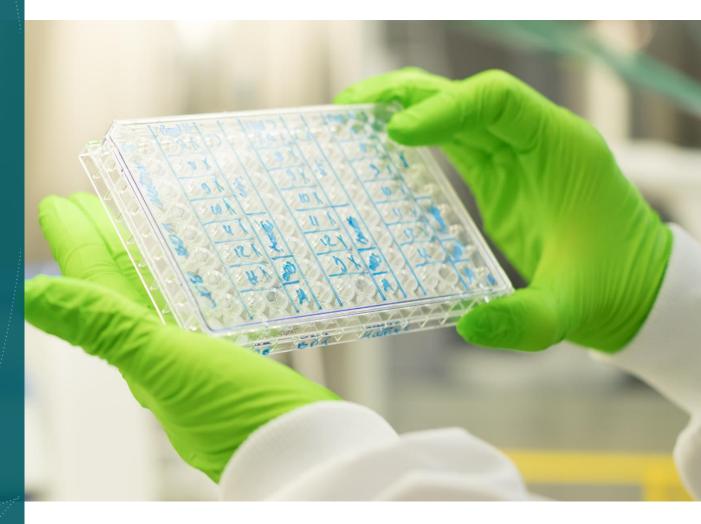
BIONTECH

Next Generation Immunotherapy

November 2020





This slide presentation includes forward-looking statements

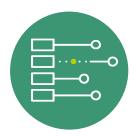
Forward-Looking Statements

Various statements in this slide presentation concerning the future expectations of BioNTech, its plans and prospects, including the Company's views with respect to the potential for mRNA therapeutics; the planned next steps in BioNTech's pipeline programs and specifically including, but not limited to, statements regarding plans to initiate clinical trials of BioNTech's product candidates and expectations for data announcements with respect to BioNTech's product candidates; the development of commercial capabilities and the transition of BioNTech to a fully integrated biopharmaceutical company; its expectations with respect to interactions with regulatory authorities such as FDA and EMA, including the potential approval of BioNTech's or its collaborators' current or future drug candidates; expected royalty and milestone payments in connection with BioNTech's collaborations; BioNTech's anticipated cash usage for fiscal year 2020 and beyond; the creation of long-term value for BioNTech shareholders; the ability of BioNTech to successfully develop and commercialize a vaccine for COVID-19 in partnership with Pfizer and Fosun Pharma; the timing for any potential emergency use authorizations or approvals for BNT162; and the ability of BioNTech to supply the quantities of BNT162 to support clinical development and, if approved, market demand, including its production estimates for 2020 and 2021 and the impact of COVID-19 on our clinical trials and business operations, are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, as amended. Words such as "expects," "plans," "potential," "target," "continue" and variations of these words or similar expressions are intended to identify forward-looking statements. Such statements are based on the current beliefs and assumptions of the management team of BioNTech and on the information currently available to the management team of BioNTech, and are subject to change. The Company will not necessarily inform you of such changes. These forward looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors that could cause the Company's actual results, performance or achievements to be materially different than any future results, performance or achievements expressed or implied by the forward-looking statements. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including the Company's ability to discover and develop its novel product candidates and successfully demonstrate the efficacy and safety of its product candidates; the pre-clinical and clinical results for its product candidates, which may not support further development of product candidates; actions of the Company's collaborators regarding continued product development and product commercialization; actions of regulatory authorities, which may affect the initiation, timing and progress of clinical trials or the ability of the Company to obtain marketing authorization for its product candidates; the Company's ability to obtain, maintain and protect its intellectual property; the Company's ability to enforce its patents against infringers and defend its patent portfolio against challenges from third parties; competition from others using technology similar to the Company's and others developing products for similar uses; the Company's ability to manage operating expenses; the Company's ability to obtain additional funding to support its business activities and establish and maintain its existing and future collaborations and new business initiatives; the Company's dependence on collaborators and other third parties for development, manufacture, marketing, sales and distribution of products; the outcome of litigation; and unexpected expenditures. Any forward-looking statements represent the Company's views only as of today and should not be relied upon as representing its views as of any subsequent date. The Company explicitly disclaims any obligation to update any forward-looking statements. The mRNA vaccines and other product candidates discussed in this slide presentation are investigational products being developed by BioNTech and its collaborators and are not currently approved by the FDA, EMA or any other regulatory authority.



Next generation Immunotherapy

Harnessing the full potential of the immune system



Broad suite of novel technology platforms



Immunotherapies for cancer and infectious diseases



Fully integrated with in-house GMP manufacturing



Industry-leading global collaborations



We collaborate with global leaders in our industry

Collaborations for clinical stage programs

Covid-19 Vaccine 50:50 gross profit share¹

FixVac Melanoma
Each company to keep 100%

of rights to own product

iNeST 50:50 cost & profit share Bispecific mABs 50:50 cost & profit share Intra-tumoral mRNA cost & profit share



REGENERON

Genentech





Pre-clinical collaborations

Seasonal Influenza royalties & milestones

Up to 10 Infectious Disease Indications worldwide opt-in right

HIV, Tuberculosis developed world rights

5 Rare Disease Indications 50:50 cost & profit share



University of Pennsylvania

BILL & MELINDA GATES foundation

GENEVANT



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

Broad progress in executing our multi-platform IO strategy

mRNA Cancer Vaccines

Randomized Phase 2 trial starts for FixVac and iNeST in multiple solid tumors expected in 2H 2020



Next Generation Immunomodulators

First Phase 1/2 data expected for PD-L1 x 4-1BB antibody in 2H 2020

Cell Therapies

- Phase 1/2 trial start for CARVac planned in 2H 2020
- Filed IND for Phase 1 trial of exvivo neoantigen T cell therapy

Antibodies

Ongoing Phase 1/2 trial for CA19-9 antibody in pancreatic cancer

Small Molecule Immunomodulators

First-in-human Phase 1/2 trial for TLR7 agonist initiated in early July 2020

Engineered Cytokines

- First Phase 1/2 data from intratumoral mRNA in 2H 2020
- Ribocytokines to enter the clinic. in 2021

Potential for multiple blockbuster opportunities with powerful combinations



Compelling data generated from innovative immunotherapy approaches

Approved PD1-/PD-L1
Inhibitors

mRNA Cancer Vaccines

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

mRNA Cancer Vaccines

Engineered Cytokines

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

Cell Therapies

mRNA Cancer Vaccines

- BNT211: Novel CLDN-6
 CAR-T approach utilizing
 <u>C</u>AR-T <u>Amplifying RNA</u>
 <u>Vac</u>cine (CARVac)
- Significant amplification of CAR-T cells in preclinical studies (published in Science, 2020)



A technology agnostic approach targets a broader addressable market

Cancer segment	Patient Population	Challenge	Our Therapeutic Strategies		
High mutational burden/ adjuvant stage cancers	Significant portion of cancer patients	Poor risk-benefit profile of checkpoint inhibitors	• mRNA Neoantigen Immunotherapy (iNeST)		
Low mutational burden cancers	>60% of cancers	Poor response to checkpoint inhibitors	• Shared Antigens (FixVac, CAR-T cells, Neoantigen- targeted T cells, Antibodies)		
"Immune desert" cancers	>40% of high-mutational cancers	Poor infiltration and activation of T-cells in TME ¹	 RNA Immunotherapy Immunostimulatory Compounds (intratumoral, RiboCytokines) 		
Cancers with MHC / B2M loss	20-30% of CPI-experienced advanced cancers	Failure of immune system to recognize tumor cells	AntibodiesCAR-Ts		
Refractory tumors	Patients with large tumors and multiple resistance mechanisms	Few treatment options	Cell TherapiesCombination Therapies		

¹Tumor microenvironment



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

Drug class	Platform	Product Candidate	Indication (Targets)	Pre- clinical	Phase 1	Phase 2	Rights / Collaborator		BNT111: Clinical data published
	FixVac (fixed combination of shared cancer antigens)	BNT111	advanced melanoma				fully-owned (Regeneron)		in <i>Nature</i> (July 2020); subsequent announcement of
		BNT112	prostate cancer				fully-owned		Regeneron collaboration
		BNT113	HPV16+ head and neck cancer ¹				fully-owned		BNT114 data update for TNBC-
⊴		BNT114	triple negative breast cancer				fully-owned		MERIT trial at ESMO Virtual
mRNA		BNT115	ovarian cancer ¹				fully-owned	,	Congress 2020
	(nation) specific cancer	RO7198457	1L melanoma				Genentech		
		(BNT122)	multiple solid tumors				(global 50:50 profit/loss)		
	Intratumoral Immunotherapy	SAR441000 (BNT131)	solid tumors (IL-12sc, IL-15sushi, GM-CSF, IFNα)				Sanofi (global profit/loss share)		BNT131 data update from Phase 1 presented at SITC
sə	Next-Gen CP ² (B Immunomodulators GE	GEN1046 (BNT311)	multiple solid tumors (PD-L1×4-1BB)			Genmab			BNT311 Interim update from Phase 1 presented at SITC
Antibodies		GEN1042 (BNT312)	multiple solid tumors (CD40×4-1BB)				(global 50:50 profit/loss)		procented at Office
An	Targeted Cancer Antibodies	BNT321 (MVT-5873)	pancreatic cancer (sLea)				fully-owned		
SMIM ³	Toll-Like Receptor Binding	BNT411	solid tumors (TLR7)				fully-owned		BNT411 FPD in Phase 1/2 trial in ES-SCLC

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



²Checkpoint Inhibitor.

³Small Molecule Immunomodulators.

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

Oncology NOOLO	
THE RESERVE AND A STATE OF THE	
FixVac BNT116 NSCLC fully-owned	
RiboMabs BNT141 multiple solid tumors fully-owned	Phase 1 start in 1H 2021
(mRNA-encoded antibodies) BNT142 multiple solid tumors (CD3+CLDN6) fully-owned multiple solid tumors	Phase 1 start in 2H 2021
RiboCytokines BN I 151 (optimized IL-2) fully-owned	Phase 1 start in 1H 2021
(mRNA-encoded Cytokines) BNT152, BNT153 multiple solid tumors (IL-7, IL-2) fully-owned	Phase 1 start in 1H 2021
BNT211 multiple solid tumors (CLDN6) fully-owned	Phase 1/2a start in 2H 2020
BNT212 pancreatic, other cancers (CLDN18.2) fully-owned	
CAR-T Cells BNT212 pancreatic, other cancers (CLDN18.2) fully-owned Neoantigen-based T cell therapy BNT221 multiple solid tumors fully-owned	Phase 1 start in 1H 2021
TCRs to be selected all tumors fully-owned	
BNT161 influenza Pfizer	
Infectious Disease undisclosed up to 10 indications Penn ³	
Immunotherapies	า
BNT171 not disclosed Conquent	
Rare Disease PRT ² undisclosed 4 additional rare disease indications (global 50:50 profit/loss	

We expect to initiate multiple phase 1 trials in 2021

mRNA	Infectious Disease Immunotherapies	BNT161	influenza	Pfizer	
		undisclosed	up to 10 indications	Penn ³	
		undisclosed	HIV and tuberculosis	Bill & Melinda Gates Foundation	
	Rare Disease PRT ²	BNT171	not disclosed	Genevant	
		undisclosed	4 additional rare disease indications	(global 50:50 profit/loss)	

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



Positioned for transformative 2021

- Focused on executing ongoing BNT162 Phase 3 trial and regulatory submission processes globally
- Commercial preparation activities for manufacturing and global distribution progressing for BNT162 with partners Pfizer and Fosun
- Advancing oncology pipeline towards multiple late-stage clinical trial initiations
- Additional first-in-human trials of novel product candidates expected across proprietary platforms
- Well capitalized to deliver on key commercial, operational and pipeline milestones
- Transformational opportunity ahead to positively impact the world and accelerate our long-term vision to build a next generation immunotherapy leader



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Deeper dive on our key programs



COVID-19 vaccine program (project "Lightspeed")

mRNA vaccines - FixVac and iNeST

Antibodies

Small Molecule Immunomodulators

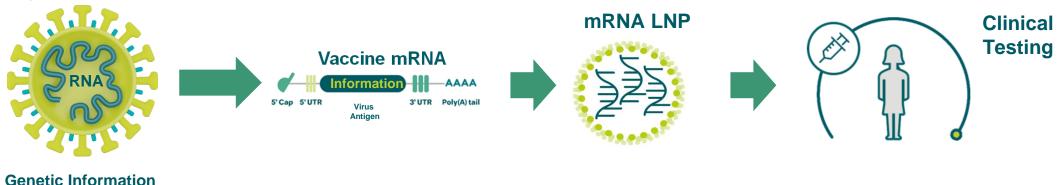
CARVac platform – CLDN6 CAR-T

RiboCytokines



mRNA pharmaceuticals as pandemic vaccines

- Synthetic variants of naturally occurring genetic molecules
- High purity and free of animal product
- Inherent immune-activating qualities with no need for additional adjuvant
- Stimulates both antibody and T-cell immune response at low doses
- More than 400 patients dosed in cancer setting since 2013 (observing both safety and efficacy data)
- More than 44,000 healthy subjects dosed with Covid-19 vaccine
- Highly scalable production with potential to manufacture hundreds of millions of doses





SARS-CoV-2

Timeline of COVID-19 vaccine program

Candidate/ Dose Selection

BNT162b2 July 24, 2020



Initiated

subjects

2b / 3 Trial

Pivotal Phase

July 27, 2020 Start

with up to 44,000

COVID-19 mRNA **Vaccine Program** Initiation

January 27, 2020









SARS-CoV-2 **Genetic Sequence**

Made Public January 12, 2020

Collaborations

Fosun Pharma: March 16, 2020

Pfizer: March 17, 2020

Phase 1 / 2a Trial

Germany Started April 23, 2020

• Up to 200 subjects aged 18 - 55

U.S. Started May 4, 2020

• Up to 360 subjects aged 18 - 85

FDA Fast Track designation

July 13, 2020

Initiated Rolling Submissions

EMA: October 6, 2020 Canada: October 7, 2020 UK: October 9, 2020

Primary Efficacy Endpoint:

To evaluate the efficacy of prophylactic BNT162b2 against confirmed COVID-19 in participants with (and without) evidence of infection before vaccination

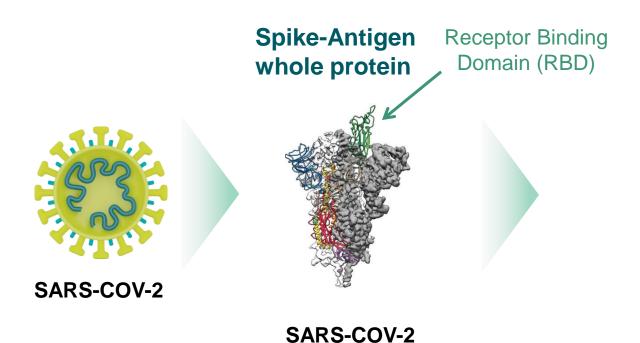


November 9, 2020

Interim analysis finds more than 90% effective in preventing COVID-19 in participants without evidence of prior SARS-CoV-2 infection



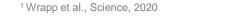
BNT162b2 selected as lead candidate for phase 2b/3



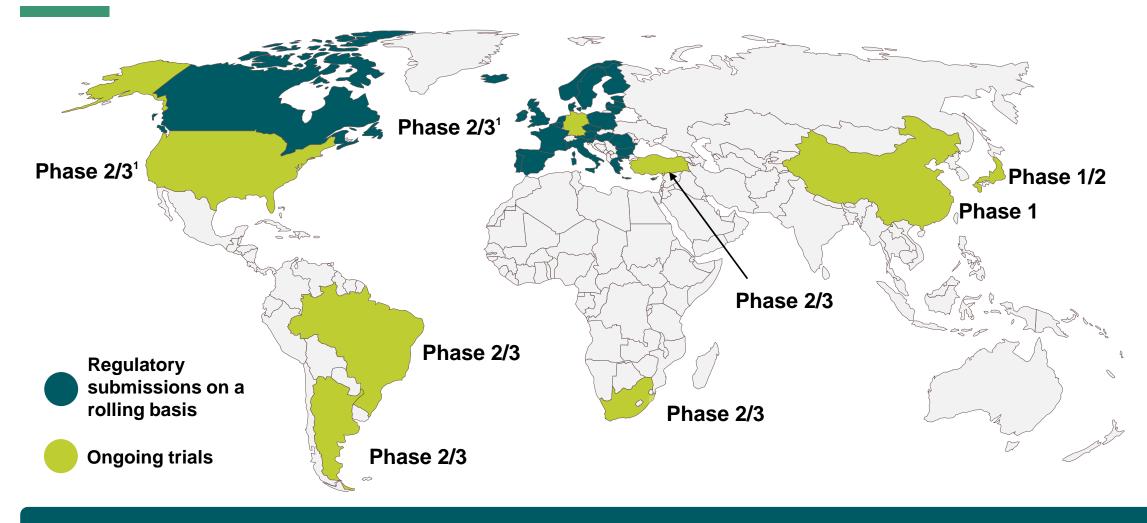
Spike Protein 3D Structure¹

Variant	Target	RNA construct	Immunization
162a1	RBD subunit	uRNA	prime/ boost
162b1	RBD subunit	modRNA	prime/ boost
162b2	2P-mutated full spike protein	modRNA	prime/ boost
162c2	2P-mutated full spike protein	saRNA	single injection

Received Fast Track designation



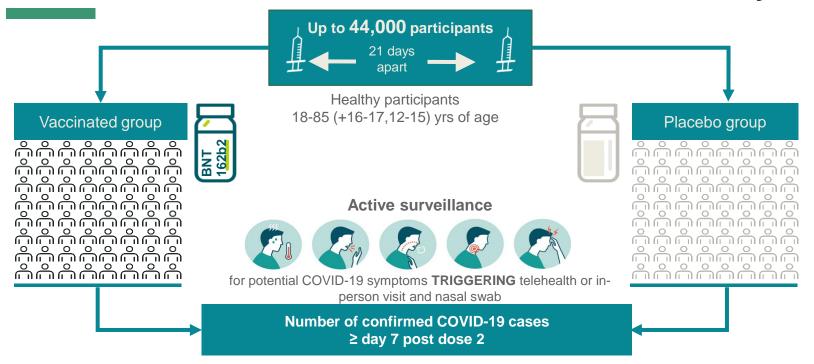
BNT162: Global development program expanded to additional regions



Regulatory submission on a rolling basis to EMA, MHRA (UK) and Health Canada initiated in October



BNT162b2: Achieved success in first interim analysis from phase 3 study



- Interim analysis of unblinded data by independent data monitoring committee on Nov 8, 2020 :
 - 94 disease cases accrued, split of disease cases indicates >90% vaccine efficacy
 - Benign safety profile
- Final efficacy analysis at 164 disease cases expected end of November, 2020
- Vaccinated participants will continue to be monitored for up to 2 years

Primary Efficacy Objectives

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

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

43,538 participants enrolled 38,955 received 2nd dose

Race/Ethnicity	Overall Study
Asian	5%
Black	10%
Hispanic/Latinx	26%
Native American	0.8%

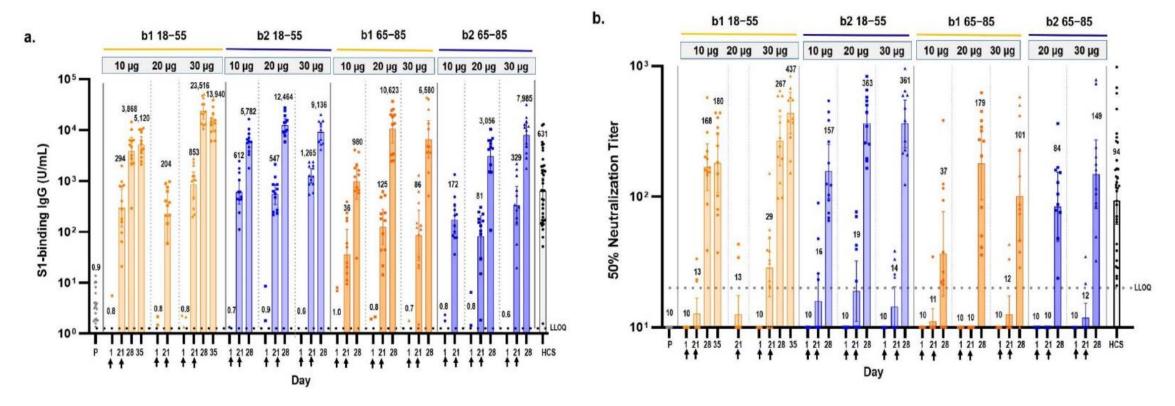
Data as of November 08th, 2020



BNT162b2: Interim immunogenicity results in human (phase 1)

Two 30 µg doses of BNT162b2 elicited neutralizing GMTs generally similar to GMTs elicited by BNT162b1

 BNT162b2 elicited GMTs in younger adults 3.8 times GMT of sera panel and GMTs in older adults 1.6 times sera panel

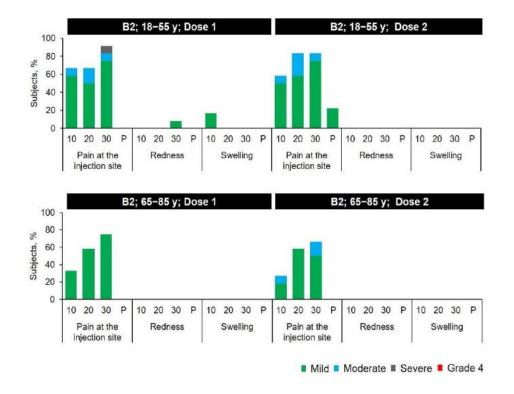


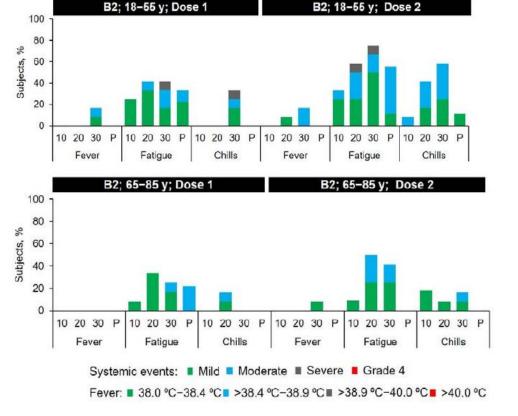
Concurrent induction of high magnitude CD4+ and CD8+ with trend towards stronger CD8+ T cell responses

BNT162b2: Interim safety and tolerability results in human (phase 1)

Preliminary Phase 1 data demonstrated favorable overall tolerability profile

Generally mild to moderate and transient local and systemic adverse events and no serious adverse events







BNT162 global collaborations



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

FOSUNPHARMA 复星医药

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



BNT162: Global commercial supply commitments*

- Both BioNTech and Pfizer jointly scaling up manufacturing capacity to enable global supply:
 - BioNTech already producing vaccine for clinical supply at 2 manufacturing sites in Germany
 - Pfizer will activate 3 manufacturing sites in the U.S. and 1 site in Europe
- > 570 million doses committed* for 2020 and 2021 in 13 countries and the EU with an option to purchase an additional 600 million doses
- Additional commercial discussions ongoing with multiple countries and supranational organizations including COVAX

Commercial supply commitments*					
Region	Number of Doses	Order value			
Canada	Not disclosed	Not disclosed			
EU	EU 200 million with option for additional 100 million				
Japan	120 million	Not disclosed			
United Kingdom	30 million	Not disclosed			
United States	100 million with option for additional 500 million	\$1.95 billion for first 100 million doses			
Nine additional countries	Not disclosed	Not disclosed			



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mRNA vaccines – FixVac and iNeST

Antibodies

Small Molecule Immunomodulators

CARVac platform – CLDN6 CAR-T

RiboCytokines

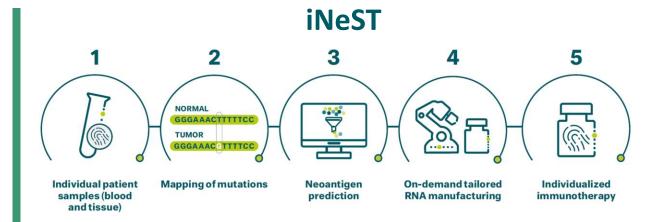


Our mRNA vaccine platforms: FixVac and iNeST

FixVac



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



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

Proprietary RNA-LPX formulation for systemic dendritic cell targeting

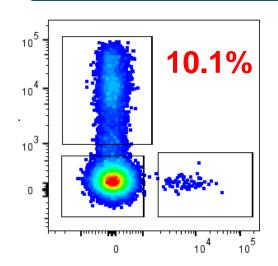
Strong immunogenicity observed *in vivo* via TLR7-driven adjuvant effect

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

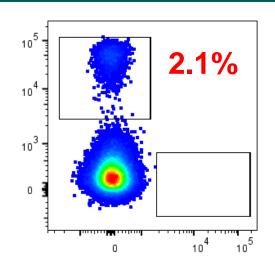


Our RNA-LPX vaccine approach

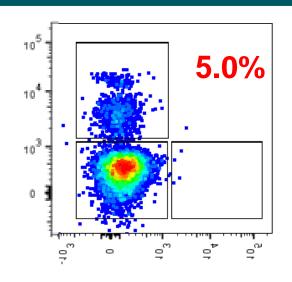
Strong vaccine-induced ex vivo CD8+ T cell responses¹ across different cancer types



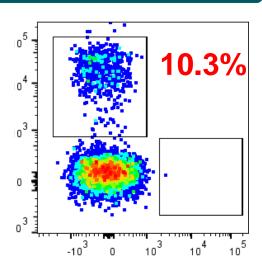
NY-ESO-1 Melanoma BNT111, Lipo-MERIT trial



MAGE-A3
Melanoma
BNT111, Lipo-MERIT trial



HPV16-E7
Head Neck Cancer
BNT113, HARE40 trial



Mutant Neoantigen
TNBC
BNT114, TNBC MERIT trial

FixVac

iNeST



BNT111 FixVac Melanoma: Planning to initiate randomized phase 2 trial

Ongoing Phase
1 trial in
Advanced
Melanoma
published in
Nature

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

Regeneron strategic collaboration and planned Phase 2 trial

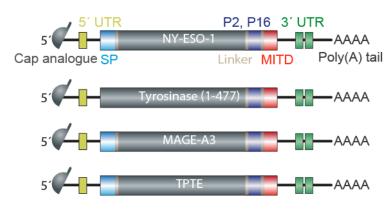
- Signed strategic collaboration to jointly conduct randomized Phase 2 trial with BNT111 and Libtayo® (cemiplimab anti-PD-1 therapy)
- Targeting patients with anti-PD1-refractory/relapsed, unresectable Stage III or IV cutaneous melanoma
- Companies to share development costs equally and keep full commercial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



BNT111 interim clinical activity data in advanced melanoma

Summary

- Advanced melanoma patients (stage III, IV); dose range: 14µg -100µg
- Out of 74 patients with available follow-up radiological imaging 42
 patients were assessed for preliminary analysis as of July 29, 2019
- of 25 patients with metastatic melanoma who received BNT111
 monotherapy following progression on CPI* and in some cases other
 therapies
 - 3 patients with partial response (PR)
 - 1 patient with metabolic complete response¹
 - 7 patients with stable disease (SD)
 - 14 progressive disease (PD)
- of 17 patients with metastatic melanoma who received BNT111 in combination with CPI after progression on CPI monotherapy
 - 6 patients with partial response (PR)
 - 2 patients with stable disease (SD)
 - 9 progressive disease (PD)
- Adjuvant cohort of 32 patients still in study



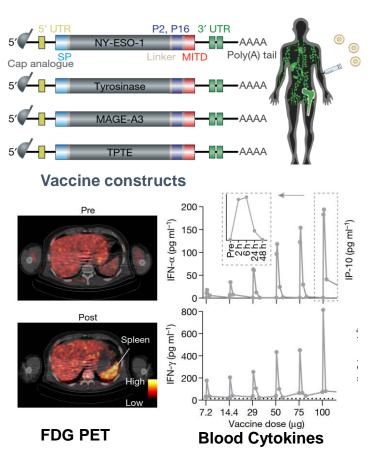
Cumulative patient coverage of FixVac melanoma targets is over 90%

Report phase 1 data 1H 2020 Start randomized phase 2 trial in 1H 2021

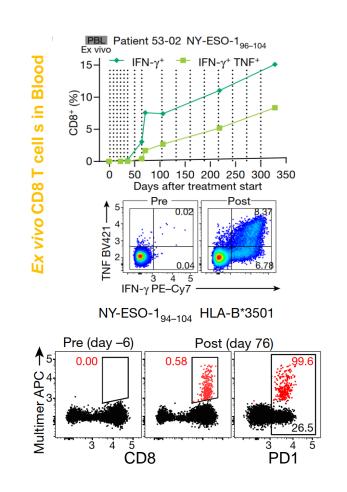


BNT111 publication in Nature highlights

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

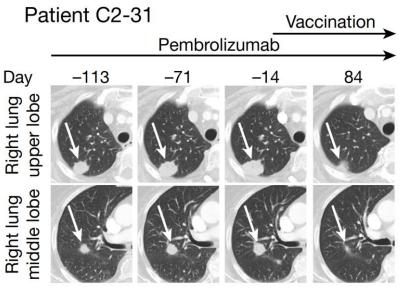


Strong CD4+, CD8+ T cell responses Multifunctional CD8+ PD1+ T cells



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

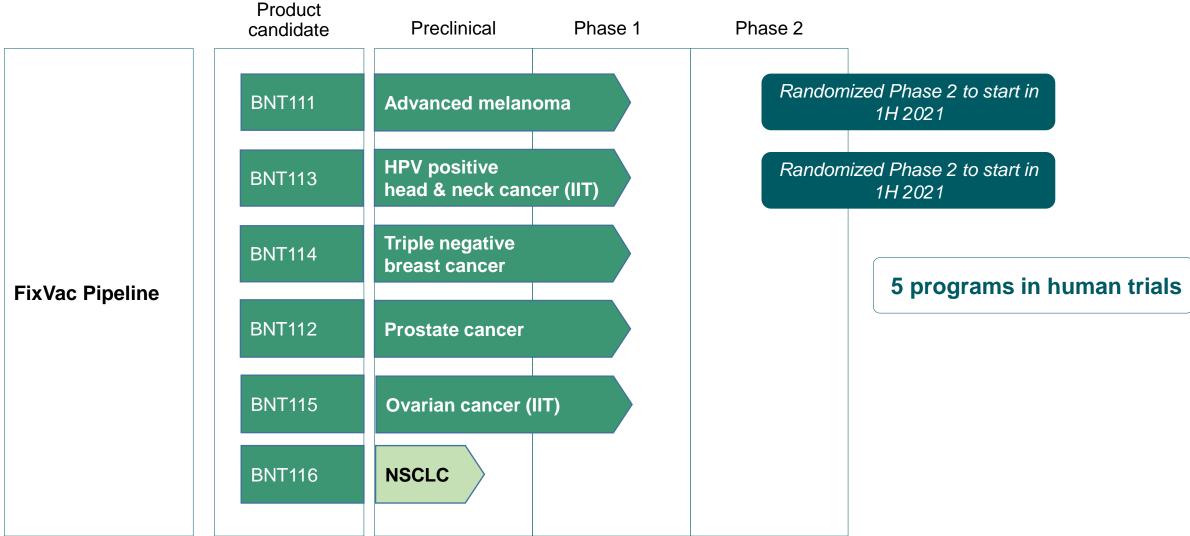
- ORR of BNT111 monotherapy: 4/25
- ORR of BNT111 + anti-PD1: 6/17 (35%) (CPI resensitizing activity of BNT111)



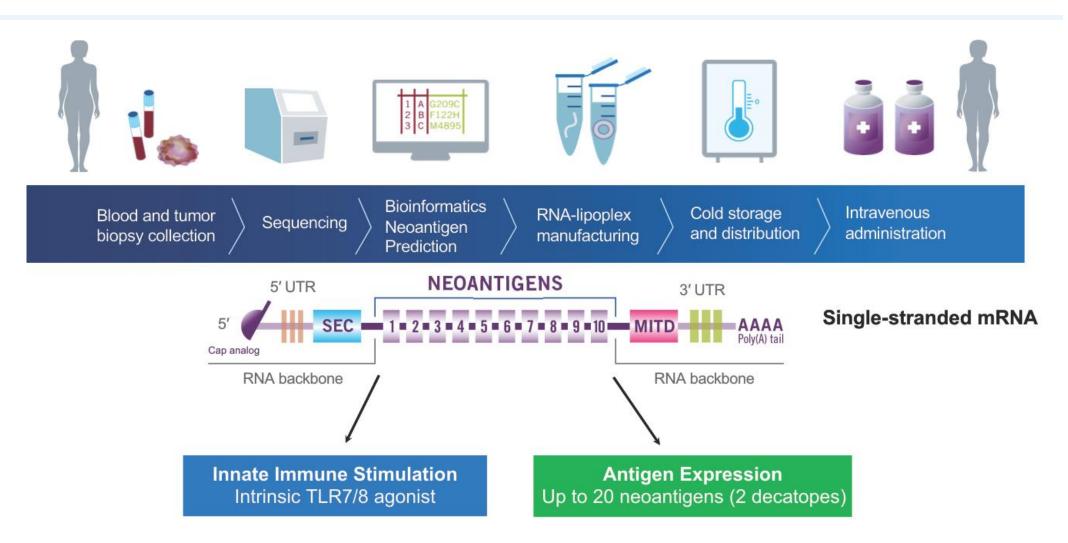
Lung CT scans before & after BNT111



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



iNeST: Individualized neoantigen specific immunotherapy





iNeST: Recent update from BNT122 reported at AACR

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

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

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

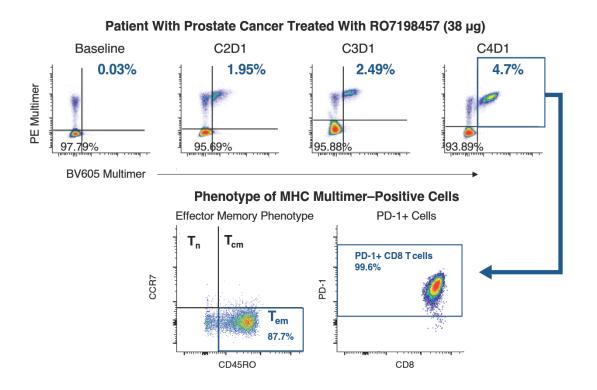
- 132 patients enrolled, cohorts with doses ranging from 15-50µg
- Heavily pre-treated patient population
 - · Both CPI experienced and inexperienced
 - Most patients with low PD-1
- Clinical responses associated with T cell response, correlating immune profiling of patients' T cells to cancer-specific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

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

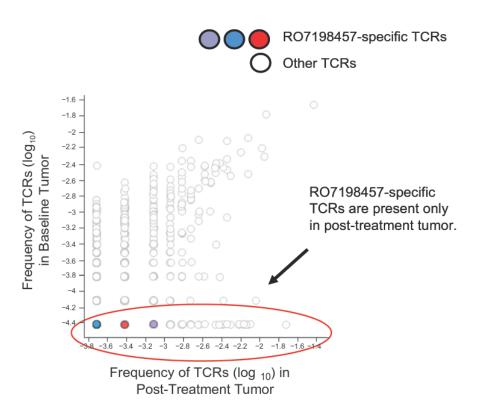


iNeST: Recent update from BNT122 reported at AACR (Cont'd)

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



BNT122 induces CD8+ T cell infiltrates in tumors





BNT122 iNeST randomized Phase 2 trials ongoing and planned

First-line advanced melanoma

Study
design and
patient
population

A Phase 2, open-label, multicenter randomized trial of the efficacy and safety of BNT122 in combination with pembrolizumab vs. pembrolizumab in patients with previously untreated Advanced Melanoma

Rationale

- Evaluate added benefit of 1L BNT122 in an advanced CPIsensitive tumor (PFS, ORR)
- Success ungates 1L use of iNeST in CPI-sensitive advanced cancers for combination therapy

Adjuvant non-small cell lung cancer

A Phase 2, open-label, multicenter, randomized trial of the efficacy and safety of BNT122 in combination with atezolizumab vs. atezolizumab alone following adjuvant platinum-doublet chemotherapy in patients who are ctDNA positive after surgical resection of Stage II-III NSCLC

- Evaluate added benefit of BNT122 in a micrometastatic CPI-sensitive tumor (RFS)
- Success ungates adjuvant use of iNeST in CPI-sensitive ctDNA+ cancer types

Adjuvant colorectal cancer

A Phase 2, open-label, multicenter randomized trial to compare the efficacy of BNT122 versus watchful waiting in patients with ctDNA positive, surgically resected Stage 2/3 rectal cancer, or Stage 2 high risk/stage 3 colon cancer

- Evaluate added benefit of BNT122 in a micrometastatic CPI-insensitive tumor (RFS)
- Success ungates adjuvant use of iNeST for CPI-insensitive ctDNA+ cancer types

Status

Enrollment update in 2H 2020

To start in 2H 2020

To start in 2H 2020



Digitization and automation for neo-antigen vaccine manufacturing





Paperless documentation

Semi-automatic manufacturing

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



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Antibodies

Small Molecule Immunomodulators

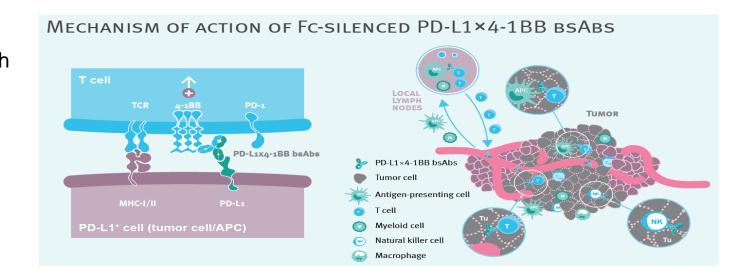
CARVac platform – CLDN6 CAR-T

RiboCytokines



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

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



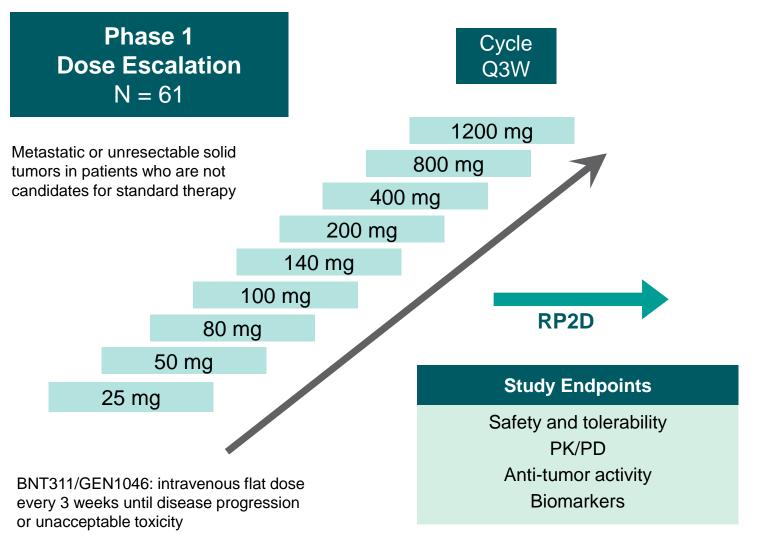
Interim results
of ongoing
Phase 1/2a trial
presented at
SITC 2020

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

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



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



Phase 2a Dose Expansion N = Up to 40 per cohort

EC1: NSCLC ≤ 2-4L p. ICI

EC2: NSCLC ≤ 2-4L ICI n.

EC3: Urothelial Ca ≤ 2-4L p. ICI

EC4: Endometrial Ca ≤ 2-4L ICI n.

EC5: TNBC ≤ 2-4L CPI n./ p. ICI

EC6: SCCHN ≤ 2-4L CPI n./ p. ICI

EC7: Cervical Ca ≤ 2-4L ICI n.

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



BNT311: Interim results of ongoing Phase 1/2a trial Manageable safety profile and initial clinical activity in FIH trial

Safety

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

Dose escalation

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

Dose expansion

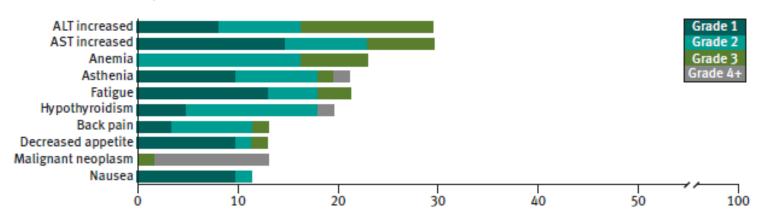
- Encouraging preliminary efficacy in 12 PD-L1 relapsed/refractory NSCLC patients
 - 2 confirmed partial responses
 - 1 unconfirmed partial response
 - 4 patients demonstrated stable disease
- Enrollment ongoing in 6 additional cohorts



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

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

TEAEs occurring in ≥10% of patients



TRAEs occurring in ≥10% of patients

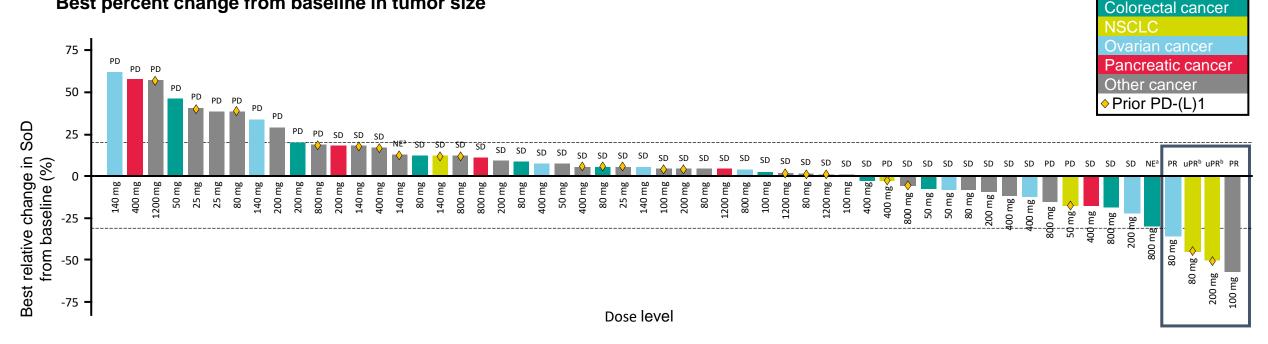
Dose escalation cohort	All patients (N=61)			
	All grades, n (%)	Grade 3, n (%)	Grade 4, n (%)	
Any TRAE	43 (70.5)	15 (24.6)	3 (4.9)	
TRAEs in ≥10% of patients, by preferred term Transaminase elevation	16 (26.2)	6 (9.8)	0	
Hypothyroidism Fatigue	11 (18.0) 8 (13.1)	0 1 (1.6)	1 (1.6) 0	

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



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

Best percent change from baseline in tumor size



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

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

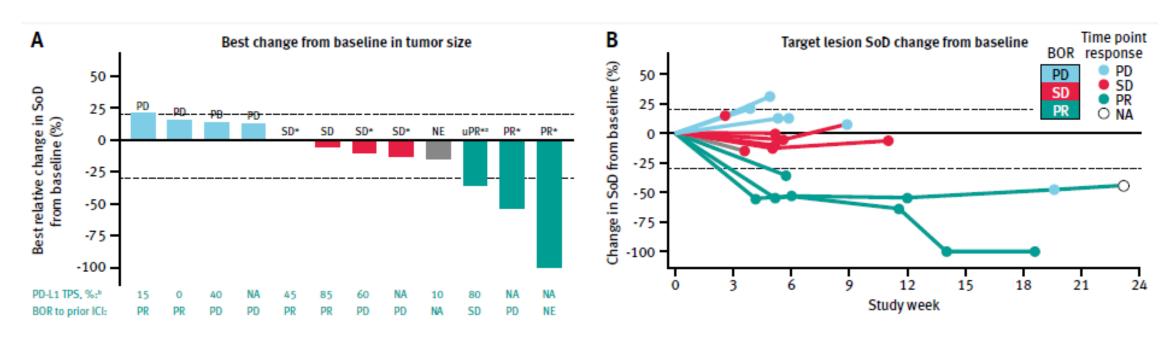


^aMinimum duration of response (5 weeks) per RECIST v1.1 not reached.

^bPR was not confirmed on a subsequent scan.

NE, non-evaluable; NSCLC, non-small cell lung cancer; PD, progressive disease; PD-(L)1, programmed death (ligand) 1; PR, partial response; SD, stable disease; SoD, sum of diameters; uPR, unconfirmed partial response.

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



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

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

Data cut-off: October 12, 2020.

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

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



^{*}Denotes patients with ongoing treatment.

aPR was not confirmed by a subsequent scan.

Agenda

Overview and business outlook

Deeper dive on our key programs



COVID-19 vaccine program (project "Lightspeed")

mRNA vaccines - FixVac and iNeST

Antibodies

Small Molecule Immunomodulators

CARVac platform – CLDN6 CAR-T

RiboCytokines



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

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

Study design:

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



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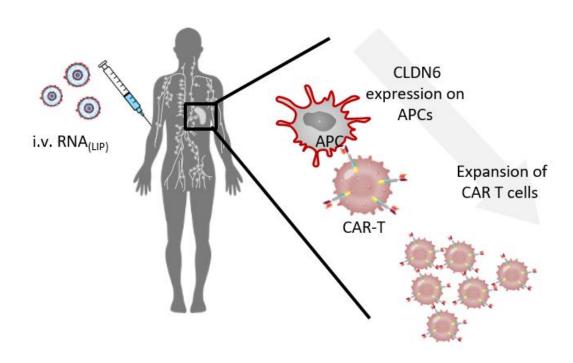
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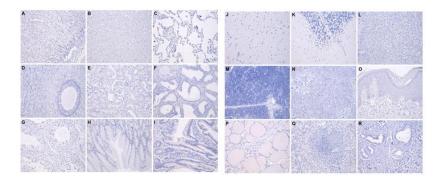


BNT211: Next generation CAR-T targeting CLDN6 with CARVac "primer"

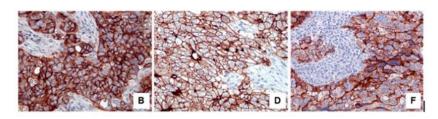


CAR-T cell therapy + RNA Vaccine to amplify CAR-T cell in vivo

CLDN6 is <u>not</u> present in healthy tissues



CLDN6 is expressed in multiple cancers

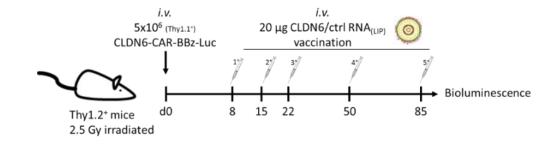


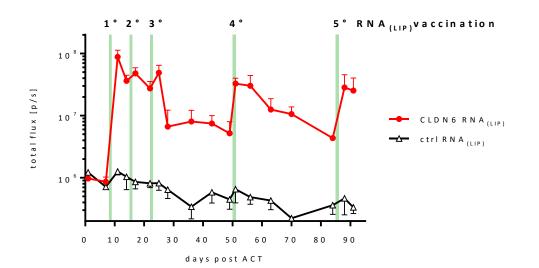
Ovarian cancer Testicular tumor Lung cancer

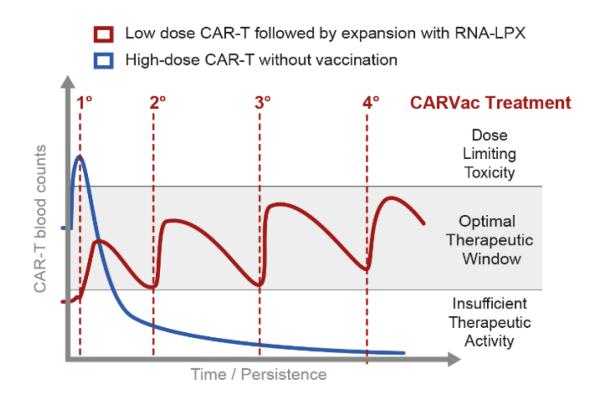
Eradication of advanced tumors demonstrated in an ovarian carcinoma xenograft model



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







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

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



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RiboCytokines



RiboCytokines: a novel therapeutic platform

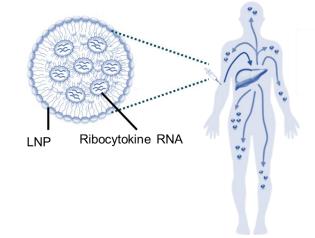
The concept

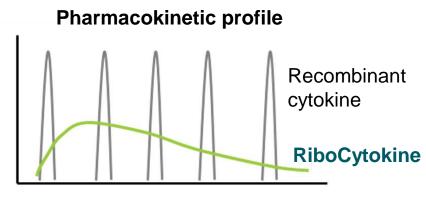
- Cytokines encoded by mRNA and produced in the patient
- Improved PK properties to improve tolerability and activity
- Cytokine design to improve immunological properties and tolerability

Therapeutic goals

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

Worldwide rights; wholly owned

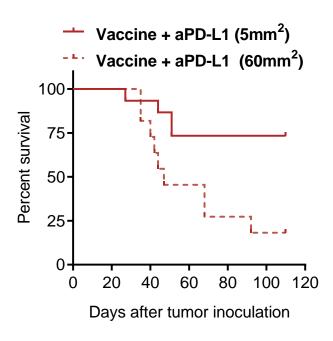




Product Candidate	Preclinical	Phase 1	Phase 2	
BNT151	Optimized IL-2			Expected to enter the clinic in 1H 2021
BNT152+BNT153	IL-7, IL-2			Expected to enter the clinic in 1H 2021



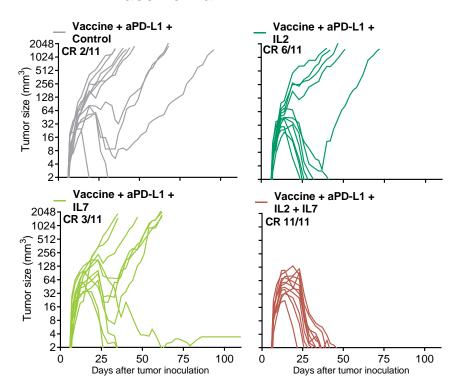
RiboCytokines boosted activity of vaccination and PD-L1 blockade in mouse model

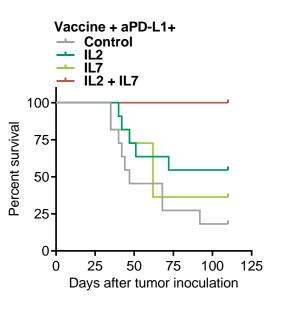


CT26 tumor model, vaccine antigen: gp70

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

Vaccine + aPD-L1 +





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

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





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