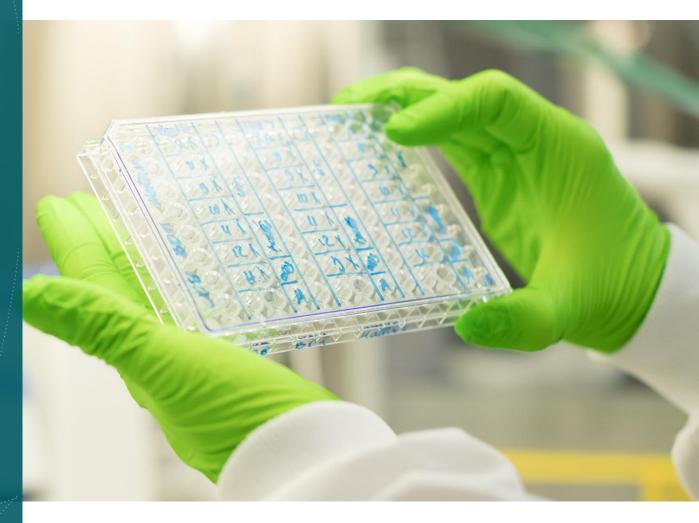
BIONTECH

Next Generation Immunotherapy

January 2021





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 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.



Safety Information

Authorized use in the U.S.:

• The Pfizer-BioNTech COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

Important safety information from U.S. FDA emergency use authorization prescribing information:

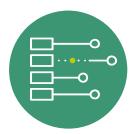
- Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any <u>component</u> of the Pfizer-BioNTech COVID-19 Vaccine
- Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine
- Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/)
- Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine
- The Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients
- In clinical studies, adverse reactions in participants 16 years of age and older included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%)
- Severe allergic reactions have been reported following the Pfizer-BioNTech COVID-19 Vaccine during mass vaccination outside of clinical trials. Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine
- · Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy
- Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion
- There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series.

 Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series
- Vaccination providers must report Adverse Events in accordance with the Fact Sheet to VAERS at https://vaers.hhs.gov/reportevent.html or by calling 1-800-822-7967. The reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report
- Vaccination providers should review the Fact Sheet for Information to Provide to Vaccine Recipients/Caregivers and Mandatory Requirements for Pfizer-BioNTech COVID-19 Vaccine Administration Under Emergency Use Authorization



Next generation Immunotherapy

Harnessing the full potential of the immune system



Building a fully integrated biopharmaceutical company



Immunotherapies for cancer & infectious diseases and beyond



Broad suite of novel technologies



Industry-leading global collaborations



Opportunity in 2021 and beyond

Building a global, multi-product, immunotherapy powerhouse

Poised to usher in new era of vaccines and immunotherapies in multiple therapeutic areas



Advance broad pipeline of >20 product candidates



Ability to invest COMIRNATY cash flows to accelerate diverse portfolio



Proven execution capabilities and maturation toward a commercial organization

Deep expertise in immunology

Cutting edge platforms across 4 drug classes

Bioinformatics driven approach leveraging AI and machine learning In-house GMP manufacturing of mRNA and cell therapies



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





mRNA technology poised to revolutionize immunotherapy

mRNA Today

mRNA vaccines established as a New Drug Class



Accelerated learning path for COVID vaccine leads to diversification and maturation of the mRNA technology

mRNA Tomorrow

mRNA technology to **Displace traditional modalities**

mRNA vaccines for additional infectious diseases

mRNA cancer vaccines

CAR-T cell amplifying mRNA vaccine

Systemic mRNA encoded immuno-therapies

mRNA in the Future

"Beyond the Horizon"

Autoimmune diseases

Rare diseases

Other therapeutic areas

Novel targets Innovative modalities New disease areas



Infectious diseases represent a long-term growth pillar

Unmet Medical Needs

- Increasing number of highly unaddressed indications
- Only <u>7</u> infectious disease vaccines approved by the FDA from 2017 to 2020
- Many high incident infections with <u>no</u> <u>vaccine or therapy approved</u>
- Efficacy of multiple approved vaccines is suboptimal

BioNTech infectious diseases portfolio

COMIRNATY

Next generation COVID-19 vaccines

Influenza, HIV and TB vaccines

6 undisclosed programs



Rationally designed multi-platform immuno-oncology strategy

mRNA Cancer Vaccines

- FixVac and iNeST
- Multi-specificity, multi-valency, high (neo)antigen specific T cell responses with unprecedented potency
- Ongoing Phase 2 randomized trials (iNeST)
- Next-gen CAR-T and TCR therapies targeting Solid Tumours
- Paired with mRNA vaccination to enhance PK and persistence
- Novel targets from BioNTech's library
- Phase 1 FIH trials to start in 2021

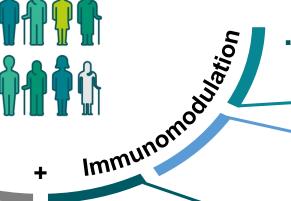
Cell Therapies





Ongoing Phase 1/2 trial

Antibodies



- TLR7 agonist potently modulates innate immunity
- Potential for combination with other IO agents
- Ongoing Phase 1 trial in SCLC

Small Molecule Immunomodulators

- Next Generation Immunomodulators
- Next-generation checkpoint inhibitors to address a broad range of cancers
- Ongoing Phase 1/2 trials of 2 bi-specific antibodies

- mRNA encoded cytokines with a prolonged T1/2 and improved safety profile
- Amplify vaccines and CPIs
- Phase 1 FIH trials to start in 2021

Engineered Cytokines

Multiple blockbuster opportunities with synergistic combinations



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



Advancing innovation beyond current boundaries

NEOSTIM T cell therapy CARVac¹ **RiboCytokines** RiboMabs² CAR-T cell amplifying mRNA Individualized Neoantigen specific mRNA encoded Cytokines mRNA encoded Antibodies therapy for solid tumors T cell therapy Expansion of Pharmacokinetic Profile Recombinant cvtokine RiboCytokine BNT 211 (CLDN 6 CAR) BNT 221 (PBMC) BNT 151 (modified IL2) BNT 141 (undisclosed) derived ex vivo T cell BNT152 & 153 (IL-2/IL- BNT 142 (CD3xCLDN6) therapy) 7) Wholly owned 2021 2021 2021 2021 FIH start

Key pipeline milestones expected in 2021

5+ data updates across pipeline

- COMIRNATY updates
- Next-gen immunomodulator: BNT311 (GEN1046)

BNT312 (GEN1042)

- CLDN6 CARVac: BNT211
- Small molecule: BNT411

Up to 3 programs moving into randomized phase 2 trials

- FixVac melanoma: BNT111
- FixVac HPV16+ head and neck cancer: BNT113
- **iNeST**: BNT122 (RO7198457)

6 pre-clinical programs to move into phase 1 across novel platforms

- RiboMabs: BNT141, BNT142
- RiboCyokines: BNT151, BNT152+BNT153
- CLDN6 CARVac: BNT211
- NEOSTIM neoantigen-based
 T cell therapy: BNT221



Better placed than ever to bring innovation to patients

2021 Corporate Outlook

- Deliver COMIRNATY to up to 1 billion people globally
- Advance up to 3 oncology programs into randomized Phase 2 trials
- Initiate first trials in oncology with registrational potential
- Extend mRNA technology into new disease areas
- Expand global capabilities and footprint in the U.S., Europe, and Asia
- Continue to hire the best and brightest

Longterm

- Usher in a new era of individualized cancer medicine
- Build a global business and commercialize our own products
- Become a 21st century immunotherapy powerhouse



Agenda

Overview and business outlook

Pipeline

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



Oncology pipeline: 11 product candidates in 12 ongoing clinical trials

Drug class	Platform	Product Candidate	Indication (Targets)	Preclinical Phase 1	Phase 2 Phase 3	Rights Collaborator	Milestones
	FixVac (fixed combination of shared cancer antigens)	BNT111	advanced melanoma			fully-owned	FPD ⁴ phase 2: 1H 2021
		BNT112	prostate cancer			fully-owned	
		BNT113	HPV16+ head and neck cancer ¹			fully-owned	FPD ⁴ phase 2: 1H 2021
₹		BNT114	triple negative breast cancer			fully-owned	
mRNA		BNT115	ovarian cancer ¹			fully-owned	
	(nationt enecitic cancer	RO7198457 (BNT122)	1L melanoma			Genentech	
			solid tumors			(global 50:50 profit/loss)	Phase 2 trial planned in adjuvant CRC: FPD ⁴ in 1H 2021
	Intratumoral Immunotherapy	SAR441000 (BNT131)	solid tumors (IL-12sc, IL-15sushi, GM-CSF, IFNα)			Sanofi (global profit/ loss share)	
es	Next-Gen CP ² Immunomodulators	GEN1046 (BNT311)	solid tumors (PD-L1×4-1BB)			Genmab	Data update 2H 2021
Antibodies		GEN1042 (BNT312)	solid tumors (CD40×4-1BB)			(global 50:50 profit/loss)	Data update 2H 2021
	Targeted Cancer Antibodies	BNT321 (MVT-5873)	pancreatic cancer (sLea)			fully-owned	
SMIM ³	Toll-Like Receptor Binding	BNT411	solid tumors (TLR7)			fully-owned	Data update 2H 2021

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



²Checkpoint Inhibitor.

³Small Molecule Immunomodulators.

⁴FPD = First Patient Dosed

Early-stage oncology pipeline: 6 first-in-human trials to begin in 2021

Drug class	Platform	Product Candidate	Indication (Targets)	Rights Collaborator	Milestones
mRNA	FixVac	BNT116	NSCLC	fully-owned	
	RiboMabs (mRNA-encoded antibodies)	BNT141	solid tumors	fully-owned	Phase 1 start in 2H 2021
		BNT142	solid tumors (CD3+CLDN6)	fully-owned	Phase 1 start in 2H 2021
	RiboCytokines (mRNA-encoded Cytokines)	BNT151	solid tumors (optimized IL-2)	fully-owned	Phase 1 start in 1H 2021
		BNT152, BNT153	solid tumors (IL-7, IL-2)	fully-owned	Phase 1 start in 1H 2021
- -	CAR-T Cells	BNT211	solid tumors (CLDN6)	fully-owned	Phase 1/2 start in 1H 2021 Data update in 2021
		BNT212	pancreatic, other cancers (CLDN18.2)	fully-owned	
	Neoantigen-based T cell therapy	BNT221 (NEO-PTC-01)	solid tumors	fully-owned	Phase 1 start in 1H 2021
	TCRs	to be selected	all tumors	fully-owned	



Broad infectious disease pipeline

Drug Class	Product Candidate	Indication (Targets)	Pre-clinical	Phase 1	Phase 2	Phase 3	Commercial	Rights / Collaborator
	COMIRNATY	COVID-19						Pfizer/Fosun
	BNT162c2 (saRNA)	COVID-19						Pfizer/Fosun
	BNT162b3 (modRNA)	COVID-19						Pfizer/Fosun
	BNT161	Seasonal Influenza						Pfizer
	Un-named program	Tuberculosis						BMGF
mRNA Vaccine	Un-named program	HIV						BMGF
	Undisclosed program	-						
	Undisclosed program	-						
	Undisclosed program	-						
	Undisclosed program	-						
	Undisclosed program	_						
Antibodies	Undisclosed program	COVID-19						Wholly-owned

BMGF= Bill & Melinda Gates Foundation

Infectious Disease Pipeline Target: File 1-2 INDs per year for the next 3 years



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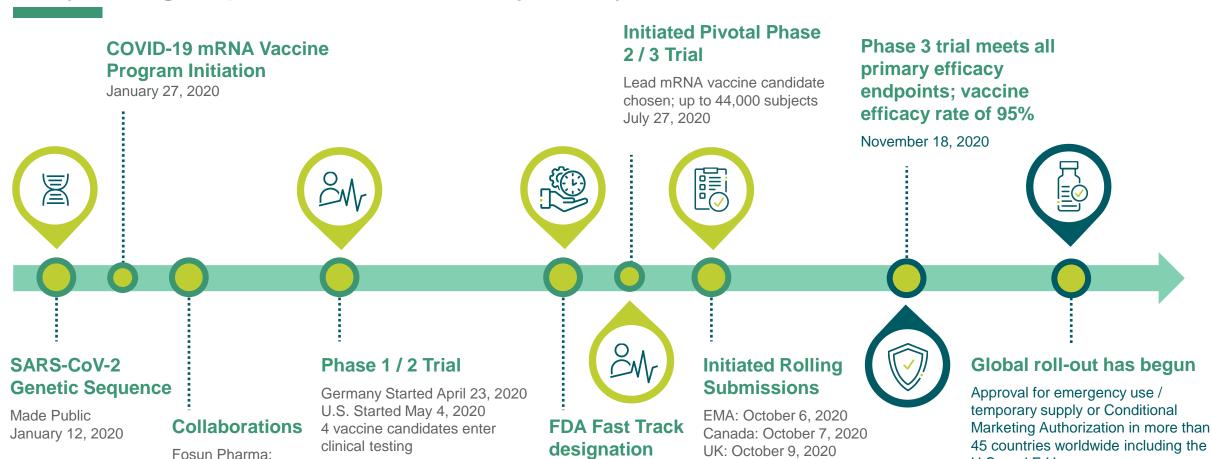
Small Molecule Immunomodulators

CARVac platform – CLDN6 CAR-T

RiboCytokines



Project Lightspeed – a 10-month journey to an effective and safe vaccine



July 13, 2020

Singapore

New Zealand

...and other countries



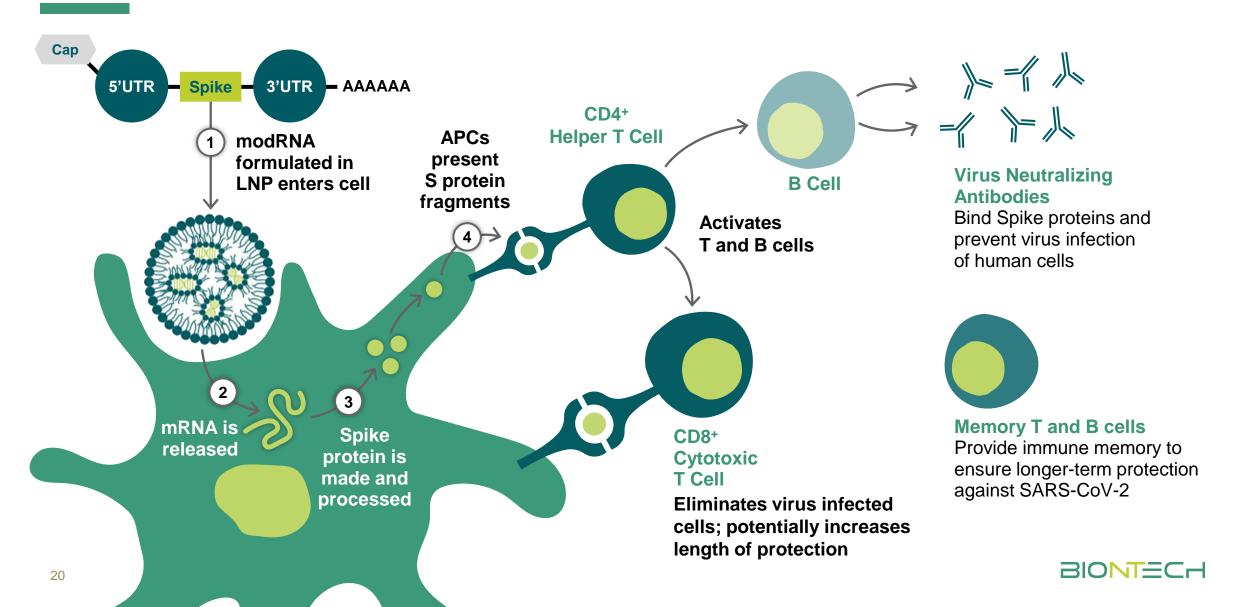
U.S. and E.U.

March 16, 2020

March 17, 2020

Pfizer:

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



mRNA is a natural solution for vaccines especially in a pandemic

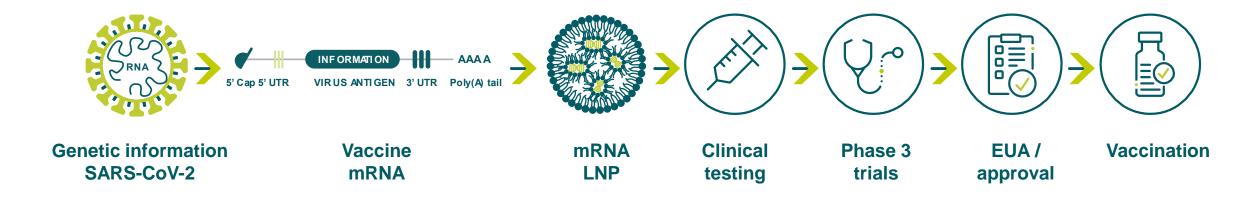
Natural molecule with well-characterized bio-safety properties

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

High purity and animal free

Highly scalable production

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





COVID-19 will likely become an endemic disease

Unmet Medical Needs

Key Strengths

2 Emergence of new viral variants

Ability to create re-engineered vaccine in 6 weeks¹

Naturally waning immune response mRNA vaccine well-suited for re-vaccination



COMIRNATY: Leading the fight against COVID-19

- First vaccine authorized for use in the US and the EU
- Authorization for Emergency Use / Temporary Use or Conditional Approval in > 45 countries
- 32.9m million doses shipped¹
- Global phase 3 trial data indicates vaccine is highly efficacious and generally well tolerated
 - 95% vaccine efficacy in 43,000+ participants
 - 94% efficacy in participants older than 65 years
 - Generally well tolerated with most adverse events being mild to moderate in intensity and transient in effect
 - Most common adverse events are fatigue, headache, pain at injection sites, chills, muscle and joint pain
- Broad immunogenicity profile (poly-epitopic, multi-effector), inducing high titer of neutralizing antibody and T cell responses



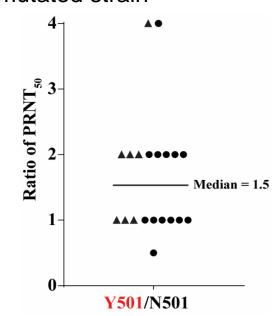


For use in individuals 16 years and older

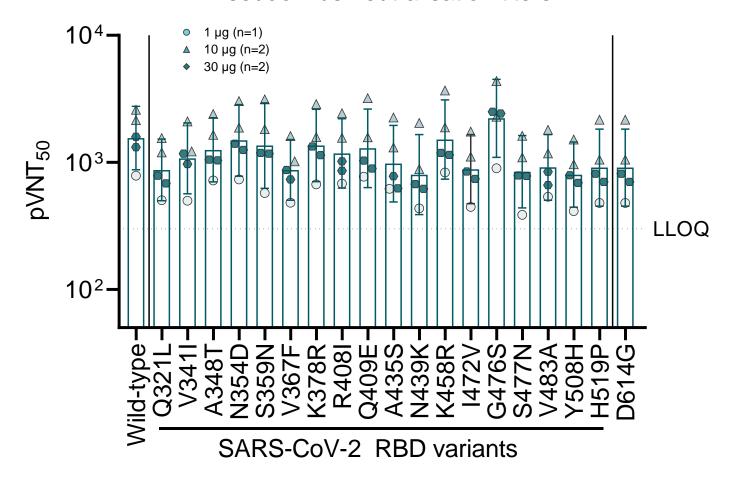


BNT162b2 induced antibodies cross-neutralize SARS-COV-2 variants

 Sera of 20 Phase 3 trial participants contained equivalent neutralizing activity against N501Y mutation found in two highly transmissible strains as compared to the unmutated strain²

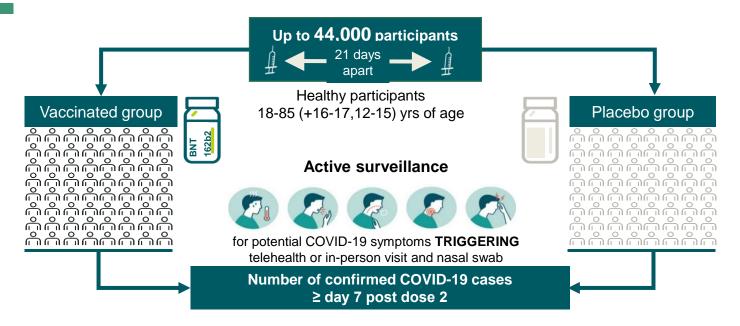


Pseudovirus neutralisation titers





BNT162 met all primary efficacy endpoints in global Phase 3 trial



- Primary efficacy analysis demonstrated 95% vaccine efficacy beginning 28 days after first dose
- Observed >94% vaccine efficacy in adults over 65 years of age; 41% of global participants were 56-85 years old
- Primary efficacy analysis case split: 162 in placebo group vs. 8 in vaccine group
- Ten severe COVID-19 cases observed in the trial with 9 occurring in placebo group and 1 occurring in vaccine group
- Well tolerated across all populations

Primary Efficacy Objectives

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

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

43,661 participants enrolled 41,135 received 2nd dose

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

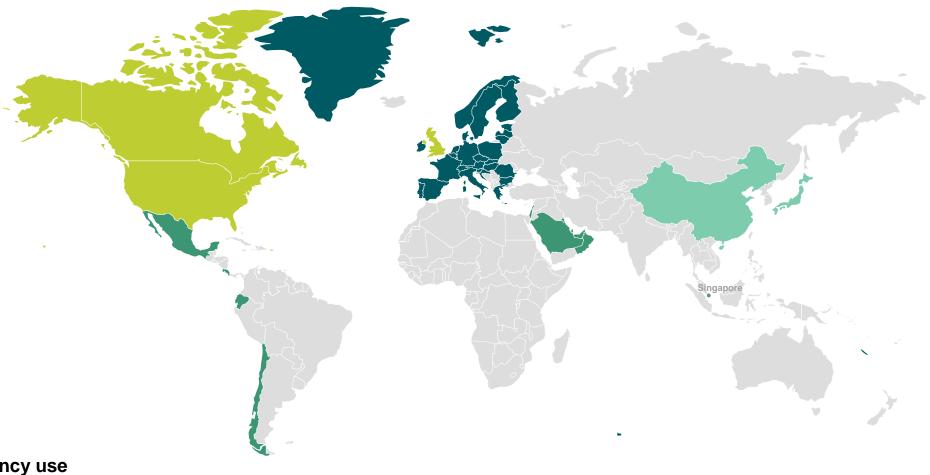
Data as of November 16th, 2020



Project Lightspeed: A concerted and large-scale global effort

- Conditional Marketing
 Authorization in the EU
 and Switzerland¹
- Approved Emergency
 Use Authorization /
 Temporary Use Approval
- Vaccination with our
 COVID-19 vaccine
 already underway under
 Emergency Use
 Authorization/Temporary
 Use Approval
- Ongoing Phase 2 trials in China and Japan

Rolling application for emergency use authorization in further countries underway.

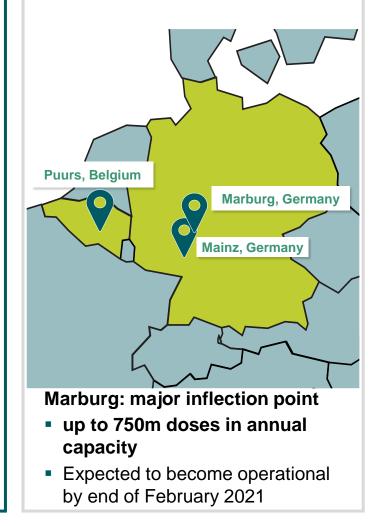




Supply up to two billion vaccine doses in 2021



- FY 2021 manufacturing capacity target: 2.0 billion doses*
- Committed Doses for 2021:>1 billion doses
- 50:50 gross profit share with Pfizer (worldwide ex-China); 35-40% gross profit share with Fosun Pharma in China
- 6 manufacturing sites in Pfizer and BioNTech alliance
- Additional external CMO sites expanding LNP and fill-finish capacity



Multiple strategic levers to expand COMIRNATY access



Increase Supply Capacity

- 6-dose vial
- Continous process improvements
- New sites, suppliers and CMOs

Expand label

- Pediatric indications
- Pregnant women
- Additional sub-populations

Broaden global distribution

- New country / regional authorizations
- BLA submission in U.S. and other regions
- Order book growth

Develop optimized formulations

- Further stability testing update for current formulation
- Improved thermostable formulation
- PEG-free formulation



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



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CARVac platform – CLDN6 CAR-T

RiboCytokines

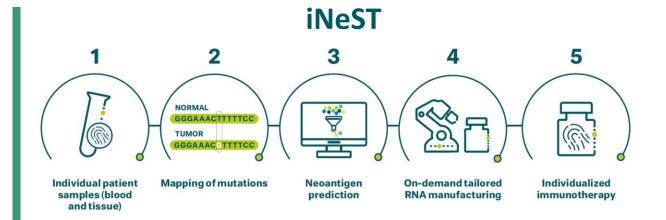


Our mRNA vaccine platforms: FixVac and iNeST

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



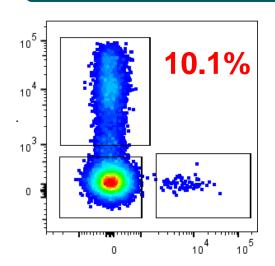
- Fully individualized mRNA immunotherapy
- Targeting 20 neo-antigens unique to each patient
 - Vast majority of neo-antigens are unique to individual patients
 - Applicable across solid tumor types

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

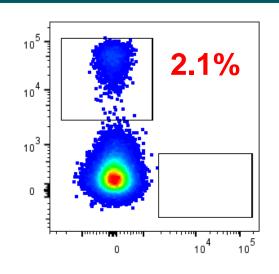


Our RNA-LPX vaccine approach

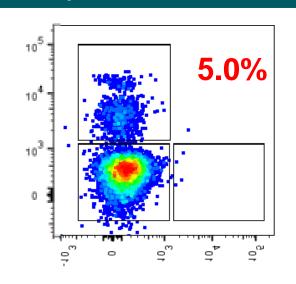
Strong vaccine-induced ex vivo CD8+ T cell responses¹ across different cancer types



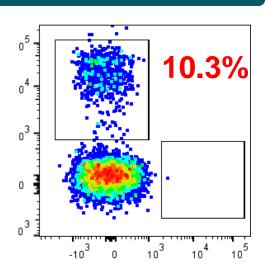
NY-ESO-1 Melanoma BNT111, Lipo-MERIT trial



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

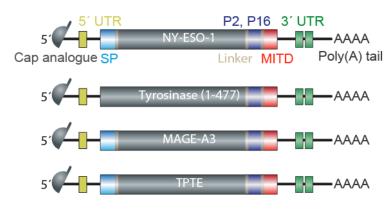
- Signed strategic collaboration to jointly conduct randomized Phase 2 trial with BNT111 and Libtayo® (cemiplimab anti-PD-1 therapy)
- Targeting patients with anti-PD1-refractory/relapsed, unresectable Stage III or IV cutaneous melanoma
- Companies to share development costs equally and keep full commercial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



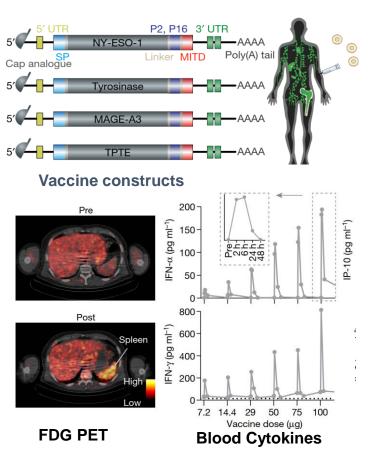
Cumulative patient coverage of FixVac melanoma targets is over 90%

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

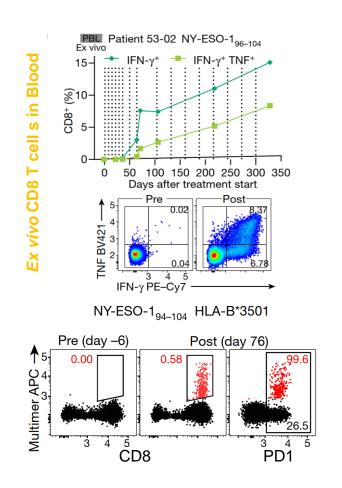


BNT111 publication in Nature highlights

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

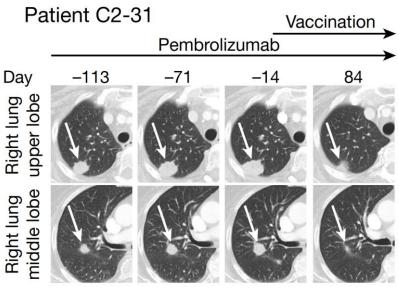


Strong CD4+, CD8+ T cell responses Multifunctional CD8+ PD1+ T cells



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

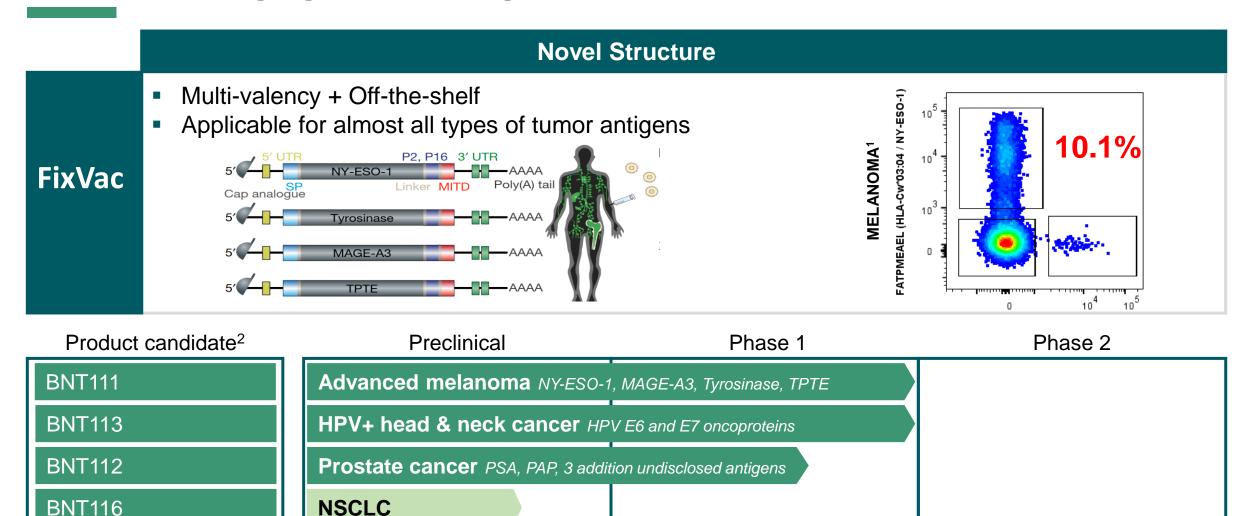
- ORR of BNT111 monotherapy: 4/25
- ORR of BNT111 + anti-PD1: 6/17 (35%) (CPI resensitizing activity of BNT111)



Lung CT scans before & after BNT111

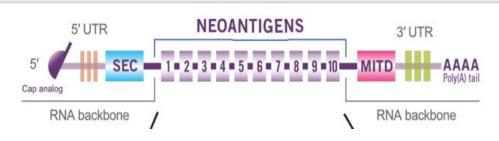


FixVac: Leveraging shared antigens to break immune tolerance



BIONTECH

iNeST¹: Tailored treatment to exploit individual targets



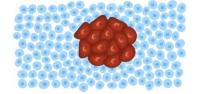
- Fully customized to the individual Patient
- Targeting 20 neo-antigens per patient

ADJUVANT



iNeST

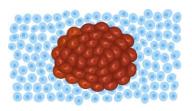




Residual cancer cells may remain – emphasis on recurrence free survival

- Phase 2 trial planned
- 8 of 8 stage III/IV melanoma patients with stable disease cancer free for up to 60 months (BNT121)¹

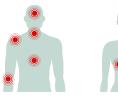
1L METASTATIC



Rapidly growing but often still in early phase of metastases

Ongoing Phase 2 trial in 1L melanoma

LATE-LINE METASTATIC



- Bulky tumors with multiple organs involved
- Single agent activity in melanoma² and gastric³ Cancer
- Encouraging efficacy signal validates iNeST potential in early settings



¹ iNeST is partnered with Genentech/Roche in a 50:50 cost/profit split

² Sahin et. al. Nature 20

³ AACR 2020

iNeST: Recent update from BNT122 reported at AACR

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

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

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

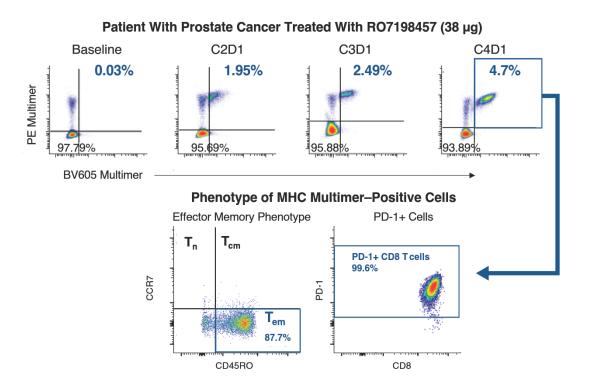
- 132 patients enrolled, cohorts with doses ranging from 15-50μg
- Heavily pre-treated patient population
 - Both CPI experienced and inexperienced
 - Most patients with low PD-1
- Clinical responses associated with T cell response, correlating immune profiling of patients' T cells to cancer-specific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

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

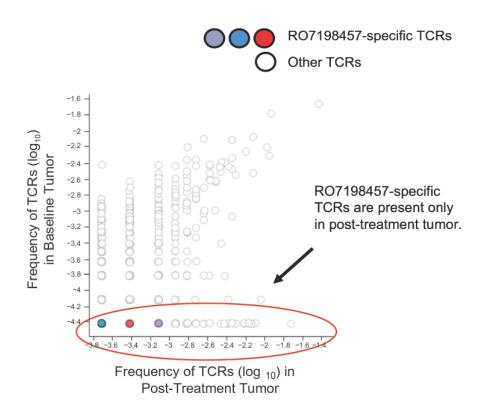


iNeST: Recent update from BNT122 reported at AACR (Cont'd)

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



BNT122 induces CD8+ T cell infiltrates in tumors





BNT122 iNeST randomized Phase 2 trials ongoing and planned

First-line advanced melanoma

Adjuvant colorectal cancer

Study design and patient population

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

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

Rationale

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

- 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

Currently enrolling

To start in 1H 2021



Digitalization and automation for neo-antigen vaccine manufacturing





Paperless documentation

Semi-automatic manufacturing

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



Agenda

Overview and business outlook

Pipeline

Deeper dive on our key programs



COVID-19 vaccine program (project "Lightspeed")

mRNA vaccines - FixVac and iNeST

Antibodies

Small Molecule Immunomodulators

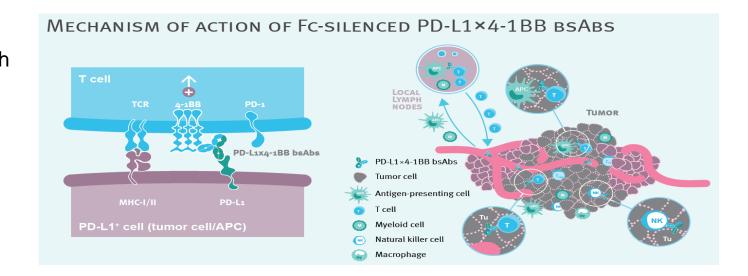
CARVac platform – CLDN6 CAR-T

RiboCytokines



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



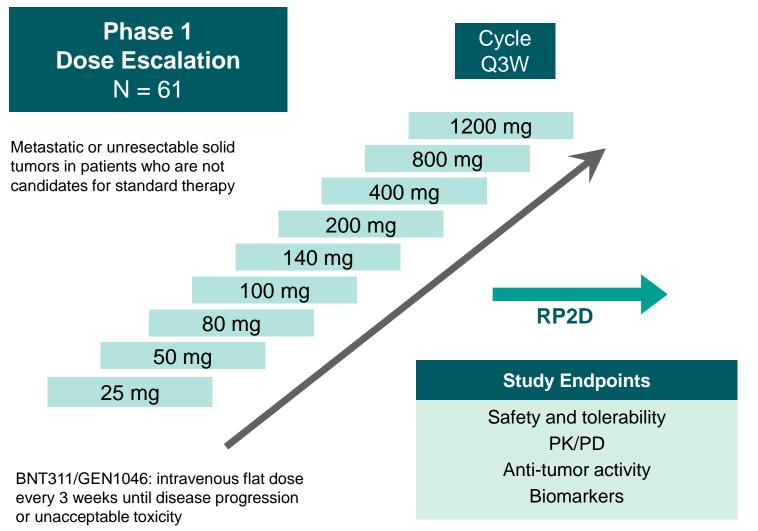
Interim results
of ongoing
Phase 1/2a trial
presented at
SITC 2020

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)



7 expansion cohorts are currently recruiting

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

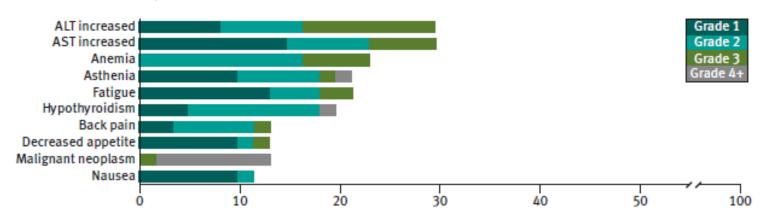
- Encouraging preliminary efficacy in 12 PD-L1 relapsed/refractory NSCLC patients
 - 2 confirmed partial responses
 - 1 unconfirmed partial response
 - 4 patients demonstrated stable disease
- Enrollment ongoing in 6 additional cohorts



^{*}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

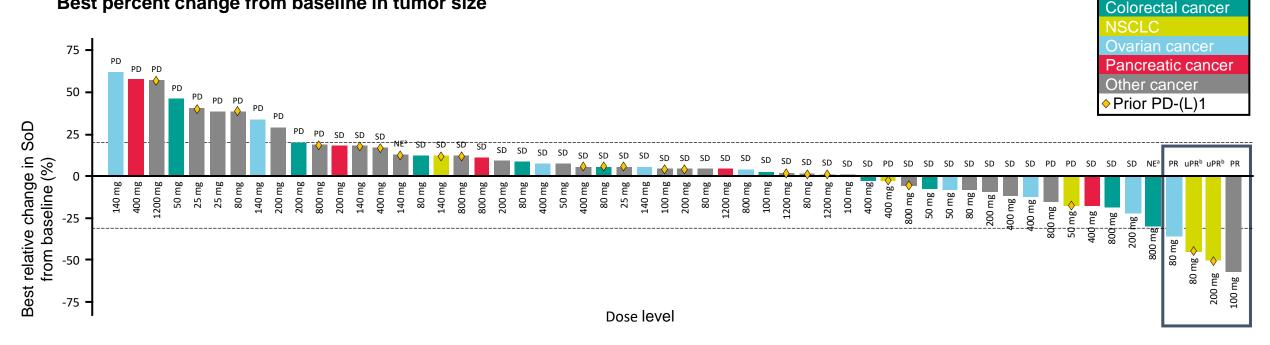
Dose escalation cohort	All patients (N=61)		
	All grades, n (%)	Grade 3, n (%)	Grade 4, n (%)
Any TRAE	43 (70.5)	15 (24.6)	3 (4.9)
TRAEs in ≥10% of patients, by preferred term			
Transaminase elevation	16 (26.2)	6 (9.8)	0
Hypothyroidism	11 (18.0)	0	1 (1.6)
Fatigue	8 (13.1)	1 (1.6)	0

- 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.

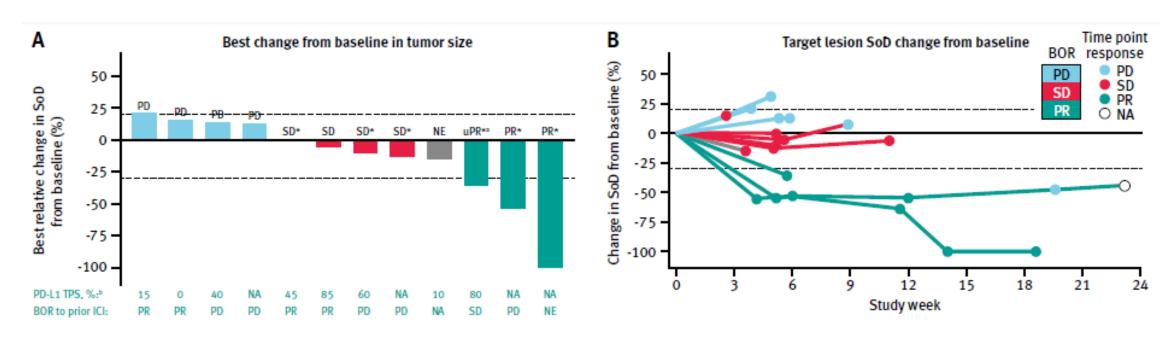


^aMinimum duration of response (5 weeks) per RECIST v1.1 not reached.

^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

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RiboCytokines



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

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

Study design:

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



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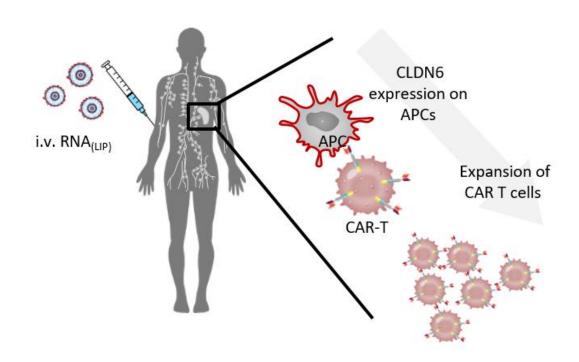
Small Molecule Immunomodulators

CARVac platform – CLDN6 CAR-T

RiboCytokines

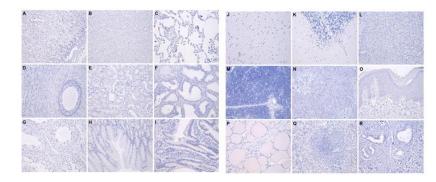


BNT211: Next generation CAR-T targeting CLDN6 with CARVac "primer"

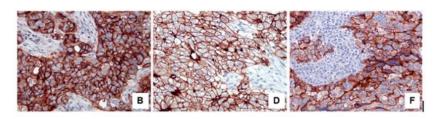


CAR-T cell therapy + RNA Vaccine to amplify CAR-T cell in vivo

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



CLDN6 is expressed in multiple cancers

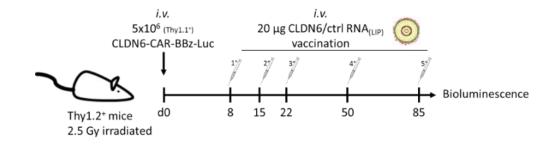


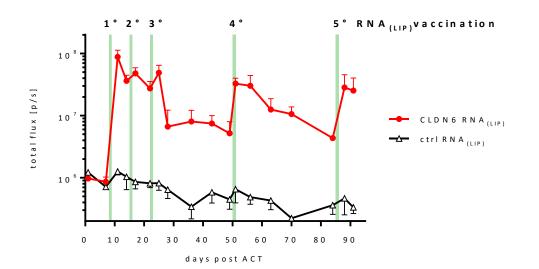
Ovarian cancer Testicular tumor Lung cancer

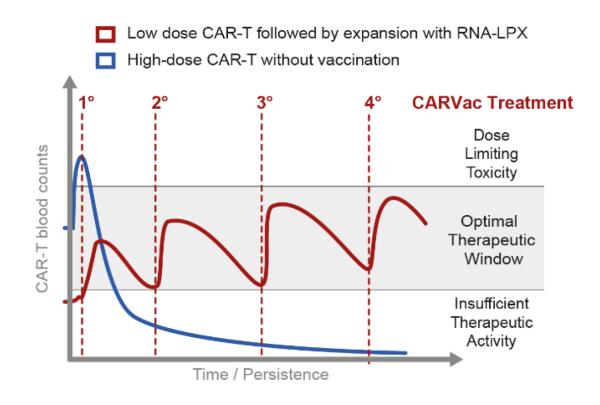
Eradication of advanced tumors demonstrated in an ovarian carcinoma xenograft model



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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CARVac platform – CLDN6 CAR-T

RiboCytokines



RiboCytokines: a novel therapeutic platform

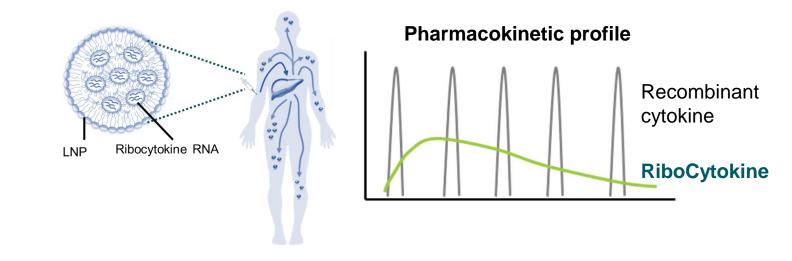
The concept

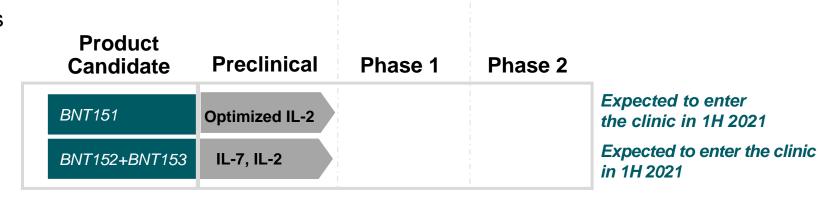
- Cytokines encoded by mRNA and produced in the patient
- Improved PK properties to improve tolerability and activity
- Cytokine design to improve immunological properties and tolerability

Therapeutic goals

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

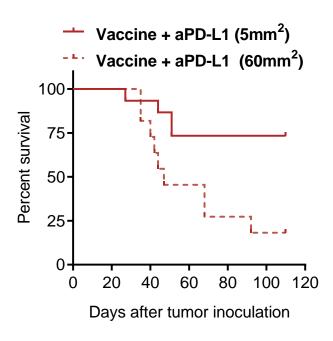
Worldwide rights; wholly owned







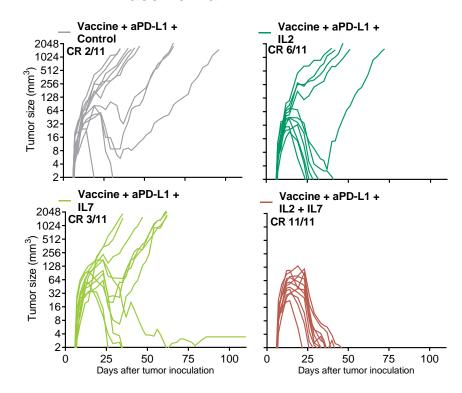
RiboCytokines boosted vaccination activity & PD-L1 blockade pre-clincally

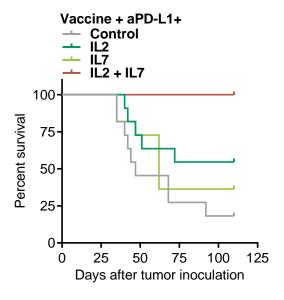


CT26 tumor model, vaccine antigen: gp70

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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