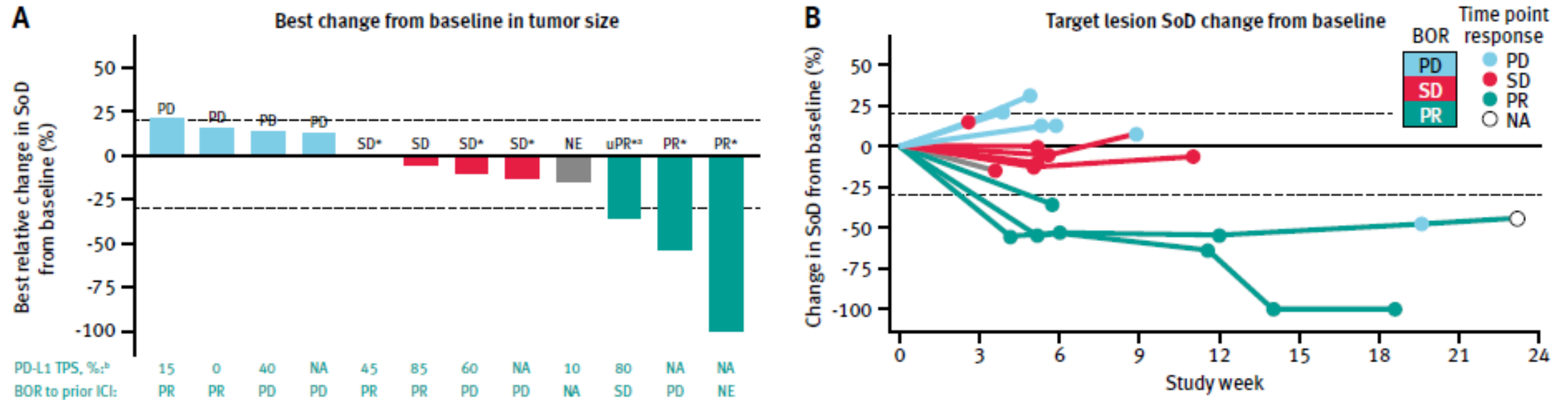
Data cut-off: September 29, 2020. Post-baseline scans were not conducted for five patients.

^aMinimum duration of response (5 weeks) per RECIST v1.1 not reached.

^bPR 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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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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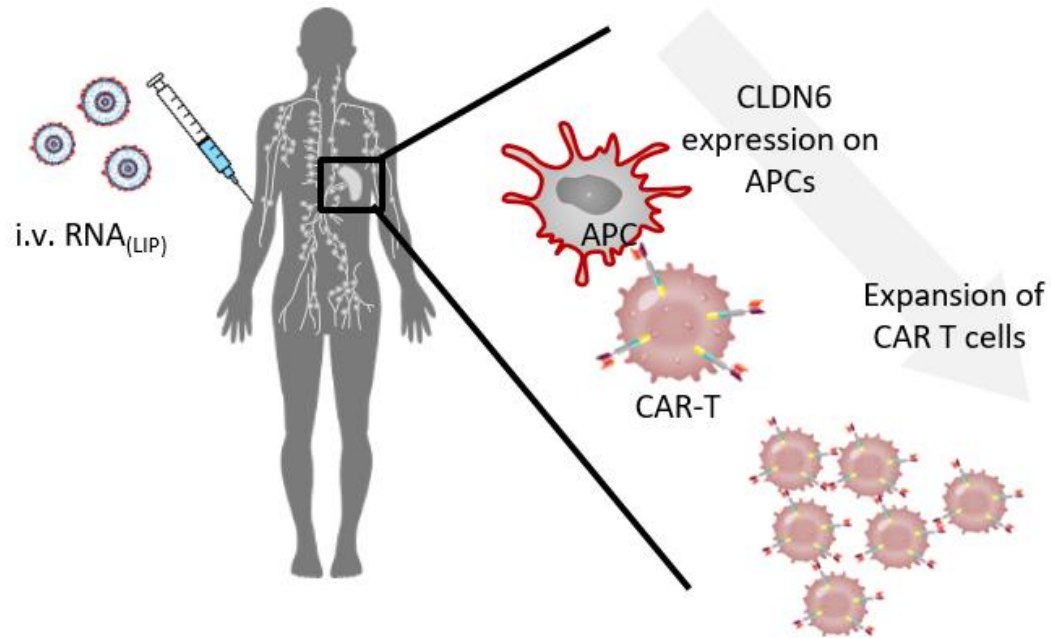
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CARVac platform – CLDN6 CAR-T

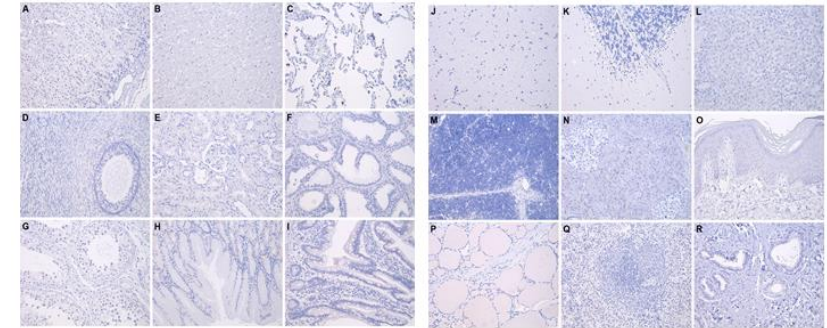
RiboCytokines

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

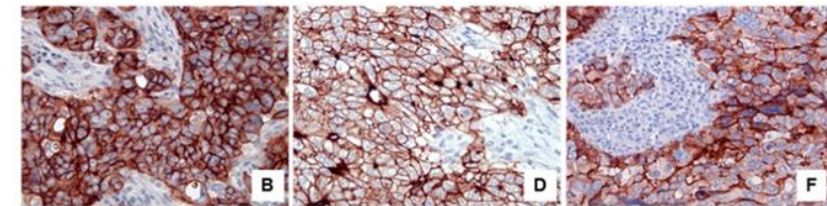


- CAR-T cell therapy + RNA Vaccine to amplify CAR-T cell *in vivo*

CLDN6 is not present in healthy tissues



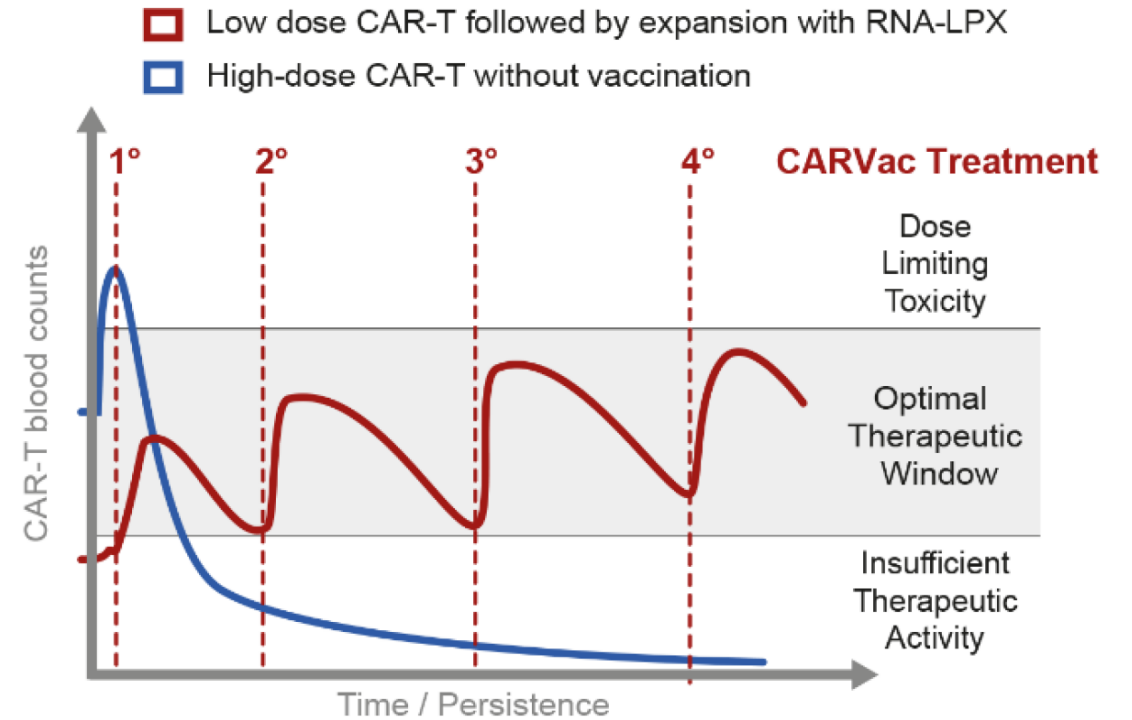
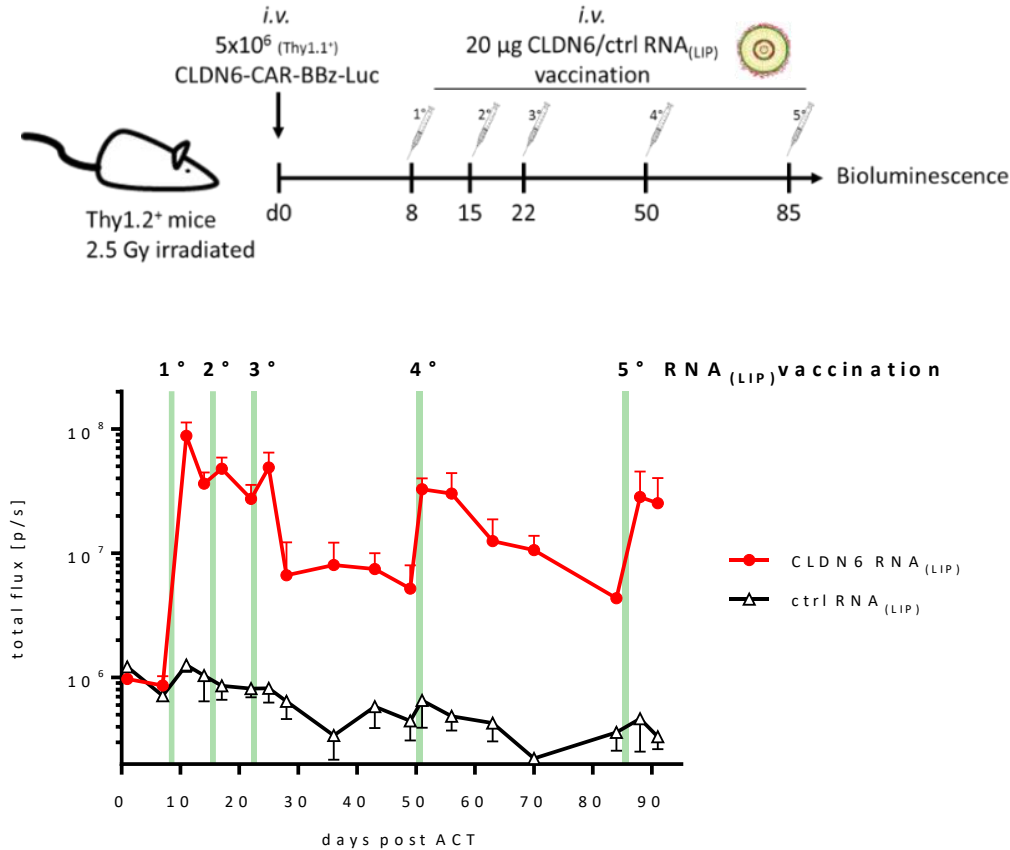
CLDN6 is expressed in multiple cancers



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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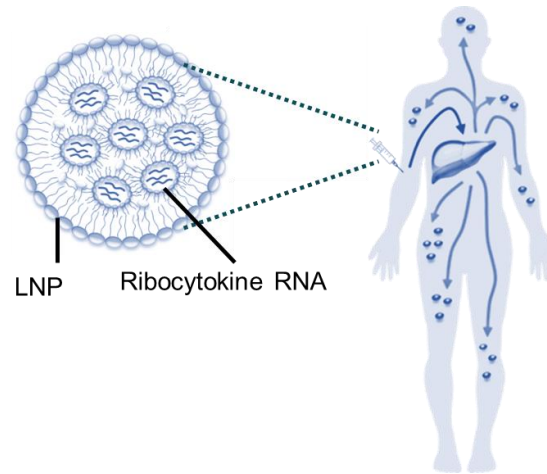
CARVac platform – CLDN6 CAR-T

RiboCytokines

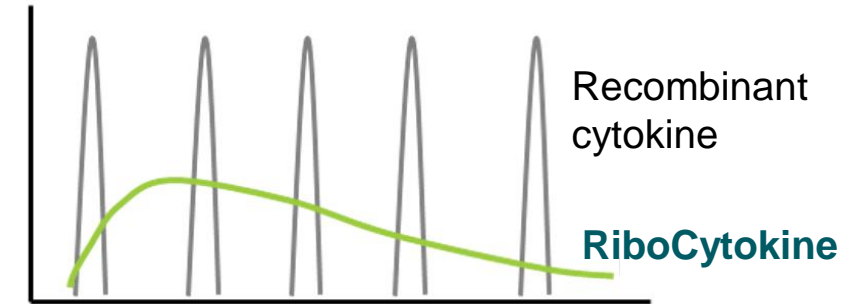
RiboCytokines: a novel therapeutic platform

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



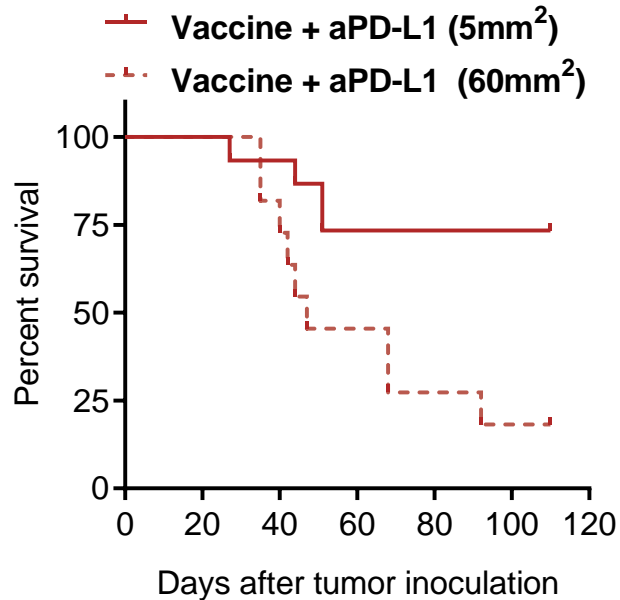
Therapeutic goals

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

Worldwide rights; wholly owned

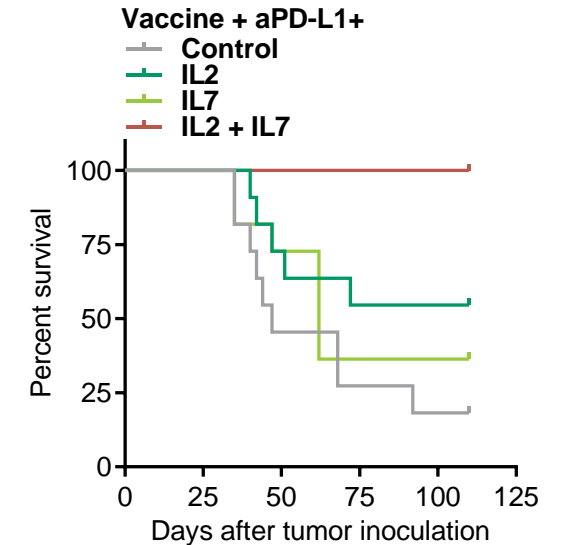
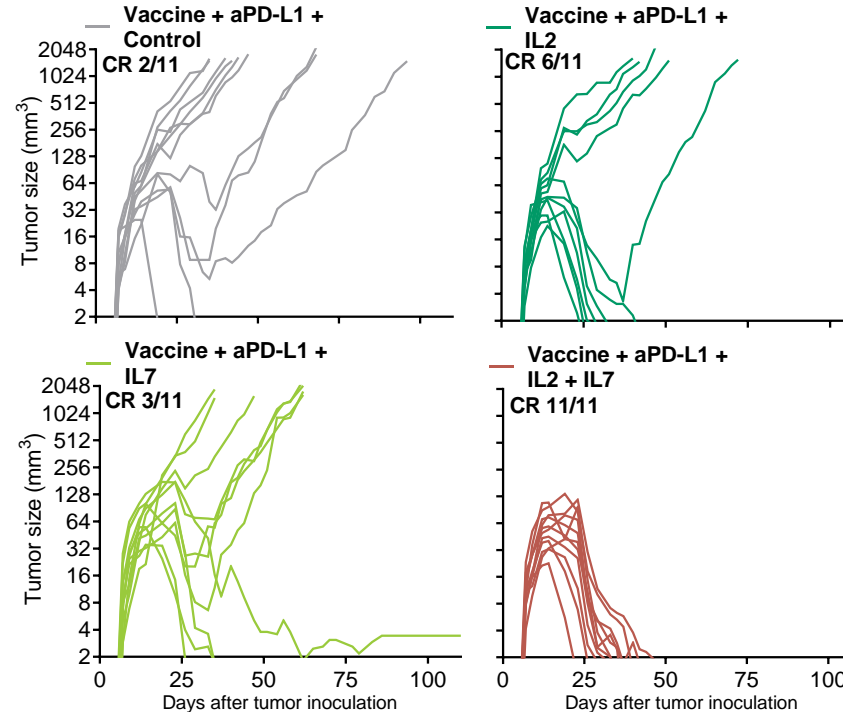


RiboCytokines boosted activity of vaccination and PD-L1 blockade in mouse model



CT26 tumor model, vaccine antigen: gp70

Vaccine + aPD-L1 +



CT26 tumor model, tumor size: 60mm²
 CR: complete response,
 vaccine antigen:gp70

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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