

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

FOR THE MONTH OF JANUARY 2020  
COMMISSION FILE NUMBER 001-39081

**BioNTech SE**

(Translation of registrant's name into English)

**An der Goldgrube 12 D-55131 Mainz  
Germany  
+49 6131-9084-0**

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F: Form 20-F  Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

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**EXHIBITS**

Exhibit

Description of Exhibit

99.1

Presentation: Corporate Presentation January 2020.

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**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

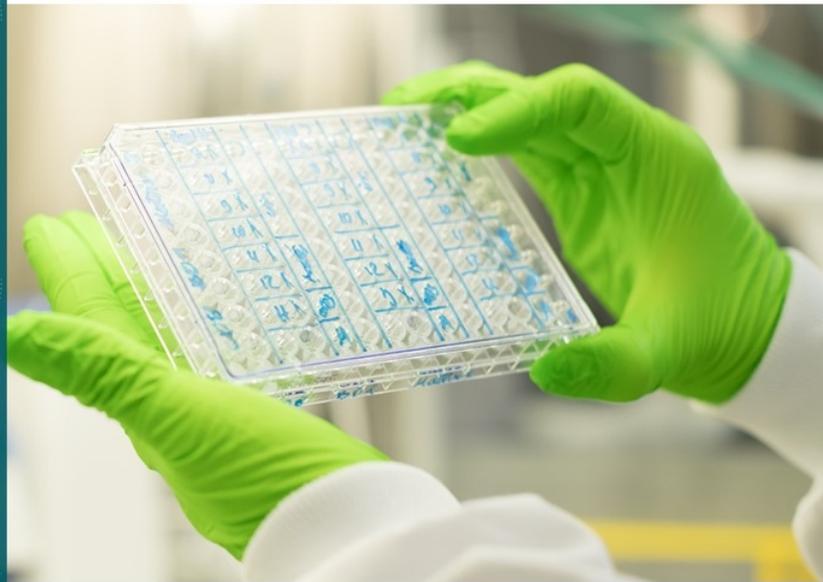
**BioNTech SE**

By: /s/ Dr. Sierk Poetting  
Name: Dr. Sierk Poetting  
Title: Chief Financial Officer

Date: January 27, 2020

**Corporate  
Presentation**

January 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, 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 key platforms and programs



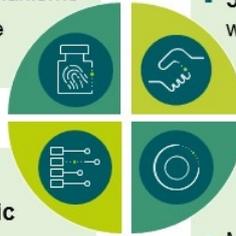
Outlook in 2020 and beyond

# 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

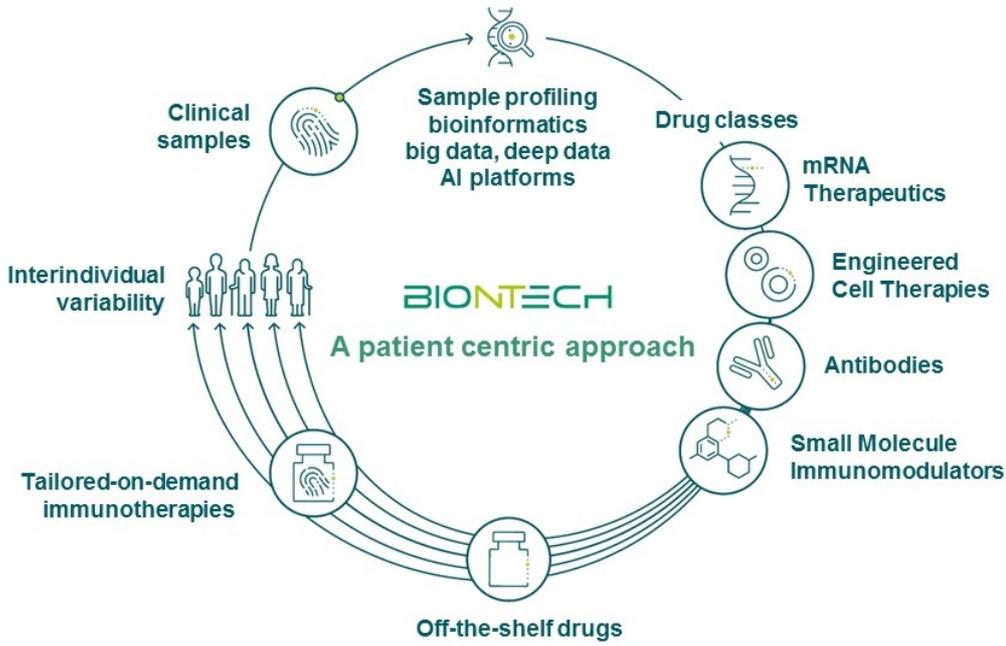
- More than **USD 90bn solid tumor market**<sup>3</sup> addressed
- Commercialization or co-commercialization rights retained in key geographies



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

4 <sup>1</sup>with Genentech and Genmab; <sup>2</sup>BNT111; <sup>3</sup>Source: Global Data Total WW Market, top 10 available products 2018-2024 + other

# 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

## Achievements 2019 and Outlook 2020

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### 2019 accomplishments:

- Raised USD 225m in Series B financing and USD 149m in Nasdaq IPO
- Initiated 6 clinical trials across 2 drug classes and 4 different platforms
- Started first randomized phase 2 trial for iNeST
- Dosed more than 440 patients across all BNTX programs<sup>1</sup> as of end 2019
- Entered into strategically important agreements with Bill & Melinda Gates Foundation and Regeneron
- Site for building new iNeST manufacturing facility purchased, planning and design work initiated, secured loan of USD 55m (EUR 50m) from European Investment Bank (EIB)

### Goals for 2020:

- Start 8 or more clinical trials (alone or with our collaborators)
- Move FixVac into a pivotal phase 3 trial and iNeST into additional phase 1/2 clinical trials
- Further invest in individualized manufacturing capacities
- Establish presence on East Coast of US

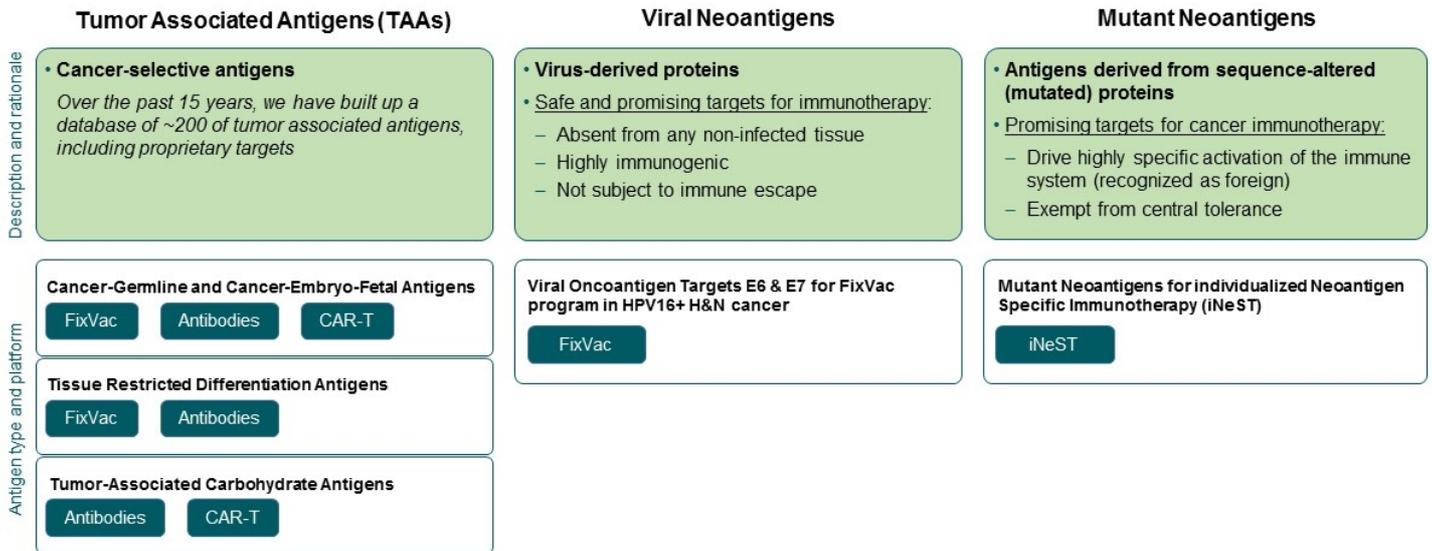
6 <sup>1</sup> BNTX programs: all BioNTech trials including trials sponsored by collaborators

## A technology agnostic approach increases our addressable market

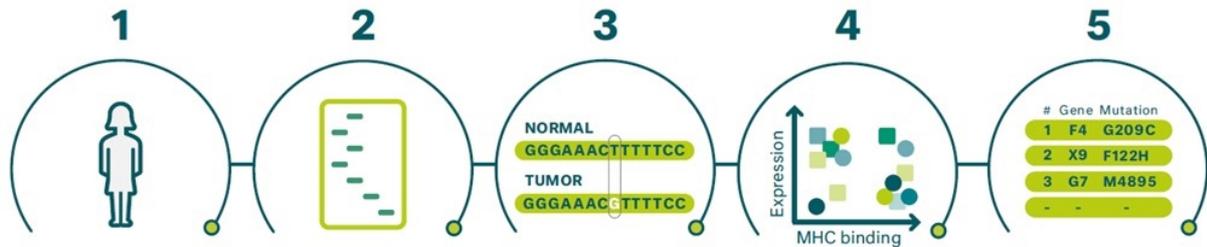
Cancer segment	Patient Population	Challenge	Our Therapeutic Strategy
High mutational burden/ adjuvant stage cancers	Significant portion of cancer patients	Poor risk-benefit profile of checkpoint inhibitors	<ul style="list-style-type: none"> <li>• <b>mRNA Neoantigen Immunotherapy (iNeST)</b></li> </ul>
Low mutational burden cancers	>60% of cancers	Poor response to checkpoint inhibitors	<ul style="list-style-type: none"> <li>• <b>Shared Antigens (FixVac, CAR-T cells, Antibodies)</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>mRNA Immunotherapy</b></li> <li>• <b>Immunostimulatory Compounds (intratumoral, RiboCytokines)</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>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>Engineered Cell Therapies</b></li> <li>• <b>Combination Therapies</b></li> </ul>

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

## ...and enables us to exploit our proprietary cancer antigen library



# We have pioneered a truly individualized immunotherapy approach...



Unique patient

Sequencing patient's tumor

Mapping of mutations

Bioinformatic algorithms

Selection of neoepitopes

**Sequencing**

- Sequence patient's tumor and healthy tissue using **next-generation sequencing technology**
- Compare patient's sequenced tumor and healthy samples to **identify targets for the design of individualized cancer immunotherapies**

**Mutation Detection (MyMUT<sup>1</sup>)**

- Technology combines tumor modeling with mutation detection
- **MyMUT is a next-generation mutation detection system** combining
  - High specificity
  - Robustness at low tumor content
  - Intratumor heterogeneity
  - Quality control
  - Suitable for routine clinical specimen

**Neoepitope Selection**

- Only a portion of mutated peptides (neoepitopes) are suitable for raising an immune response in vivo.
- Our approach **focuses on evoking responses involving both CD8+ T cells and CD4+ T cells**
- **Continuously evolving Machine Learning and Artificial Intelligence algorithms**, data collection from various sources

## ...and ability to leverage deep OMICS capabilities across all our platforms

### Molecular Cancer Profiling

- Next-generation sequencing (NGS)
- Genomics
- Bioinformatics, Machine Learning, Artificial Intelligence
- High-Performance Computing

#### HT NGS

- HiSeq
- NovaSeq 6000
- 10X Genomics Chromium



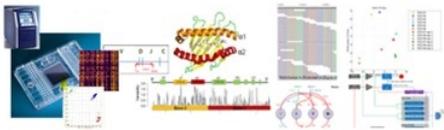
#### HT qRT-PCR

- Fluidigm Biomark



#### NGS analysis pipelines

- seq2HLA
- MyMut®
- uMut®

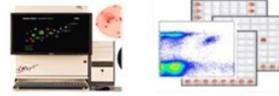


### Immune Response Analyses

- Target validation (CD8+, CD4+, antibodies)
- Pre-clinical models & mode of action
- Immunology & immune therapies

#### Immune monitoring

- Flow cytometry and sorting
- ELISpot



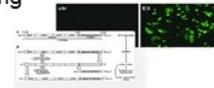
#### Animal models and imaging

- Syngeneic and xenogeneic models
- In vivo imaging



#### Target expression

- RNA vectors
- Cloning



#### Histology

- Immunohistochemistry
- Cryo-immunofluorescence



Collaboration with TRON Translational Research Center

# Our strategy to commercialize our own products is reflected by differentiated collaboration agreements

## Collaborating with leaders in oncology

### 50:50 Cost and Profit share (2016)

- Co-development and Co-commercialization of novel mRNA-based, individualized cancer vaccines (iNeST – BNT122)
- USD 310m upfront & near-term payments
- 50/50 cost and profit share on global profits
- Genentech conducting ongoing clinical trials
- BioNTech with right to co-commercialize in the US and certain European markets

### 50:50 Cost and Profit share (2015)

- Co-Development and co-commercialization of Bispecific antibodies (BNT311, BNT312)
- USD 10m upfront milestones
- 50/50 cost and profit share on global profits
- Genmab conducting ongoing clinical trials
- BioNTech with right to co-commercialize worldwide

### Cost and Profit share (2015)

- Development and commercialization of up to 5 intratumoral mRNA cancer immunotherapies, e.g., BNT131
- USD 60m upfront and milestones; extended collaboration in 2018 with equity investment
- Potential for up to EUR 260m in development, regulatory, and commercial milestones on each of the immunotherapies (with up to low double-digit royalties on net sales)
- Option to convert the financial terms for 2 of these immunotherapies to a cost and profit share arrangement (first option exercised)
- BioNTech with right to co-commercialize in the US and certain EU markets

## Our other collaboration agreements are structured to expand our footprint while managing risk

### Collaborating with leaders in oncology, infectious diseases and rare diseases

#### Co-development Co-commercialization (2018)

BIONTECH GENEVANT

- Co-development and Co-commercialization agreement for 5 mRNA protein replacement therapies for rare diseases
- 50/50 global cost and profit share
- For each co-development project, one or the other party will take lead responsibility for commercialization (and book sales)
- 5 exclusive oncology LNP licenses to BioNTech – Genevant to receive milestones and royalties on oncology licenses

#### Licensing Agreement (2018)

BIONTECH Pfizer

- mRNA based prophylactic flu vaccine (BNT161)
- USD 120m in upfront, equity investment and first milestones
- Up to USD 325m in potential additional milestone payments
- Up to very low double-digit royalties on worldwide sales

#### Strategic R&D Alliance (2018)

BIONTECH UPenn

- mRNA based vaccines in up to 10 infectious disease collaborations
- R&D payments to Penn of USD 15m, with USD 5m paid on signing
- UPenn to conduct preclinical testing of mRNA vaccine compounds
- BioNTech retains the option to license in the mRNA vaccine candidates for clinical development; milestones and royalties to be paid under certain circumstances

#### R&D Agreement (2019)

BIONTECH BILL & MELINDA GATES FOUNDATION

- HIV and tuberculosis (TB) and up to 3 additional infectious diseases
- USD 55m as an equity investment to advance prevention and/or treatment of HIV and TB
- Up to USD 45m in additional grants to fund additional activities in up to 3 additional infectious disease projects within the first 5 years of the collaboration

#### Licensing Agreement (2015)

BIONTECH Lilly

- Novel tumor targets and corresponding T-cell receptors
- USD 60m in upfront and equity investment
- Potential development, regulatory, and commercial milestones up to an aggregate of approx. USD 300m
- Up to very low double-digit royalties per drug candidate

## We own in-house manufacturing capabilities for individualized treatments

We intend to further strengthen our position as a leader in the highly automated, on-demand production of individualized therapies.

### mRNA Manufacturing:

- Unique process utilizing digitization and automation/robotics to ensure robust, consistent repeatability, quality control and on-demand manufacturing
- **2 mRNA GMP production facilities:** Idar-Oberstein (GMP since 2011) and Mainz (GMP since 2018)
- Completion and GMP licensure of new Mainz facility for iNeST expected in 2022/23



### Cell & Gene Therapy Manufacturing:

- **Innovative and robust** cell therapy manufacturing process
- Idar-Oberstein: GMP certified cell and gene therapy facility **since 1999**
- Ongoing facility **expansion** providing additional, state-of-the-art cell therapy manufacturing capacity



## We are led by an experienced and entrepreneurial team

### Management



**Prof. Ugur Sahin, MD**  
Co-Founder and CEO



**Sean Marett**  
CBO / CCO



**Dr. Sierk Poetting**  
CFO / COO



**Dr. Özlem Türeci**  
Co-Founder and CMO



**Ryan Richardson**  
Chief Strategy Officer

### Supervisory Board

**Helmut Jeggle**

- Managing Director, Athos
- Former Head of Business Planning & Analyses at Hexal

**Michael Motschmann**

- Founder of MIG Verwaltungs AG
- Significant experience in building companies

**Prof. Christoph Huber, MD**

- Co-founder of BioNTech
- Prof. Emeritus at the Mainz University

**Dr. Ulrich Wandschneider**

- Former CEO at Asklepios Kliniken

### Scientific Advisory Board

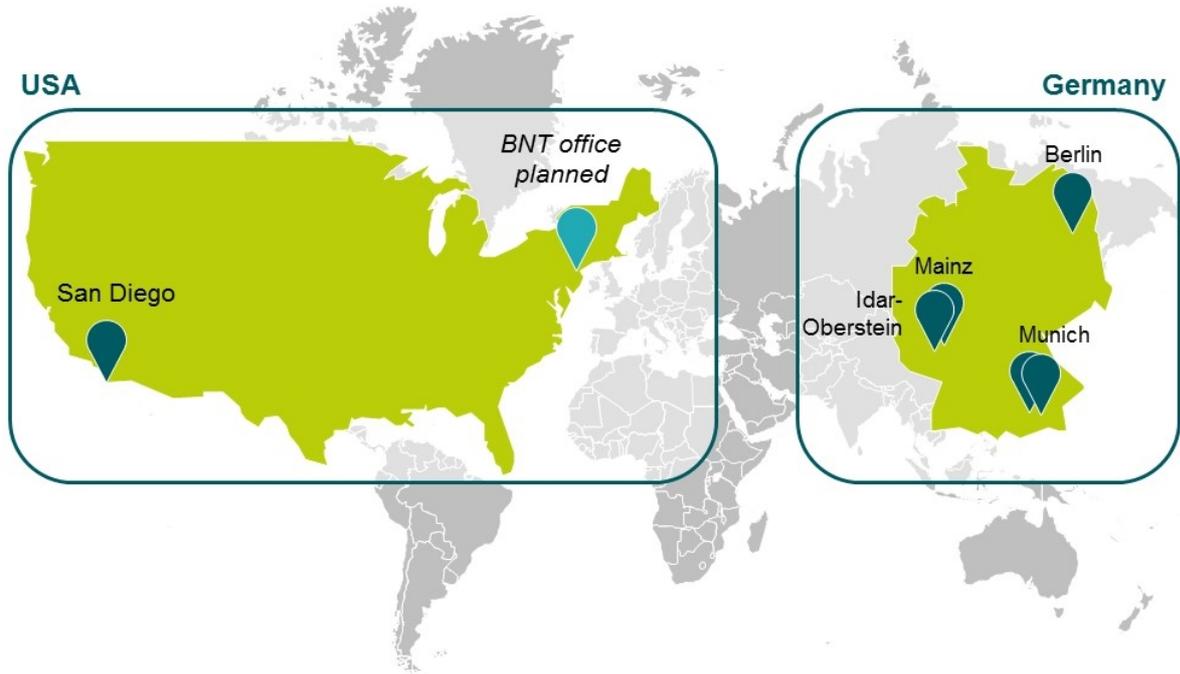
**Prof. Dr. Rolf Zinkernagel**

- Nobel Prize in Physiology or Medicine in 1996 for his discovery of immune recognition of virus-infected cells
- Professor Emeritus at Zurich University

**Prof. Dr. Hans Hengartner**

- Professor Emeritus at ETH Zurich and University of Zurich
- World renowned immunologist

## Building a global biotechnology company



# Agenda

Who we are and what we do

Our key platforms and programs



Outlook in 2020 and beyond

## We have a broad pipeline of mRNA product candidates in oncology

Drug Class	Platform	Product Candidate	Indication (Targets)	Preclinical	Phase 1	Phase 2	Rights Collaborator	Milestones
Oncology	mRNA	FixVac (fixed combination of shared cancer antigens)	BNT111	advanced melanoma (adjuvant & metastatic)			fully-owned	report phase 1 data and phase 2 start 1H 2020; phase 3 start 2H 2020
			BNT112	prostate cancer			fully-owned	
			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	
			BNT116	NSCLC			fully-owned	
	iNeST (patient specific cancer antigen therapy)	RO7198457 (BNT122 <sup>4</sup> )	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>5</sup>	

<sup>1</sup>BNT113 and BNT115 are currently being studied in investigator-initiated phase 1 trials; <sup>2</sup>Checkpoint Inhibitor; <sup>3</sup>Update on the ongoing study including patient enrollment number, efficacy and safety data for an interim update expected in the second half of 2021; <sup>4</sup>BNT122 (iNeST) is also being investigated in arm 2 (N=15) of the 3 arm TNBC-MERIT trial, with BNT114 as an optional treatment; BNT114 is investigated in arm 1 (N=12) and arm 3 (N=15) of the TNBC-MERIT trial (total patients in study: N=42; <sup>5</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 have a broad pipeline of mRNA product candidates in oncology...

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	phase 1 start 2H 2020
		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	phase 1 start 1H 2020
		BNT152+ BNT153	multiple solid tumors (IL-7, IL-2)				fully-owned	phase 1 start 2H 2020 or 1H 2021

## We expect additional oncology trial starts in 2020 - with first data in 2021

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> × <i>4-1BB</i> )				Genmab (global 50:50 profit/loss)	data update 2H 2020
		GEN1042 (BNT312)	multiple solid tumors ( <i>CD40</i> × <i>4-1BB</i> )					-
	Targeted Cancer Antibodies	BNT321 (MVT-5873)	pancreatic cancer ( <i>sLe<sup>a</sup></i> )				fully-owned	
SMIM <sup>6</sup>	Toll-Like Receptor Binding	BNT411	solid tumors ( <i>TLR7</i> )				fully-owned	phase 1 start 1H 2020

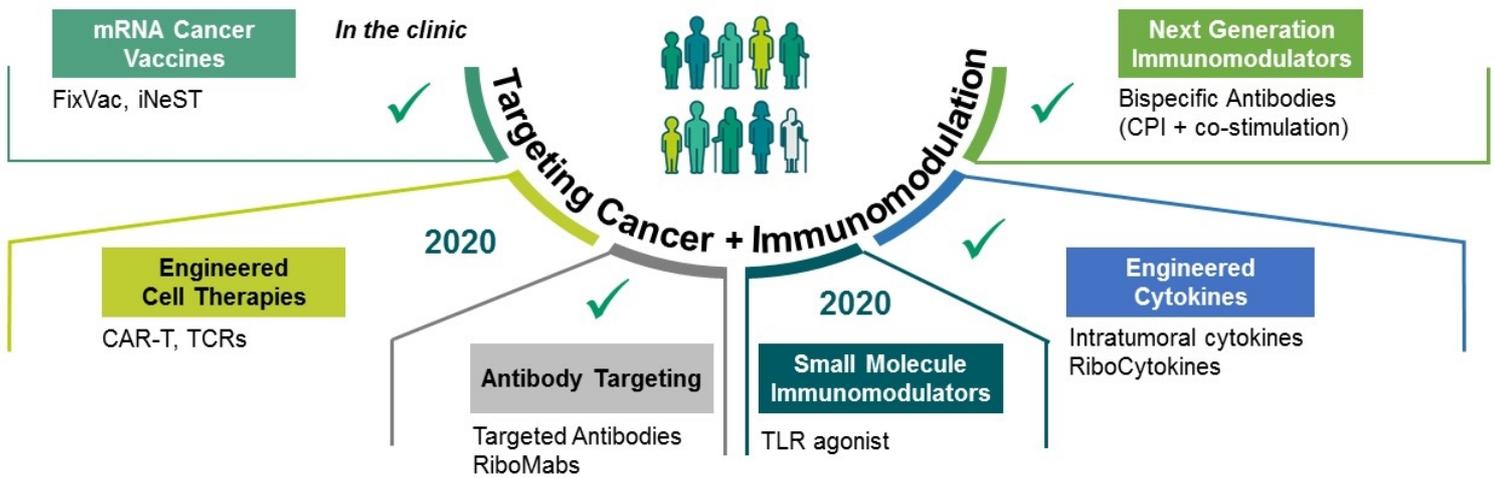
<sup>5</sup>Checkpoint; <sup>6</sup>Small Molecule Immunomodulators

## Our first trial starts outside of oncology are expected by the end of 2020

Drug Class	Platform	Product Candidate	Indication (Targets)	Preclinical	Phase 1	Phase 2	Rights Collaborator	Milestones
mRNA Other	Infectious Disease Immunotherapies	Undisclosed	Influenza				Pfizer	start first study by end of 2020
		Undisclosed	up to 10 indications				Penn <sup>1</sup>	first phase 1 trial to start 1H 2021
		Undisclosed	HIV and tuberculosis				Bill & Melinda Gates Foundation	-
	Rare Disease PRT <sup>2</sup>	BNT171	Not disclosed				Genmab (global 50:50 profit/loss)	first phase 1 trial to start 2H 2020
		Undisclosed	5 rare disease indications					-

<sup>1</sup>We are eligible to receive worldwide licenses; <sup>2</sup>Protein Replacement Therapy

# Our IO strategy exploits complementary therapeutic platforms



**We expect to have all core platforms in the clinic by the end of 2020**

# Agenda

Who we are and what we do

Our key platforms and programs



mRNA vaccines – FixVac and iNeST

Antibodies

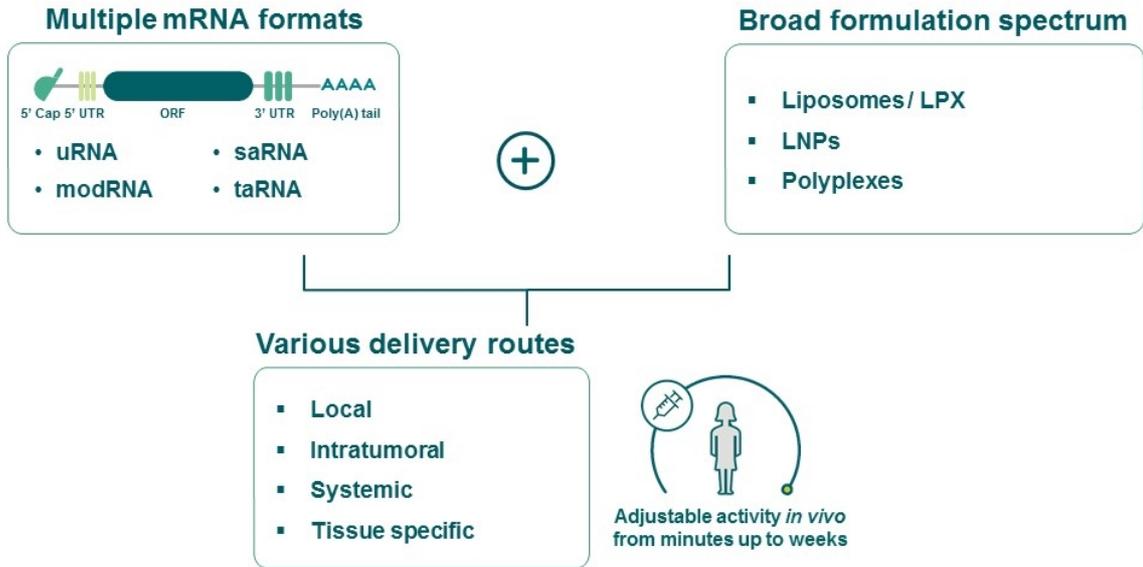
CARVac platform – CLDN6 CAR-T

RiboCytokines

Small Molecule Immunomodulator program

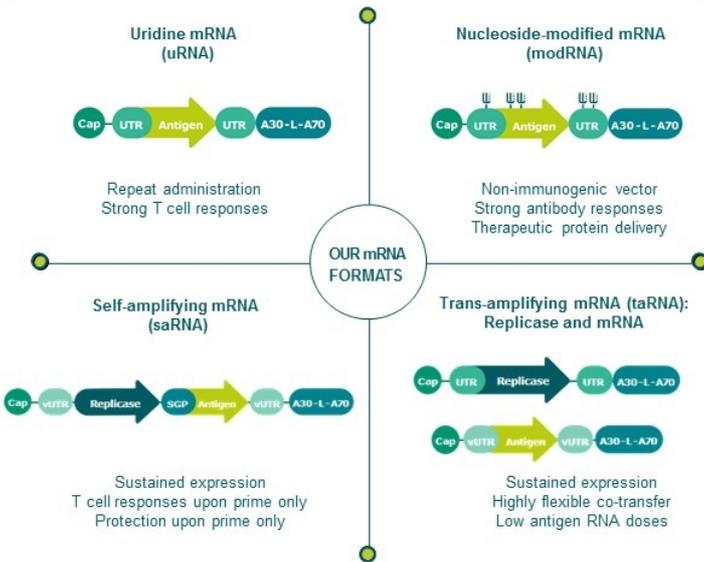
Outlook in 2020 and beyond

# One of the broadest mRNA toolkits in the industry

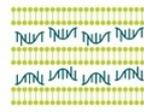


# We have developed multiple proprietary mRNA formats and formulations

## Our mRNA formats



## Our mRNA delivery formulations



**Lipoplexes**  
(FixVac, iNeST, CARVac)



**LNPs**  
(RiboMabs, RiboCytokines, Rare Disease)



**Polyplexes**  
(Discovery Programs)

- **Lipoplex:** Our lipoplex formulation, or LPX, embeds the mRNA between a lipid bilayer, which is used for our FixVac and iNeST platforms
- **LNPs:** For other applications, we encapsulate our mRNA in lipid nanoparticles, or LNPs. These formulations are suitable for our RiboMab, RiboCytokine and rare disease protein replacement therapy platforms
- **Polyplexes:** Our portfolio also comprises polyplexes, which are being utilized in certain of our discovery programs, in which the mRNA is bound to a polymer and then forms nanoparticles

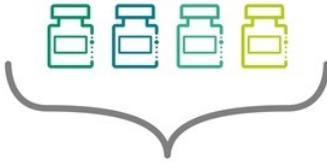
## We are developing multiple mRNA therapeutic platforms

	mRNA Platform	Drug Targets	mRNA Formats	Delivery Formulations
	7 mRNA platforms	Broad range of biological targets	4 types of mRNA	Multiple optimized formulations
Oncology	FixVac	Shared Antigens	uRNA	RNA-LPX
	iNeST	Neoepitopes	uRNA	RNA-LPX
	Intratumoral Immunotherapy	Immunomodulators	modRNA	Various formulations Intratumoral
	RiboMabs	mAb targets	modRNA	LNPs Intravenous delivery
	RiboCytokines	Cytokines	modRNA	Various LNP formulations
Other	Infectious Disease Vaccines	Pathogens	saRNA, taRNA, modRNA	Various LNPs for i.m. & s.c. delivery
	Rare Disease Protein Replacement Therapy	Diverse Proteins	modRNA	Liver targeted LNPs

uRNA: uridine mRNA; modRNA: nucleoside-modified mRNA; saRNA: self-amplifying mRNA; taRNA: trans-amplifying mRNA;

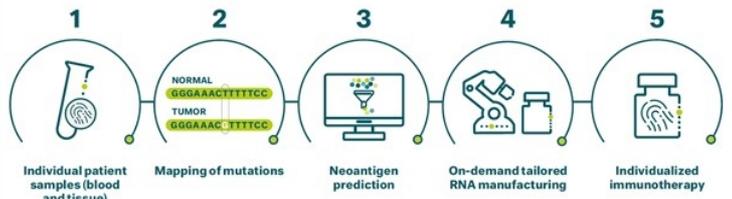
## Our mRNA vaccine platforms: FixVac and iNeST

### 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

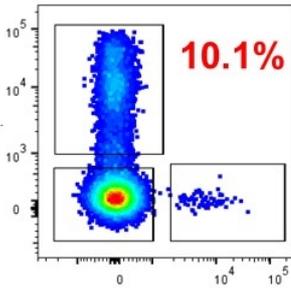


- **Fully individualized mRNA immunotherapy**
- **Targeting 20 neo-antigens unique to each patient**
  - Vast majority of neo-antigens are unique to individual patients
  - Applicable across solid tumor types

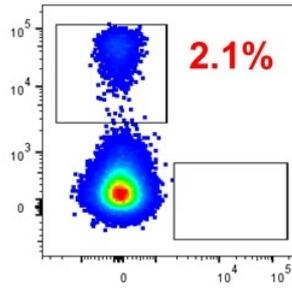
- **Proprietary RNA-LPX formulation for systemic dendritic cell targeting**
- **Strong immunogenicity observed *in vivo* via TLR7-driven adjuvant effect**
- **Potent induction of strong *ex vivo* CD4+ and CD8+ T cell responses**

## Our RNA-LPX vaccine approach

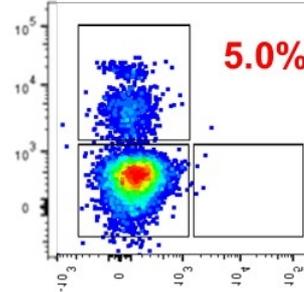
Strong vaccine-induced *ex vivo* CD8+ T cell responses<sup>1</sup> across different cancer types



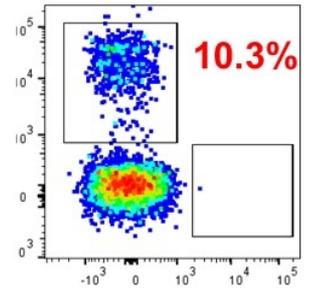
**NY-ESO-1**  
Melanoma  
BNT111, Lipo-MERIT trial



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



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



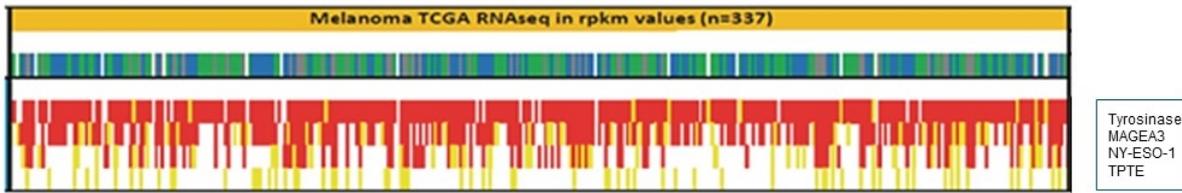
**Mutant Neoantigen**  
TNBC  
BNT114, TNBC MERIT trial

FixVac

iNeST

27 <sup>1</sup>T cell responses analyzed by *ex vivo* multimer staining analysis in blood

## Cumulative patient coverage of FixVac Melanoma targets is over 90%

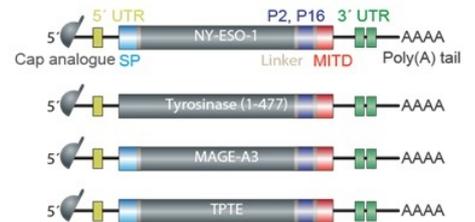


- **Computational pipeline for antigen-discovery and RT-PCR validation**
  - RNA-Seq data from 337 melanoma samples in TCGA
- **Target-criteria**
  - High expression in melanoma
  - No expression in toxicity-relevant normal cells and tissues
  - Coverage of as many patients as possible with at least 1 antigen
  - Coverage of a substantial fraction of patients with more than 1 antigen

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

### Summary

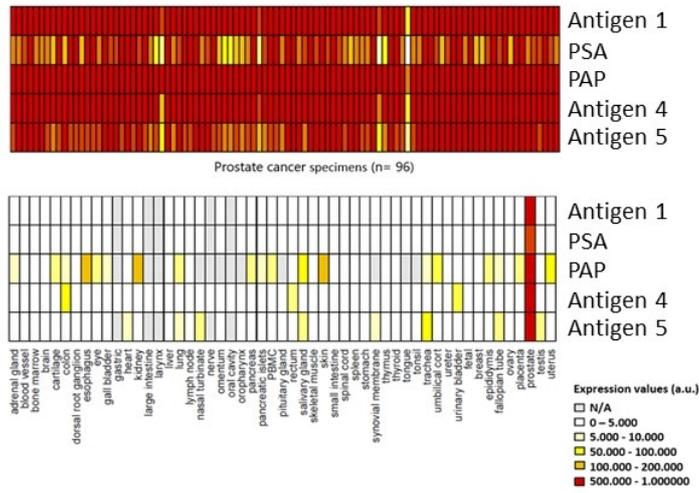
- Advanced melanoma patients (stage III, IV)
- Out of **74 patients** with available follow-u radiological imaging **42 patients** were assessed for preliminary analysis as of July 29, 2019
- **of 25 patients** with metastatic melanoma who received BNT111 monotherapy following progression on CPI\* and in some cases other therapies
  - 3 patients with partial response (PR)
  - 1 patient with metabolic complete response
  - 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



### Shared Antigens Targeted

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

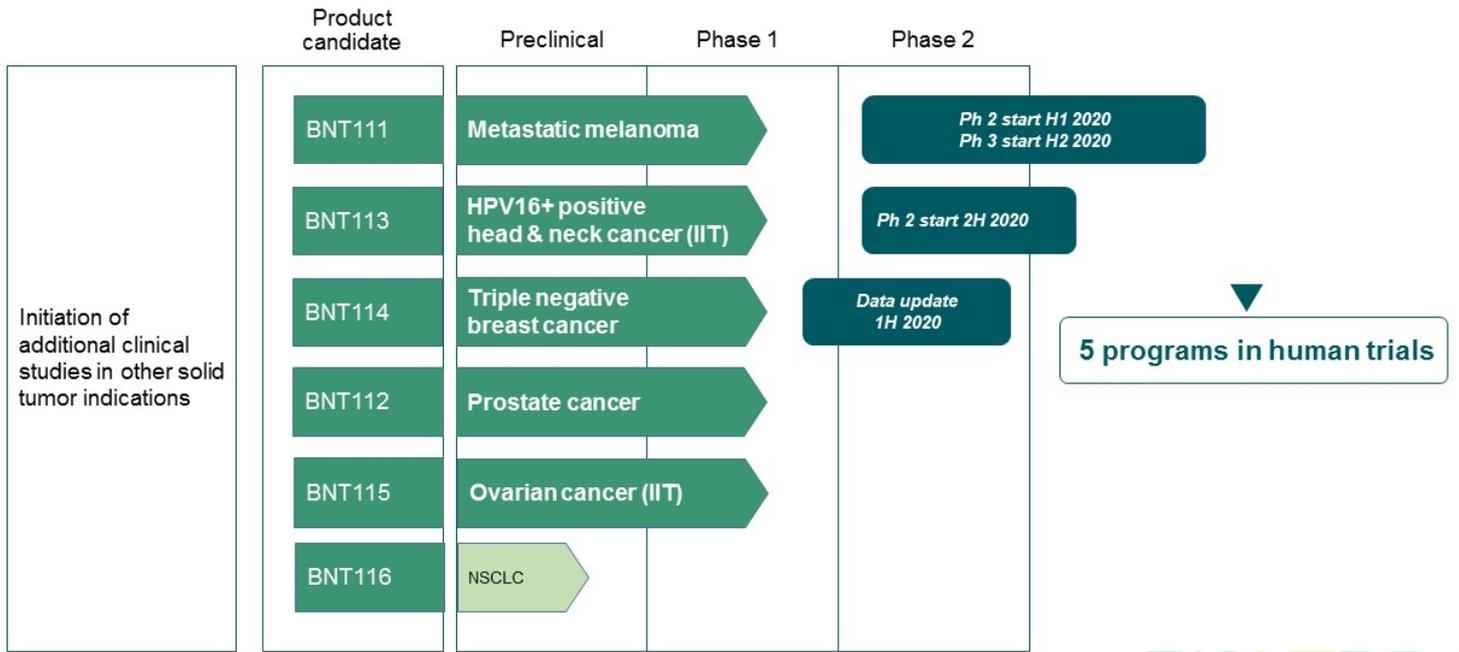
# BNT112: FixVac Prostate Cancer



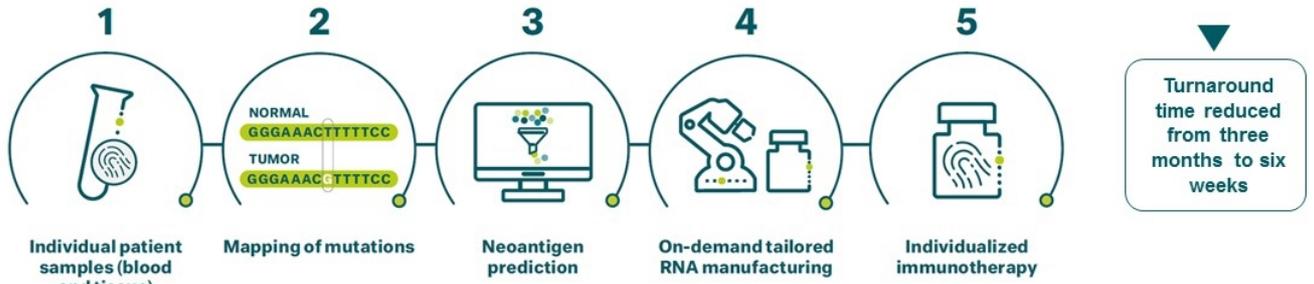
## Ph1/2: first patient enrolled in December 2019

- 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: a flexible format which can rapidly be adapted for different tumors

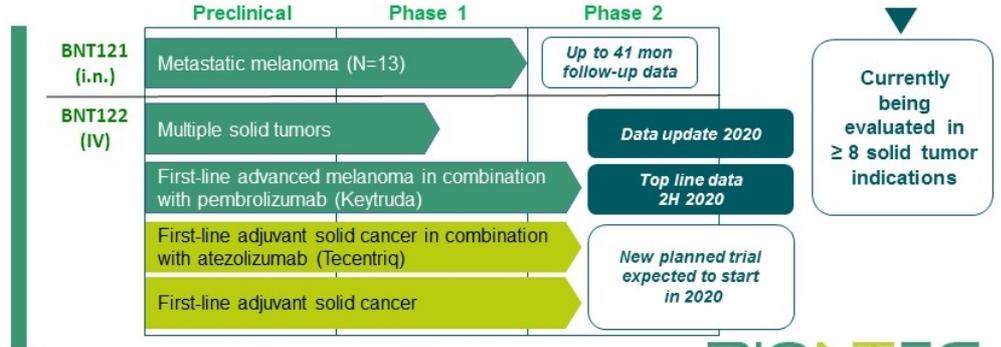


# Individualized Neoantigen Specific Immunotherapy (iNeST)



## Overview

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



## 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):

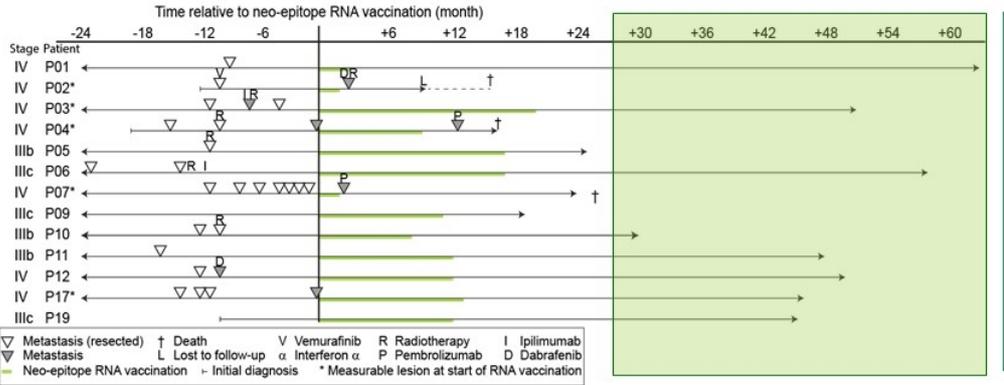
- iNeST can be manufactured for individual patients with clinically relevant turn-around times across a range of tumor types
- iNeST +/- atezolizumab (Tecentriq) has a manageable safety profile
- Strong iNeST immunogenicity across a range of tumor types

Clinical efficacy evaluation in randomized phase 2 trials initiated

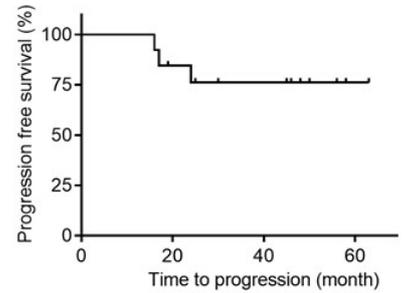
# Update for BNT121 (as of October 2019)

Melanoma Stage IIIB, IIIC, and IV, 13 patients, intranodal delivery against 10 neoantigens

## Metastatic relapse analyses

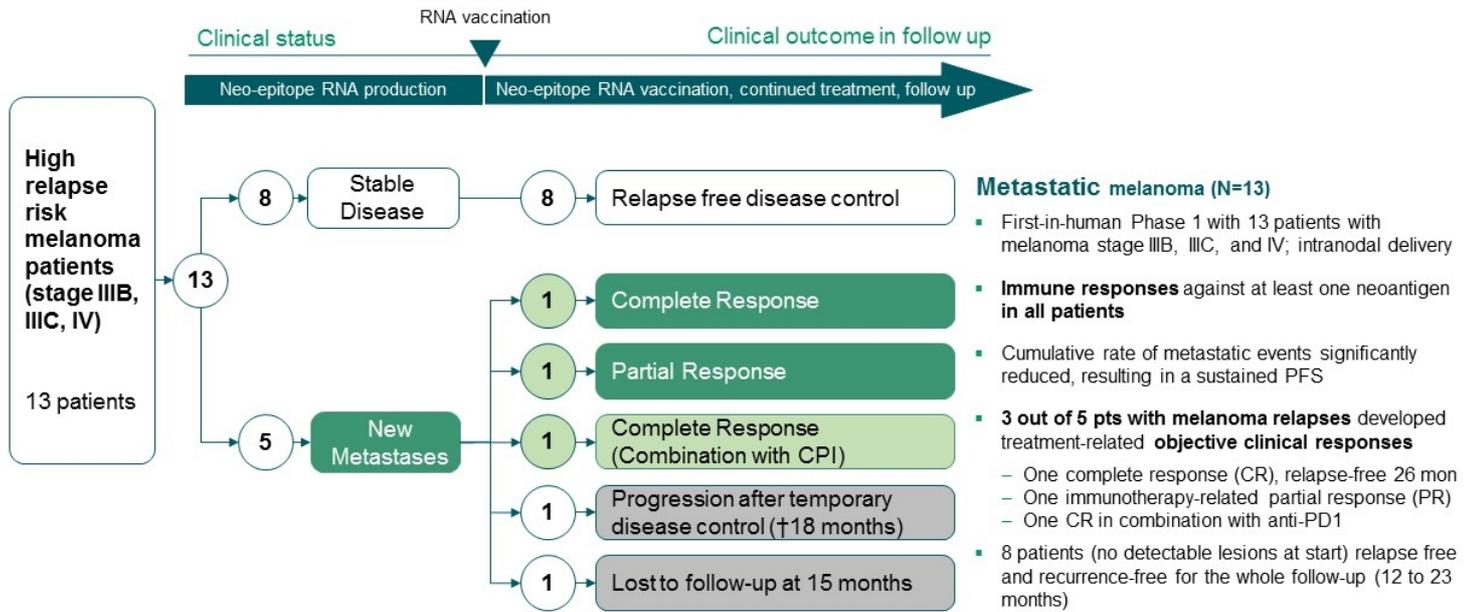


9 of 13 patients without documented PFS events



**Stable progression free survival in adjuvant melanoma**

# BNT121: Interim clinical activity data (dose range 14µg -100µg)

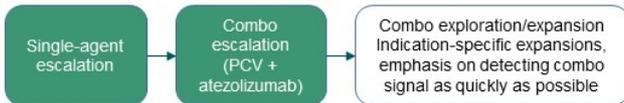


## iNeST: Results expected for phase 1 in 2020, for phase 2 in 2H 2020

### Phase 1a/1b in Multiple Solid Tumors: Open-label, dose-escalation study of safety and pharmacokinetics

Genentech

- **Enrollment:** Up to 770
- **Start date:** Dec 2017
- **Data update:** 2020
- **Tumor types:** Melanoma, NSCLC, bladder cancer, CRC, TNBC, renal cancer, H&N cancer, other solid tumors
- Phase 1a: Single-agent
- Phase 1b: Combination with atezolizumab



- Primary outcome measures in iNeST + atezolizumab treated participants compared with iNeST-only participants include:
- Dose-limiting toxicities (DLTs)
- Adverse events (AEs)

### Phase 2 in Advanced Melanoma: Interventional open-label, multicenter randomized study of efficacy and safety

Genentech

- **Enrollment:** 132
- **Start date:** Jan 2019
- **Topline data:** 2H 2020
- **Tumor types:** Advanced melanoma
- Phase 2: Combination with pembrolizumab

- Study to evaluate the efficacy and safety of iNeST in combination with pembrolizumab vs. pembrolizumab alone in participants previously untreated in advanced melanoma (first-line)

- Primary endpoint in iNeST+ pembrolizumab treated participants compared with pembrolizumab-only participants:
- Progression-free survival (PFS)

# 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

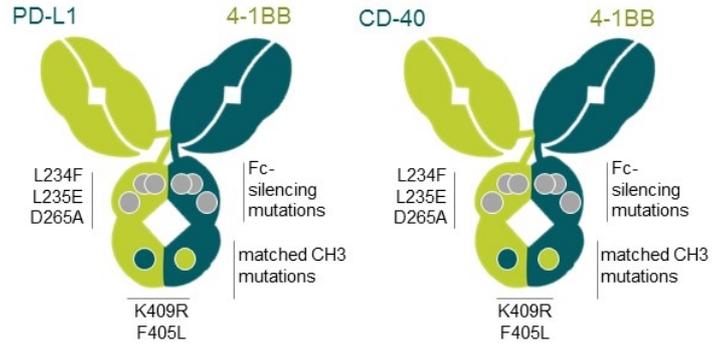
Small Molecule Immunomodulator program

Outlook in 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



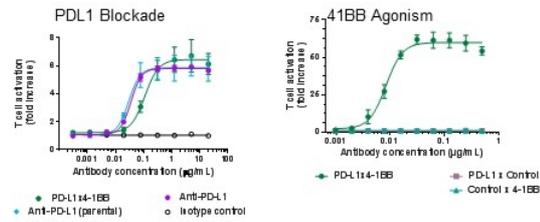
Product Candidate	Preclinical	Phase 1	Phase 2
BNT311 (GEN1046)	PD-L1x4-1BB	Ph1/2a	Data update 2H 2020
BNT312 (GEN1042)	CD-40x4-1BB	Ph1/2a	

# Next-Gen checkpoint immunomodulators

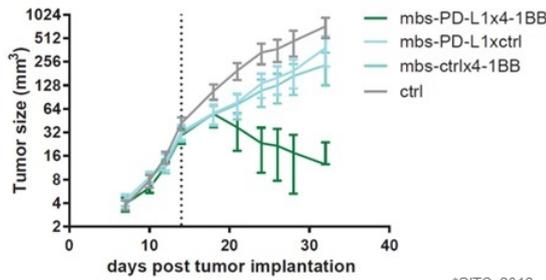
## Characteristics

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

### 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 blockade and is associated with an increase in tumor-specific CD8 T-cells

## Bispecific antibody GEN1046 (BNT311): Phase 1/2a in solid tumors

First-in-human, open-label, dose-escalation trial with expansion cohorts to evaluate safety of GEN1046 (PD-L1x4-1BB) in subjects with malignant solid tumors

- **Enrollment:** 192
- **Data update:** 2H 2020
- **Tumor types:** Malignant Solid Tumors

### Intervention:

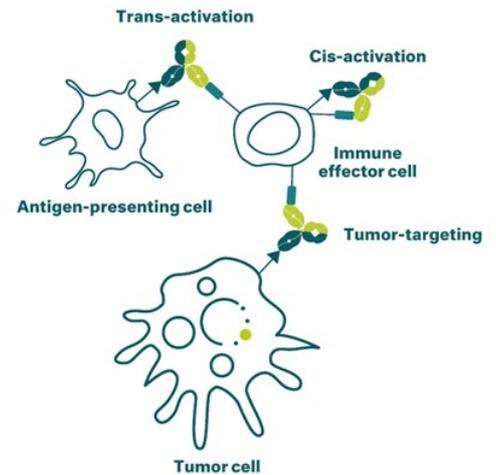
- GEN1046 (BNT311) is a PD-L1x4-1BB bispecific antibody that induces conditional activation of T cells through 4-1BB stimulation which is dependent on simultaneous binding to PD-L1
- GEN1046 (BNT311) IV once every 21 days
- Dose levels determined by the starting dose and the escalation steps taken in the trial

### Description:

- Open-label safety trial
- Two parts, a dose escalation (phase 1, first-in-human) and an expansion part (phase 2a)

### Key Primary endpoints:

- Dose limiting toxicity
- Adverse events
- Safety laboratory parameters



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

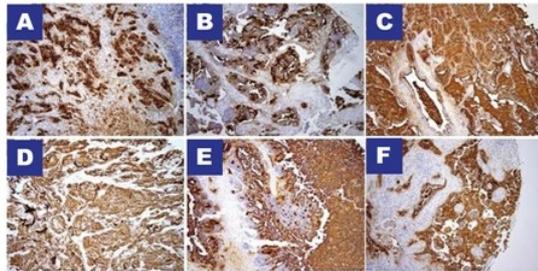
## Characteristics

- 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>

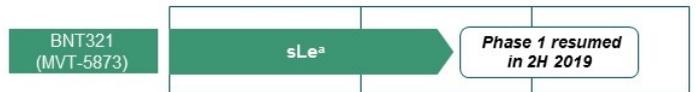
## Preliminary data

- 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



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Antibodies

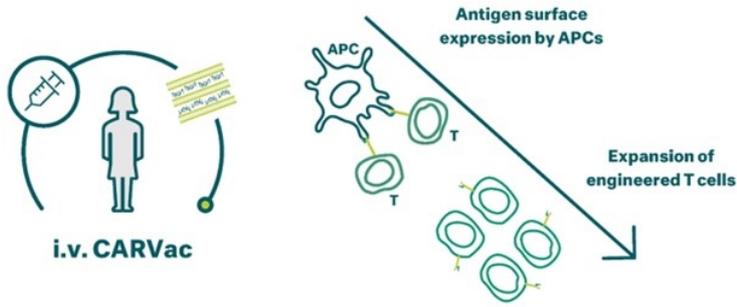
CARVac platform – CLDN6 CAR-T

RiboCytokines

Small Molecule Immunomodulator program

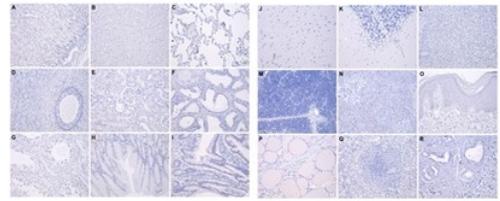
Outlook in 2020 and beyond

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

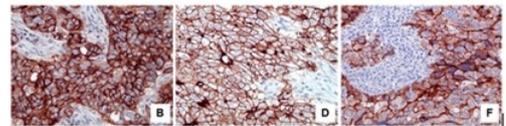


CAR-T cell therapy + RNA Vaccine to amplify CAR-T cell in vivo

CLDN6 is not present in healthy tissues



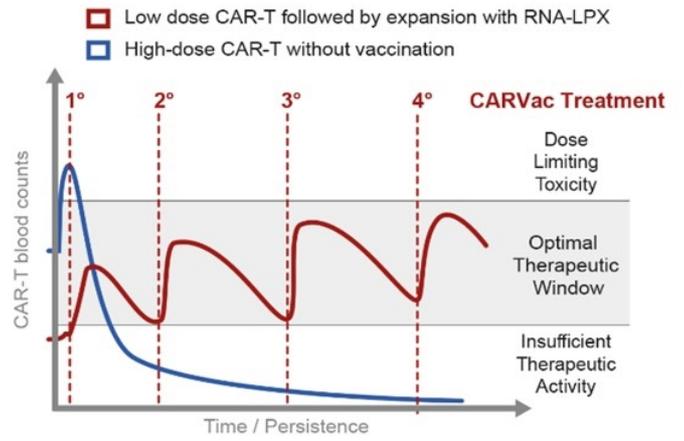
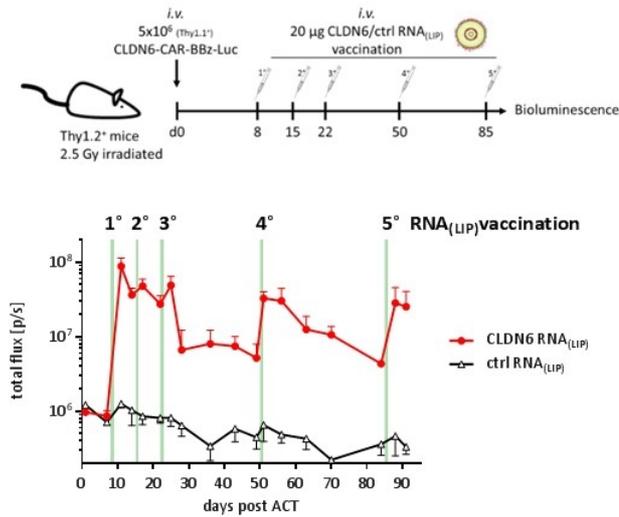
CLDN6 is expressed in multiple cancers



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

## 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).

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RiboCytokines

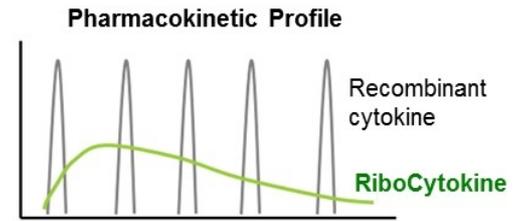
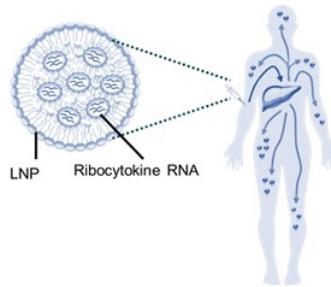
Small Molecule Immunomodulator program

Outlook in 2020 and beyond

# 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



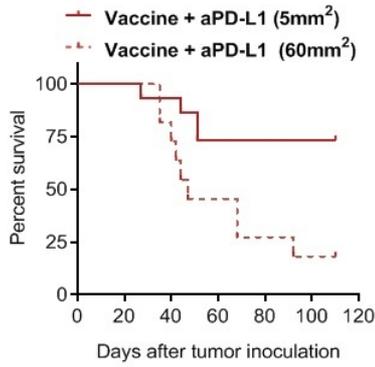
## Therapeutic Goals

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

Worldwide rights; wholly owned

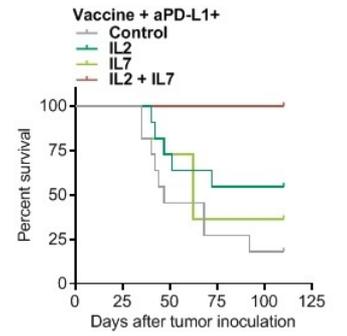
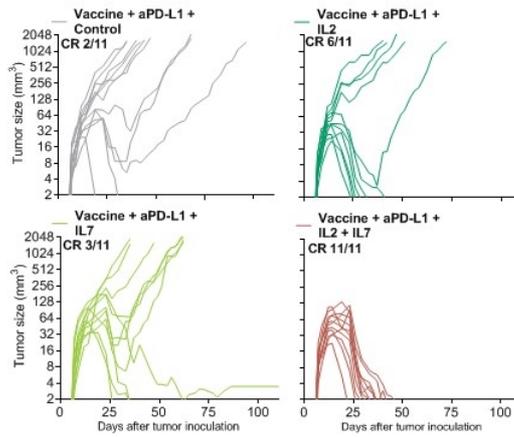
Product Candidate	Preclinical	Phase 1	Phase 2	
BNT151	Optimized IL-2			Expected to enter the clinic in 1H 2020
BNT152/ BNT153 combo	IL-7, IL-2			Expected to enter the clinic in 2H 2020

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



CT26 tumor model, vaccine antigen: gp70

## Vaccine + aPD-L1 +



CT26 tumor model, tumor size: 60mm<sup>2</sup>  
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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CARVac platform – CLDN6 CAR-T

RiboCytokines

Small Molecule Immunomodulator program

Outlook in 2020 and beyond

## BNT411: TLR7 agonist has entered the clinical stage

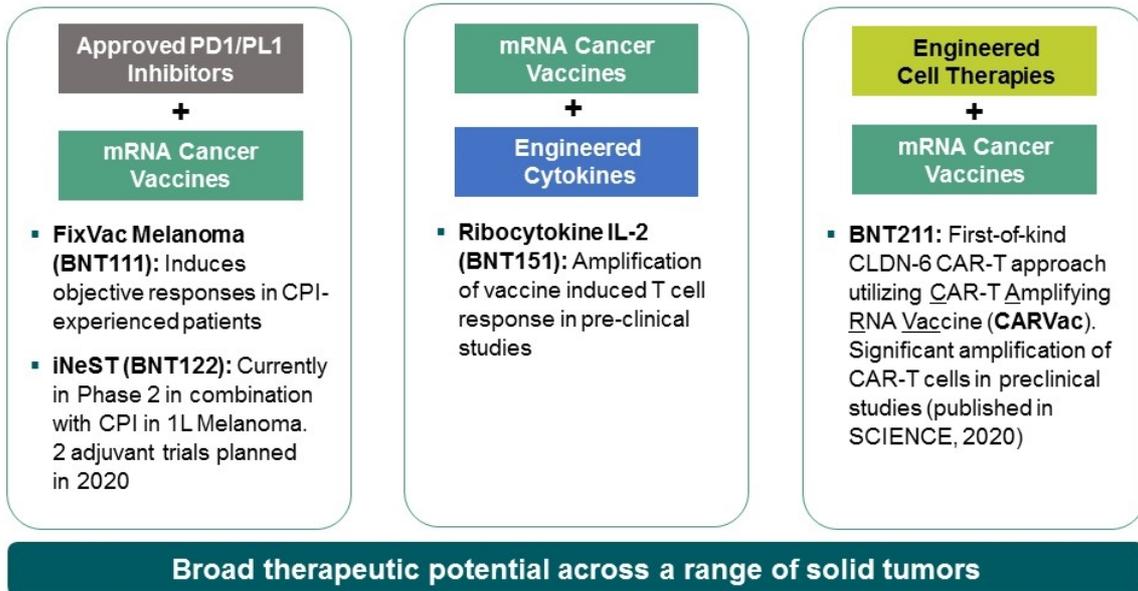
- Intravenously administered small molecule TLR7 (toll-like receptor 7) agonist
- Engineered for high potency and high selectivity for TLR7 receptor at the therapeutically active dose range
- Activates both adaptive and innate immune system
- Type 1 interferon-dominated release of cytokines and chemokines and potent stimulation of antigen-specific CD8+ T cells, B cells and innate immune cells such as NK cells and macrophages
- To be used in combination with chemotherapy and checkpoint inhibitors. Qualifies for various solid tumor indications and small cell lung cancer
- IND filed in November 2019
- We expect to initiate a Phase 1/2a clinical trial as a mono and combination therapy in solid tumors in H1/2020

### Planned study design for FIH trial:

Phase 1/2a, first-in-human, open-label, dose-escalation trial with expansion cohorts to evaluate 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-naive extensive-stage small cell lung cancer (ES-SCLC)

H1 2020

## Multiple angles for therapeutic synergy across platforms



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Outlook in 2020 and beyond

## We expect a significant news flow in the upcoming 12-18 months

Platform	Candidate	Indication (Target)	1H-2020	2H-2020	2021 <sup>3</sup>	2022 <sup>3</sup>
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 (IL-12sc, IL-15sushi, GM-CSF, IFNα)		Report Phase 1/2 <sup>2</sup>		
RiboMabs	BNT141	Multiple ST		Start Phase 1		
	BNT142	Multiple ST (CD3+CLDN6)		Start Phase 1		
RiboCytokines	BNT151	Multiple ST (Optimized IL-2)	Start Phase 1			Phase 1
	BNT152/153	Multiple Solid Tumors (IL-7, IL-2)		Start Phase 1		
CAR-T Cells	BNT211	Multiple ST (CLDN6)	Start Phase 1/2			Phase 1/2
Next-Gen CP Immunomodulators	BNT311	Multiple ST (PD-L1x4-1BB)		Report Phase 1/2		
	BNT312	Multiple ST (CD40x4-1BB)				
Antibodies	BNT321	Pancreatic Cancer (CA19-9)				
TLR7 Ligand	BNT411	Multiple ST (TLR7)	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

53 <sup>1</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>2</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; <sup>3</sup>Our expectations for timing of milestones beyond 2020 are premised on and subject to the achievement of earlier milestones on their expected timelines. Press releases will be issued once first patient has been dosed.

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

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### 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)

The logo for BionTech, featuring the word "BIONTECH" in a stylized, uppercase font. The letters "B", "I", "O", "N", "T", "E", and "C" are in a light green color, while "H" is in a darker green. The letters are spaced out and have a modern, sans-serif appearance.

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