

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):

EXHIBITS

Exhibit

Description of Exhibit

99.1

Presentation: Corporate Update January 2020.

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 13, 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

Our Vision: We aspire to individualize cancer medicine



Next generation immunotherapies for cancer and other diseases

- **Vertical integration** with in-house manufacturing
- Over 1,300 employees (~500 in R&D)¹



World-leading collaborators

- **7 pharmaceutical collaborators** and multiple leading academic institutions
- **50:50 cost and profit share agreements** with leaders in oncology²



Broad & diversified pipeline

- **10 product candidates in the clinic**
- First **registrational trial** start in H2 2020³

Large addressable market opportunity in solid tumors

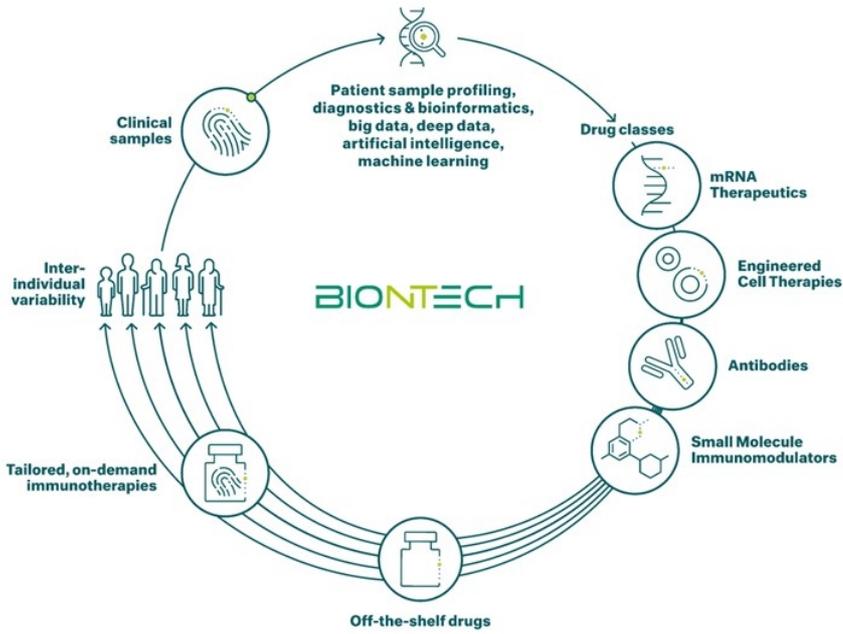
- Targeting some of the **largest oncology indications** with first-in-class potential
- Commercialization or co-commercialization rights retained in key geographies



Up to 5 clinical data updates expected in the next 12 months

4 ¹As of Dec 31, 2019; ²with Genentech and Genmab; ³BNT111

Our unique approach



Harnessing the full potential of the immune system

Broadening the universe of eligible patients

Improving the treatment success rate

Focusing on curative approaches

Achievements 2019 and Outlook 2020

2019 accomplishments:

- Raised \$225m in Series B financing and \$149m in Nasdaq IPO
- Initiated 6 clinical trials across 2 drug classes and 4 different platforms
- 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, European Investment Bank funding secured

Goals for 2020:

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

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

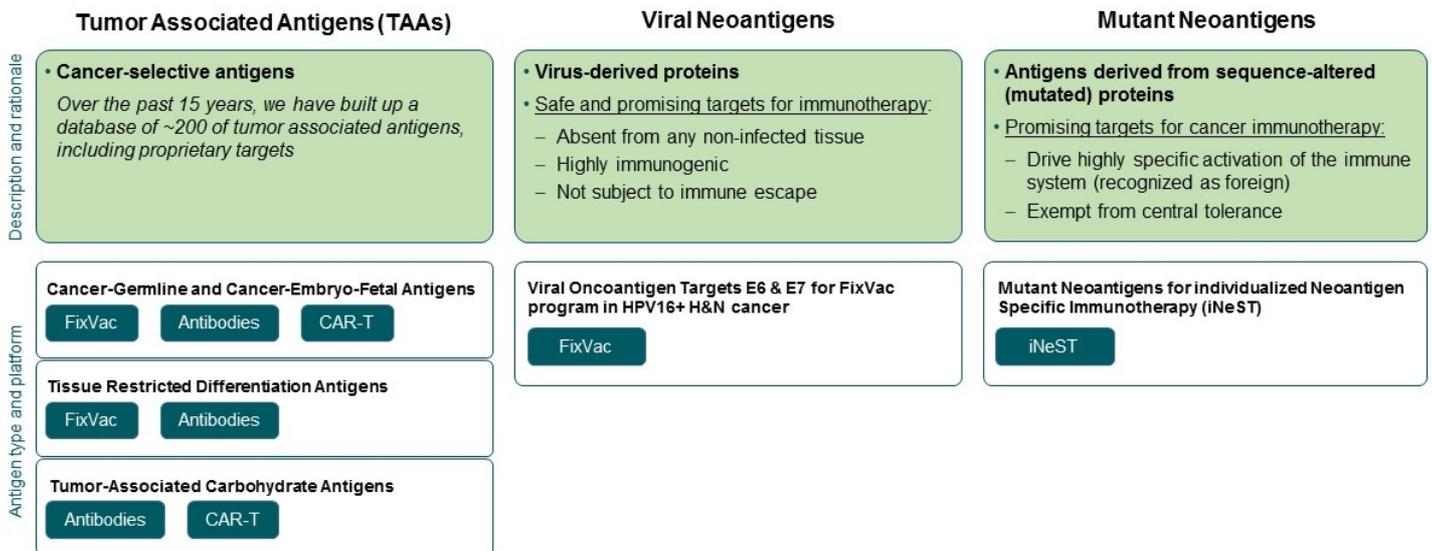


A technology agnostic approach increases our addressable market...

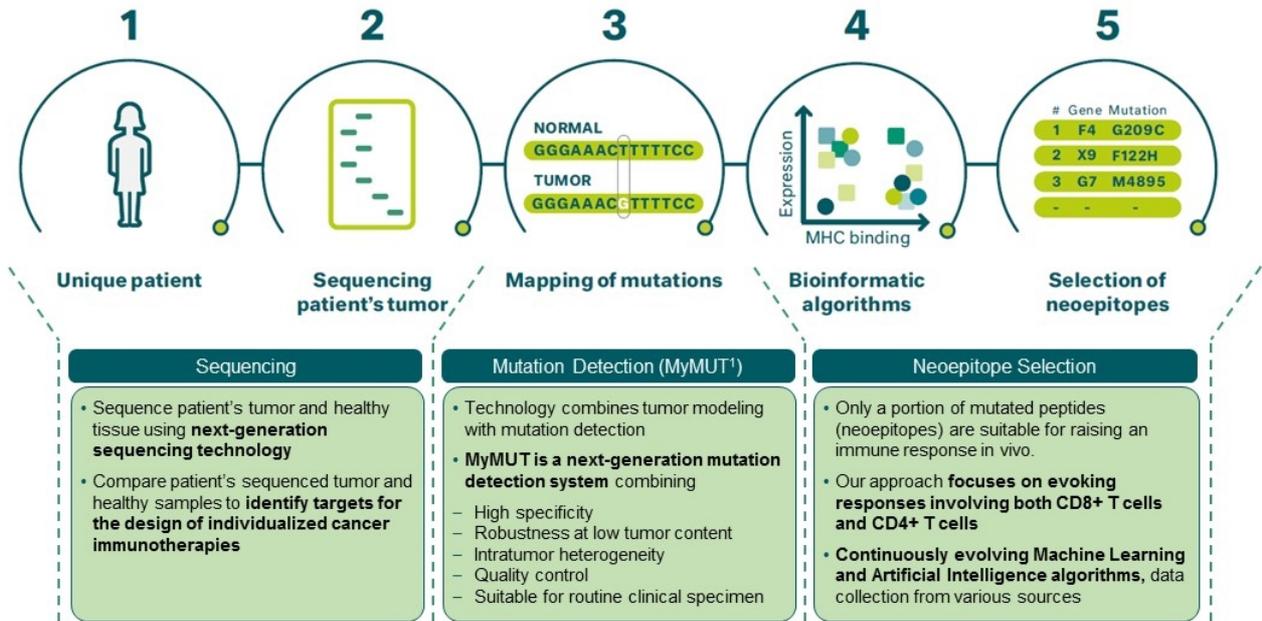
Cancer segment	Patient Population	Addressed Problem	Our Therapeutic Strategy	
High mutational burden/ adjuvant stage cancers	Significant portion of cancer patients	Poor risk-benefit profile of checkpoint inhibitors	<ul style="list-style-type: none"> • <i>mRNA Neoantigen Immunotherapy (iNeST)</i> 	
Low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

We believe a molecular classification and segmentation of cancer types based on an understanding of the challenges of current therapies is best suited to address the challenge of cancer.

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



We have pioneered a truly individualized immunotherapy approach...



...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



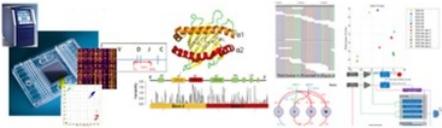
HT qRT-PCR

- Fluidigm Biomark



NGS analysis pipelines

- seq2HLA
- MyMut®
- uMut®

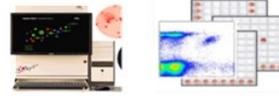


Immune Response Analyses

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

Immune monitoring

- Flow cytometry and sorting
- ELISpot



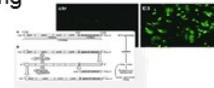
Animal models and imaging

- 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 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 (w/ 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 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 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

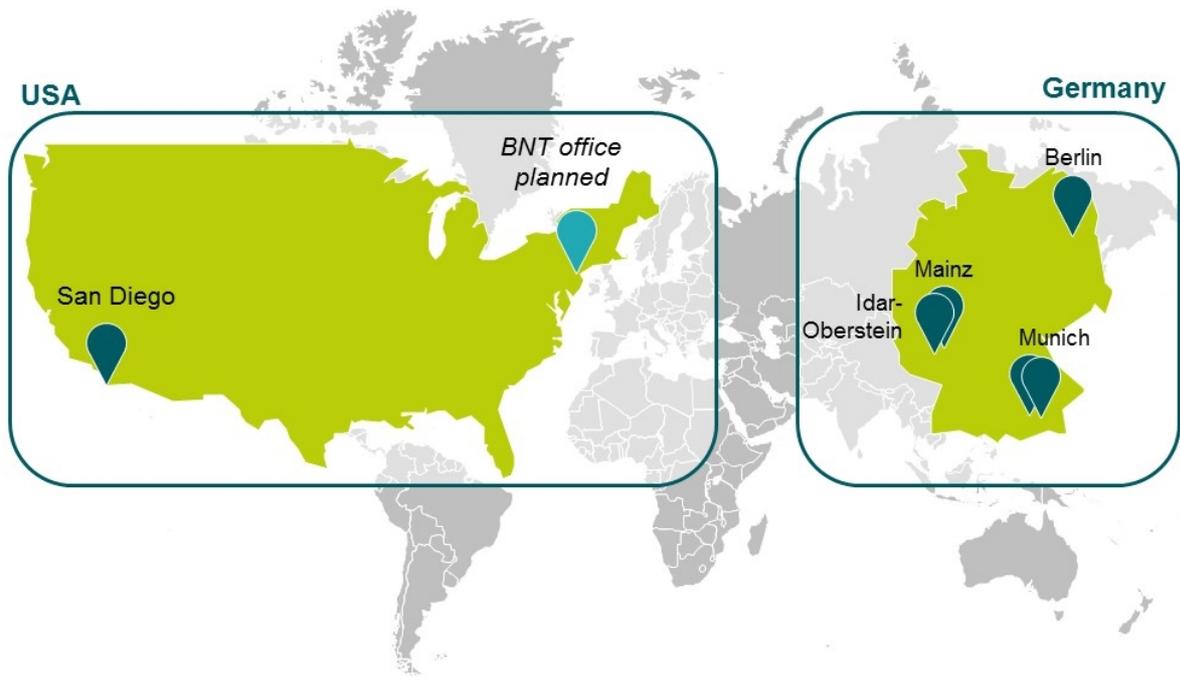
Prof. Dr. Rolf Zinkernagel

- 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
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	first patient enrolled in phase 1/2 in Dec 2019 (plan: 2H 2019) new
		BNT113	HPV+ head and neck cancer ¹				fully-owned	phase 2 start 2H 2020
		BNT114	triple negative breast cancer				fully-owned	data update 1H 2020
		BNT115	ovarian cancer ¹				fully-owned	new
		BNT116	NSCLC				fully-owned	-
	iNeST (patient specific cancer antigen therapy)	RO7198457 (BNT122)	1L melanoma with CPI ²				Genentech (global 50:50 profit/loss)	top line data 2H 2020 ³
			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 ⁴

¹BNT113 and BNT115 are currently being studied in an investigator-initiated Phase 1 trial; ²Checkpoint Inhibitor; ³We 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; ⁴As 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 (<i>CD3+CLDN6</i>)	▶			fully-owned	phase 1 start 1H 2021
	RiboCytokines (mRNA-encoded Cytokines)	BNT151	multiple solid tumors (<i>optimized IL-2</i>)	▶			fully-owned	phase 1 start 1H 2020
		BNT152+ BNT153	multiple solid tumors (<i>IL-7, IL-2</i>)	▶			fully-owned	phase 1 start 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 ⁵ Immunomodulators	GEN1046 (BNT311)	multiple solid tumors (<i>PD-L1</i> × <i>4-1BB</i>)				Genmab (global 50:50 profit/loss)	data update 1H 2021
		GEN1042 (BNT312)	multiple solid tumors (<i>CD40</i> × <i>4-1BB</i>)					-
	Targeted Cancer Antibodies	BNT321 (MVT-5873)	pancreatic cancer (<i>sLe^a</i>)				fully-owned	patient enrolled to resume phase 1 in Dec 2019 (plan: 2H 2019) new
SMIM ⁶	Toll-Like Receptor Binding	BNT411	solid tumors (<i>TLR7</i>)				fully-owned	phase 1 start 1H 2020

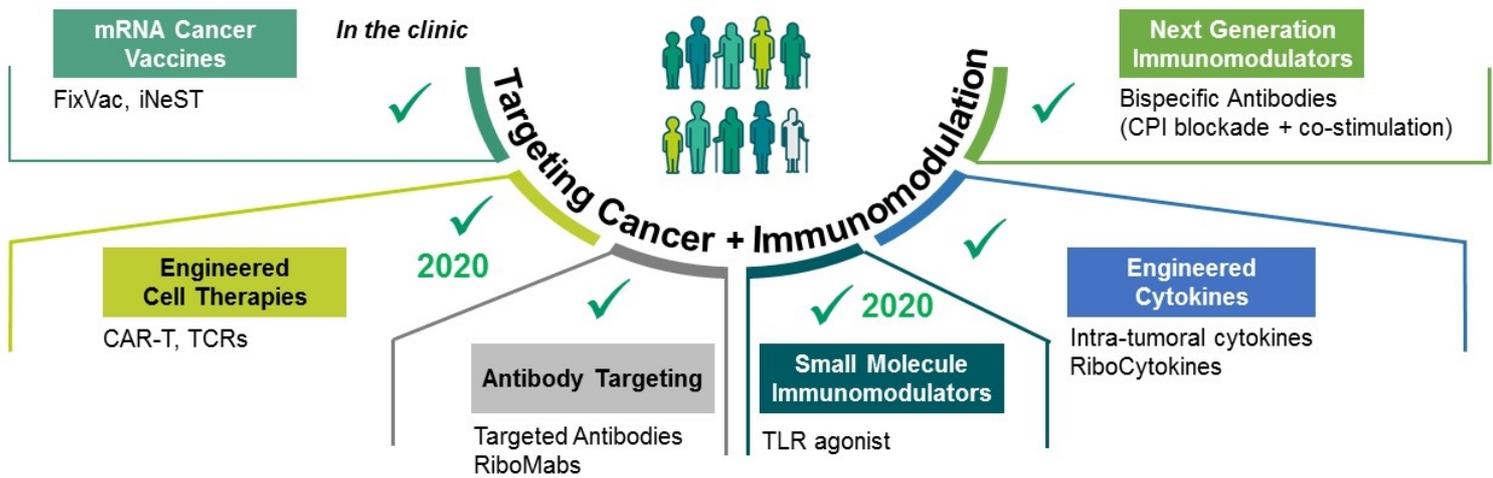
⁵Checkpoint; ⁶Small Molecule Immunomodulators

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

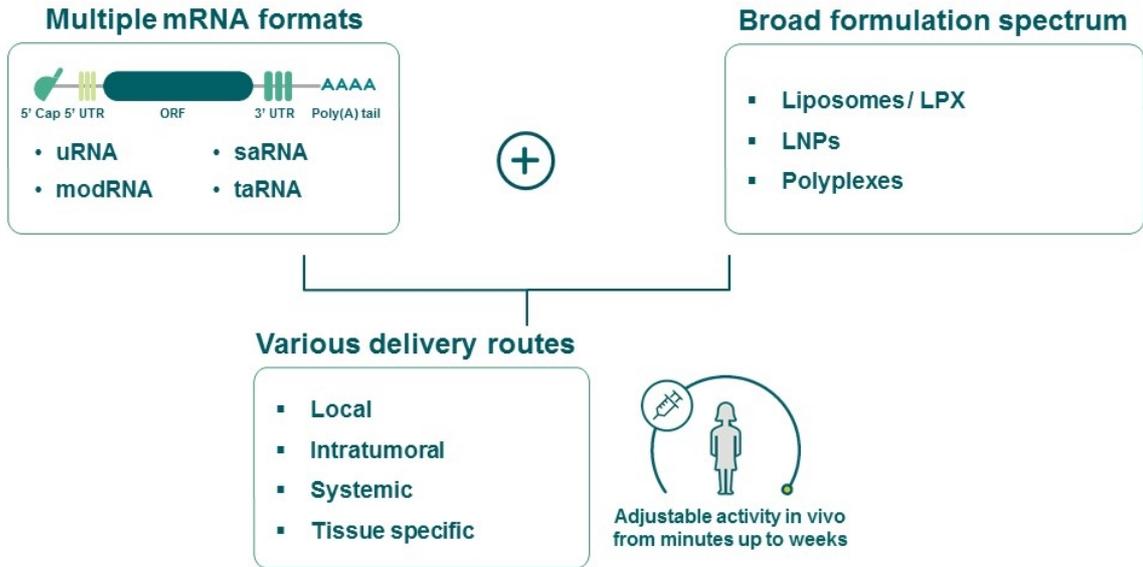
Drug Class	Platform	Indication (Targets)	Discovery	Preclinical	Phase 1	Phase 2	Rights Partner	Milestones
mRNA Other	Infectious Disease Immunotherapies	Influenza					Pfizer	start first study by end of 2020
		up to 10 indications					Penn ¹	first phase 1 trial to start 1H 2021
		HIV and tuberculosis					Bill & Melinda Gates Foundation	
	Rare Disease PRT ²	5 rare disease indications					Genevant (global 50:50 profit/loss)	first phase 1 trial to start 2H 2020

¹We are eligible to receive worldwide licenses; ²Protein Replacement Therapy

Our IO strategy exploits complementary therapeutic platforms

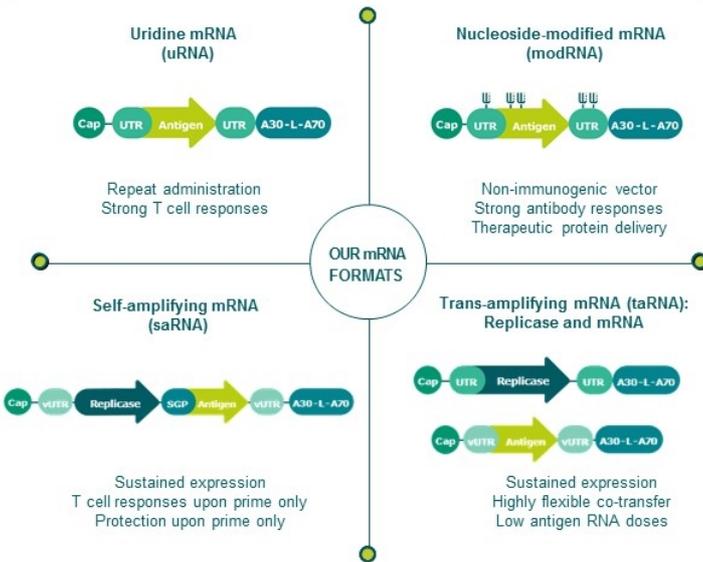


We own one of the broadest mRNA toolkits in the industry

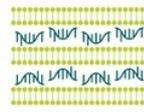


We have developed multiple proprietary mRNA formats and formulations

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;

Agenda

Who we are and what we do

Our key platforms and programs



FixVac: off-the-shelf mRNA immunotherapy

Individualized Neoantigen Specific Immunotherapy

Antibody programs

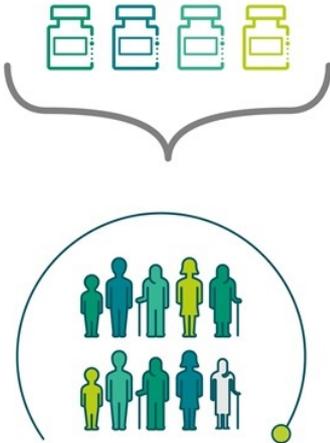
Leveraging platform synergies: CARVac + CAR-T

Small molecule immunomodulator program

Outlook in 2020 and beyond

FixVac: mRNA immunotherapy targeting shared tumor associated antigens

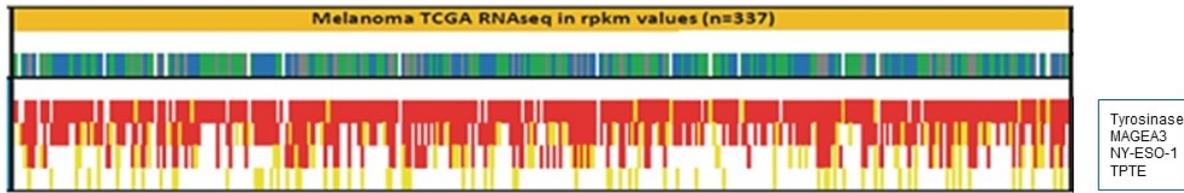
FixVac



Fixed vaccine combination against shared tumor-associated antigens expressed in high percentages of target cancer.

- **Off-the-shelf mRNA immunotherapy**
- **Targeting a fixed combination of tumor shared antigens**
 - Antigen selection on the basis of antigens shared among patients within a particular cancer type
 - Applicable for almost all types of tumor antigens
- **Proprietary RNA-LPX delivery formulation**
 - Allows systemic dendritic cell targeting
- **Strong immunogenicity observed in vivo**
 - TLR7-driven adjuvant effect
 - Type-I interferon driven innate and adaptive immune stimulation
 - Overcomes tolerance against self-antigens

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

BNT111 has demonstrated strong antigen specific immune responses in melanoma

Shared Antigens Targeted

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

Phase 1 Study Overview

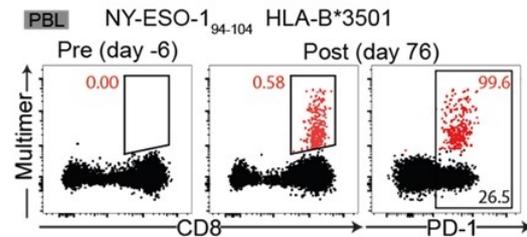
- Dose escalation to evaluate safety and tolerability
- 8 treatment cycles
- Planned total 115 patients with stage III/IV melanoma
 - First patient in: May 27, 2015
 - 95 dosed as of July 29, 2019

Interim Safety Data as of July 29, 2019

- The overall adverse event profile was dominated by mild-to-moderate, transient and manageable flu-like symptoms. These symptoms were managed by pre-medication with non-steroidal antipyretics, such as ibuprofen and acetaminophen. Eight of the 95 subjects dosed with BNT111 experienced related treatment-emergent serious adverse events, or TESAEs. There were confounding factors, such as treatment with other therapies or underlying medical conditions, for the subjects with related TESAEs.

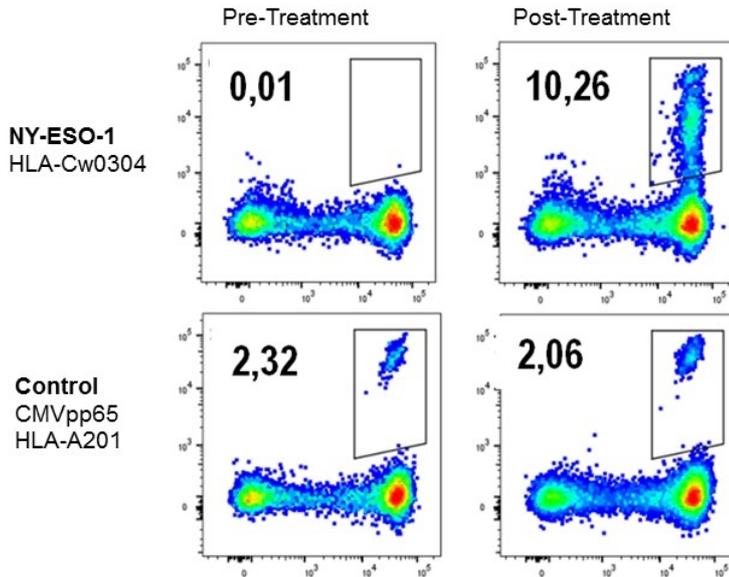
Interim Immunogenicity Data

- Immunogenicity analyzed by independent assays including Elispot, intracellular cytokine staining and HLA multimer analyses
- Subset of 18 patients with IVS Elispot demonstrating de novo and augmented T cell responses in all patients
- Ex-vivo T-cell responses observed in > 75% of patients
- Both CD8+ and CD4+ T-cells induced (Th1 Phenotype, PD1+)
- T-cell responses persisted for months after stop of vaccination



Example ex vivo HLA-peptide analysis

FixVac: Induced immune responses were robust



Patient Case:

Antigen specific T-cells in blood before/after vaccination

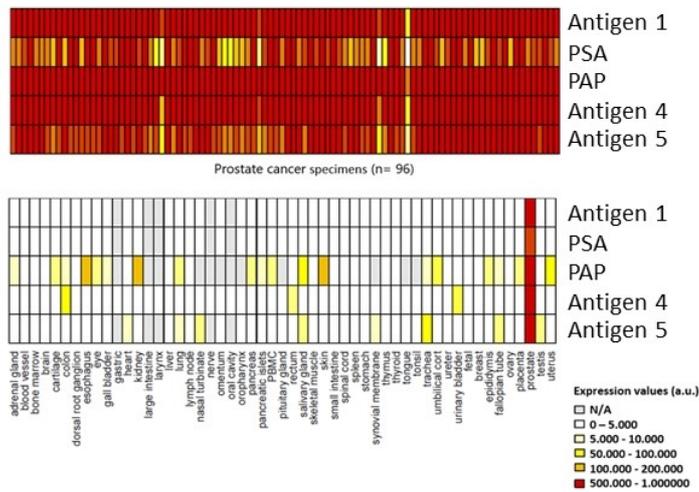
- Objective responses are associated with strong T-cell expansion
- 1,000 fold expansion within 4-8 weeks
- Evidence of strong tumor cell killing activity

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

Summary

- Advanced melanoma patients (Stage III, IV)
- Out of **74 patients** with available follow-up radiological imaging **42 patients** were assessed for preliminary analysis as of July 29, 2019
- **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 metabolic complete response
 - 7 patients with stable disease (SD)
 - 14 progressive disease (PD)
- **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

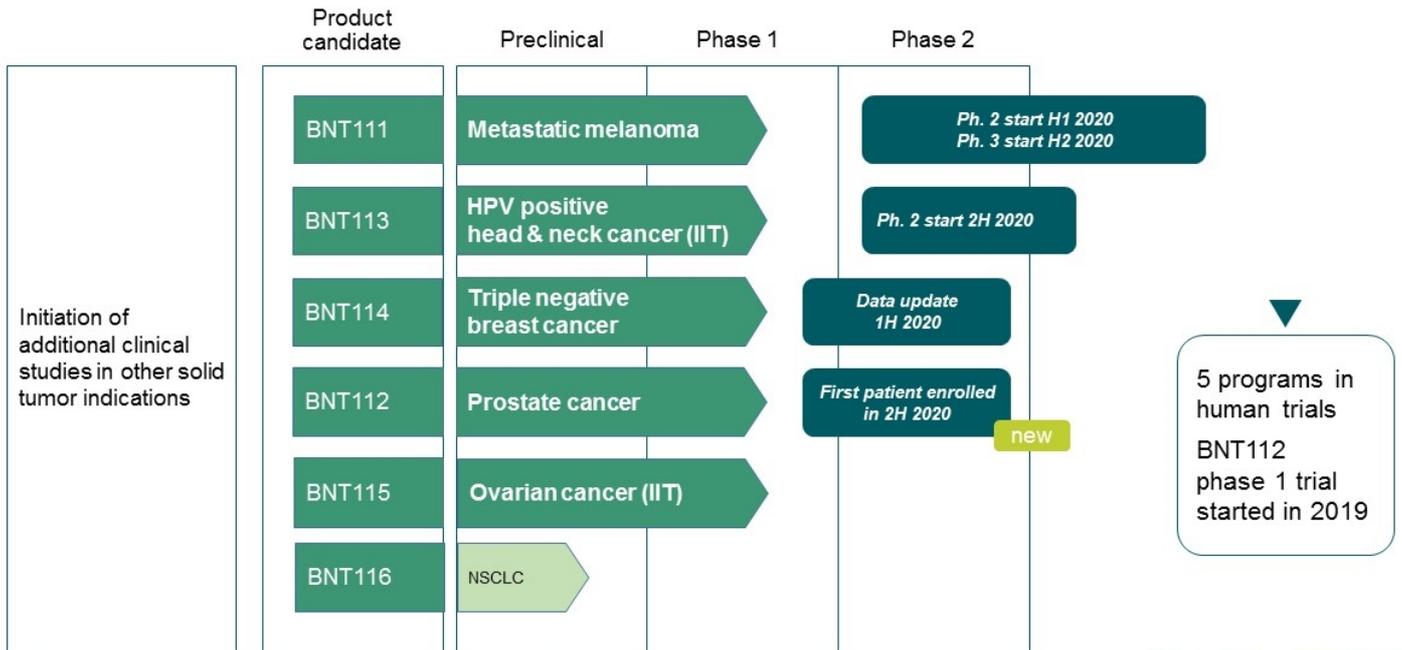
BNT112: FixVac Prostate Cancer



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
- Eligible are patients with
 - mCRPC symptomatic patient population after two lines of systemic chemotherapy for treatment with BNT112 alone or in combination with cemiplimab (aPD1, Regeneron)
 - Newly diagnosed high risk localized prostate cancer for treatment with BNT112 in combination with goserelin acetate & cemiplimab (aPD1, Regeneron) followed by surgery

FixVac: A flexible format which can rapidly be adapted for different tumors



Agenda

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Our key platforms and programs



FixVac: off-the-shelf mRNA immunotherapy

Individualized Neoantigen Specific Immunotherapy

Antibody programs

Leveraging platform synergies: CARVAC + CAR-T

Small molecule immunomodulator program

Outlook in 2020 and beyond

Conclusions from iNeST clinical trials

Preliminary observations in ongoing trials with BNT122 (IV administration):

- iNeST can be manufactured for individual patients with clinically relevant turn-around times across a range of tumor types
- iNeST +/- anti-PDL1 has a manageable safety profile
- Strong iNeST immunogenicity across a range of tumour types

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

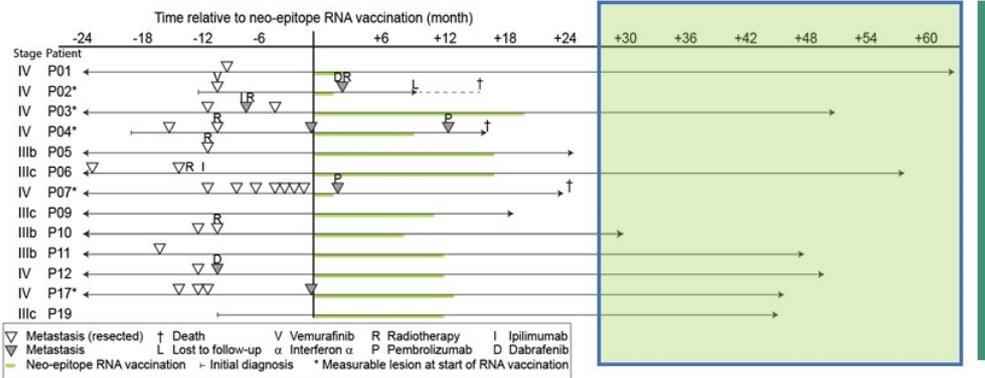
- Long-term relapse free disease activity with BNT121 iNeST in adjuvant Melanoma

Clinical efficacy evaluation in randomized phase II studies initiated

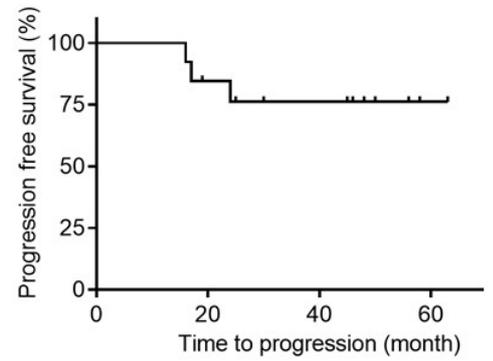
Update for BNT121 (as of October 2019)

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

Metastatic Relapse Analyses

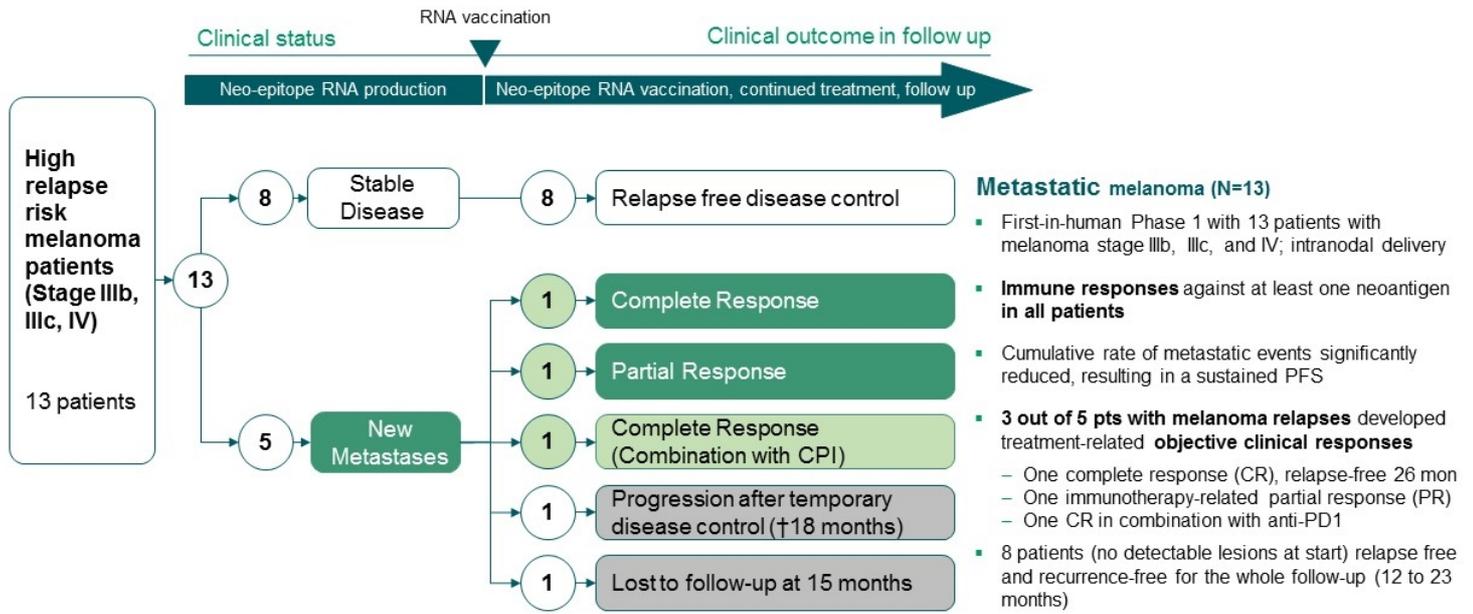


9 of 13 patients without documented PFS Events



Stable progression free survival in adjuvant melanoma

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

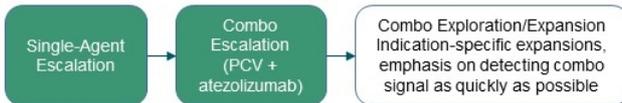


iNeST: Results expected for phase 1 in 2020, for phase 2 in 2H 2020

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, CRC, TNBC, Renal, H&N, 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

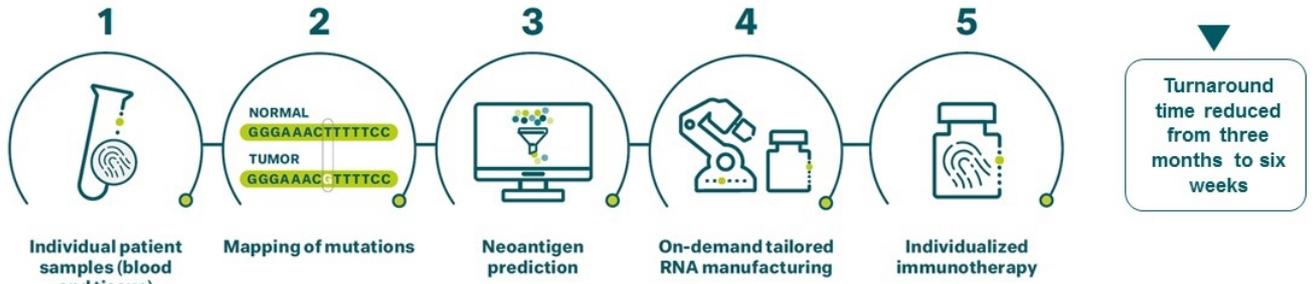
Genentech

- **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)

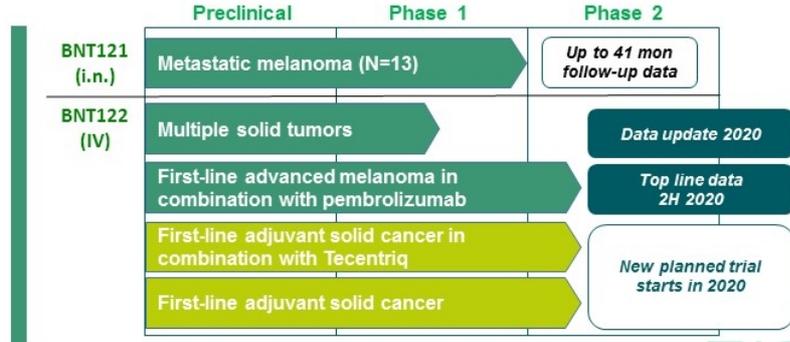
- Primary endpoint in iNeST+ pembrolizumab treated participants compared with pembrolizumab-only participants:
- Progression-free Survival (PFS)

Individualized Neoantigen Specific Immunotherapy (iNeST)



Overview

- Dosed first-in-human individualized mRNA immunotherapy
- 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 >8 solid tumor indications

Agenda

Who we are and what we do

Our key platforms and programs



FixVac: off-the-shelf mRNA immunotherapy

Individualized Neoantigen Specific Immunotherapy

Antibody programs

Leveraging platform synergies: CARVac + CAR-T

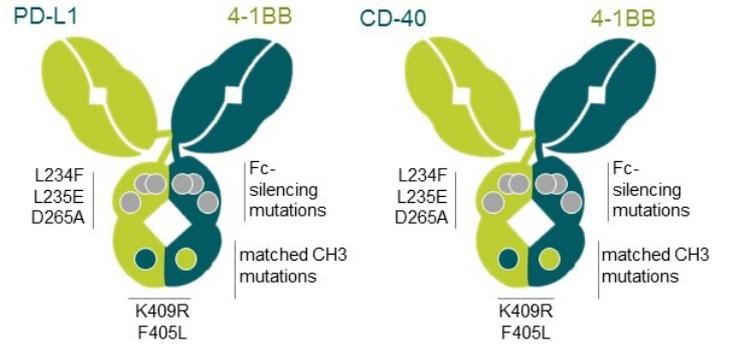
Small molecule immunomodulator program

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



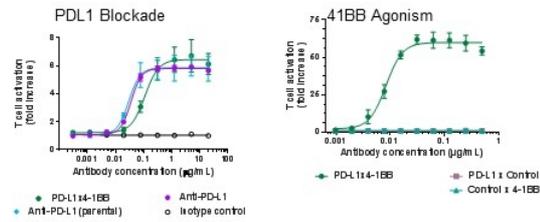
Product Candidate	Preclinical	Phase 1	Phase 2
BNT311 (GEN1046)	PD-L1x4-1BB	Ph1/2a	Data update 1H 2021
BNT312 (GEN1042)	CD-40x4-1BB	Ph1/2a	

Next-Gen checkpoint immunomodulators

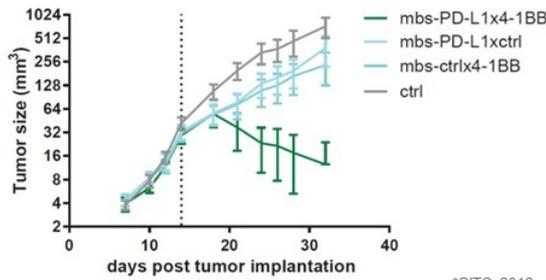
Characteristics

- 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+ 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 blockage 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:** 1H 2021
- **Tumor types:** Malignant Solid Tumors

Intervention:

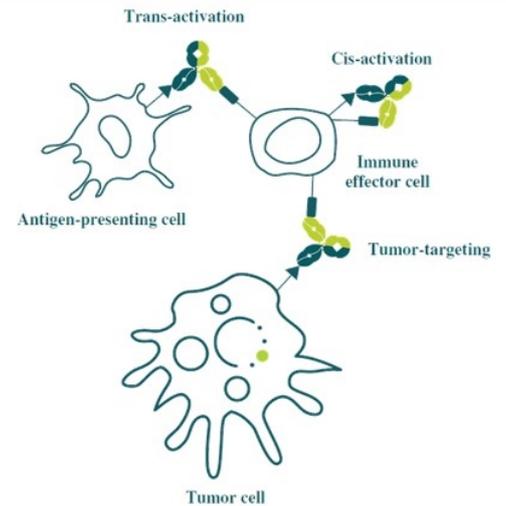
- GEN1046 (BNT311) is a PD-L1x4-1BB bispecific antibody that induces conditional activation of T cells through 4-1BB stimulation which is dependent on simultaneous binding to PD-L1
- GEN1046 (BNT311) IV once every 21 days
- Dose levels determined by the starting dose and the escalation steps taken in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

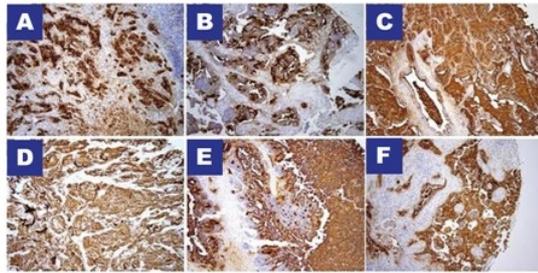


BNT321: Cancer antibody targeting Cancer Associated Carbohydrate sLe^a

Characteristics

- MVT-5873 (5B1) was acquired as clinical stage product from MabVax Therapeutics Holdings Inc. in 2019
- Fully human IgG1 mAb with subnanomolar affinity, potent cell killing by ADCC & CDC activity
- Targets sialyl Lewis A epitope (sLe^a) 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 carcinogenesis¹.
- 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^a 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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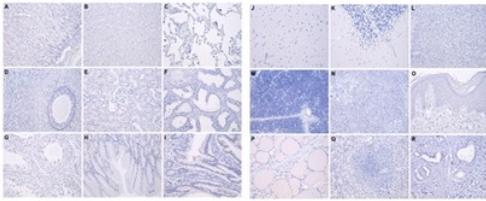
Leveraging platform synergies: CARVac + CAR-T

Small molecule immunomodulator program

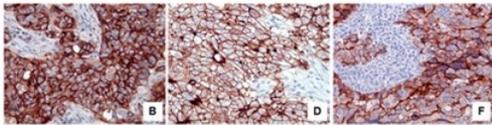
Why invest in BioNTech

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

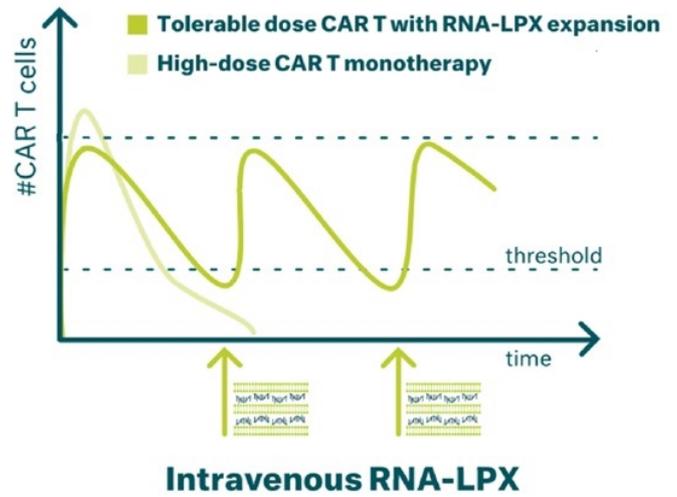
CLDN6 is not present in healthy tissues



CLDN6 is expressed in multiple cancers

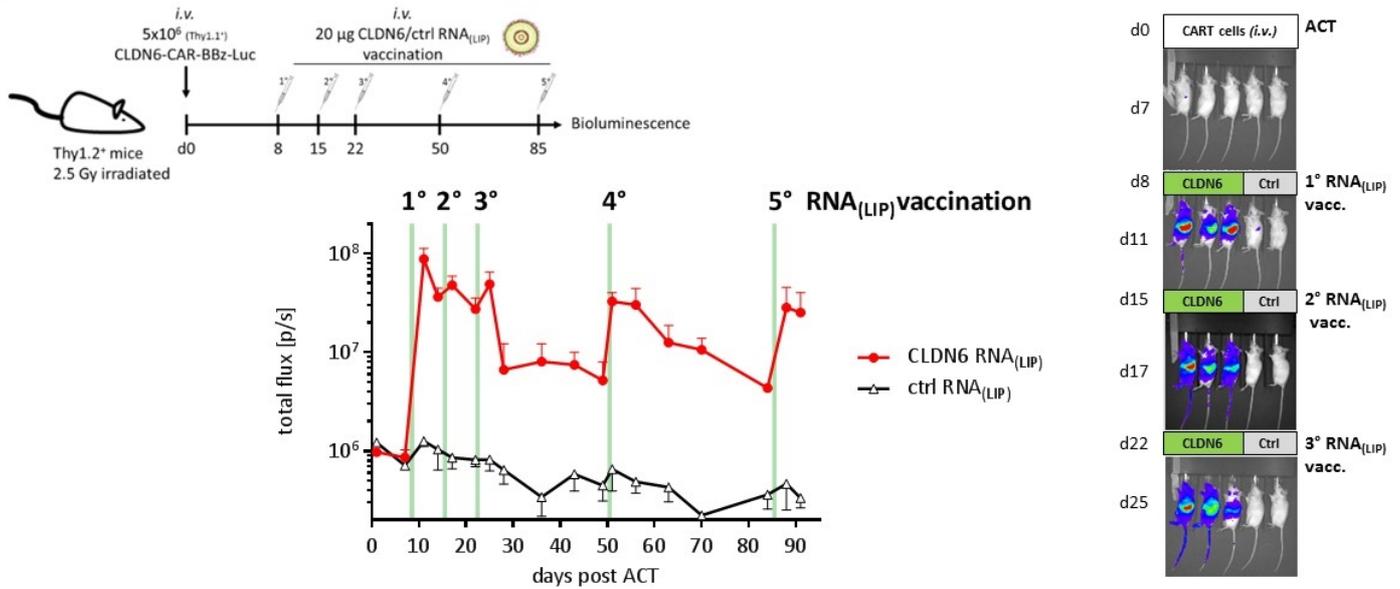


Ovarian cancer Testicular tumor Lung cancer



Complete eradication of advanced tumors in an ovarian carcinoma xenograft model

Second-generation CAR-T therapy targeting CLDN6 combined with CLDN6



RNA-lipoplex vaccine enhances expansion & persistence

Agenda

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Leveraging platform synergies: CARVac + CAR-T

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 was filed** on November 5, 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

Agenda

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Outlook in 2020 and beyond

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

Platform	Candidate	Indication (Target)	1H-2020	2H-2020	2021 ³	2022 ³
FixVac	BNT111	Advanced Melanoma	Report Phase 1 Start Phase 2	Start Phase 3	Phase 2/3	
	BNT112	Prostate Cancer				Phase 1/2
	BNT113	HPV+ 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 ¹	Phase 2	
		Multiple ST (baskettrial)	Data update Phase 1/2			
Intratumoral Immunotherapy	SAR441000 (BNT131)	Solid tumors (IL-12sc, IL-15sushi, GM-CSF, IFNα)		Report Phase 1/2 ²		
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)	Start Phase 1			
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 5 Rare Disease Indications		Start first Phase 1	Start first Phase 1	

Legend Expected begin of trial Expected data readout / update

50 ¹We 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; ²As 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; ³Our 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.



Back-up



Year End Cash Balance 2019 (unaudited) – and Outlook

Total Business

In EURm	<u>December 31,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
Cash and cash equivalents	520*	411

We expect net cash used in operating activities and other investments to total of approx. EUR 300m** in 2020.

* EUR 520m -> approx. USD 584m

**EUR 300m -> approx. USD 337m

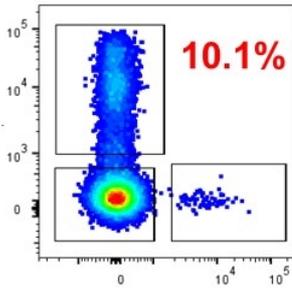
Conversion rate 1.12

The estimates above represent the most current information available to our management and do not present all necessary information for an understanding of our financial condition as of and the results of operations for the year ended December 31, 2019. We are currently preparing our financial results for the quarter and year ended December 31, 2019. There is no assurance that our cash and cash equivalents as of and for the year ended December 31, 2019 to be reported in our financial statements for the period, when finalized and reviewed, will not differ from the estimates provided. Any such differences could be material, and accordingly prospective investors should not place undue reliance on these estimates.

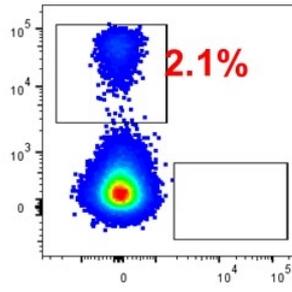
The preliminary financial data included in this document has been prepared by, and is the responsibility of our management. Our independent registered public accounting firm has not audited, reviewed, compiled or applied agreed upon procedures with respect to the preliminary financial data.

Our RNA-LPX vaccine approach

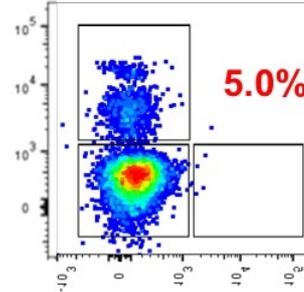
Strong vaccine-induced ex vivo CD8 + T cell responses* across different cancer types



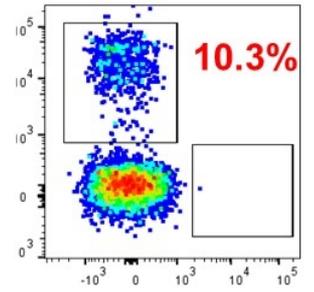
NY-ESO-1
Melanoma
BNT111, Lipomerit trial



MAGE-A3
Melanoma
BNT111, Lipomerit trial



HPV16-E7
Head Neck Cancer
BNT113, HARE40 trial



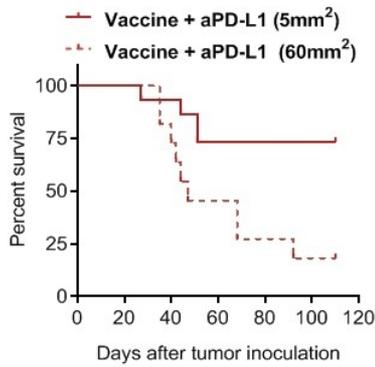
Mutant Neoantigen
TNBC
BNT114, TNBC Merit trial

FixVac

iNeST

Ribocytokines boost therapeutic efficacy of vaccination and PD-L1 blockade

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

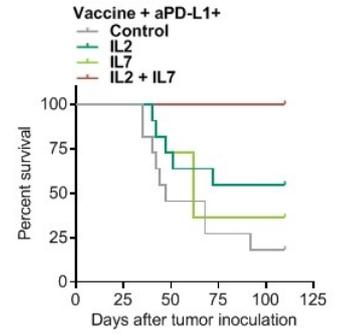
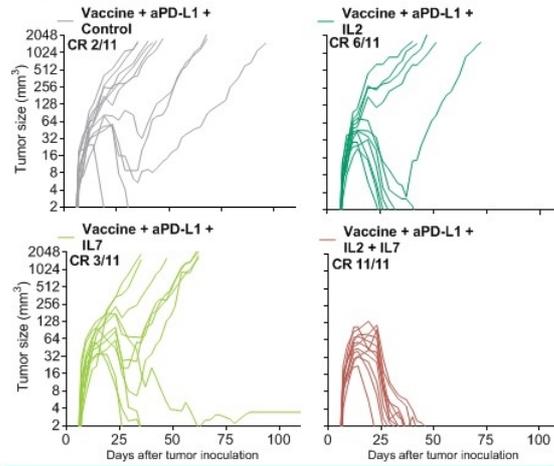


CT26 tumor model, vaccine antigen:gp70

Therapeutic efficacy of vaccination + aPD-L1 is reduced in large tumors

Ribocytokines boost the efficacy of vaccination + aPD-L1 in large tumors

Vaccine + aPD-L1 +



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

Complete rejection of large tumors when combining RNA vaccination, PD-L1 blockade as well as IL2 and IL7 Ribocytokines.

The logo for BionTech, with 'BIONTECH' in a light green, sans-serif font. The background of the entire page is a dark teal color with a pattern of faint, white, overlapping circular lines that create a grid-like effect.

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