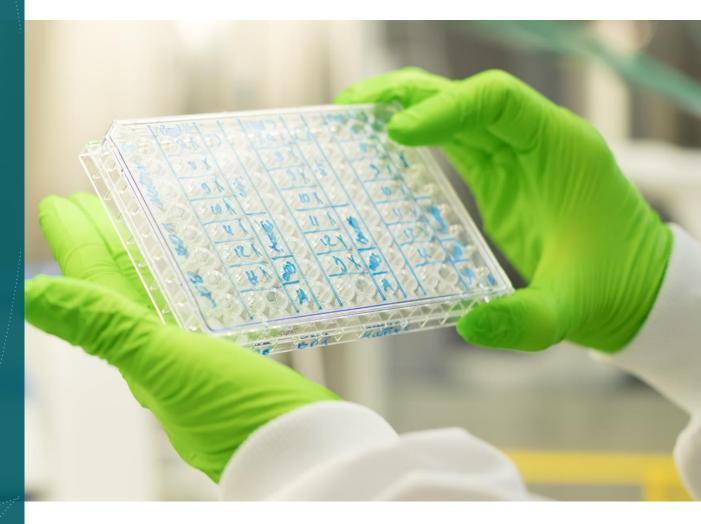
BIONTECH

Next Generation Immunotherapy

April 2021





This slide presentation includes forward-looking statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including BioNTech's expected revenues and net profit related to sales of BioNTech and Pfizer's COVID-19 vaccine, referred to as COMIRNATY® in the European Union as authorized for use under conditional marketing approval, in territories controlled by BioNTech's collaboration partners, particularly those such figures that are derived from preliminary estimates provided by BioNTech's partners; the extent to which a COVID-19 vaccine continues to be necessary in the future; competition from other COVID-19 vaccines or related to BioNTech's other product candidates, including those with different mechanisms of action and different manufacturing and distribution constraints, on the basis of, among other things, efficacy, cost, convenience of storage and distribution, breadth of approved use, side-effect profile and durability of immune response; the pricing and reimbursement of BioNTech and Pfizer's COVID-19 vaccine and BioNTech's investigational medicines, if approved; the rate and degree of market acceptance of BioNTech and Pfizer's COVID-19 vaccine and BioNTech's investigational medicines, if approved; the initiation, timing, progress, results, and cost of BioNTech's research and development programs and BioNTech's current and future preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and BioNTech's research and development programs; the timing of and BioNTech's ability to obtain and maintain regulatory approval for BioNTech's product candidates; the ability and willingness of BioNTech's third-party collaborators to continue research and development activities relating to BioNTech's development candidates and investigational medicines; the impact of the COVID-19 pandemic on BioNTech's development programs, supply chain, collaborators and financial performance; unforeseen safety issues and claims for personal injury or death arising from the use of BioNTech and Pfizer's COVID-19 vaccine, and other products and product candidates developed or manufactured by BioNTech; the development of and projections relating to BioNTech's competitors or its industry; BioNTech's ability to effectively scale its production capabilities and manufacture its products, including BioNTech and Pfizer's COVID-19 vaccine, and BioNTech's product candidates; and BioNTech's target vaccine production for 2021. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forwardlooking statements contain these words.

The forward-looking statements are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond BioNTech's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. You should review the risks and uncertainties described under the heading "Risk Factors" in BioNTech's Annual Report on Form 20-F filed with the US Securities and Exchange Commission (SEC) on March 31, 2020 and in subsequent filings made by BioNTech with the SEC, including the third quarter report, which are available on the SEC's website at www.sec.gov. Except as required by law, BioNTech disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on BioNTech's current expectations and speak only as of the date hereof.



Safety Information

AUTHORIZED USE IN THE U.S.:

The Pfizer-BioNTech COVID19 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:

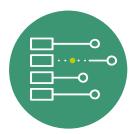
- Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine.
- Appropriate medical treatment used to manage immediate allergic reactions must be immediately available 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, including anaphylaxis, 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 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.

Please see Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including Full EUA Prescribing Information available at www.cvdvaccine-us.com.



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 COVID-19 vaccine 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 Al and machine learning In-house GMP manufacturing of mRNA and cell therapies



mRNA technology poised to revolutionize immunotherapy

Today

mRNA vaccines established as a **New Drug Class**

BNT162b2

Diversification and maturation of our mRNA technology enabled the accelerated development of our COVID-19 vaccine

Tomorrow

mRNA technology to **Displace Traditional Modalities**

- mRNA infectious disease vaccines
- mRNA cancer vaccines
- CAR-T cell amplifying mRNA vaccine
- Systemic mRNA encoded immuno-therapies

The Future

mRNA to open up new opportunities **Beyond the Horizon**

- Autoimmune diseases
- Allergy
- Inflammation
- Regenerative medicine
- Other therapeutic areas

modRNA taRNA saRNA

Broad IP portfolio covering technologies, targets and formulations.

Deep expertise and know-how built over the course of more than a decade.



uRNA

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

COVID-19 vaccine

Next generation COVID-19 vaccines

Influenza, HIV and TB vaccines

6 undisclosed programs

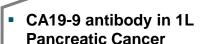


Oncology remains focus: Rationally designed multi-platform immuno-oncology strategy

mRNA Cancer Vaccines

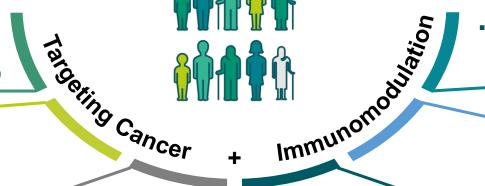
- FixVac and iNeST
- Multi-specificity, multi-valency, high (neo)antigen specific T cell responses with unprecedented potency
- Ongoing Phase 2 randomized trials (iNeST)
- Next-gen CAR-T and TCR therapies targeting Solid Tumors
- Paired with mRNA vaccination to enhance PK and persistence
- Novel targets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

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 trial started in Feb.

Engineered Cytokines

Multiple blockbuster opportunities with synergistic combinations



A technology agnostic approach targets a broader addressable cancer market

Cancer segment Patient Population C		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	



Expected pipeline milestones in 2021

5+ trial updates

- Multiple BNT162b2 updates
- BNT311: Bi-specific CPI: PD-L1 x 4-1bb in solid tumors
- BNT312: Bi-specific checkpoint
 Immunomodulator CD40 x 4-1bb in solid
 tumors
- BNT211: CLDN-6 CAR-T + CARVac in solid tumors
- BNT411: TLR-7 Agonist +/- CPI in solid tumors

3 randomized Phase 2 trial starts

- BNT111: FixVac melanoma + CPI in refractory melanoma
- BNT113: FixVac HPV16+ + CPI
 in 1L HNSCC and cervical cancers
- BNT122: iNeST (autogene cevumeran)+ CPI in adjuvant mCRC

6 First-in-human Phase 1 trial starts

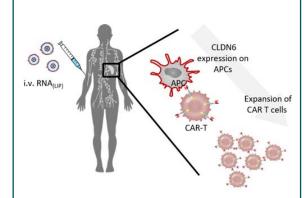
- ✓ BNT211: CLDN-6 CAR-T + CARVac in solid tumors (FPD: Feb. 2021)
- ✓ **BNT151:** Ribocytokine (modified IL-2) (FPD: Feb 2021)
- BNT152+153: RiboCytokine IL-2 / IL-7 combo in solid tumors
- BNT141: RiboMab (undisclosed)
- **BNT142:** RiboMab bi-specific CPI in solid tumors (CD3xCLDN6)
- BNT221: NEOSTIM individualized neoantigen-T cell therapy in melanoma



Next wave oncology advancing innovation beyond current boundaries

CARVac

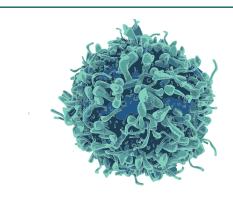
CAR-T cell amplifying mRNA therapy for solid tumors¹



BNT211 (CLDN 6 CAR)
 Next generation CAR-T targeting CLDN6 with CARVac "primer"

NEOSTIM T cell therapy

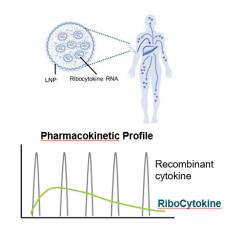
Individualized Neoantigen specific T cell therapy



BNT221
 (PBMC derived ex vivo T cell therapy)

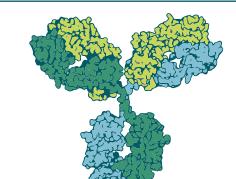
RiboCytokines

mRNA encoded Cytokines



- BNT151 (modified IL-2)
- BNT152 + BNT153 (IL-2/IL-7)

RiboMabs²
mRNA encoded Antibodies



- BNT141 (undisclosed)
- BNT142 (CD3xCLDN6)

Wholly owned:

FIH start: FPD Feb. 2021

/

1H 2021

/

FPD Feb. 2021

/

2H 2021



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



Our strategic priorities for 2021

1

Accelerate and expand innovative pipeline

Launch multiple new products in the next 5 years

Build a 21st century global immunotherapy powerhouse

Continue to execute while driving iterative innovation against COVID-19

- Execute against our goal to deliver our COVID-19 vaccine to more than 1 billion people in 2021
- Continue to innovate to build sustained global market leadership position

Broaden and diversify early- and late-stage pipeline of next generation immunotherapies

- Accelerate pipeline in core therapeutic areas:
 - Infectious Disease: Advance mRNA vaccines to address many infectious diseases
 - Immuno-oncology: Usher in new era of individualized cancer medicine and cell therapy
- Further optimize platforms and initiate early product development in emerging areas:
 - Autoimmunity and Inflammatory Diseases
 - Regenerative Medicine



Better positioned than ever to bring innovation to patients



Launch multiple new products in the next 5 years

Build a 21st century global immunotherapy powerhouse

Re-invest BNT162b2 proceeds to build long-term value for Patients, Shareholders, and Society

Expand global footprint in the U.S., Europe, and Asia

Establish new offices in strategic locations globally

Expand clinical, commercial and manufacturing infrastructure to support future product launches

Invest in digital infrastructure and capabilities

Ramp up our investment in innovation

Complement internal R&D with external innovation



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

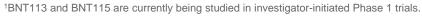
CARVac platform – CLDN6 CAR-T

RiboCytokines



Oncology pipeline: 13 product candidates in 14 ongoing clinical trials

Drug class	Platform	Product Candidate	Indication (Targets)	Preclinical Phase 1 Phas	se 2 Phase 3	Rights Collaborator	Milestones
	FixVac	BNT111	advanced melanoma			fully-owned	FPD ⁴ phase 2: 1H 2021
		BNT112	prostate cancer			fully-owned	
	(fixed combination of shared cancer antigens)	BNT113	HPV16+ head and neck cancer ¹			fully-owned	FPD ⁴ phase 2: 1H 2021
	onarod carroor anagoney	BNT114	triple negative breast cancer			fully-owned	
mRNA		BNT115	ovarian cancer ¹			fully-owned	
E	iNeST (patient specific cancer antigen therapy) autogene cevumeran (BNT122)	autogene	1L melanoma	Genentech			
		cevumeran (BNT122)	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)	
	RiboCytokines (mRNA-encoded Cytokines)	BNT151	solid tumors (optimized IL-2)			fully-owned	
Antibodii Immr	Next-Gen CP ² (mmunomodulators	GEN1046 (BNT311)	solid tumors (PD-L1×4-1BB)			Genmab	Data update 2H 2021
		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
Cell herapie	CAR-T Cells	BNT211	solid tumors (CLDN6)			fully-owned	Data update 2H 2021



²Checkpoint Inhibitor.

⁴FPD = First Patient Dosed



^{16 &}lt;sup>3</sup>Small Molecule Immunomodulators.

Early-stage oncology pipeline: 4 additional FIH¹ trials to begin in 2021

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

¹first-in-human



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
	BNT162b3 (modRNA)	COVID-19						Pfizer/Fosun
mana Manaina	BNT161	Seasonal Influenza						Pfizer
mRNA Vaccine	Un-named program	Tuberculosis						BMGF*
	Un-named program	HIV						BMGF*
	5 un-named programs	Undisclosed indications						Fully-owned
Antibodies	Undisclosed program	COVID-19						Fully-owned

^{*}BMGF= Bill & Melinda Gates Foundation



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Antibodies

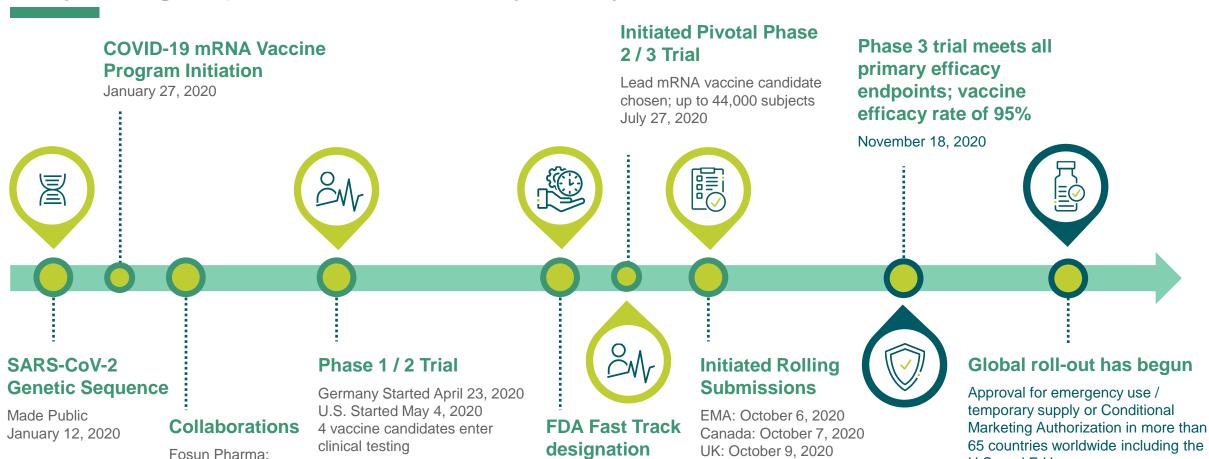
Small Molecule Immunomodulators

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



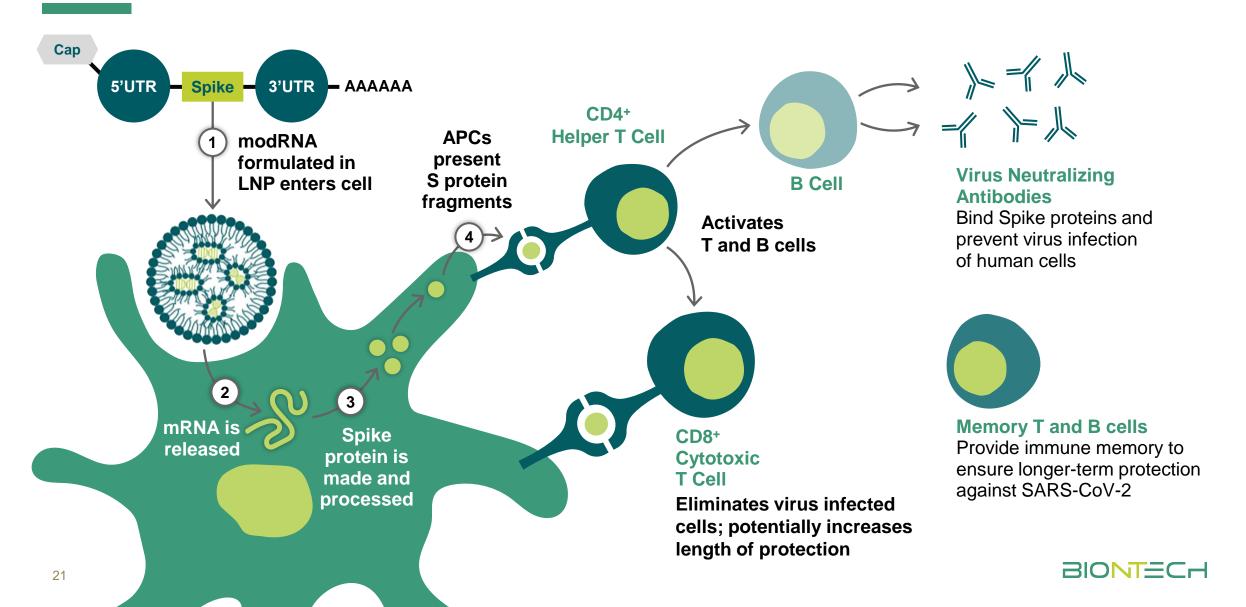
U.S. and E.U.

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

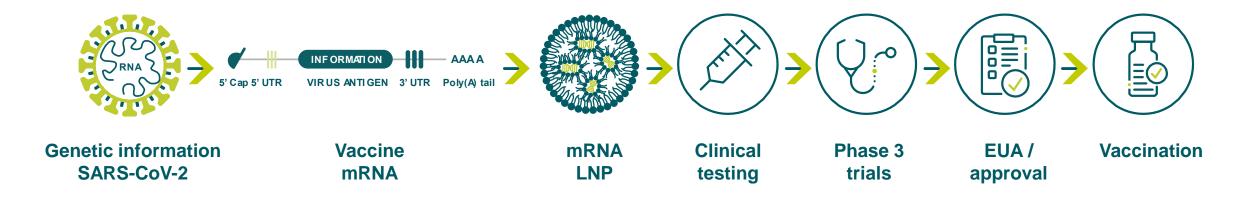
Natural molecule with well-characterized bio-safety properties

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





Strong clinical results



- 95% effective against symptomatic COVID-19 infections¹
- 94% efficacy in participants >65 years
- Well tolerated safety profile
- High titers of neutralizing antibodies
- Robust and poly-epitopic CD8+ and Th1 CD4+ T-cell responses²





Compelling real-world evidence



Two weeks post-dose 2

- About 97% effective in preventing
 - symptomatic COVID-19
 - severe/critical COVID 19
 - Hospitalizations
 - Deaths
- 94% effective against asymptomatic infection
- Protective against B.1.1.7 variant





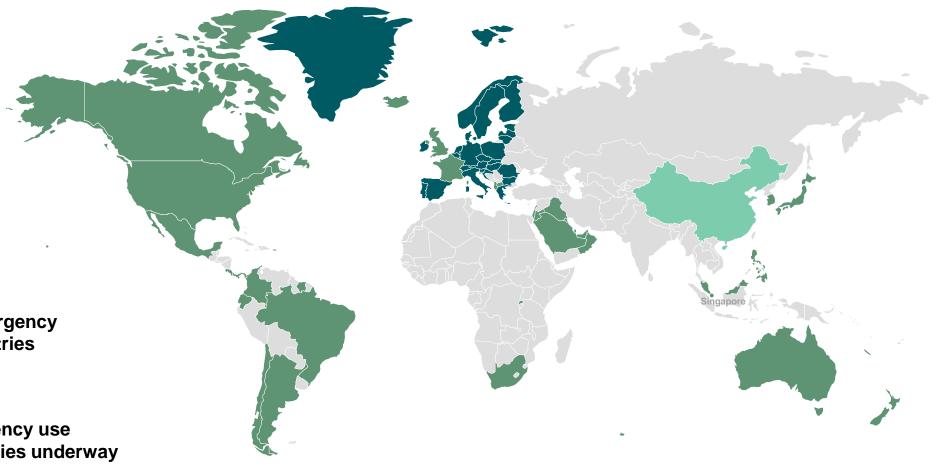
Project Lightspeed: A concerted and large-scale global effort



- Approved Emergency
 Use Authorization /
 Temporary Use Approval
- Ongoing Phase 2 trial in China

Conditional marketing or emergency use authorization in >65 countries with >200M doses delivered²

Rolling application for emergency use authorization in further countries underway



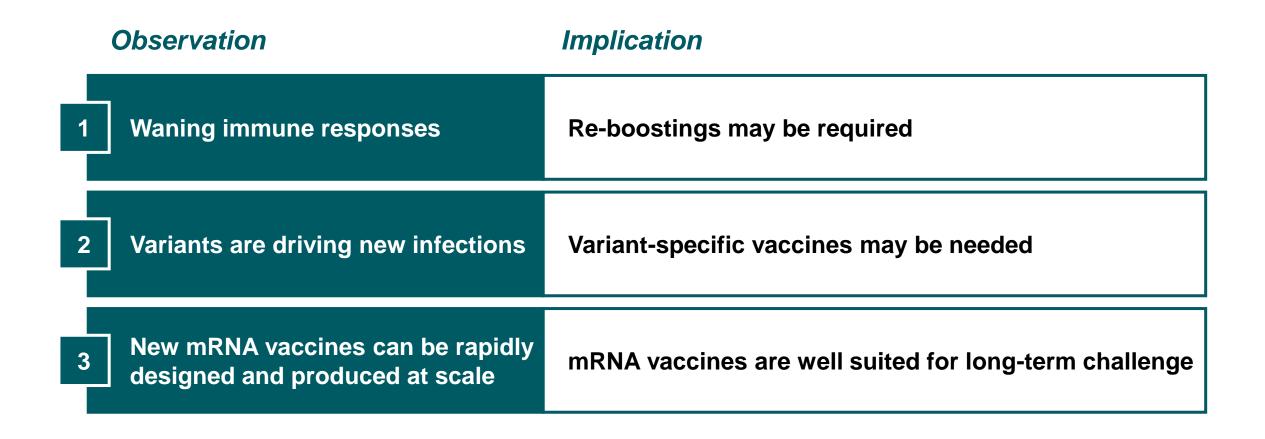


Focused on six key levers to expand COVID-19 vaccine reach

Increased manufacturing capacity	 Up to 2.5 billion doses by end of 2021 Continuous process improvements, expansion of supplier and CMO network
Additional populations	 Global Phase 2/3 trial in healthy pregnant women ≥ 18 years of age ongoing Data in children 12-15 years of age to regulatory authorities in Q2 Study in children 6 months to 11 years of age started
Additional geographies	 Approved in more than 65 countries Japan's Health Ministry approved BNT162b2 Submission to regulatory authorities in Mainland China in process
Broadened & decentralized vaccine access	 U.S. FDA and EMA updated label with 2-week storage and transport at -25°C to -15°C Stability optimized, ready-to-use and lyophilized formulations expected in 2021 BLA submission expected in United States in Q2
Addressing SARS-CoV-2 variants	 Initiated variant-specific registration-enabling trial Additional variant-specific trials expected to be initiated in Q2
Addressing waning immune responses	Initiated trial to evaluate effect of third dose of BNT162b2 at 6 to 12 months post-dose 2



COVID-19 will likely become endemic. Re-vaccination may also be required.



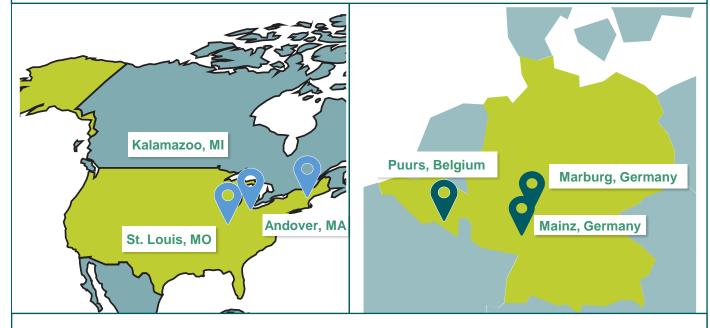


Scaling up manufacturing capacity to address pandemic demand

1.4 billion doses contracted to date for 2021¹

Selected Regions	Current Orders		
EU	500M confirmed 100M option		
US	300M		
Japan	144M		
UK	30M		
Other	~450M		
Ongoing discussions for additional doses in 2021/2022			

Up to 2.5 billion doses* manufacturing capacity

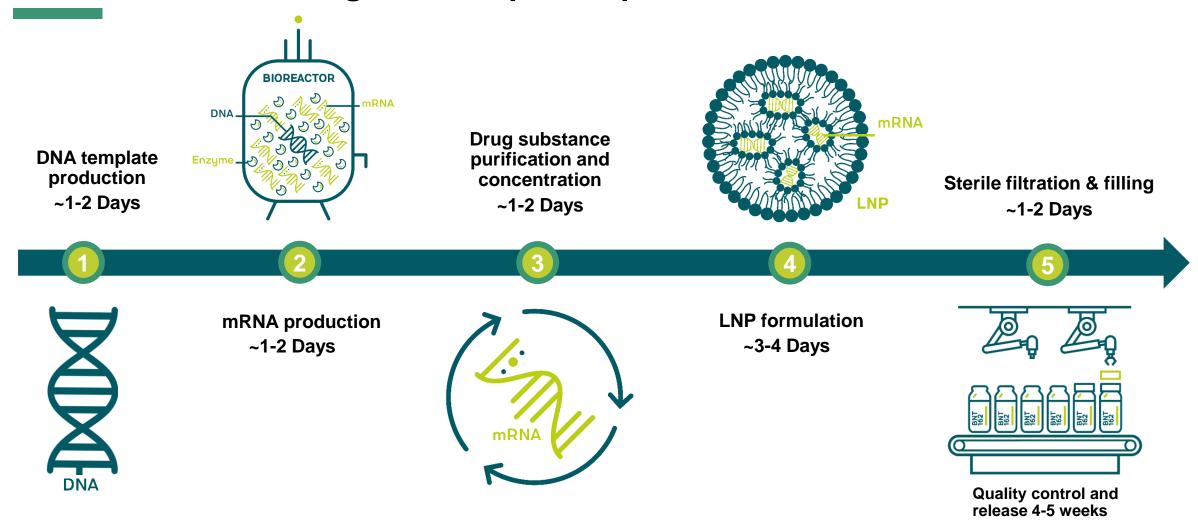


Marburg facility

- Up to 1 billion doses in annual run-rate capacity
- First vaccines scheduled for distribution in April



Flexible manufacturing allows rapid adaptation to variants





Global consortium to address pandemic - 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

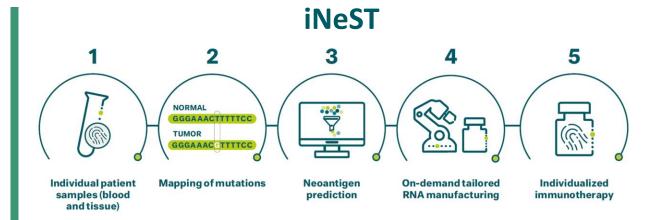


Our mRNA vaccine platforms: FixVac and iNeST

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



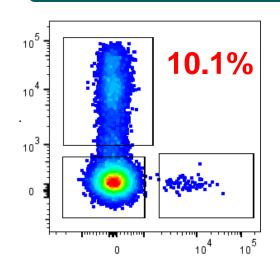
- Fully individualized mRNA immunotherapy
- Targeting 20 neo-antigens unique to each patient
 - Vast majority of neo-antigens are unique to individual patients
 - Applicable across solid tumor types

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

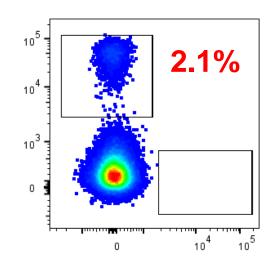


Our RNA-LPX vaccine approach

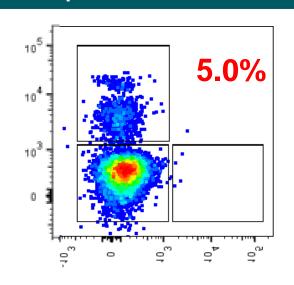
Strong vaccine-induced ex vivo CD8+ T cell responses¹ across different cancer types



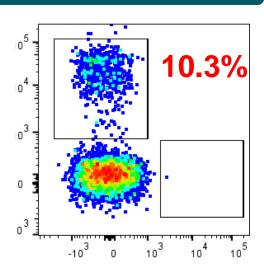
NY-ESO-1 Melanoma BNT111, Lipo-MERIT trial



MAGE-A3
Melanoma
BNT111, Lipo-MERIT trial



HPV16-E7
Head Neck Cancer
BNT113, HARE40 trial



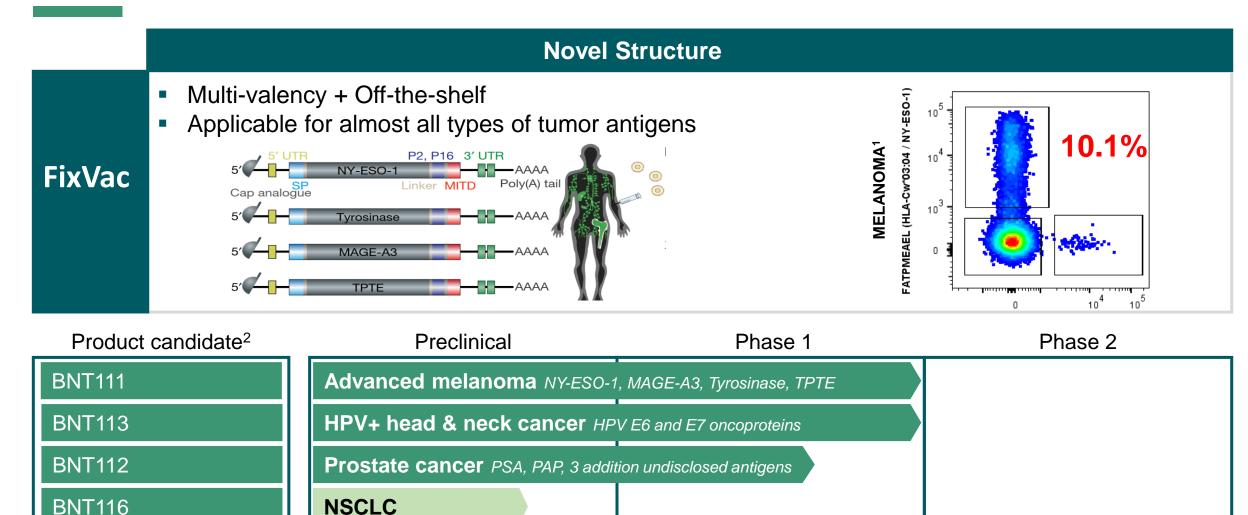
Mutant Neoantigen TNBC BNT114, TNBC MERIT trial

FixVac

iNeST



FixVac: Leveraging shared antigens to break immune tolerance





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

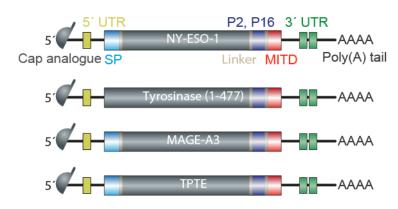
- Signed strategic collaboration to jointly conduct randomized Phase 2 trial with BNT111 and Libtayo® (cemiplimab anti-PD-1 therapy)
- Targeting patients with anti-PD1-refractory/relapsed, unresectable Stage III or IV cutaneous melanoma
- Companies to share development costs equally and keep full commercial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



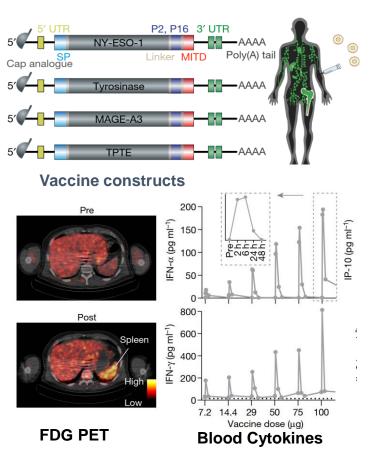
Cumulative patient coverage of FixVac melanoma targets is over 90%

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

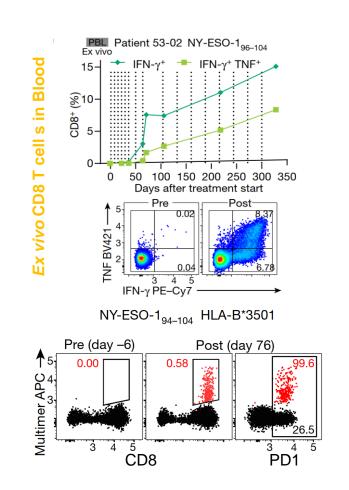


BNT111 publication in Nature highlights

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

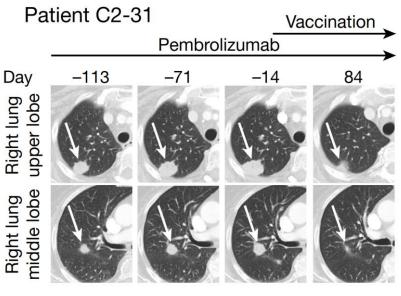


Strong CD4+, CD8+ T cell responses Multifunctional CD8+ PD1+ T cells



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

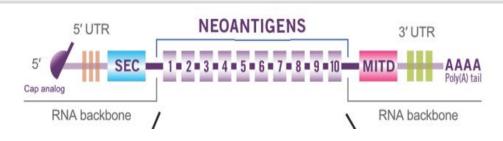
- ORR of BNT111 monotherapy: 4/25
- ORR of BNT111 + anti-PD1: 6/17 (35%) (CPI resensitizing activity of BNT111)



Lung CT scans before & after BNT111



iNeST¹: Tailored treatment to exploit individual targets



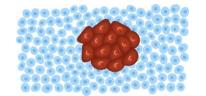
- Fully customized to the individual Patient
- Targeting 20 neo-antigens per patient

ADJUVANT



Normal DNA

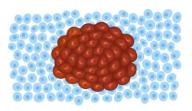




Residual cancer cells may remain – emphasis on recurrence free survival

- 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

iNeST



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 pre-treated patients

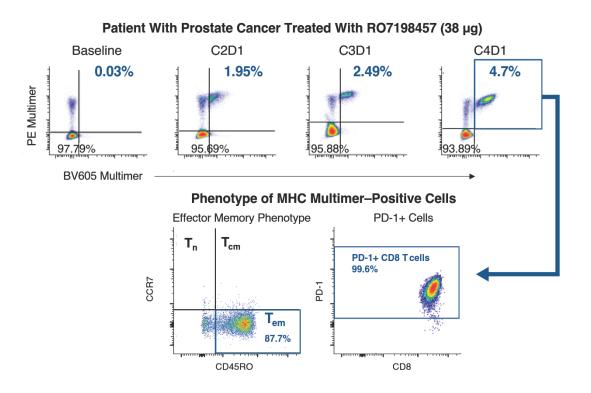
- 132 patients enrolled, cohorts with doses ranging from 15-50μg
- Heavily pre-treated patient population
 - Both CPI experienced and inexperienced
 - Most patients with low PD-1
- Clinical responses associated with T cell response, correlating immune profiling of patients' T cells to cancer-specific 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 <u>both effector and memory phenotype</u> 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

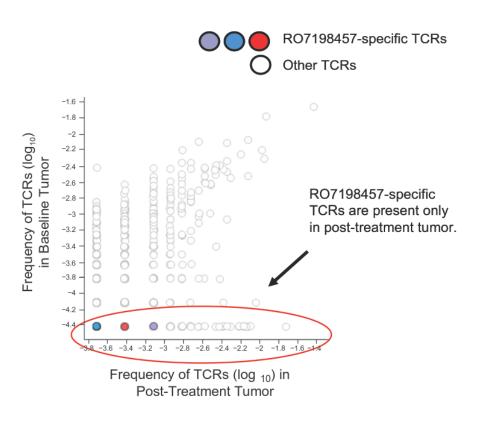


iNeST: Recent update from BNT122 reported at AACR (Cont'd)

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

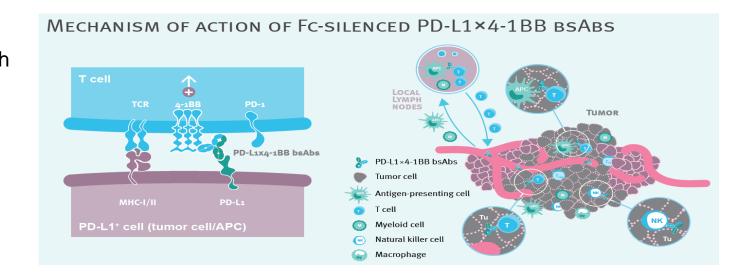
CARVac platform – CLDN6 CAR-T

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



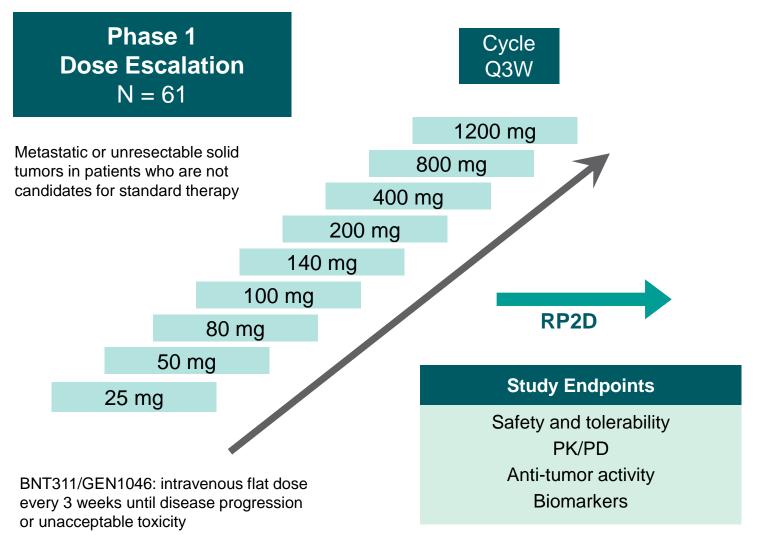
Interim results
of ongoing
Phase 1/2a trial
presented at
SITC 2020

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

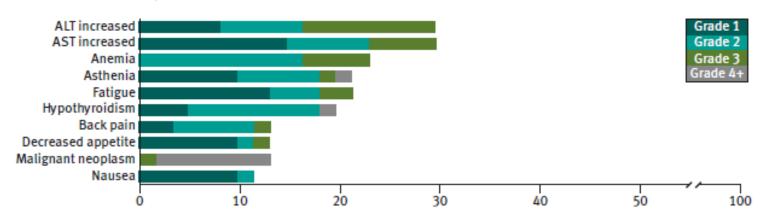
Dose expansion

- 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



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

TEAEs occurring in ≥10% of patients



TRAEs occurring in ≥10% of patients

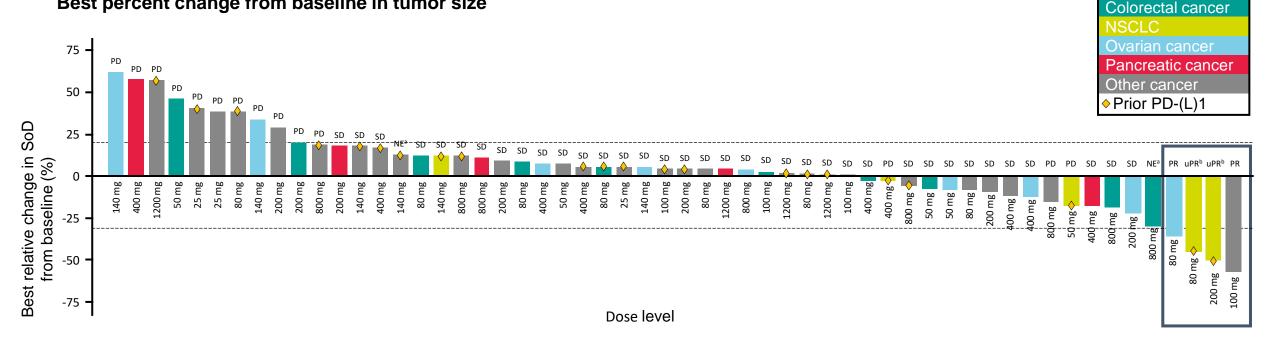
Dose escalation cohort	All patients (N=61)		
	All grades, n (%)	Grade 3, n (%)	Grade 4, n (%)
Any TRAE	43 (70.5)	15 (24.6)	3 (4.9)
TRAEs in ≥10% of patients, by preferred term			
Transaminase elevation	16 (26.2)	6 (9.8)	0
Hypothyroidism	11 (18.0)	0	1 (1.6)
Fatigue	8 (13.1)	1 (1.6)	0

- 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.

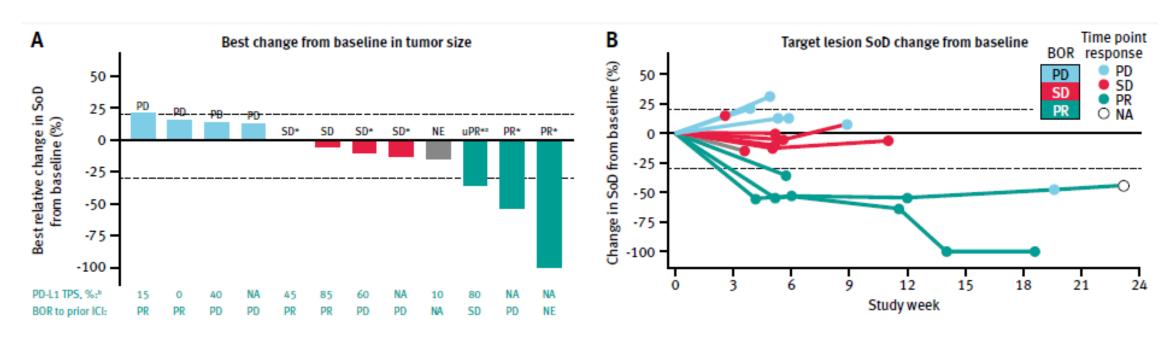


^aMinimum duration of response (5 weeks) per RECIST v1.1 not reached.

^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

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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



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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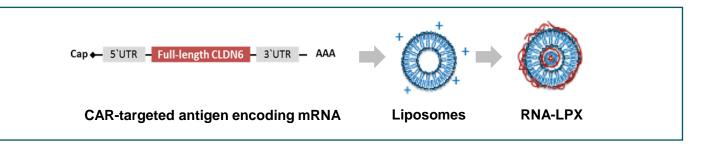
RiboCytokines



BNT211: Repeated CARVac dosing enables tunable expansion of CAR-T cells

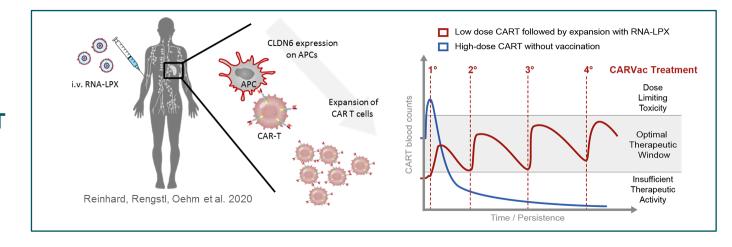
<u>CAR-T cell Amplifying RNA Vaccine</u> (CARVac) drives in vivo expansion and efficacy of CAR-T against solid tumors

CARVac production



- CARVac is based on RNA-LPX that selectively targets secondary lymphoid organs
- I.V. administration of CLDN6 RNA-LPX results in expression of CAR antigen on APCs

CARVac based CAR-T expansion



- Repetitive administration of CARVac results in increased frequency, persistence and activity of CAR-T cells with a memory phenotype
- Combination of sub-therapeutic CAR-T dose and CARVac demonstrated eradication of advanced tumors in mice



BNT211: CLDN6-CAR demonstrates potent and robust target recognition

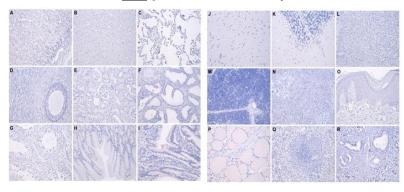
CANCER IMMUNOTHERAPY

An RNA vaccine drives expansion and efficacy of claudin-CAR-T cells against solid tumors

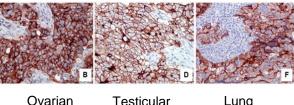
Katharina Reinhard1*, Benjamin Rengstl1*, Petra Oehm1*, Kristina Michel1, Arne Billmeier1, Nina Hayduk¹, Oliver Klein¹, Kathrin Kuna¹, Yasmina Ouchan¹, Stefan Wöll¹, Elmar Christ¹, David Weber², Martin Suchan², Thomas Bukur², Matthias Birtel¹, Veronika Jahndel¹, Karolina Mroz¹, Kathleen Hobohm¹, Lena Kranz¹, Mustafa Diken², Klaus Kühlcke¹, Özlem Türeci¹+, Ugur Sahin^{1,2,3}+±



CLDN6 not present in healthy tissues



CLDN6 expressed in multiple cancers

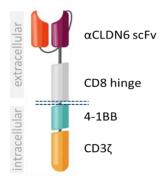


Testicular

Lung

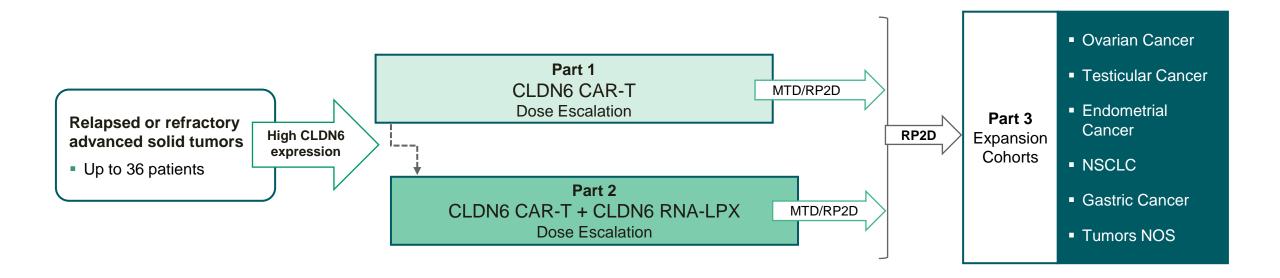
- Directed against new carcino-embryonic antigen CLDN6
- 2nd generation CAR functionalized with antibody-derived CLDN6-binding domain (αCLDN6-scFv)
- Binding domain mediates exclusive specificity and high sensitivity for CLDN6
- Costimulatory domain (4-1BB) mediates prolonged survival and repetitive killing ability
- CLDN6-CAR showed strong recognition and lysis of CLDN6-positive target cells in preclinical studies

BNT211 CAR Structure





BNT211: First-in-human CARVac trial with first data expected this year



- Phase 1/2a: Evaluation of safety and tolerability of CLDN6 CAR-T +/- CLDN6 RNA-LPX in patients with CLDN6-positive relapsed or refractory advanced solid tumors
- 3+3 dose escalation with bifurcated trial design



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CARVac platform – CLDN6 CAR-T

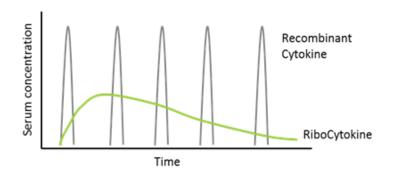
RiboCytokines



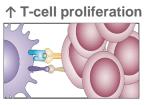
BNT151: Designed to overcome limitations of recombinant cytokine therapy

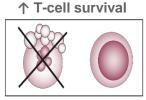
RiboCytokines: A novel therapeutic concept

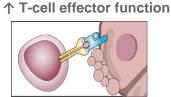
- Cytokines encoded by mRNA and produced in patient
- Major improvements over recombinant cytokine therapies
 - Prolonged serum half-life
 - High bioavailability
 - Lower and less frequent dosing
 - Lower Toxicity
 - Sequence modifications easy to introduce



BNT151: Optimized mRNA-encoded IL-2



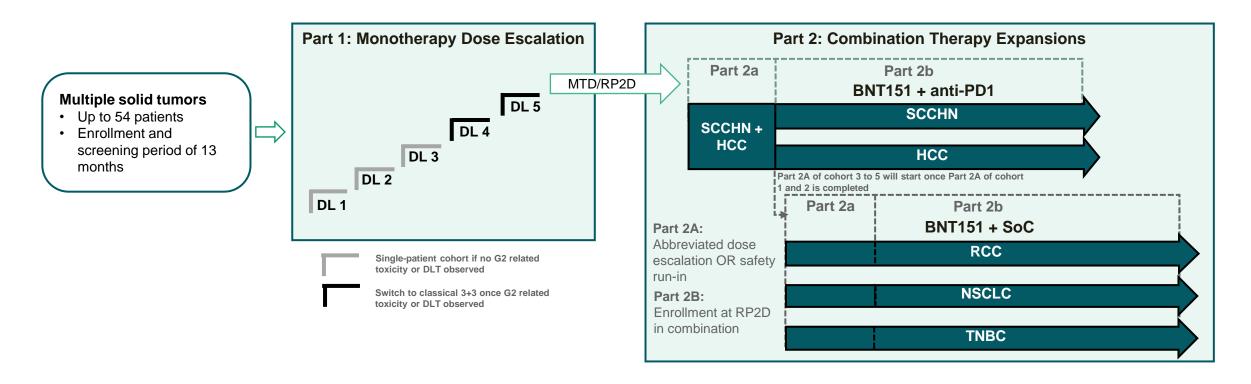




- BNT151 is nucleoside-modified mRNA encoding human
 IL-2 variant fused to human albumin
- IL-2 is a key cytokine in T cell immunity, supporting differentiation, proliferation, survival and effector functions of T cells
- BNT151 stimulates anti-tumoral T cells without extensively triggering immunosuppressive T_{regs}
- First patient dosed in first-in-human Phase 1/2a Trial



BNT151-01 Open-label, multicenter Phase 1/2a, first-in-human trial



Evaluation of dose escalation, safety, pharmacokinetics and pharmacodynamics of BNT151 with expansion cohorts in multiple solid tumor indications





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