

## J.P. Morgan Healthcare Conference

January 2020

Ugur Sahin, MD  
CEO and Co-Founder



# 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, its expectations with respect to the timing and results of clinical trials and release of clinical data (both in respect of its proprietary product candidates and of product candidates of its collaborators), 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, and expected royalty and milestone payments in connection with BioNTech's collaborations, constitute forward-looking statements. Words such as "expects," "plans," "potential," "target," "continue" and variations of these words or similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. 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 initiation, timing, progress, results and cost of the Company's research and development programs and its current and future preclinical studies and clinical trials; the timing of and the Company's ability to obtain and maintain regulatory approval for its product candidates; the Company's ability to identify research opportunities and discover and develop investigational medicines; the Company's expectations regarding the size of the patient populations for its product candidates, if approved for commercial use; the Company's estimates of its expenses, ongoing losses, future revenue and capital requirements and its needs for or ability to obtain additional financing; the Company's ability to identify, recruit and retain key personnel; the Company's and its collaborators' ability to protect and enforce its intellectual property protection for its proprietary and collaborative product candidates, and the scope of such protection; the development of and projections relating to the Company's competitors or its industry; the Company's ability to commercialize its product candidates, if approved; the rate and degree of market acceptance of the Company's investigational medicines; the Company's ability to manage its development and expansion; regulatory developments in the United States and foreign countries; the Company's ability to manufacture its product candidates with advantages in turnaround times or manufacturing cost; and the Company's ability to implement, maintain and improve effective internal controls. The preceding list is not intended to be an exhaustive list of all of the Company's forward-looking statements. 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.

# Agenda

Who we are and what we do

Our platforms and programs



Outlook for 2020 and beyond

# Building a 21<sup>st</sup> century individualized immunotherapy company



## Next generation immunotherapies for cancer and other diseases

- **Technology agnostic** approach
- Exploiting **novel** targets and mechanisms
- **Vertical Integration** with in house manufacturing



## World-leading collaborators

- **7 pharmaceutical collaborators** and multiple leading academic institutions
- **50:50 cost and profit share agreements** with leaders in oncology<sup>1</sup>



## Broad & diversified pipeline

- **10 product candidates in the clinic**
- First **registrational trial** expected to start in **2020**<sup>2</sup>



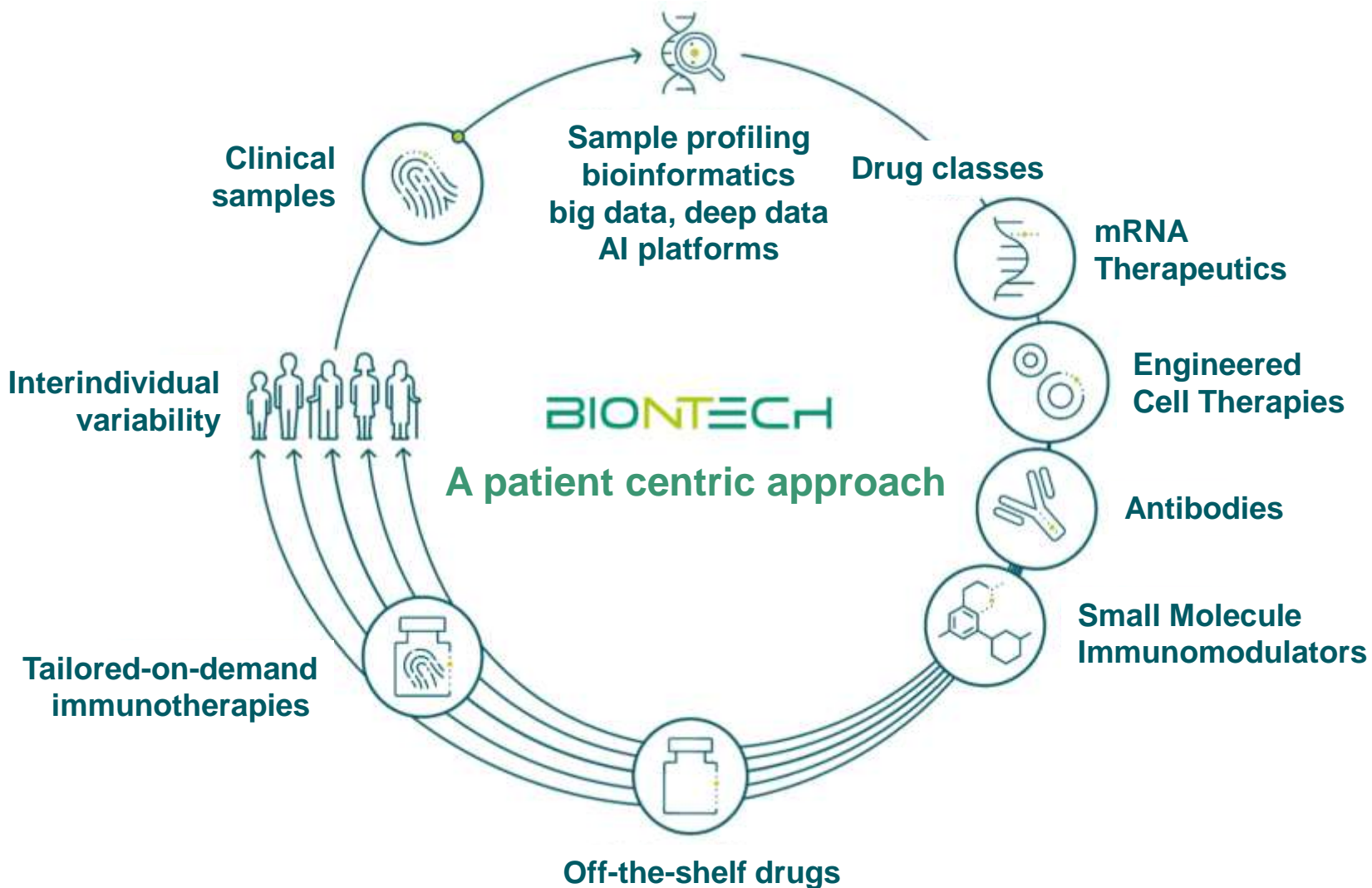
## Large addressable market opportunity in solid tumors

- More than **USD 90bn solid tumor market**<sup>3</sup> addressed
- Commercialization or co-commercialization rights **retained in key geographies**



*Up to 7 clinical data updates expected in the next 18 months*

# Our Vision: We aspire to individualize cancer medicine



In-house diagnostics & bio-informatics

Multi-drug platform approach

Off-the-shelf drugs and individualized therapies

In-house manufacturing with on-demand production capabilities

## We collaborate with global leaders in our industry

### Oncology Collaborations with at least one program in the clinic

50:50

Cost and Profit share (2016)

Genentech

50:50

Cost and Profit share (2015)

Genmab

Cost and Profit share (2015)

SANOFI

### Other Oncology, Infectious Diseases and Rare Diseases Collaborations

Co-development

Co-commercialization (2018)

GENEVANT

Licensing Agreement

(2018)

Pfizer

Strategic R&D

Alliance (2018)

UPenn

R&D Agreement

(2019)

BILL & MELINDA  
GATES foundation

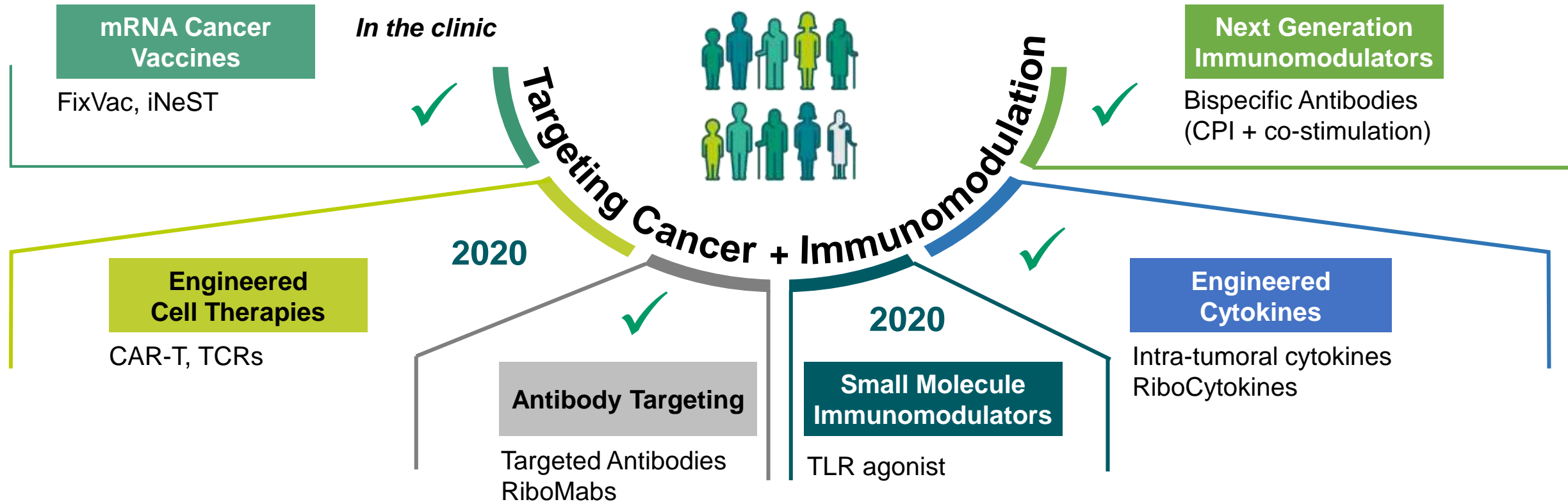
Licensing Agreement

(2015)

Lilly



## Our IO strategy exploits complementary therapeutic platforms



## A technology agnostic approach increases our addressable market

Cancer segment	Patient Population	Challenge	Our Therapeutic Strategy
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><i>mRNA Neoantigen Immunotherapy (iNeST)</i></b></li> </ul>
Low mutational burden cancers	>60% of cancers	Poor response to checkpoint inhibitors	<ul style="list-style-type: none"> <li>• <b><i>Shared Antigens (FixVac, CAR-T cells, Antibodies)</i></b></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><i>mRNA Immunotherapy</i></b></li> <li>• <b><i>Immunostimulatory Compounds (intratumoral, RiboCytokines)</i></b></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><i>Antibodies</i></b></li> <li>• <b><i>CAR-Ts</i></b></li> </ul>
Refractory tumors	Patients with large tumors and multiple resistance mechanisms	Few treatment options	<ul style="list-style-type: none"> <li>• <b><i>Engineered Cell Therapies</i></b></li> <li>• <b><i>Combination Therapies</i></b></li> </ul>

***Portfolio approach based on molecular classification and segmentation of cancer types***



# One of the broadest mRNA toolkits in the industry

## Multiple mRNA formats



- uRNA
- saRNA
- modRNA
- taRNA



## Broad formulation spectrum

- Liposomes / LPX
- LNPs
- Polyplexes

## Various delivery routes

- Local
- Intratumoral
- Systemic
- Tissue specific







Adjustable activity in vivo  
from minutes up to weeks

## Additional late stage trial starts planned for FixVac and iNeST in 2020









Drug Class	Platform	Product Candidate	Indication (Targets)	Preclinical	Phase 1	Phase 2	Rights Collaborator	Milestones	
Oncology									
mRNA	FixVac (fixed combination of shared non-mutated cancer antigens)	BNT111	advanced melanoma (adjuvant & metastatic)				fully-owned	report phase 1 data and phase 2 start 1H 2020; <b>phase 3 start 2H 2020</b>	
		BNT112	prostate cancer				fully-owned	first patient enrolled in phase 1/2 in Dec 2019 (plan: 2H 2019)	new
		BNT113	HPV16+ head and neck cancer <sup>1</sup>				fully-owned	phase 2 start 2H 2020	
		BNT114	triple negative breast cancer				fully-owned	data update 1H 2020	
		BNT115	ovarian cancer <sup>1</sup>				fully-owned	first patient dosed in Dec 2019	new
		BNT116	NSCLC				fully-owned	-	new
	iNeST (patient specific cancer mutated antigen therapy)	RO7198457 (BNT122)	1L melanoma with CPI <sup>2</sup>				Genentech (global 50:50 profit/loss)	top line data 2H 2020 <sup>3</sup>	
			multiple solid tumors					data update 2020	
	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)	data update 2H 2020 <sup>4</sup>	

<sup>1</sup>BNT113 and BNT115 are currently being studied in an investigator-initiated phase 1 trials; <sup>2</sup>Checkpoint Inhibitor; <sup>3</sup>We expect this topline data update to include an update on the ongoing study, including patient enrollment numbers, with full efficacy and safety data for an interim update expected in the second half of 2021; <sup>4</sup>As the trial is sponsored and conducted by Sanofi, the timing of data updates is not under our control, and is subject to change by Sanofi.

## We plan to start first-in-human trials for RiboMabs & RiboCytokines in 2020

Drug Class	Platform	Product Candidate	Indication (Targets)	Preclinical	Phase 1	Phase 2	Rights Collaborator	Milestones
Oncology								
mRNA	RiboMabs (mRNA-encoded antibodies)	BNT141	multiple solid tumors				fully-owned	<b>phase 1 start 2H 2020</b>
		BNT142	multiple solid tumors (CD3+CLDN6)				fully-owned	phase 1 start 2H 2020 or 1H 2021
	RiboCytokines (mRNA-encoded Cytokines)	BNT151	multiple solid tumors (optimized IL-2)				fully-owned	<b>phase 1 start 1H 2020</b>
		BNT152+ BNT153	multiple solid tumors (IL-7, IL-2)				fully-owned	phase 1 start 2H 2020 or 1H 2021

# We now have 3 antibodies in clinical testing

Drug Class	Platform	Product Candidate	Indication (Targets)	Preclinical	Phase 1	Phase 2	Rights Collaborator	Milestones
Oncology								
Engineered Cell Therapies	CAR-T Cells	BNT211	multiple solid tumors ( <i>CLDN6</i> )				fully-owned	phase 1/2 start 1H 2020
		BNT212	pancreatic, other cancers ( <i>CLDN18.2</i> )				fully-owned	-
	TCRs	Undisclosed	undisclosed				Eli Lilly (exclusive license)	-
		To be selected	all tumors				fully-owned	-
Antibodies	Next-Gen CP <sup>5</sup> Immunomodulators	GEN1046 (BNT311)	multiple solid tumors ( <i>PD-L1</i> ×4-1 <i>BB</i> )				Genmab (global 50:50 profit/loss)	data update 1H 2021
		GEN1042 (BNT312)	multiple solid tumors ( <i>CD40</i> ×4-1 <i>BB</i> )					-
	Targeted Cancer Antibodies	BNT321 (MVT-5873)	pancreatic cancer ( <i>sLe<sup>a</sup></i> )				fully-owned	patient enrolled to resume phase 1 in Dec 2019
SMIM <sup>6</sup>	Toll-Like Receptor Binding	BNT411	solid tumors ( <i>TLR7</i> )				fully-owned	phase 1 start 1H 2020

new

<sup>5</sup>Checkpoint; <sup>6</sup>Small Molecule Immunomodulators

# 2019 Highlights

## Pipeline

- Initiated clinical trials for 6 Investigational Medicinal Products (IMPs) across various cancer indications
- Started first randomized Phase 2 trial for iNeST
- Dosed more than 440 patients across all BNTX programs<sup>1</sup> as of end 2019

## Corporate

- Raised \$225m in Series B financing and \$149m in Nasdaq IPO
- Signed two additional agreements with Bill & Melinda Gates Foundation and Regeneron
- Purchased site for building new iNeST manufacturing facility and initiated planning and design work

## Management Team

- Agreed on new Management Board Member and Chief Strategy Officer (appointment of Ryan Richardson on Jan 12, 2020)

# Agenda

Who we are and what we do

Our key platforms and programs



mRNA vaccines – FixVac and iNeST

Antibodies

CARVac platform – CLDN6 CAR-T

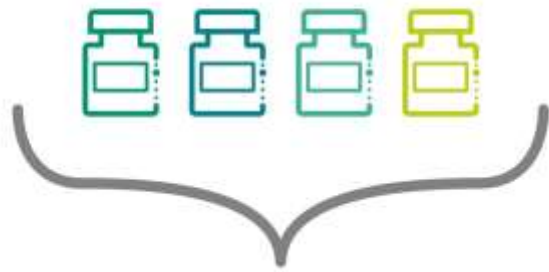
RiboCytokines

Outlook for 2020 and beyond



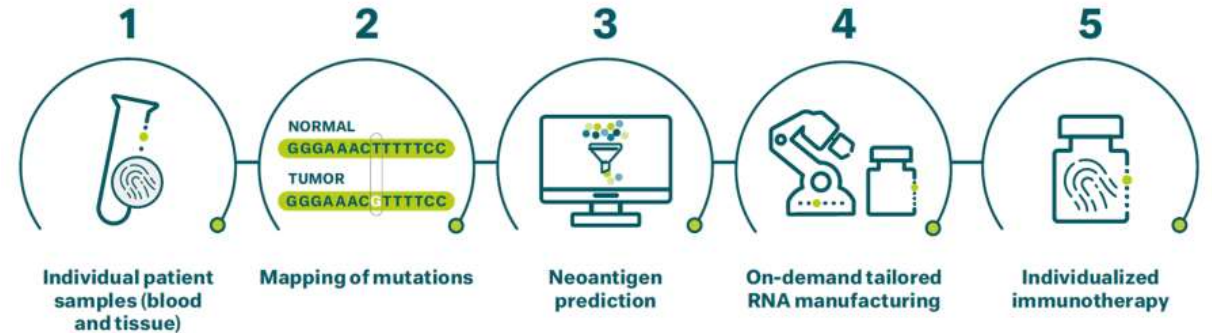
## Our mRNA vaccine platforms: FixVac and iNeST

### FixVac



- Off-the-shelf mRNA immunotherapy
- Targeting a fixed combination of shared antigens
  - Non-mutated antigens shared among patients with a specific cancer type
  - Applicable for almost all types of tumor antigens

### iNeST

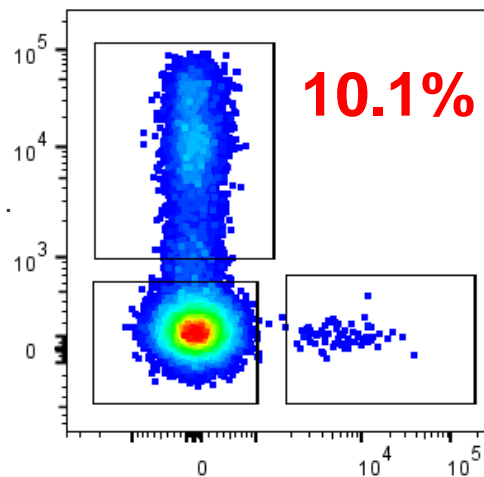


- Fully individualized mRNA immunotherapy
- Targeting 20 neo-antigens unique to each patient
  - Vast majority of neo-antigens are unique to individual patients
  - Applicable across solid tumor types

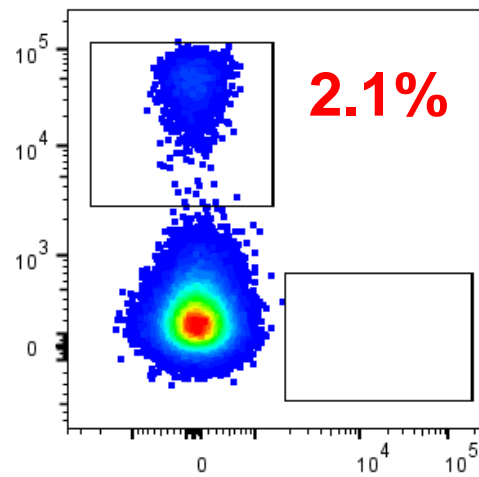
- Proprietary RNA-LPX formulation for systemic dendritic cell targeting
- Strong immunogenicity observed *in vivo* via TLR7-driven adjuvant effect
- Potent induction of strong *ex vivo* CD4+ and CD8+ T cell responses

## Our RNA-LPX vaccine approach

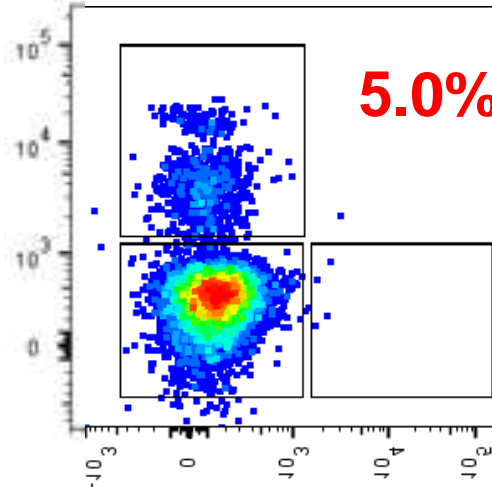
Strong vaccine-induced *ex vivo* CD8+ T cell responses<sup>1</sup> across different cancer types



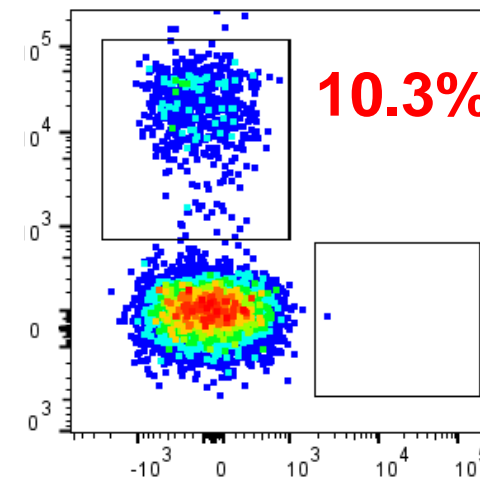
**NY-ESO-1**  
Melanoma  
BNT111, Lipo-MERIT trial



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



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



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

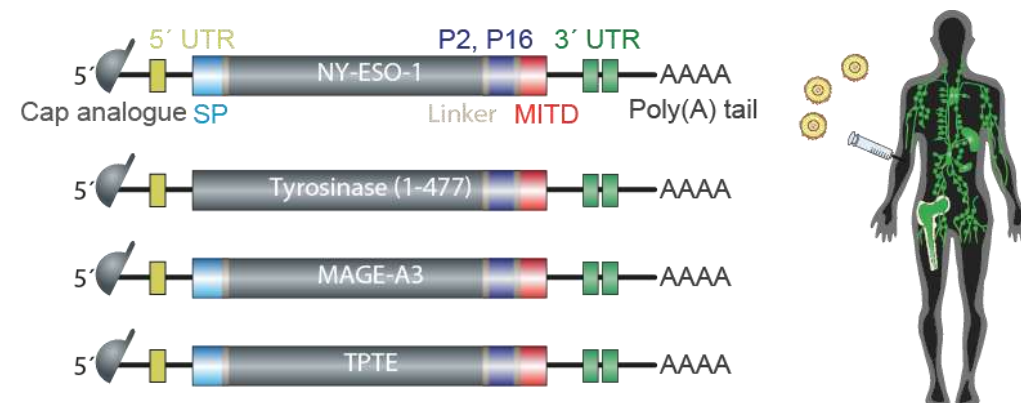
FixVac

iNeST

## FixVac: BNT111 interim clinical activity data (dose range 14µg -100µg)

### Summary

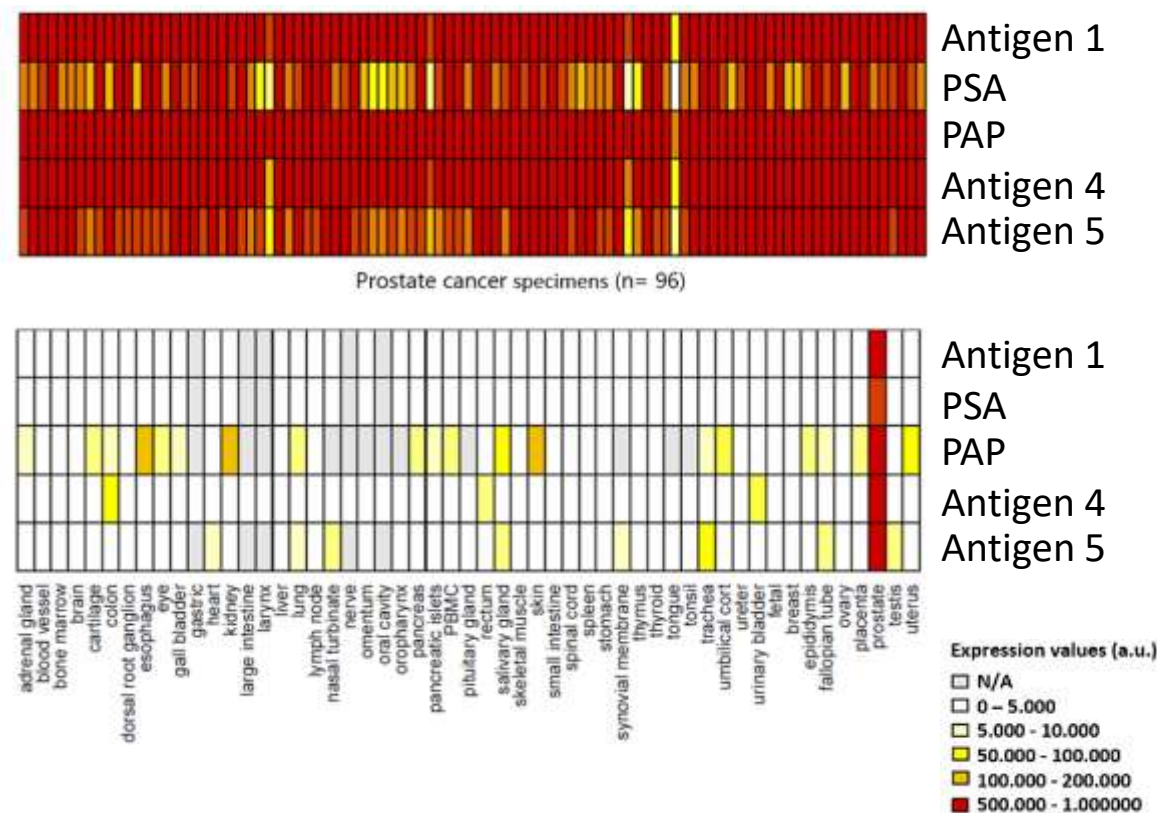
- Advanced melanoma patients (Stage IIIB,C, Stage IV)
- Out of **74 patients** with follow-up imaging **42 patients** were eligible for exploratory analysis of objective responses as of July 29, 2019
- 25 patients** with pretreated and **CPI<sup>1</sup>-experienced metastatic melanoma** who received BNT111 monotherapy
  - 3 patients with partial response (PR)
  - 1 with metabolic complete remission<sup>2</sup>
  - 7 patients with stable disease (SD)
  - 14 progressive disease (PD)
- 17 patients** with **CPI-experienced metastatic** melanoma who received BNT111 in combination with CPI
  - 6 patients with partial response (PR)
  - 2 patients with stable disease (SD)
  - 9 patients with progressive disease (PD)
- Adjuvant cohort of 32 patients still in study



### Shared Antigens Targeted

NY-ESO-1 / MAGE-A3 / Tyrosinase / TPTE

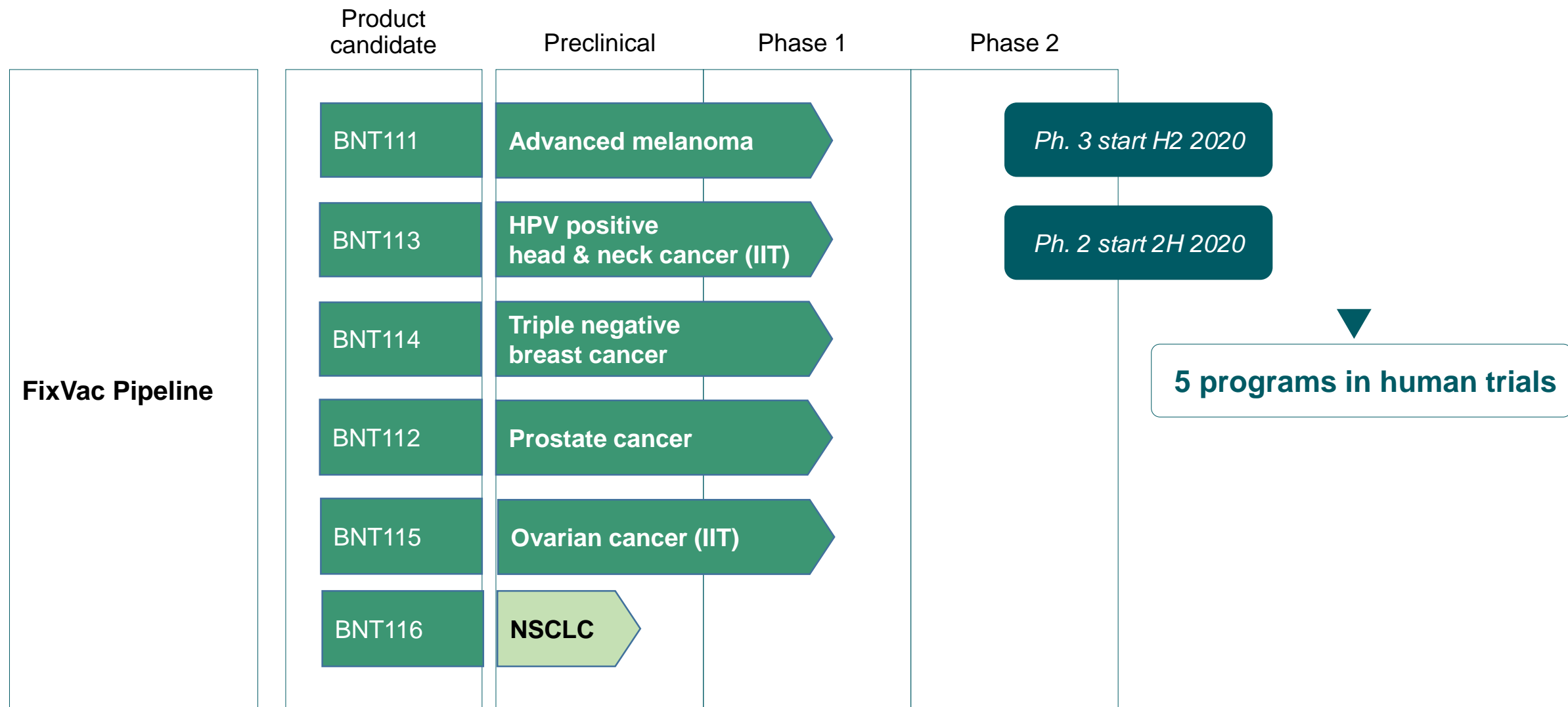
## BNT112: FixVac Prostate Cancer



### Ph1/2: first patient enrolled in December 2019

- Multipronged vaccine: Targeted antigens of BNT112 are 5 prostate cancer specific antigens (PAP, PSA and 3 undisclosed antigens)
- RNA-LPX vaccine format validated by our FixVac Melanoma program

## FixVac: an expanding pipeline of clinical stage programs



## Conclusions from iNeST clinical trials

### Long-term follow-up of completed trial with BNT121 (Intra-nodal administration, RNA):

- Long-term relapse free disease activity with BNT121 iNeST in adjuvant melanoma

### Preliminary observations in ongoing trials with BNT122 (RO7198457) (IV administration, RNA-LPX):

- iNeST can be manufactured for individual patients with clinically relevant turn-around times across a range of tumor types
- iNeST +/- atezolizumab (Tecentriq) has a manageable safety profile
- Strong iNeST immunogenicity across a range of tumor types

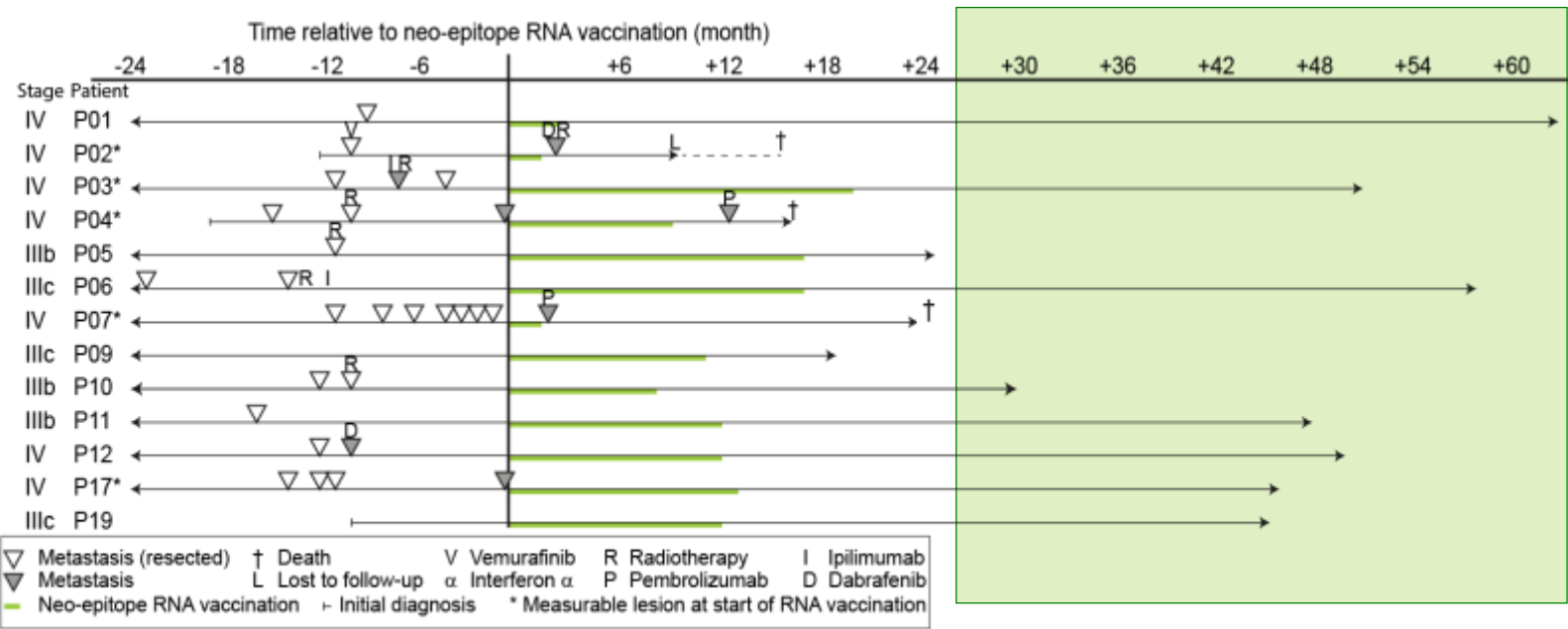
**Clinical efficacy evaluation in randomized phase 2 trials initiated**



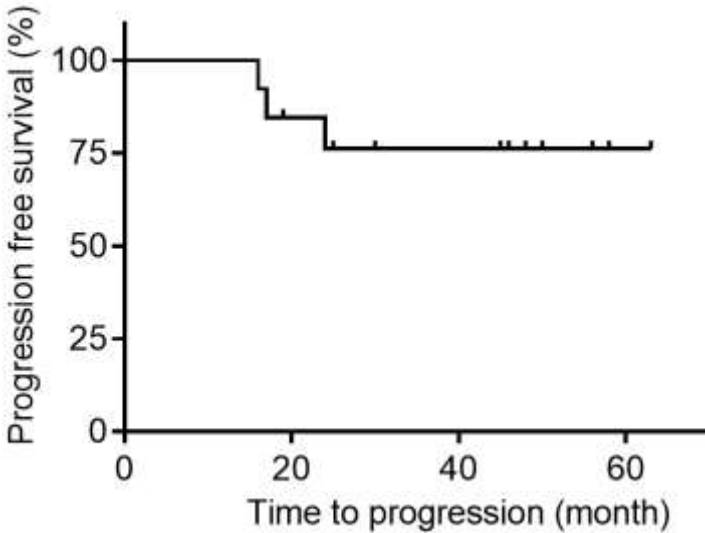
# Update for BNT121 (as of October 2019)

Melanoma Stage IIIb, IIIc, and IV, 13 patients, intranodal delivery against 10 neoantigens

## Metastatic relapse analyses



9 of 13 patients without documented PFS Events



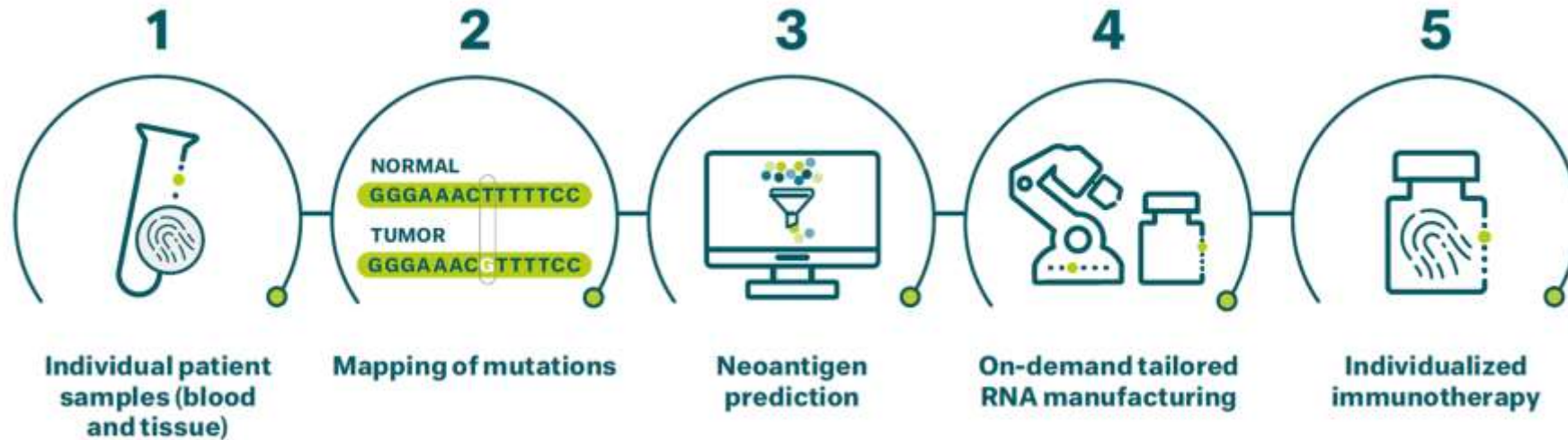
Stable progression free survival in adjuvant melanoma

## A technology agnostic approach increases our addressable market

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

***Portfolio approach based on molecular classification and segmentation of cancer types***

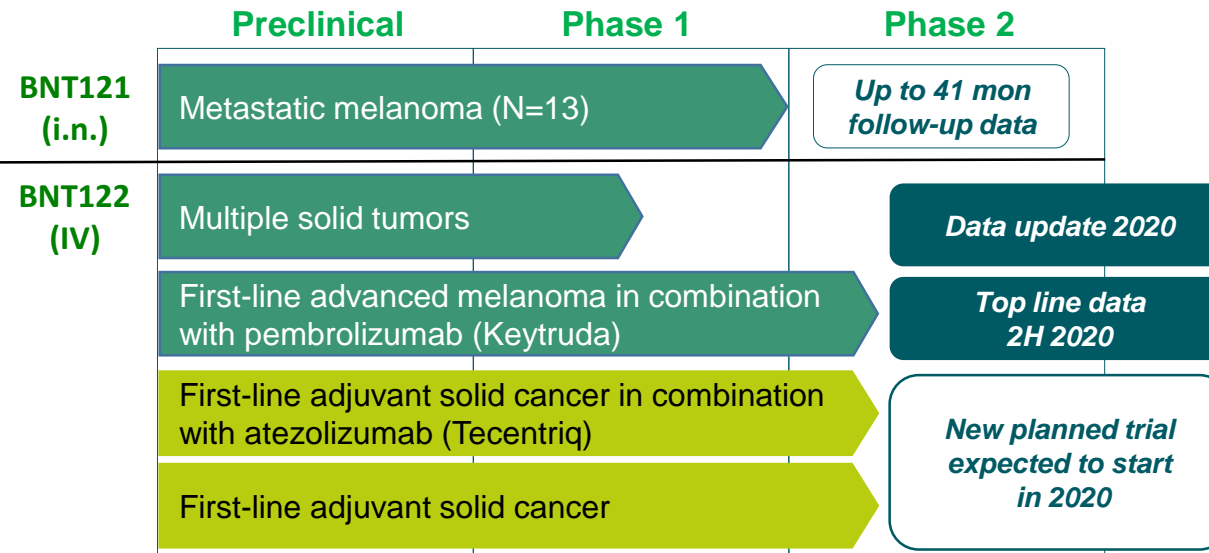
# Individualized Neoantigen Specific Immunotherapy (iNeST)



Turnaround time reduced from three months to six weeks

## Overview

- Targeting multiple neoantigens
- Intended to be a universal approach applicable for the majority of cancers
- 50:50 profit/loss share with Genentech



Currently being evaluated in  $\geq 8$  solid tumor indications

## Digitization and automation for neo-antigen vaccine manufacturing



### Paperless documentation

- 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



### Semiautomatic manufacturing

**SIEMENS**  
**BIONTECH**

# Agenda

Who we are and what we do

Our platforms and programs



mRNA vaccines – FixVac and iNeST

Antibodies

CARVac platform – CLDN6 CAR-T

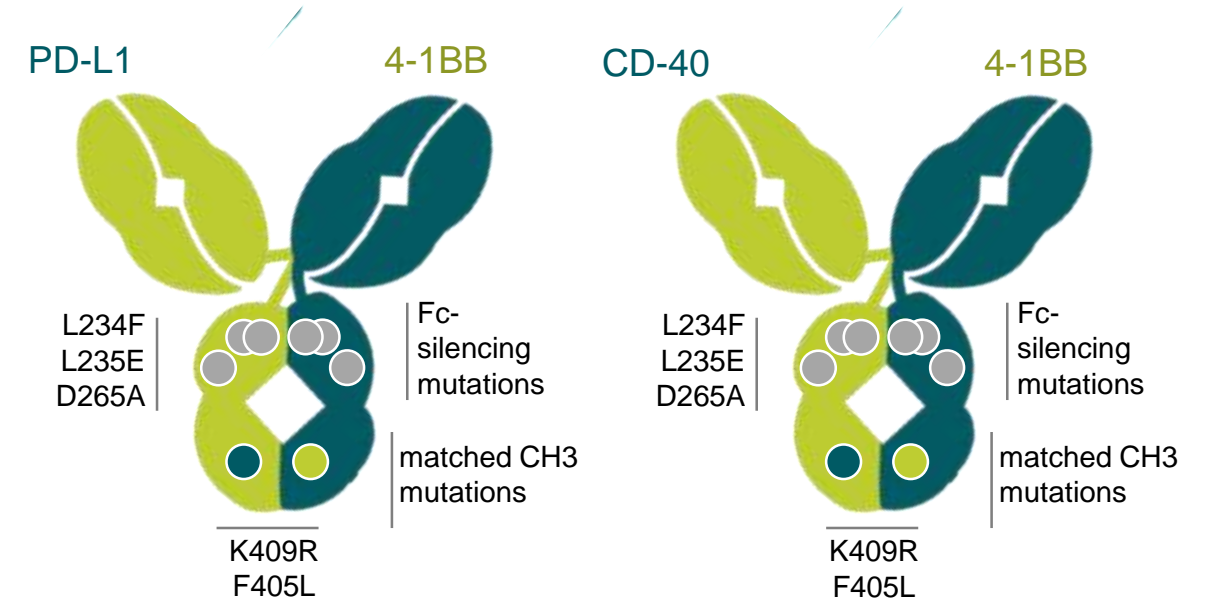
RiboCytokines

Outlook for 2020 and beyond

## Next-Gen checkpoint immunomodulators

### Two bispecific antibodies partnered with Genmab

- Potential “first-in-class” bispecific antibodies
- Conditional activation of immuno-stimulatory checkpoint activity
- 50:50 profit/loss share
- Both programs are now in the clinic



Product Candidate	Preclinical	Phase 1	Phase 2
BNT311 (GEN1046)	PD-L1x4-1BB		Ph1/2a
BNT312 (GEN1042)	CD-40x4-1BB		Ph1/2a

**Data update 1H 2021**

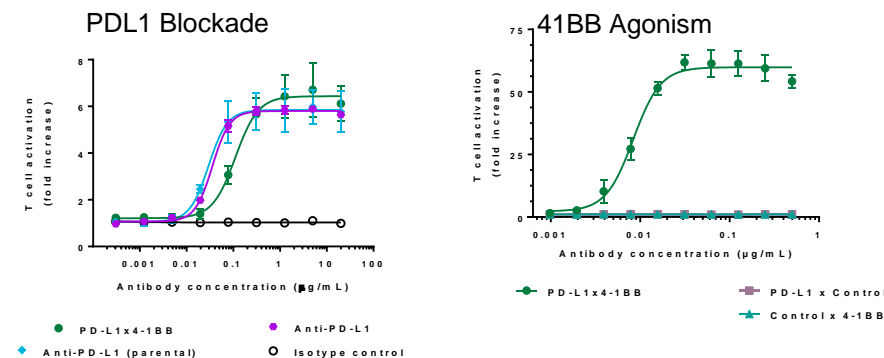


# Next-Gen checkpoint immunomodulators

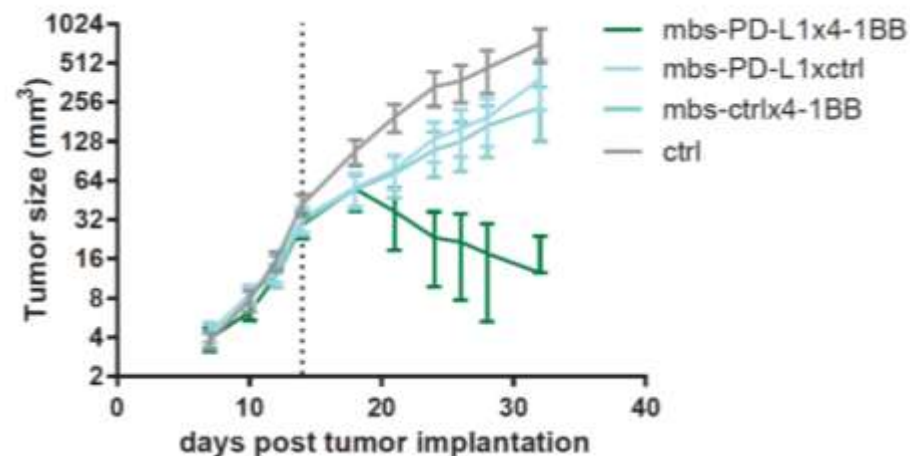
## Characteristics

- Bi-specific antibody combining constitutive CPI blockade and conditional co-stimulatory activity
- Enhanced proliferation of antigen specific activated T cells in the presence of PD-L1-positive cells

### Mode of Action



### Preclinical antitumor activity beyond PDL1 blockade



**1** Constitutive PD-L1 blockade & Conditional 4-1BB agonism

**2** Increased tumor infiltrating lymphocyte (TIL) expansion in human tumor tissue cultures *ex vivo*

**3** Induced tumor regression of murine tumors superior to pure PD-L1 blockage associated with an increase in tumor-specific CD8 T-cells

## A technology agnostic approach increases our addressable market

Cancer segment	Patient Population	Challenge	Our Therapeutic Strategy
High mutational burden/ adjuvant stage cancers	Significant portion of cancer patients	Poor risk-benefit profile of checkpoint inhibitors	• <b><i>mRNA Neoantigen Immunotherapy (iNeST)</i></b>
Low mutational burden cancers	>60% of cancers	Poor response to checkpoint inhibitors	• <b><i>Shared Antigens (FixVac, CAR-T cells, Antibodies)</i></b>
“Immune desert” cancers	>40% of high-mutational cancers	Poor infiltration and activation of T-cells in TME	• <b><i>mRNA Immunotherapy</i></b> • <b><i>Immunostimulatory Compounds (intratumoral, RiboCytokines)</i></b>
Cancers with MHC / B2M loss	20-30% of CPI-experienced advanced cancers	Failure of immune system to recognize tumor cells	• <b><i>Antibodies</i></b> • <b><i>CAR-Ts</i></b>
Refractory tumors	Patients with large tumors and multiple resistance mechanisms	Few treatment options	• <b><i>Engineered Cell Therapies</i></b> • <b><i>Combination Therapies</i></b>

***Portfolio approach based on molecular classification and segmentation of cancer types***

# BNT321: Cancer antibody targeting Cancer Associated Carbohydrate sLe<sup>a</sup>

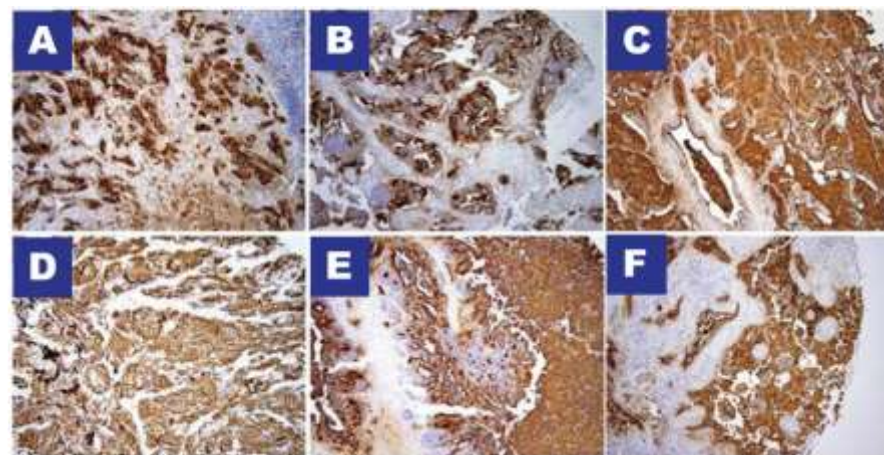
## Characteristics

- Fully human IgG1 mAb with subnanomolar affinity, potent cell killing by ADCC & CDC activity.
- Targets sialyl Lewis A epitope (sLe<sup>a</sup>) epitope present in a range of glyco-proteins collectively known as CA19-9
- CA19-9 is specifically expressed in pancreatic and various other cancers. Shedded CA19-9 is a prognostic marker in these cancers
- CA19-9 is functionally associated with carcinogenesis<sup>1</sup>

## Preliminary data

- Six patients evaluated in combination with chemotherapy; four of them met the criteria for partial response and two patients met the criteria for stable disease. BNT321 was generally well tolerated by all six patients
- First patient enrolled to resume the BNT321 trial against pancreatic cancer in December 2019

sLe<sup>a</sup> expression in human cancers

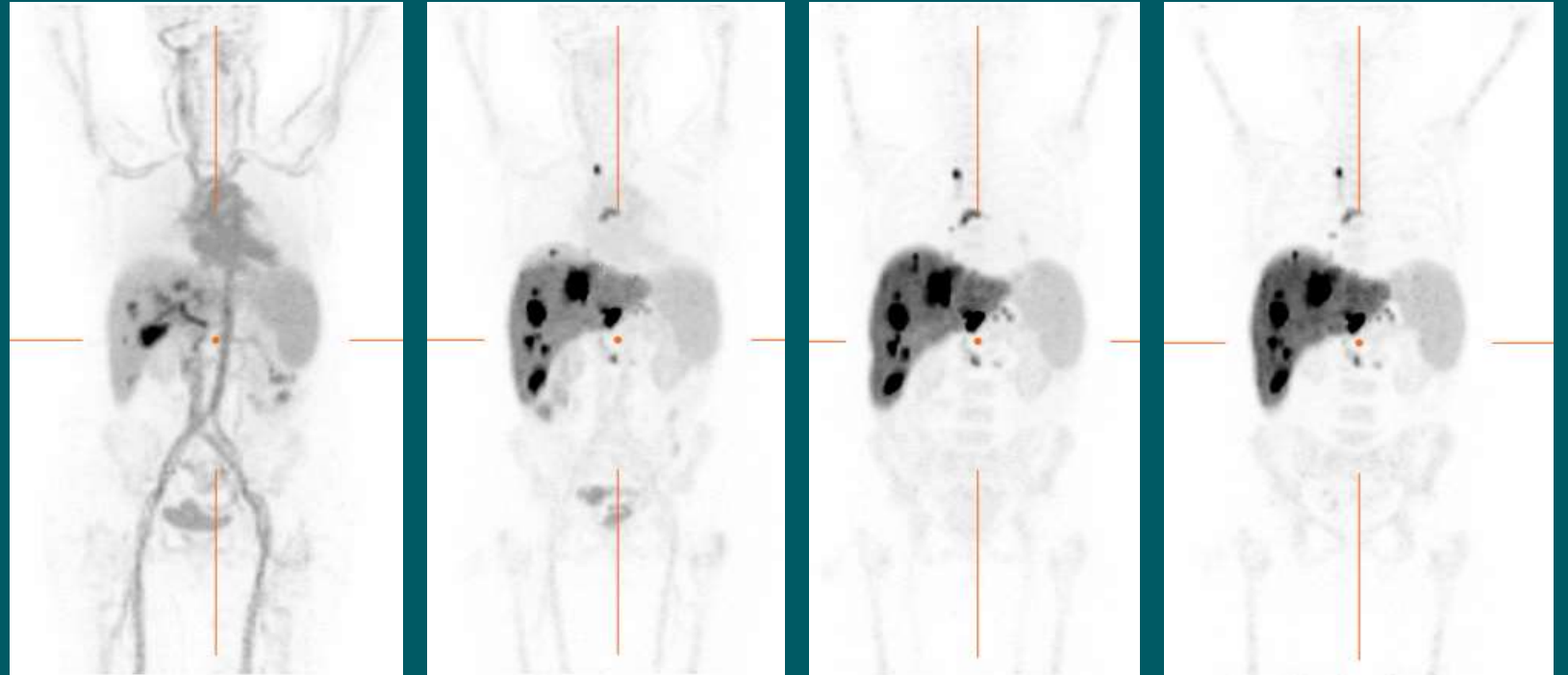


- A. Pancreatic ductal adenocarcinoma
- B. Colon carcinoma
- C. Lung adenocarcinoma
- D. Urinary bladder, mucinous adenocarcinoma
- E. Colon metastatic to ovary
- F. Breast carcinoma, lymph node



## First-in-human Ph1 trial also supports theranostic potential

PET/CT imaging study with MVT-2163 (PET conjugated Ab version;  $^{89}\text{Zr}$ -DFO-HuMab-5B1)



- Robust accumulation in tumors lesions; tumor uptake increasing over time.
- Validates the target and the antibody and indicates utility of BNT321 also for detection by radio-imaging and for radiotherapy.

# Agenda

Who we are and what we do

Our platforms and programs



mRNA vaccines – FixVac and iNeST

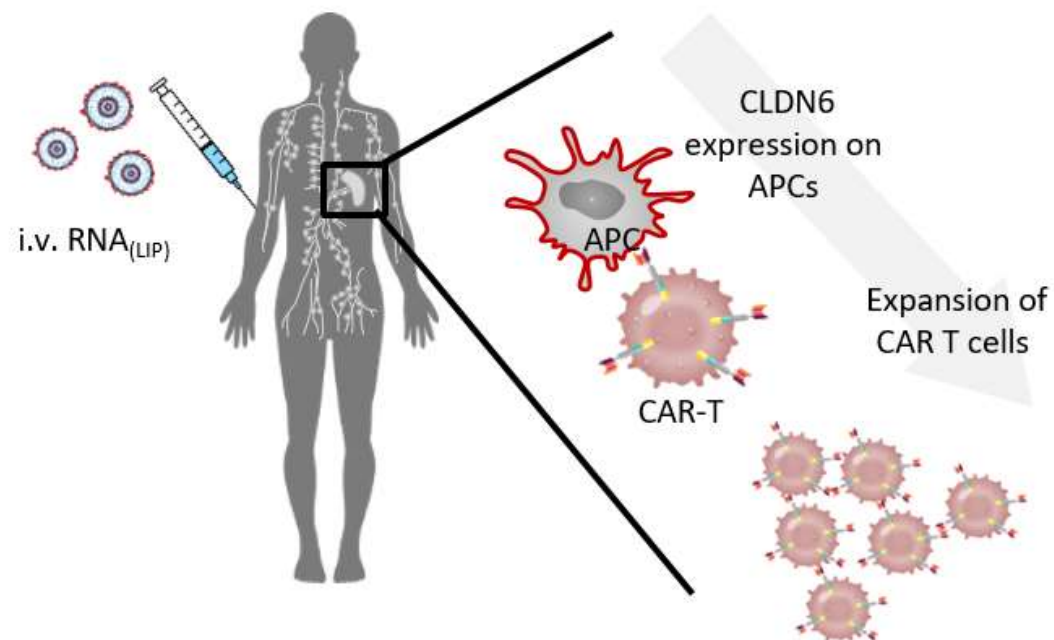
Antibodies

CARVac platform – CLDN6 CAR-T

RiboCytokines

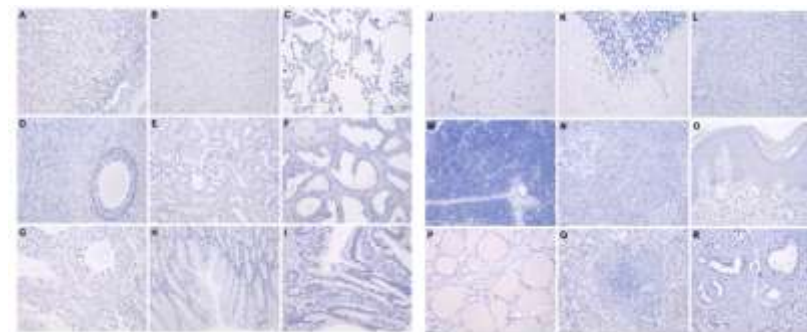
Outlook for 2020 and beyond

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

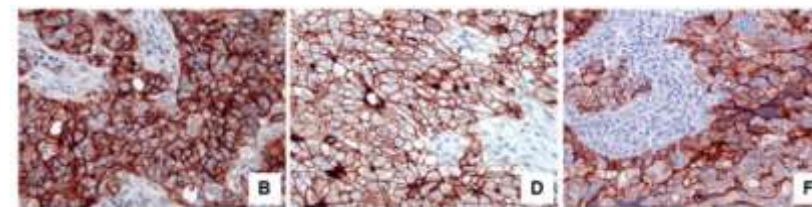


CAR-T cell therapy + RNA Vaccine to amplify CAR-T cell *in vivo*

CLDN6 is not present in healthy tissues



CLDN6 is expressed in multiple cancers

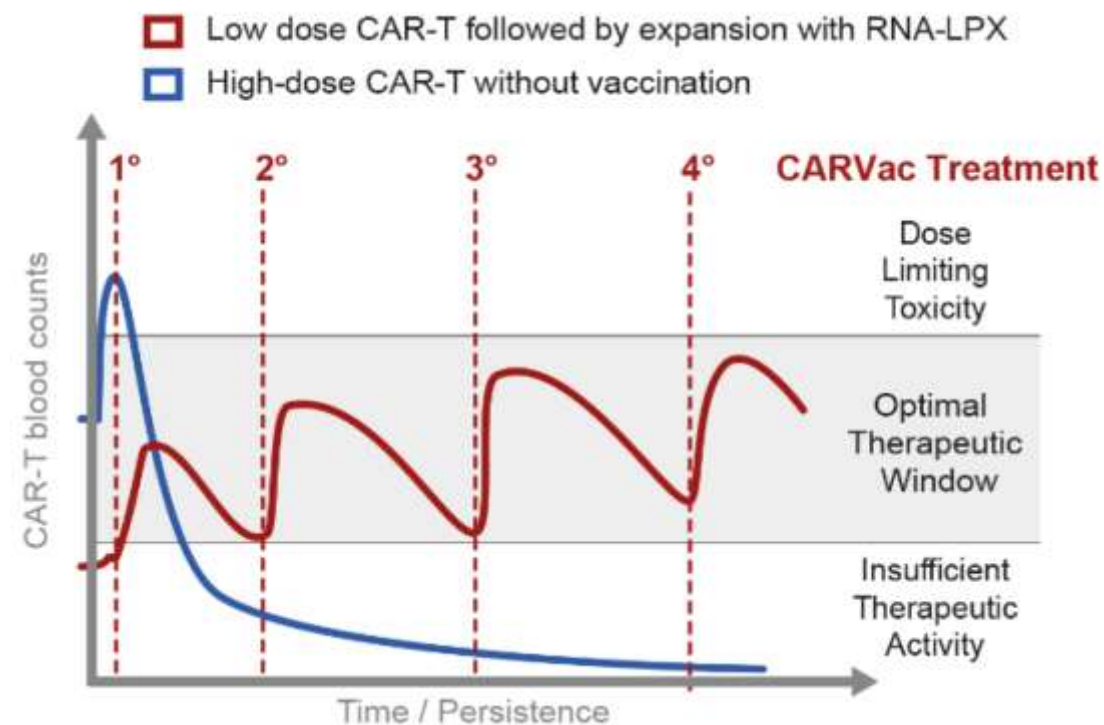
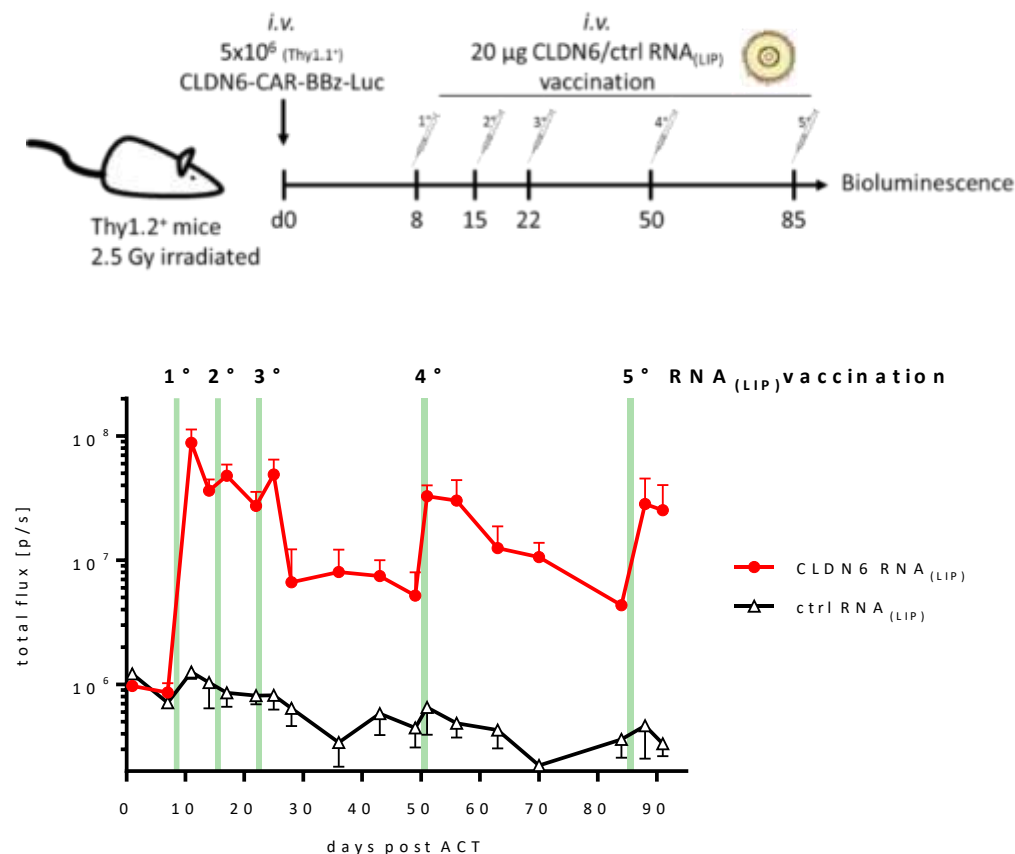


Ovarian cancer   Testicular tumor   Lung cancer

**Complete 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 enhances expansion & persistence of CAR T**

## A technology agnostic approach increases our addressable market

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

***Portfolio approach based on molecular classification and segmentation of cancer types***

## Further development of engineered T cell therapies

### Key Plans

- Start first-in-human trial for CLDN6 CAR-T in solid tumors
- Second CAR-T in pipeline for solid tumors: CLDN18.2 CAR-T
- Develop CARVac with other CAR-T therapies
- Plan to announce first TCRs for TCR engineered therapies
- Expansion of certified GMP T cell manufacturing facilities planned to be completed in 2020



**Idar-Oberstein: GMP certified Cell Therapy Manufacturing**

Front view model of final layout with the existing buildings A/B and the new buildings C and D (D behind B).

# Agenda

Who we are and what we do

Our platforms and programs



mRNA vaccines – FixVac and iNeST

Antibodies

CARVac platform – CLDN6 CAR-T

RiboCytokines

Outlook for 2020 and beyond

## A technology agnostic approach increases our addressable market

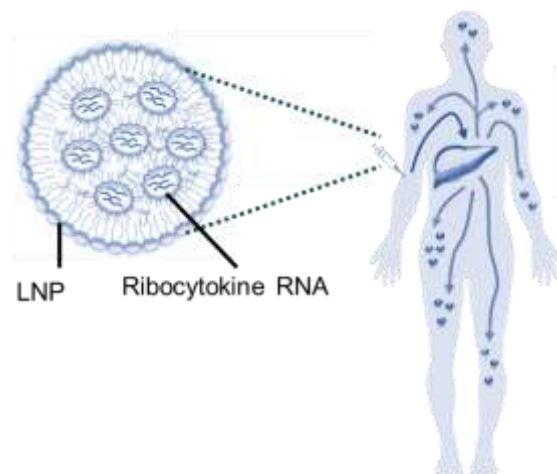
Cancer segment	Patient Population	Challenge	Our Therapeutic Strategy
High mutational burden/ adjuvant stage cancers	Significant portion of cancer patients	Poor risk-benefit profile of checkpoint inhibitors	<ul style="list-style-type: none"> <li>• <b><i>mRNA Neoantigen Immunotherapy (iNeST)</i></b></li>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

***Portfolio approach based on molecular classification and segmentation of cancer types***

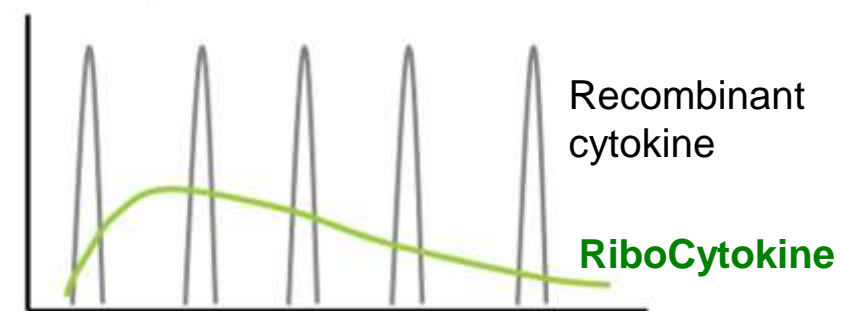
# RiboCytokines: a novel therapeutic platform

## 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

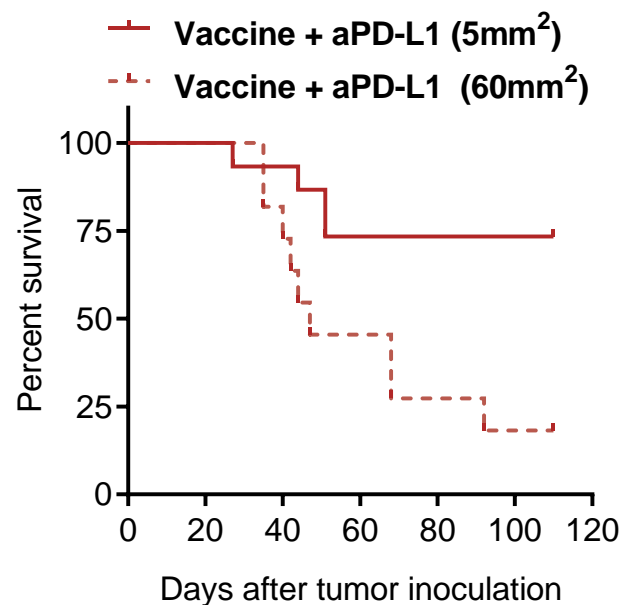
**Worldwide** rights; wholly owned

Product Candidate	Preclinical	Phase 1	Phase 2
BNT151	Optimized IL-2		
BNT152 / BNT153 combo	IL-7, IL-2		

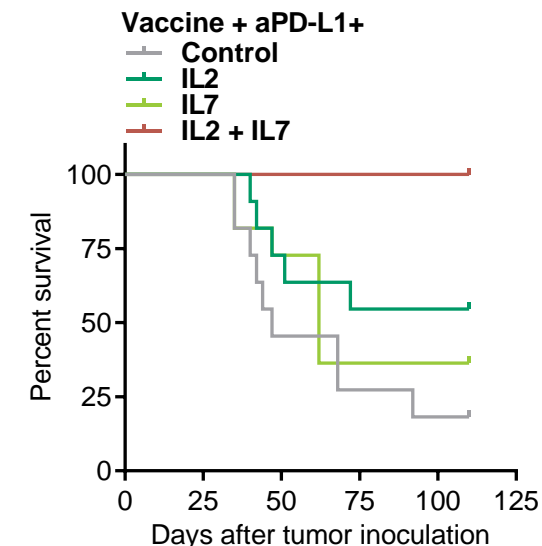
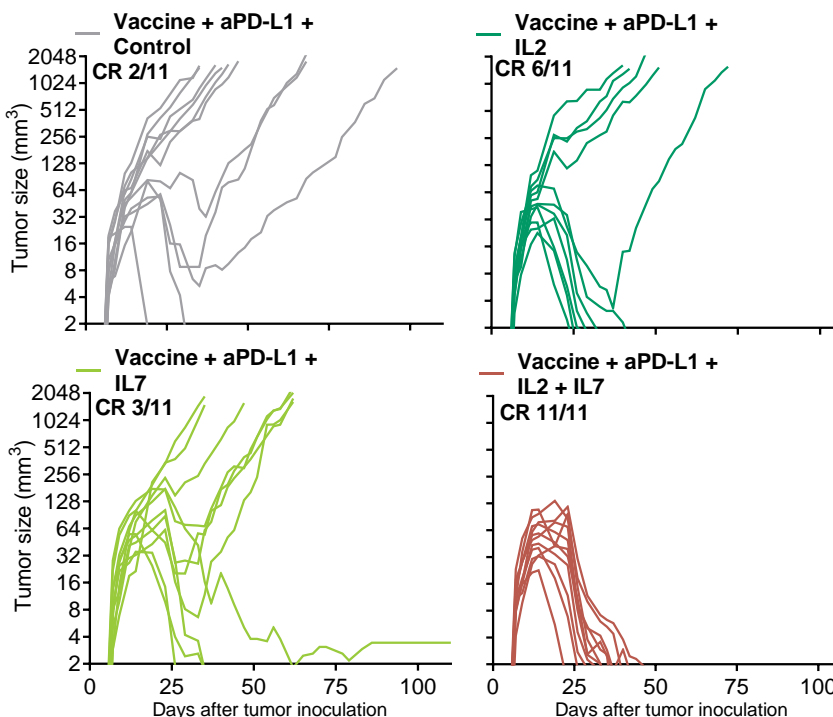
*Expected to enter the clinic in 1H 2020*

*Expected to enter the clinic in 2H 2020*

# RiboCytokines boost clinical activity of vaccination and PD-L1 blockade



## Vaccine + aPD-L1 +

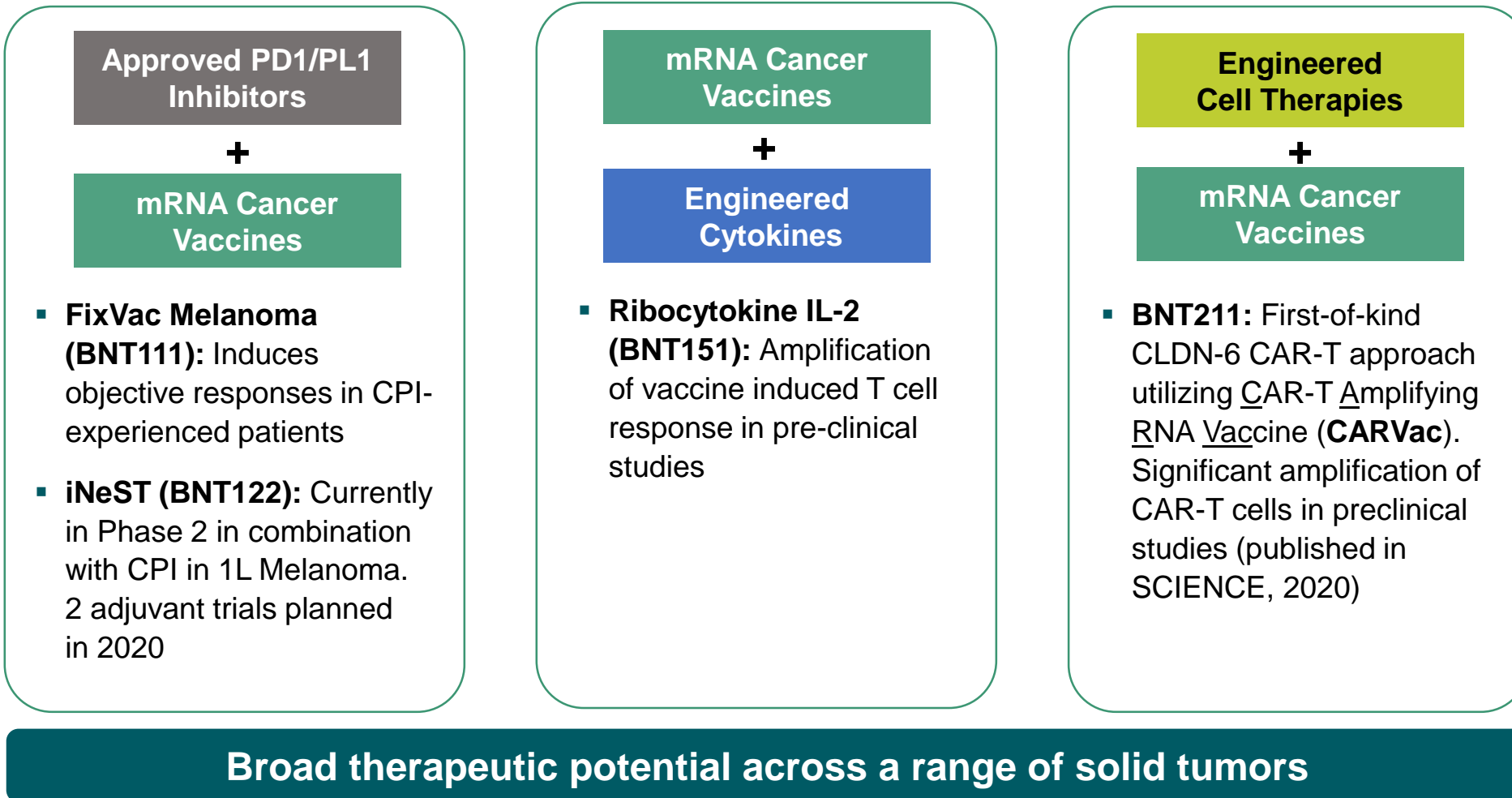


Effect of tumor size on treatment success of vaccination + aPD-L1

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



## Multiple angles for therapeutic synergy across platforms





# Agenda



Who we are and what we do

Our platforms and programs



Outlook for 2020 and beyond

# We expect a significant news flow in the upcoming next 18 months

	Platform	Candidate	Indication <i>(Target)</i>	1H-2020	2H-2020	2021 <sup>3</sup>	2022 <sup>3</sup>
mRNA	FixVac	BNT111	Advanced Melanoma	Report Phase 1 Start Phase 2	Start Phase 3	Phase 2/3	
		BNT112	Prostate Cancer				Phase 1/2
		BNT113	HPV16+ H&N Cancer		Start Phase 2		
		BNT114	Triple Negative Breast Cancer	Data update Phase 1			
	iNeST	RO7198457 (BNT122)	1L Melanoma with CPI		Trial progress update <sup>1</sup>	Phase 2	
			Multiple ST (basket trial)	Data update Phase 1/2			
	Intratumoral Immunotherapy	SAR441000 (BNT131)	Solid tumors <i>(IL-12sc, IL-15sushi, GM-CSF, IFNα)</i>		Report Phase 1/2 <sup>2</sup>		
	RiboMabs	BNT141	Multiple ST		Start Phase 1		
		BNT142	Multiple ST <i>(CD3+CLDN6)</i>		Start Phase 1		
	RiboCytokines	BNT151	Multiple ST <i>(Optimized IL-2)</i>	Start Phase 1			Phase 1
BNT152/153		Multiple Solid Tumors <i>(IL-7, IL-2)</i>		Start Phase 1			
Others	CAR-T Cells	BNT211	Multiple ST <i>(CLDN6)</i>	Start Phase 1/2			Phase 1/2
	Next-Gen CP Immunomodulators	BNT311	Multiple ST <i>(PD-L1x4-1BB)</i>			Report Phase 1/2	
		BNT312	Multiple ST <i>(CD40x4-1BB)</i>				
	Antibodies	BNT321	Pancreatic Cancer <i>(CA19-9)</i>				
	TLR7 Ligand	BNT411	Multiple ST <i>(TLR7)</i>	Start Phase 1		Report Phase 1/2	
	Infectious and Rare Diseases		Influenza		Start first study		
		Up to 10 Infectious Disease Indications			Start first Phase 1		
		5 Rare Disease Indications		Start first Phase 1			

Legend Expected begin of trial Expected data readout / update ST: solid tumors

# Building a 21<sup>st</sup> Century Immunotherapy Company

## 2020 Outlook

- 1** **5 trial updates** (incl. publishing BNT111 FixVac Melanoma Phase 1/2 data in peer reviewed journal)
- 2** Initiate **Phase 3 registrational trial** for BNT111 FixVac Melanoma
- 3** Initiate **2 additional iNeST trials** in adjuvant stage cancers
- 4** Initiate **Phase 1/2 trial using CARVac (BNT211)** in CLDN6+ solid tumors (e.g., ovarian, testicular)
- 5** Initiate **Phase 2 trial in HPV16+ H&N cancer**
- 6** Continue to build **global clinical development organization** (US development team on East Coast)



An der Goldgrube 12  
55131 Mainz  
Germany

T: +49 6131 9084-0  
F: +49 6131 9084-390  
M: **info@biontech.de**