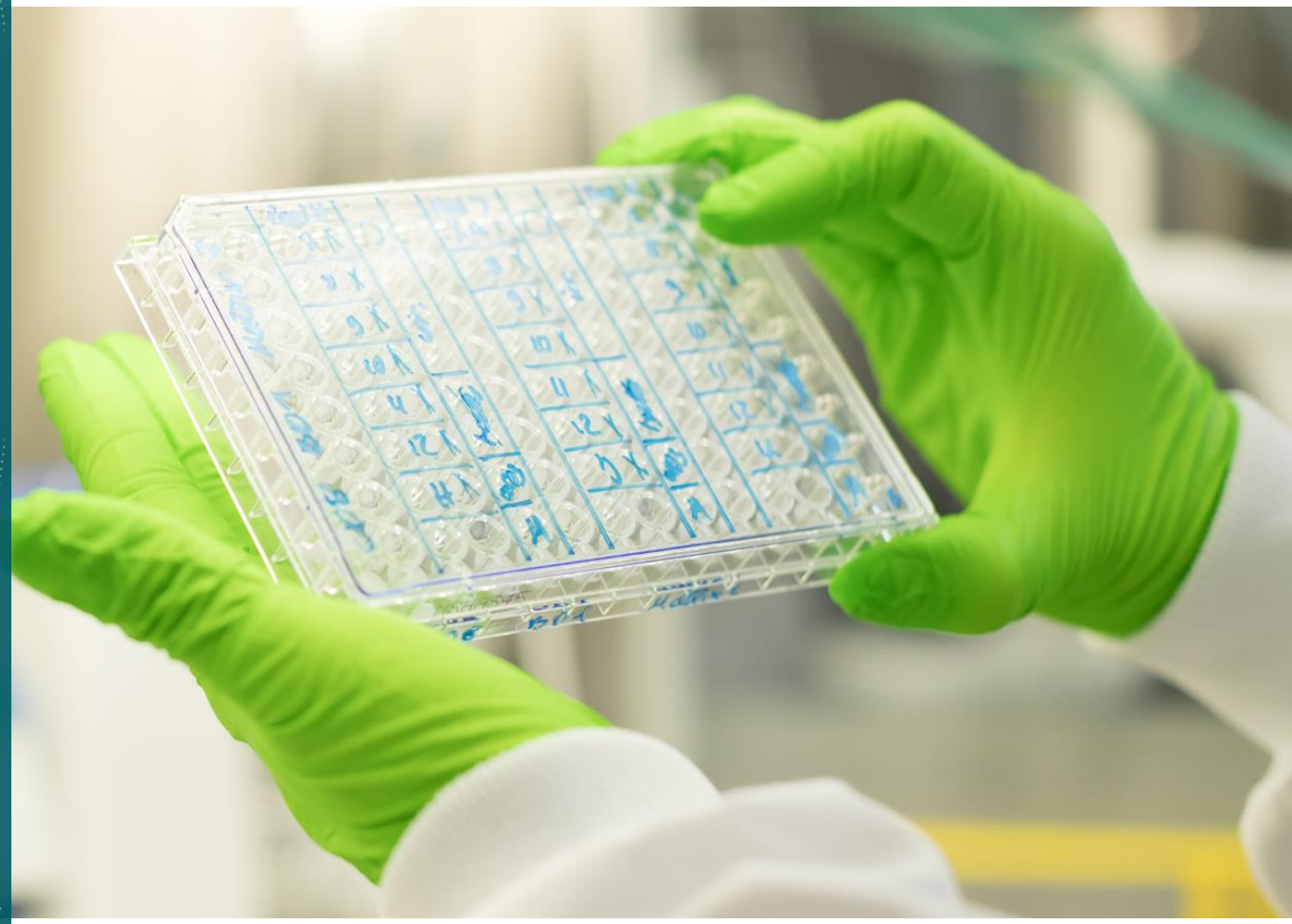
Next Generation Immunotherapy

July 2020



This slide presentation includes forward-looking statements

Forward-Looking Statements

Various statements in this slide presentation concerning the future expectations of BioNTech, its plans and prospects, including the Company's views with respect to the potential for mRNA therapeutics and vaccines, its expectations with respect to the timing and results of clinical trials and release of clinical data (both in respect of its proprietary product candidates and of product candidates of its collaborators), the development of commercial capabilities and the transition of BioNTech to a fully integrated biopharmaceutical company, its expectations with respect to interactions with regulatory authorities such as FDA and EMA, including the potential approval of BioNTech's or its collaborators' current or future drug candidates, and expected royalty and milestone payments in connection with BioNTech's collaborations, constitute forward-looking statements. Words such as "expects," "plans," "potential," "target," "continue" and variations of these words or similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements are based on the current beliefs and assumptions of the management team of BioNTech and on the information currently available to the management team of BioNTech, and are subject to change. The Company will not necessarily inform you of such changes. These forward looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors that could cause the Company's actual results, performance or achievements to be materially different than any future results, performance or achievements expressed or implied by the forward-looking statements. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including the initiation, timing, progress, results and cost of the Company's research and development programs and its current and future preclinical studies and clinical trials; the timing of and the Company's ability to obtain and maintain regulatory approval for its product candidates; the Company's ability to identify research opportunities and discover and develop investigational medicines; the Company's expectations regarding the size of the patient populations for its product candidates, if approved for commercial use; the Company's estimates of its expenses, ongoing losses, future revenue and capital requirements and its needs for or ability to obtain additional financing; the Company's ability to identify, recruit and retain key personnel; the Company's and its collaborators' ability to protect and enforce its intellectual property protection for its proprietary and collaborative product candidates, and the scope of such protection; the development of and projections relating to the Company's competitors or its industry; the Company's ability to commercialize its product candidates, if approved; the rate and degree of market acceptance of the Company's investigational medicines; the Company's ability to manage its development and expansion; regulatory developments in the United States and foreign countries; the Company's ability to manufacture its product candidates with advantages in turnaround times or manufacturing cost; and the Company's ability to implement, maintain and improve effective internal controls. The preceding list is not intended to be an exhaustive list of all of the Company's forward-looking statements. Any forward-looking statements represent the Company's views only as of today and should not be relied upon as representing its views as of any subsequent date. The Company explicitly disclaims any obligation to update any forward-looking statements. The mRNA vaccines and other product candidates discussed in this slide presentation are investigational products being developed by BioNTech and its collaborators and are not currently approved by the FDA, EMA or any other regulatory authority.

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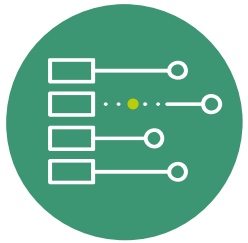
Next generation immunotherapy

Harnessing the full potential of the immune system



Broad suite of novel technology platforms

Immunotherapies for cancer and infectious diseases

Fully integrated with in-house GMP manufacturing

Industry-leading global collaborations

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We collaborate with global leaders in our industry

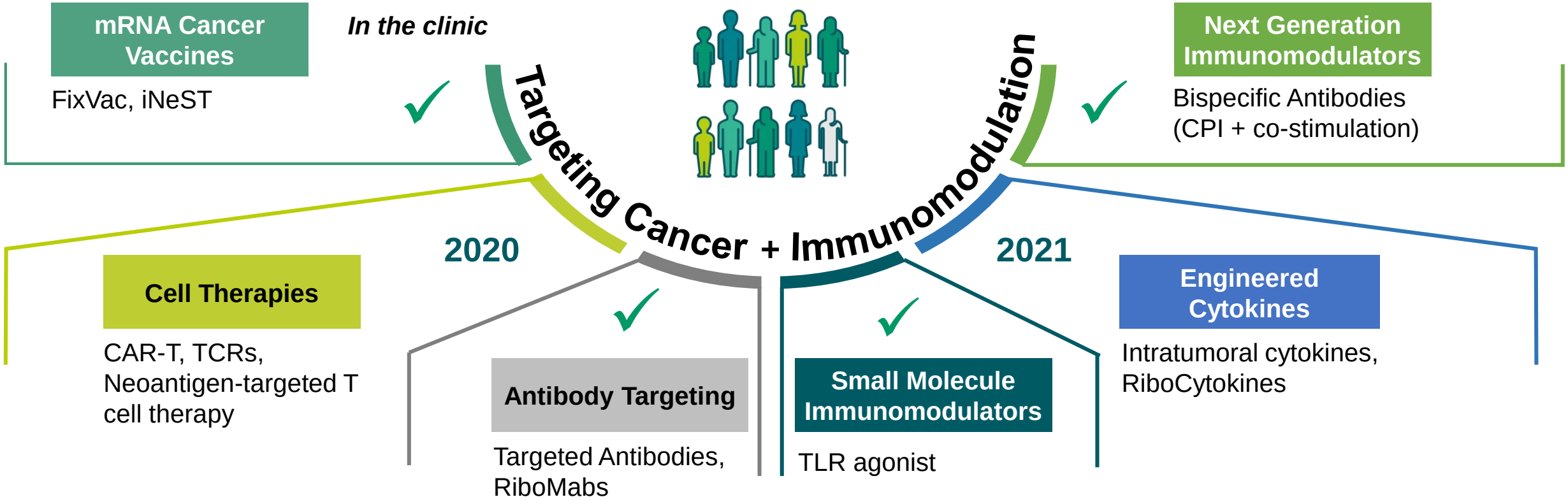
Oncology Collaborations with at least one program in the clinic

50:50 Cost and Profit share (2016)	50:50 Cost and Profit share (2015)	Cost and Profit share (2015)
Genentech	Genmab	SANOFI

Infectious Diseases and Rare Diseases Collaborations

Research Collaboration and License Agreement (2018), Collaboration Agreement (2020)	Co-development in China (2020)	Co-development Co-commercialization (2018)	Strategic R&D Alliance (2018)	R&D Agreement (2019)
Pfizer	FOSUNPHARMA	GENEVANT	University of Pennsylvania	BILL & MELINDA GATES foundation

Our IO strategy exploits complementary therapeutic programs



Potential for multiple blockbuster opportunities with powerful combinations

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Compelling data generated from innovative immunotherapy approaches

Approved PD1-/PD-L1 Inhibitors

+

mRNA Cancer Vaccines

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

mRNA Cancer Vaccines

+

Engineered Cytokines

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

Cell Therapies

+

mRNA Cancer Vaccines

- **BNT211:** Novel CLDN-6 CAR-T approach utilizing CAR-T Amplifying RNA Vaccine (**CARVac**)
- Significant amplification of CAR-T cells in preclinical studies (published in Science, 2020)

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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	• ***Antibodies*** • ***CAR-Ts***
Refractory tumors	Patients with large tumors and multiple resistance mechanisms	Few treatment options	• ***Cell Therapies*** • ***Combination Therapies***

[1]Tumor microenvironment

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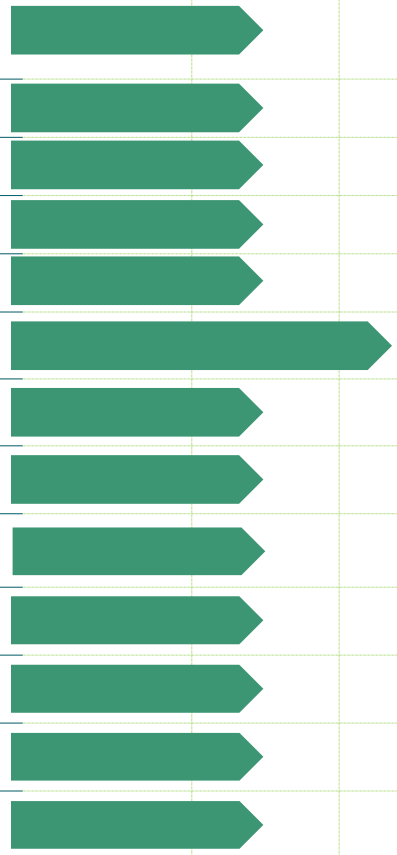
12 product candidates in 13 ongoing clinical trials

Drug class	Platform	Product Candidate	Indication (Targets)	Rights Collaborator	Milestones
mRNA	FixVac (fixed combination of shared cancer antigens)	BNT111	advanced melanoma (adjuvant & metastatic)	fully-owned	Report phase 1 data: publication upcoming Start phase 2 trial with registrational potential H2 2020
		BNT112	prostate cancer	fully-owned	
		BNT113	HPV16+ head and neck cancer[1]	fully-owned	Start phase 2 with registrational potential in 2H 2020
		BNT114	triple negative breast cancer	fully-owned	Data update in 2H 2020
		BNT115	ovarian cancer[1]	fully-owned	
	iNeST (patient specific cancer antigen therapy)	RO7198457 (BNT122[4])	1L melanoma with CPI[2]	Genentech (global 50:50 profit/loss)	Enrollment update in 2H 2020[3] ; Interim data update in 2H 2021
			multiple solid tumors		Two phase 2 trials planned in adjuvant indications in 2H 2020
	Intratumoral Immunotherapy	SAR441000 (BNT131)	solid tumors *(IL-12sc, IL-15sushi, GM-CSF, IFNα)*	Sanofi (global profit/ loss share)	Data update in 2H 2020[5]
	Infectious Disease Immunotherapy	BNT162	COVID-19	Pfizer/Fosun	Start phase 2/3 late July
Antibodies	Next-Gen CP[2] Immunomodulators	GEN1046 (BNT311)	multiple solid tumors *(PD-L1×4-1BB)*	Genmab (global 50:50 profit/loss)	Data update in 2H 2020
		GEN1042 (BNT312)	multiple solid tumors *(CD40×4-1BB)*		
	Targeted Cancer Antibodies	BNT321 (MVT-5873)	pancreatic cancer (sLea)	fully-owned	
SMIM[6]	Toll-Like Receptor Binding	BNT411	solid tumors *(TLR7)*	fully-owned	



We intend to initiate up to 5 Phase 2 trials in 2020

[1] BNT113 and BNT115 are currently being studied in investigator-initiated phase 1 trials; [2] Checkpoint Inhibitor; [3] Update on the ongoing study including patient enrollment number, efficacy and safety data for an interim update expected in the second half of 2021; [4] BNT122 (iNeST) is also being investigated in arm 2 (N=15) of the 3 arm TNBC-MERIT trial, with BNT114 as an optional treatment; BNT114 is investigated in arm 1 (N=12) and arm 3 (N=15) of the TNBC-MERIT trial (total patients in study: N=42); [5] As the trial is sponsored and conducted by Sanofi, the timing of data updates is not under our control, and is subject to change by Sanofi; [6] Small Molecule Immunomodulators

We plan to initiate FIH[1] trials for our preclinical product candidates across all platforms

Drug class Oncology	Platform	Product Candidate	Indication (Targets)	Rights Collaborator	Milestones
mRNA	**FixVac**	BNT116	NSCLC	fully-owned	
	RiboMabs (mRNA-encoded antibodies)	BNT141	multiple solid tumors	fully-owned	Phase 1 start in 1H 2021
		BNT142	multiple solid tumors *(CD3+CLDN6)*	fully-owned	Phase 1 start in 1H 2021
	RiboCytokines (mRNA-encoded Cytokines)	BNT151	multiple solid tumors *(optimized IL-2)*	fully-owned	Phase 1 start in 1H 2021
		BNT152, BNT153	multiple solid tumors *(IL-7, IL-2)*	fully-owned	Phase 1 start in 1H 2021
Cell Therapies	**CAR-T Cells**	BNT211	multiple solid tumors (*CLDN6)*	fully-owned	Phase 1/2 start in 2H 2020
		BNT212	pancreatic, other cancers *(CLDN18.2)*	fully-owned	
	Neoantigen-based T cell therapy	BNT221 (NEO-PTC-01)	multiple solid tumors	fully-owned	Phase 1 in 2H 2020
	TCRs	to be selected	all tumors	fully-owned	
mRNA	**Infectious Disease Immunotherapies**	BNT161	influenza	Pfizer	Start first study in 2021
		undisclosed	up to 10 indications	Penn[3]	First phase 1 trial to start 1H 2021
		undisclosed	HIV and tuberculosis	Bill & Melinda Gates Foundation	
	Rare Disease PRT[2]	BNT171	not disclosed	Genevant (global 50:50 profit/loss)	First phase 1 trial to start in 2H 2021
		undisclosed	4 additional rare disease indications		

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

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Significant newsflow expected over next 12-18 months

	Platform	Candidate	Indication *(Target)*	Next milestones[3]
mRNA	FixVac	BNT111	advanced melanoma	Start Phase 2 with registrational potential in 2H 2020 Report Phase 1: publication upcoming
		BNT113	HPV16+ H&N cancer	Start Phase 2 with registrational potential in 2H 2020
		BNT114	triple negative breast cancer	Data update Phase 1 in 2H 2020 [4]
	iNeST	RO7198457 (BNT122)	1L melanoma with CPI	Enrollment update in 2H 2020 [1]
			NSCLC (adjuvant) CRC (adjuvant)	Start Phase 2 in 2H 2020 Start Phase 2 in 2H 2020
	Intratumoral Immunotherapy	SAR441000 (BNT131)	Solid tumors *(IL-12sc, IL-15sushi, GM-CSF, IFNα)*	Data update Phase 1/2 in 2H 2020 [2]
	RiboMabs	BNT141	multiple solid tumors	Start Phase 1 in 1H 2021
		BNT142	multiple solid tumors *(CD3+CLDN6)*	Start Phase 1 in 1H 2021
	RiboCytokines	BNT151	multiple solid tumors *(Optimized IL-2)*	Start Phase 1 in 1H 2021
		BNT152, BNT153	multiple solid tumors *(IL-7, IL-2)*	Start Phase 1 in 1H 2021
Others	CAR-T Cells	BNT211	multiple solid tumors *(CLDN6)*	Start Phase 1/2 in 2H 2020
	Neoantigen-based T cell therapy	BNT221 (NEO-PTC-01)	multiple solid tumors	Start Phase 1 in 2H 2020
	Next-Gen CP Immunomodulators	BNT311	multiple solid tumors *(PD-L1x4-1BB)*	Data update Phase 1/2 in 2H 2020
	TLR7 Ligand	BNT411	multiple solid tumors *(TLR7)*	Start Phase 1 in 2H 2020
	Infectious and Rare Diseases	BNT161	Influenza	Start first study in 2021
		BNT162	COVID-19	Start Phase 2/3 end of July 2020

[1] We expect this update to include an update on the ongoing study, including patient enrollment numbers, with full efficacy and safety data for an interim update expected in the second half of 2021; [2] As the trial is sponsored and conducted by Sanofi, the timing of data updates is not under our control, and is subject to change by Sanofi. [3] Our expectations for timing of milestones beyond 2020 are premised on and subject to the achievement of earlier milestones on their expected timelines. Press releases will be issued once first patient has been dosed; [4] BNT122 (iNeST) is also being investigated in arm 2 (N=15) of the 3 arm TNBC-MERIT trial, with BNT114 as an optional treatment; BNT114 is investigated in arm 1 (N=12) and arm 3 (N=15) of the TNBC-MERIT trial (total patients in study: N=42);

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Building a next generation immunotherapy company

- Rapid progress in key pipeline programs in both oncology and infectious diseases
- Multiple data read-outs & late-stage trial starts anticipated in 2H 2020
- Expanded transatlantic operations with newly established R&D hub in Cambridge, U.S.
- Strong momentum toward our vision of building a global immunotherapy company

Agenda

Overview and business outlook

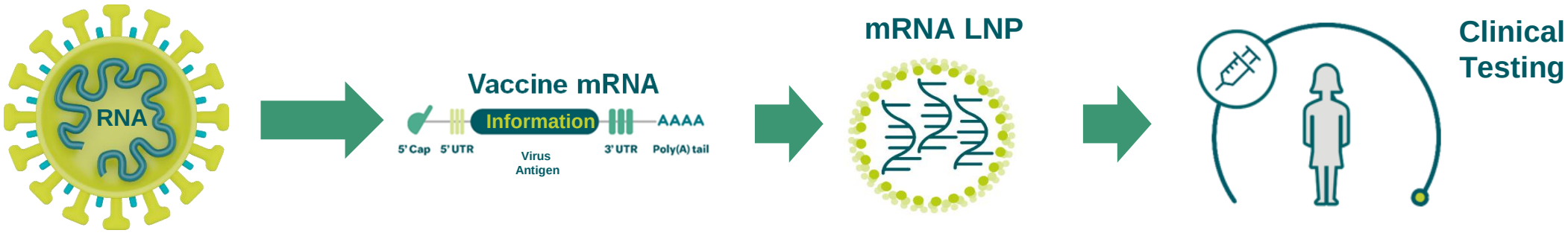
Deeper dive on our key programs

- COVID-19 vaccine program (project “Lightspeed”)
- mRNA vaccines – FixVac and iNeST
- Antibodies
- Cell therapies
- RiboCytokines

mRNA pharmaceuticals as pandemic vaccines

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

Solving for safety, speed and efficacy



Genetic Information SARS-CoV-2

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Project “lightspeed”: vaccine program with global consortium

- “Lightspeed” program includes both vaccines and therapeutics
- Exploits highly potent Lipid-Nano-Particulate (LNP) mRNA vaccine platforms for the prevention of infectious diseases
- Preclinical activity demonstrated in multiple infectious disease models including Influenza, Ebola Virus, Zika Virus, HIV and others
- To be manufactured at state-of-the-art GMP certified mRNA manufacturing facilities in Europe

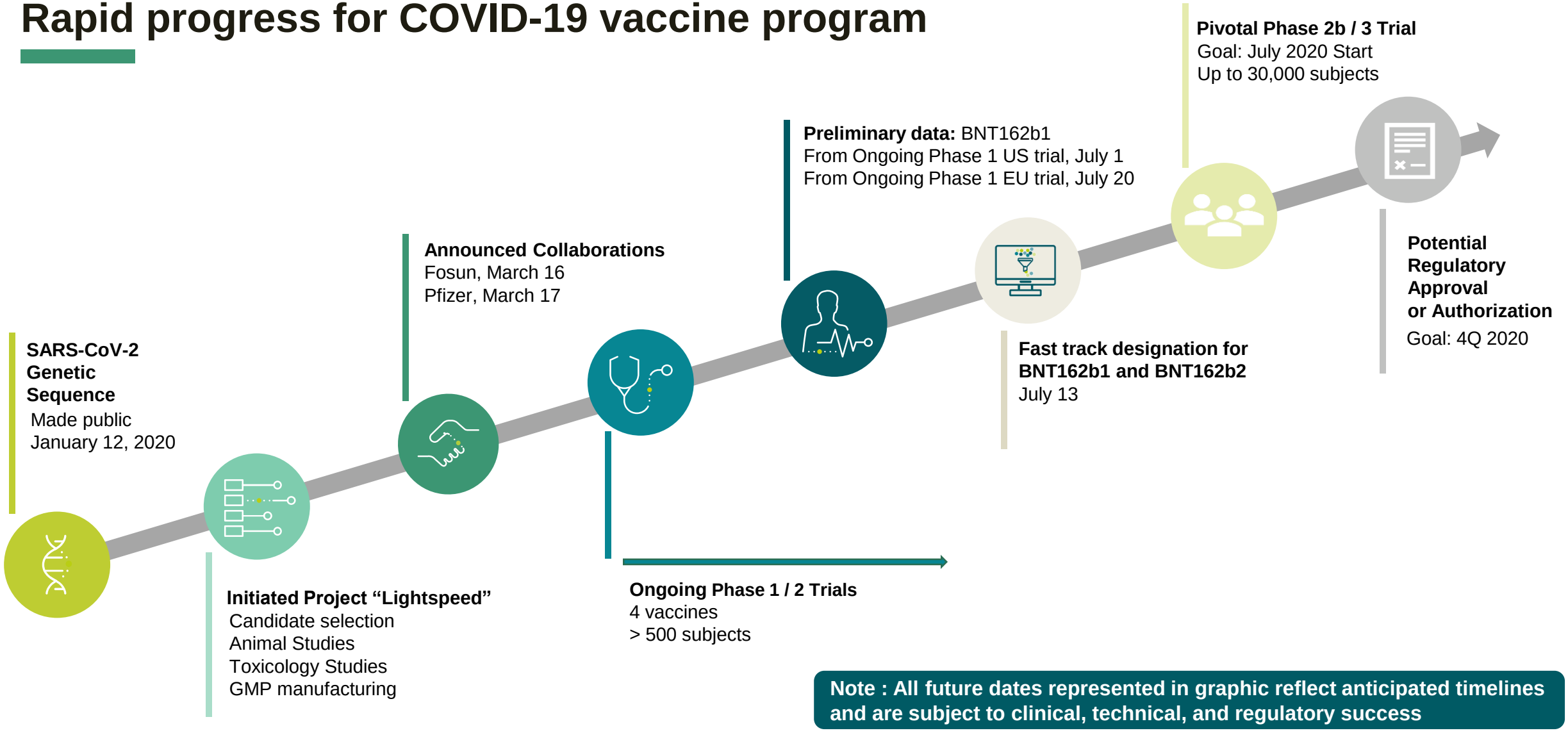
Pfizer

- Co-development and distribution outside China with R&D sites from both partners
- Pfizer paid **$185m upfront**, including **$113m equity investment;** BioNTech eligible to receive **milestone payments of up to $563m**
- **50/50 development cost** split with Pfizer funding 100% initially; 50% share to be repaid if milestones are reached

FOSUNPHARMA 复星医药

- **Joint development in China** and collaboration to **conduct trials in China**
- BNTX to receive up to **$135m in upfront, investment and milestones**
- **Companies to share gross profits from sales in China**

Rapid progress for COVID-19 vaccine program



Note : All future dates represented in graphic reflect anticipated timelines and are subject to clinical, technical, and regulatory success

Approximately 5 months

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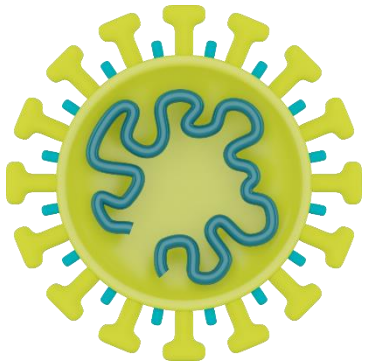
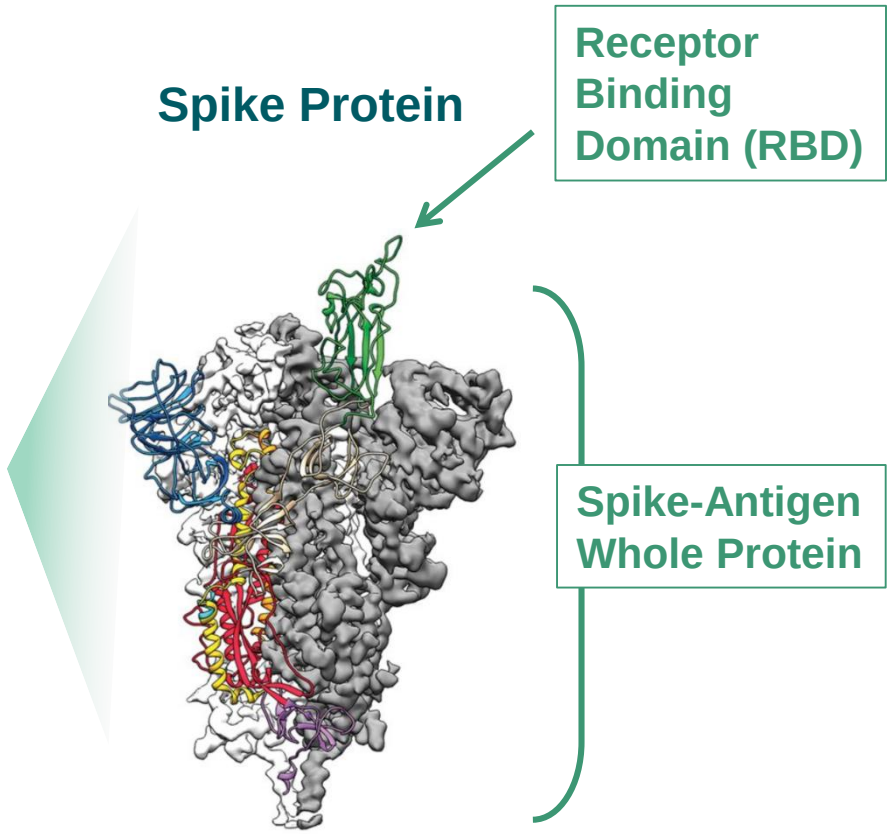
BNT162 Variants: Targeting SARS-CoV-2 Spike-Protein and RBD



SARS-COV-2



SARS-COV-2
Spike Protein 3D Structure[1]

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

Received Fast Track designation

[1] Wrapp et al., Science, 2020

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Global BNT162 clinical development program ongoing

Phase 1/2 trials ongoing in Europe and US

- Evaluating safety, efficacy and optimal dose of 4 vaccine candidates

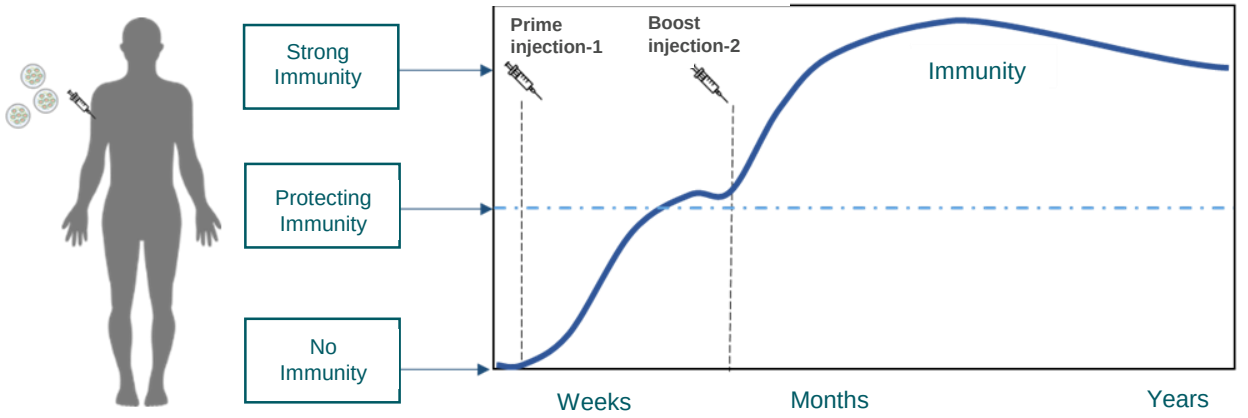
Designs

- Europe: Dose escalation part up to **200 healthy subjects** aged 18 to 55
- US: Seamless study design with several thousand subjects; Initial dose-finding part up to **360 healthy subjects** aged 18-85
- Dose range <1 µg to 100 µg
- Single-dose and 2-dose regimens to be tested in initial trial

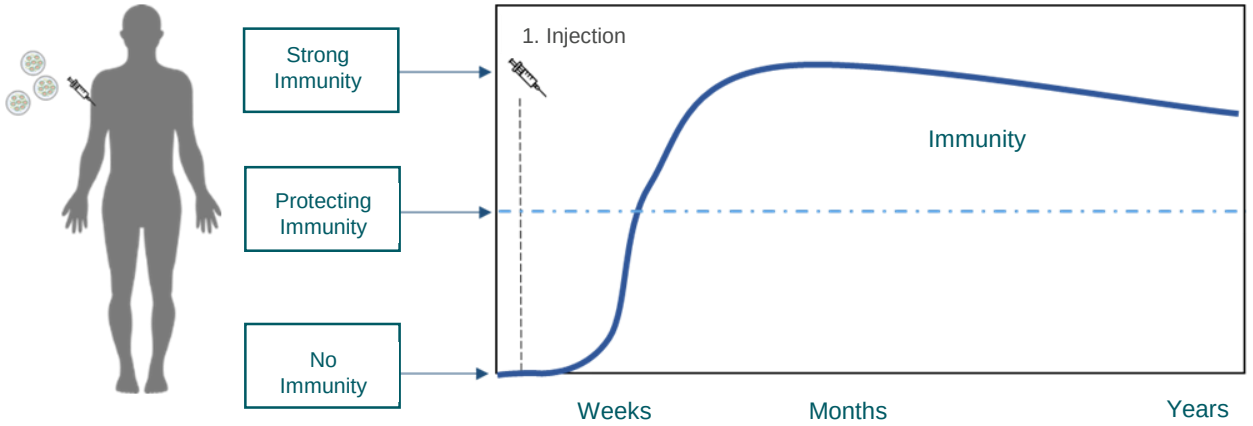
Between May 4, 2020 and June 19, 2020;
45 participants randomized and vaccinated in US study

Between April 23, 2020 and May 22, 2020;
60 participants randomized and vaccinated in German study

Prime / boost vaccine



Prime-only vaccine



Early positive data from ongoing phase 1/2 studies of BNT162b1

Ongoing German Phase 1/2: preliminary data summary

- **Generally well tolerated**
- **Neutralizing titers** seen 7 days after boost showed **1.7** (10µg), **3.3** (30µg) and **6.1 times** (50µg) **neutralizing GMT of sera panel**
- **Elevation of RBD-binding IgG concentrations** were observed, ranging **from 2,015 to 25,006 units/ml** compared to a GMC of 602 units/ml of sera panel, also at 7 days after second dose
- BNT162b1 elicited **T cell-mediated immune response of high magnitude** specifically against **SARS-CoV-2-RBD** comparable or well above prevalent T cell immunity against e.g. CMV or EBV

Ongoing U.S. Phase 1/2: preliminary data summary

- **Generally well tolerated**
- **Neutralizing titers** seen 7 days after boost showed **1.8** (10µg) and **2.8 times (**30µg) **neutralizing GMT of serum panel**
- **Elevation of RBD-binding IgG concentrations** were **8** (10µg) and **46.3 times** (30µg) **the GMC of sera panel, also** at 7 days after second dose for the same doses.

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BNT162 manufacturing and commercial update

Clinical supply

- BioNTech expects to manufacture all drug substance for clinical supply at its GMP manufacturing facilities in Idar-Oberstein and Mainz (both in Germany, partially 24/7 manufacturing)
- Drug product supply initially supported by BioNTech‘s formulation partner Polymun, with Pfizer and BioNTech ramping up own capacity

Global pandemic and commercial supply capacities

- BioNTech and Pfizer expect to manufacture up to 100 million doses by end of 2020 and potentially more than 1.3 billion doses by end of 2021.
- Joint establishment of pandemic supply capacities at many network sites
  - BioNTech: At Idar-Oberstein and Mainz facilities in Germany
  - Pfizer: At least at three U.S. sites (Massachusetts, Michigan, Missouri) and at Puurs facility (Belgium)

- Announced on July 20 supply **agreement with UK** government to supply 10 million doses, with deliveries starting by 4Q 2020, subject to clinical success and regulatory approval
- Announced on July 22 supply **agreement with U.S.** government for up to 600 million doses following FDA authorization, subject to clinical success and regulatory approval
  - U. S. government placed an initial order of 100 million doses for $1.95 billion and can acquire up to 500 million additional doses

Agenda

Overview and business outlook

Deeper dive on our key programs

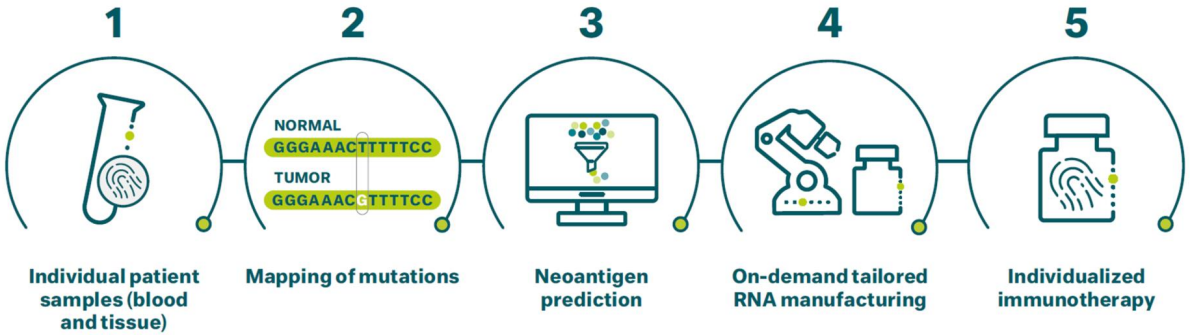
- COVID-19 vaccine program (project “Lightspeed”)
- mRNA vaccines – FixVac and iNeST
- Antibodies
- Cell therapies
- RiboCytokines

Our mRNA vaccine platforms: FixVac and iNeST

FixVac

- **Off-the-shelf mRNA immunotherapy**
- **Targeting a fixed combination of shared antigens**
  - Non-mutated antigens shared among patients with a specific cancer type
  - Applicable for almost all types of tumor antigens

iNeST



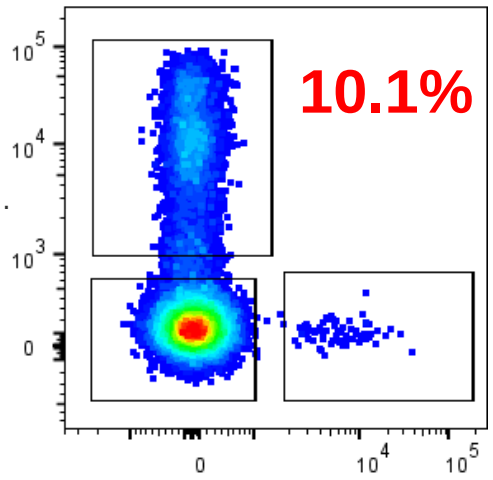
- **Fully individualized mRNA immunotherapy**
- **Targeting 20 neo-antigens unique to each patient**
  - Vast majority of neo-antigens are unique to individual patients
  - Applicable across solid tumor types

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

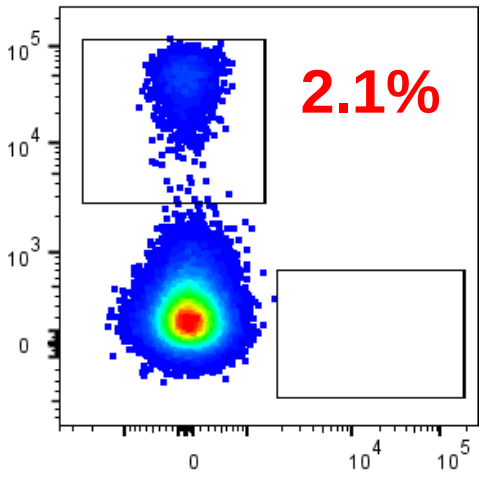
Kranz et al., Nature 2016

Our RNA-LPX vaccine approach

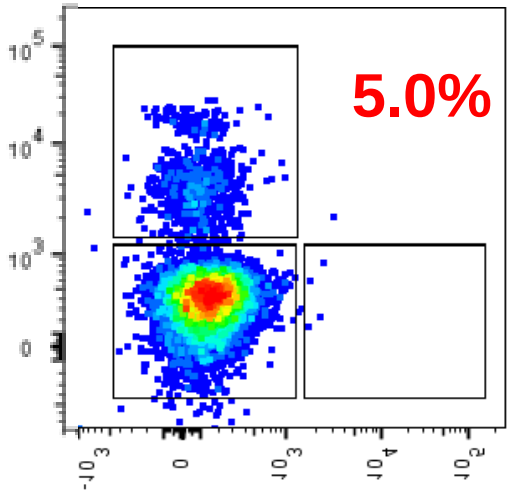
Strong vaccine-induced *ex vivo* CD8+ T cell responses[1] across different cancer types



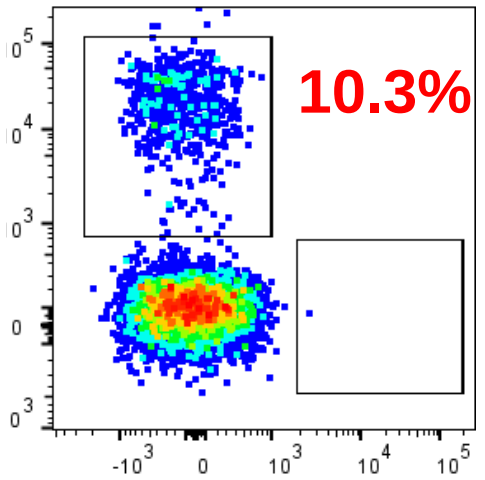
NY-ESO-1
Melanoma
BNT111, Lipo-MERIT trial



MAGE-A3
Melanoma
BNT111, Lipo-MERIT trial



HPV16-E7
Head Neck Cancer
BNT113, HARE40 trial



Mutant Neoantigen
TNBC
BNT114, TNBC MERIT trial

FixVac

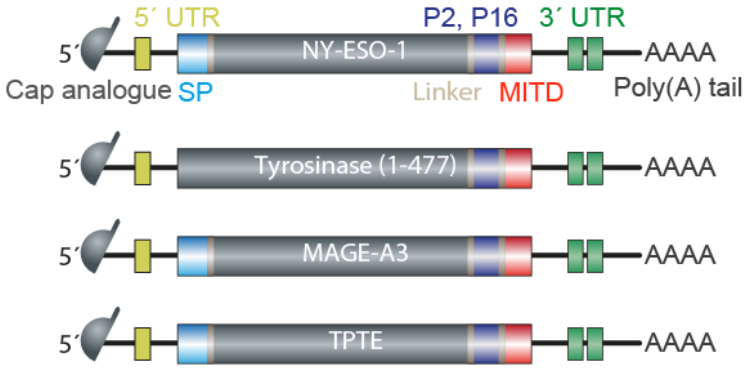
iNeST

[1]T cell responses analyzed by *ex vivo* multimer staining analysis in blood

FixVac: 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 response[1]
  - 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



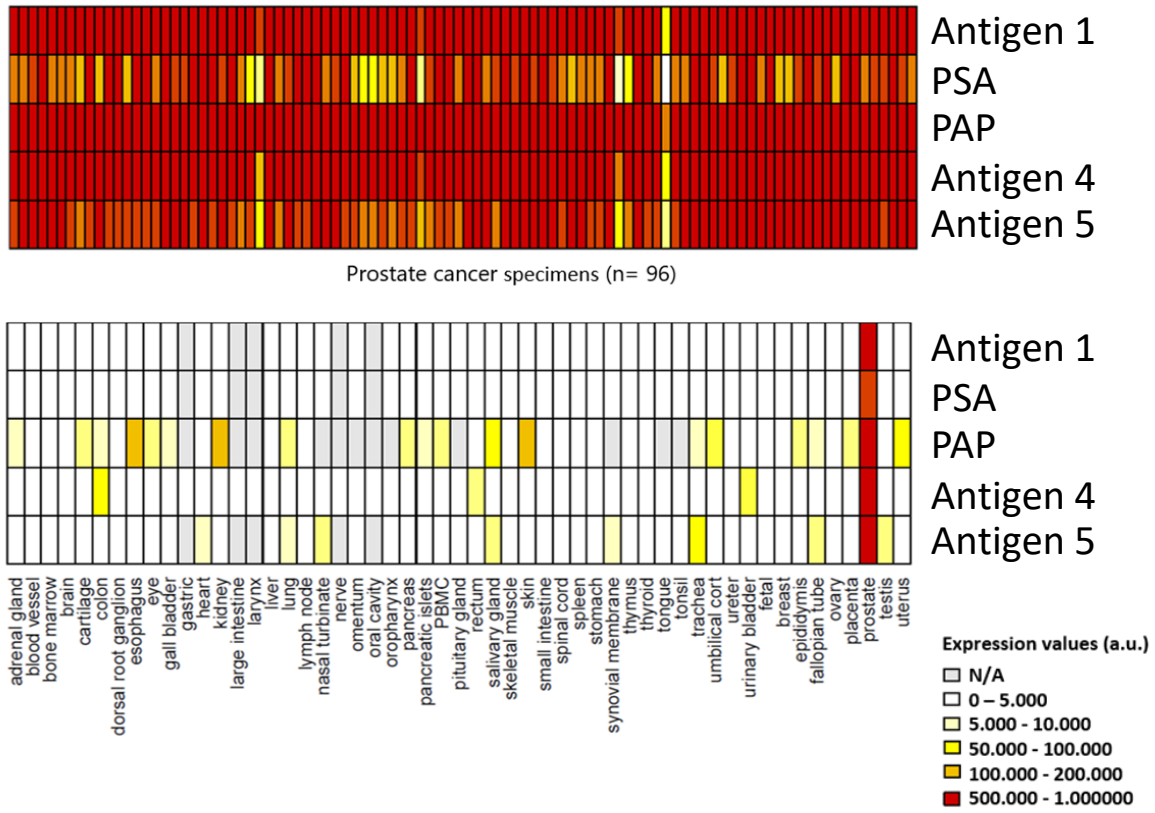
Cumulative patient coverage of FixVac melanoma targets is over 90%

Report phase 1 data 1H 2020

Start phase 2 with registrational potential in 2H 2020

*CPI: Checkpoint inhibitor; [1]based on ^{18}F-FDG-PET/CT analysis

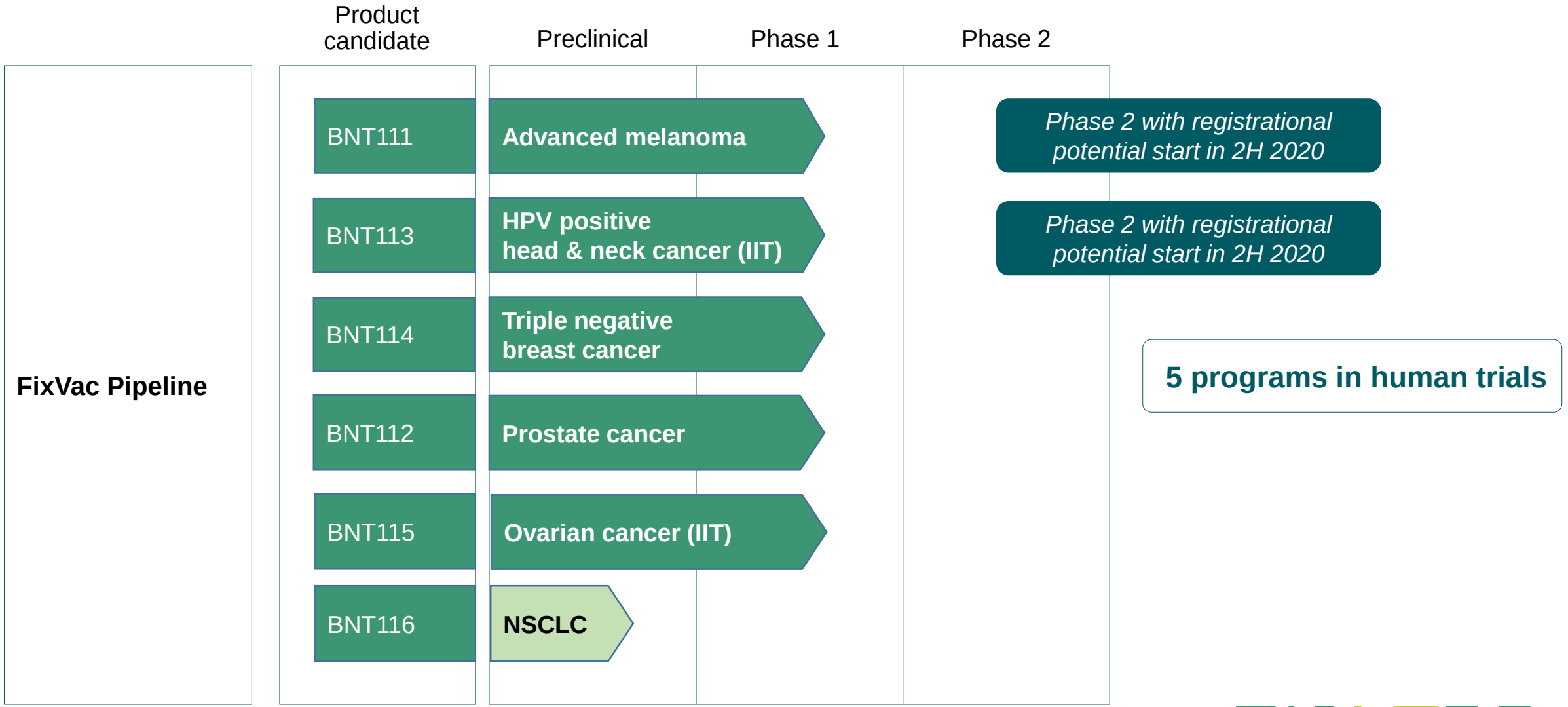
FixVac: BNT112 in Prostate Cancer



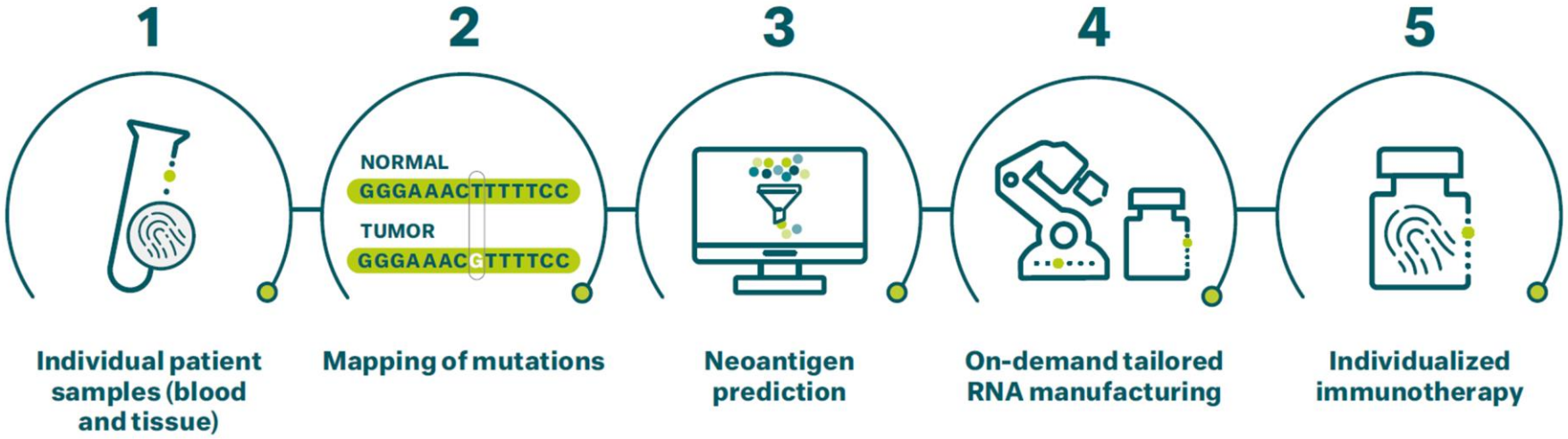
Ph1/2: first patient enrolled in December 2019

- Multipronged vaccine: Targeted antigens of BNT112 are 5 prostate cancer specific antigens (PAP, PSA and 3 undisclosed antigens)
- RNA-LPX vaccine format validated by our FixVac Melanoma program

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



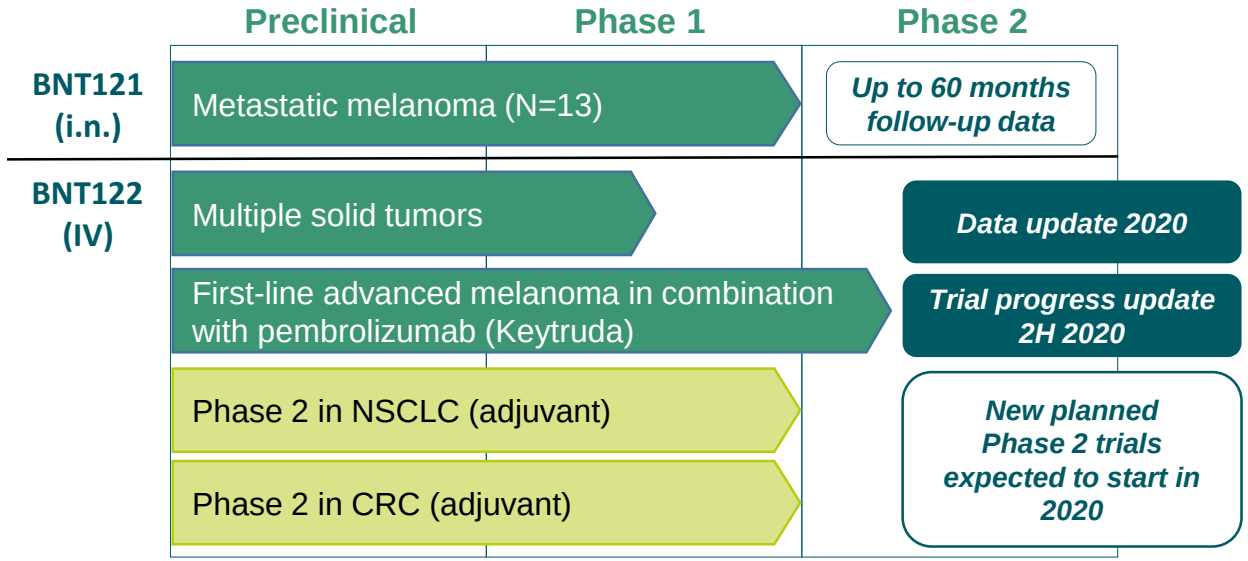
Individualized Neoantigen Specific Immunotherapy (iNeST)



Turnaround time reduced from three months to six weeks

Overview

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



Currently being evaluated in ≥ 8 solid tumor indications

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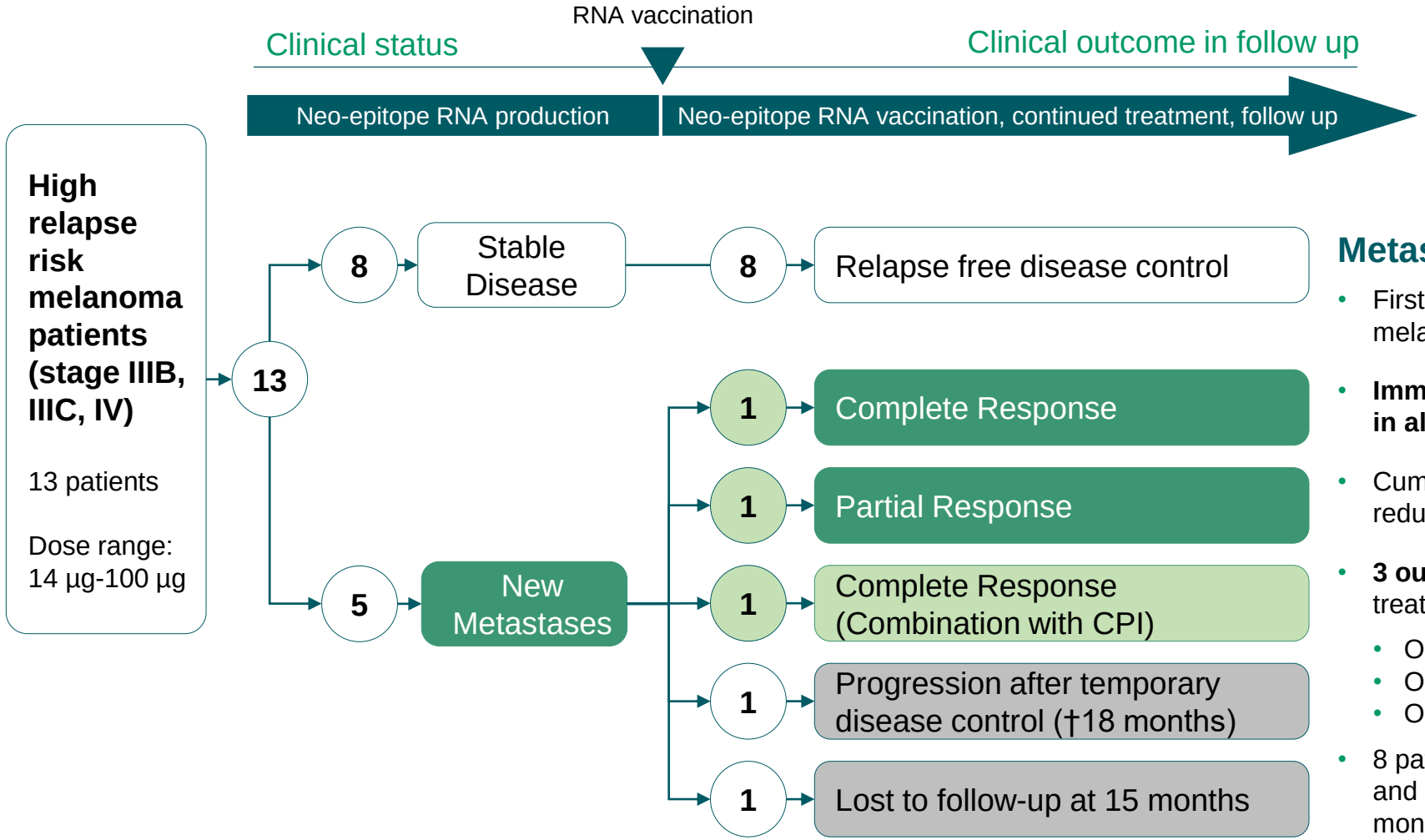
BNT121: Interim clinical activity data



Metastatic melanoma (N=13)

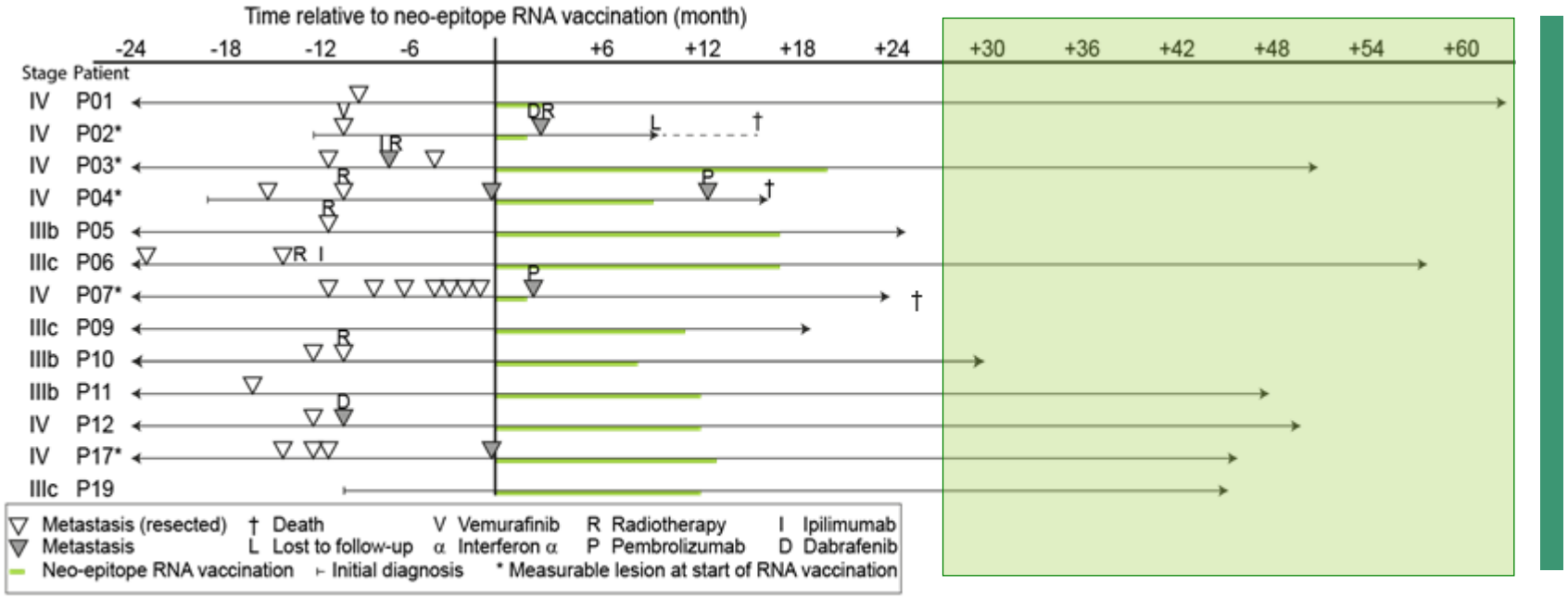
- First-in-human Phase 1 with 13 patients with melanoma stage IIIB, IIIC, and IV; intranodal delivery
- **Immune responses** against at least one neoantigen **in all patients**
- Cumulative rate of metastatic events significantly reduced, resulting in a sustained PFS
- **3 out of 5 pts with melanoma relapses** developed treatment-related **objective clinical responses**
  - One complete response (CR), relapse-free 26 mon
  - One immunotherapy-related partial response (PR)
  - One CR in combination with anti-PD1
- 8 patients (no detectable lesions at start) relapse free and recurrence-free for the whole follow-up (12 to 23 months)

Sahin et. al. Nature 2017

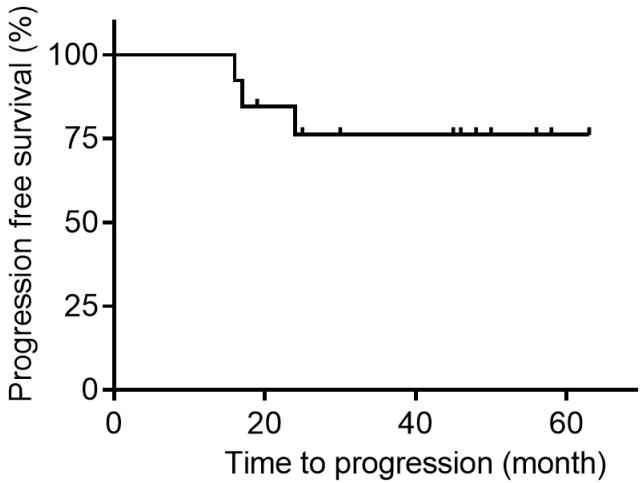
Update for BNT121 (as of October 2019)

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

Metastatic relapse analyses



9 of 13 patients without documented PFS events



Has shown relapse free disease activity with BNT121 iNeST in adjuvant melanoma

iNeST: BNT122 recent AACR data update, Phase 2 adjuvant trials planned

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

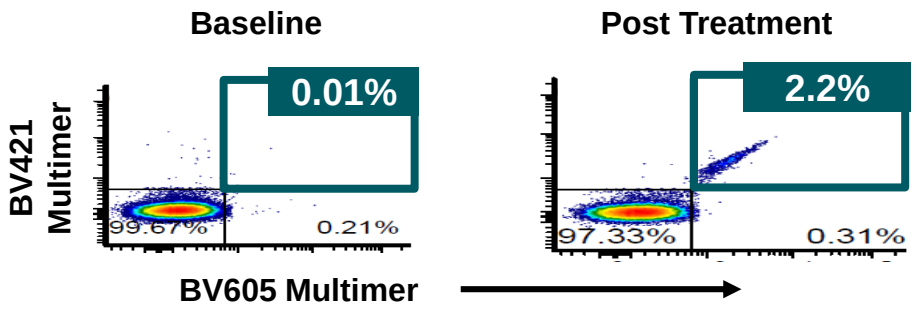
- **31 patients** enrolled, cohorts with **doses ranging from 25-100ug**
  - Most common tumor types were HR+/HER2+ breast, prostate, and ovarian cancer
  - ***Median of 5 lines of prior therapies (range 1-17)***
  - Most patients enrolled had low **level of PD-L1 expression** in tumor
- Neoantigen-specific **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**

- **Demonstrates *ability to elicit significant T cell responses of <u>both effector and memory phenotype</u> as monotherapy and in combination***
- **Successfully manufacturing patient-specific oncology vaccines**

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%)

Patient With TNBC (CPI experienced) Treated With RO7198457 (38 µg) + Atezolizumab 1200 mg IV q3w



Note: Patients in both cohorts received personalized product manufactured on per patient basis with **up to 20 patient-specific neoantigens, in both cohorts majority of AEs were Grad 1 or Grade 2**

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Digitization and automation for neo-antigen vaccine manufacturing

Paperless documentation

Semiautomatic 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

SIEMENS

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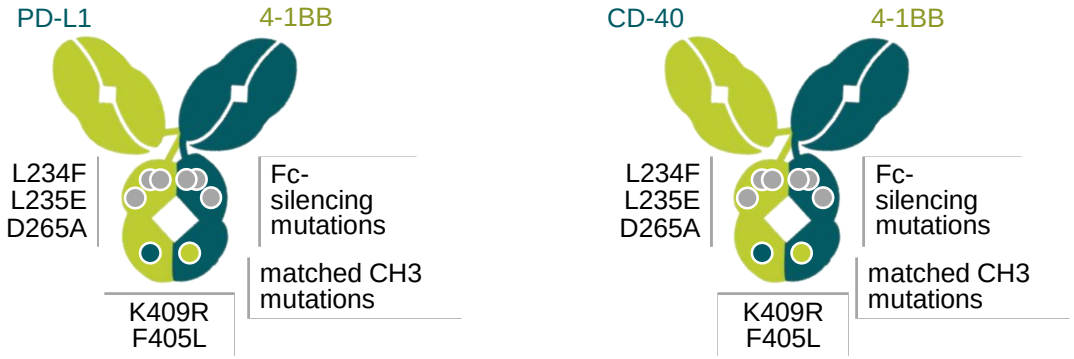
- RiboCytokines

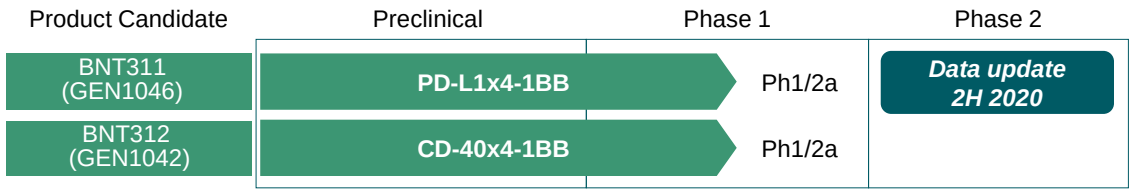
Bispecific Next-Gen CP immunomodulators and targeted cancer antibodies

BNT311 and BNT312: Next-Gen checkpoint immunomodulators

Two bispecific antibodies partnered with Genmab

- Potential “first-in-class” bispecific antibodies
- Conditional activation of immuno-stimulatory checkpoint activity
- 50:50 profit/loss share
- Both programs are now in the clinic





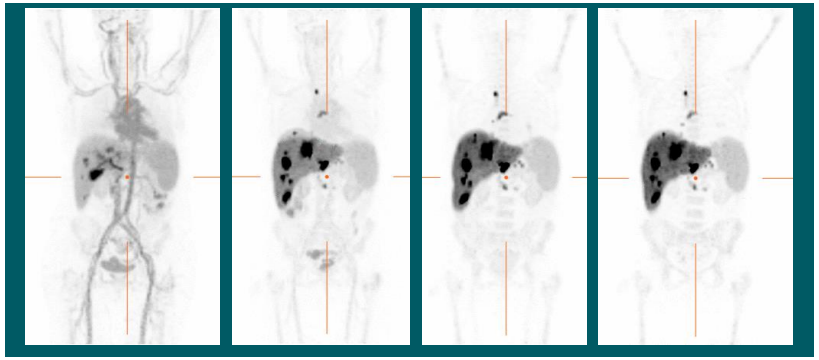
BNT321: Ab targeting Cancer Associated Carbohydrate sLe^a

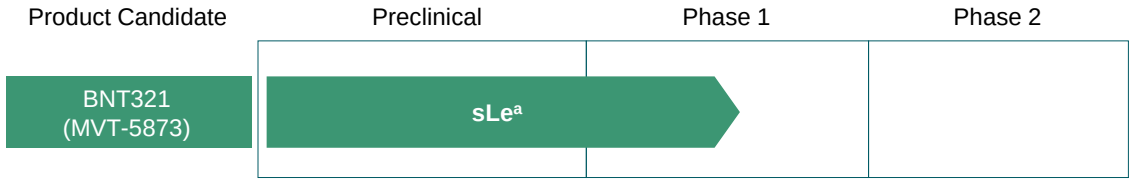
- Subnanomolar affinity, potent cell killing by ADCC &CDC
- Targets sialyl Lewis A epitope (sLe^a) present in a range of glyco-proteins (CA19-9): specifically expressed in pancreatic and other cancers
- CA19-9 also a prognostic marker and functionally associated with carcinogenesis[1]

Preliminary data

- 6 patients evaluated in combo with chemotherapy
  - 4 / 6 met the criteria for PR and 2 / 6 met the criteria for SD
  - BNT321 was generally well tolerated by all 6 patients

PET/CT imaging study with MVT-2163 (PET conjugated Ab version; ^{89}Zr-DFO-HuMab-5B1)





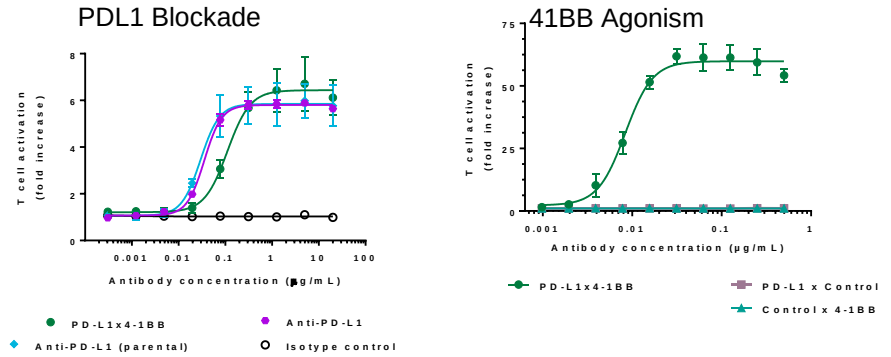
[1] Engle et al, Science 2019: The glycan CA19-9 promotes pancreatitis and pancreatic cancer in mice
CP: checkpoint; PR: partial response; SD: stable disease

Next-Gen checkpoint immunomodulator: GEN1046 (BNT311)

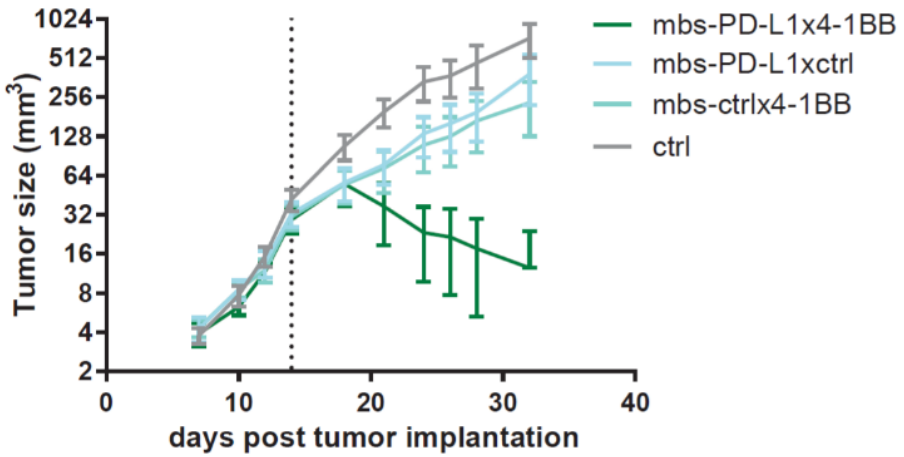
Characteristics

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

Mode of Action



Preclinical antitumor activity beyond PDL1 blockade



1. **Constitutive PD-L1 blockade & conditional 4-1BB agonism**
2. **Increased tumor infiltrating lymphocyte (TIL) expansion in human tumor tissue cultures *ex vivo***
3. **Induced tumor regression of murine tumors superior to pure PD-L1 blockage and is associated with an increase in tumor-specific CD8 T-cells**

*SITC 2018, Altintas et al

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

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

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

Intervention:

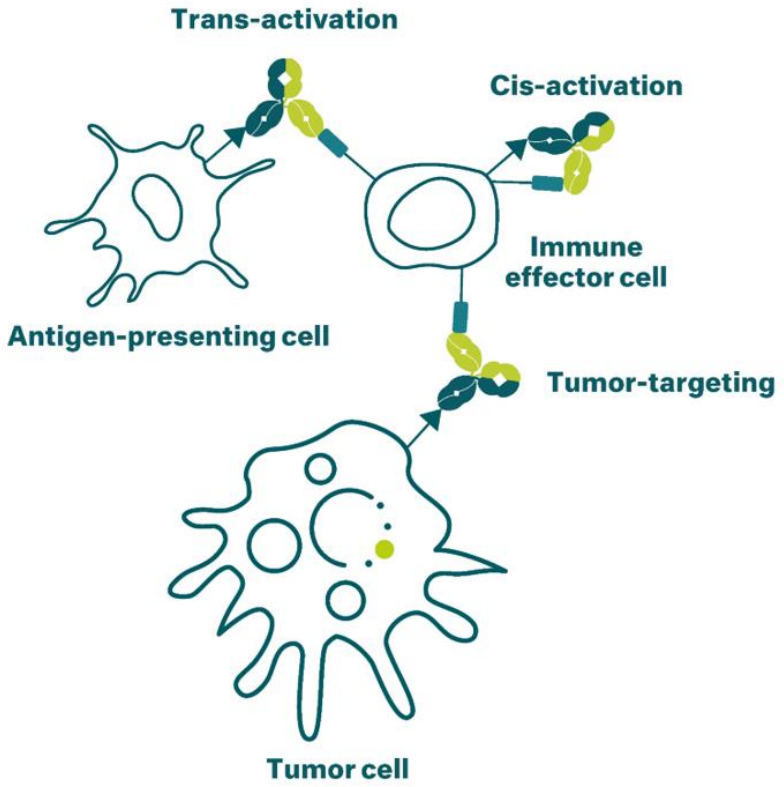
- GEN1046 (BNT311) is a PD-L1x4-1BB bispecific antibody that induces conditional activation of T cells through 4-1BB stimulation which is dependent on simultaneous binding to PD-L1
- GEN1046 (BNT311) IV once every 21 days
- Dose levels determined by the starting dose and the escalation steps taken in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

Description:

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

Key Primary endpoints:

- Dose limiting toxicity
- Adverse events
- Safety laboratory parameters



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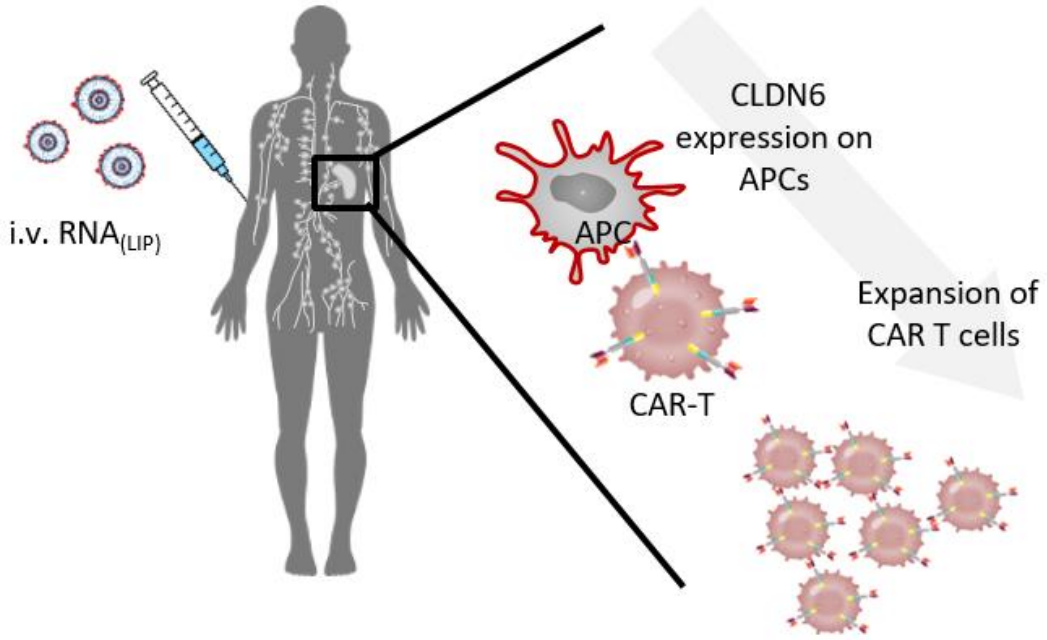
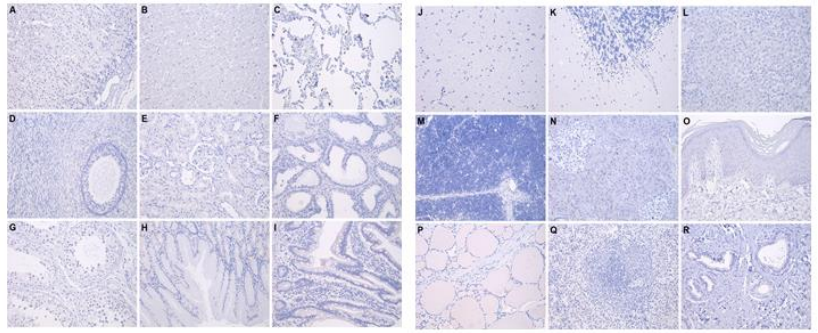
BNT211: Next generation CAR-T targeting CLDN6 with CARVac “primer”

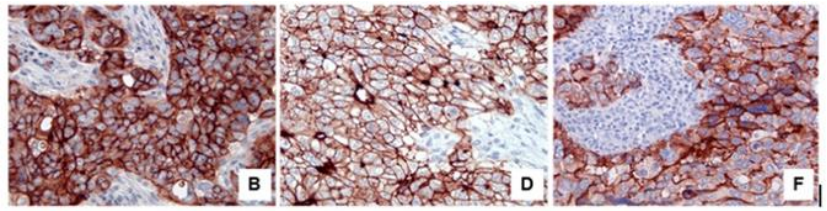


CAR-T cell therapy + RNA Vaccine to amplify CAR-T cell *in vivo*

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



CLDN6 is expressed in multiple cancers



Ovarian cancer Testicular tumor Lung cancer

Eradication of advanced tumors demonstrated in an ovarian carcinoma xenograft model

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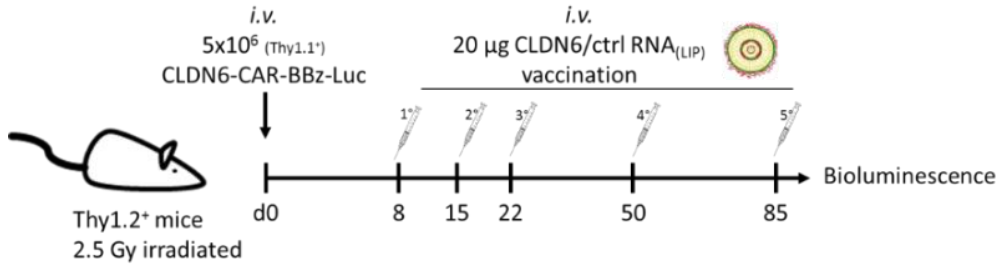
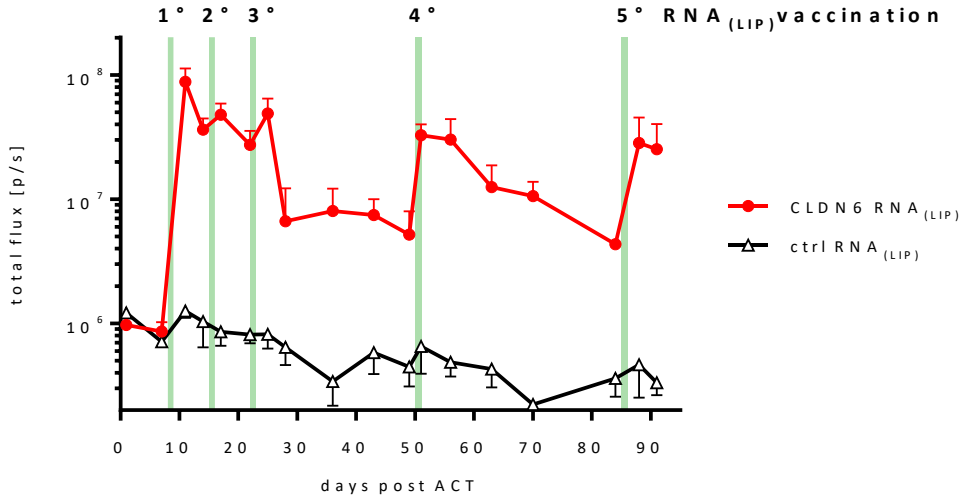
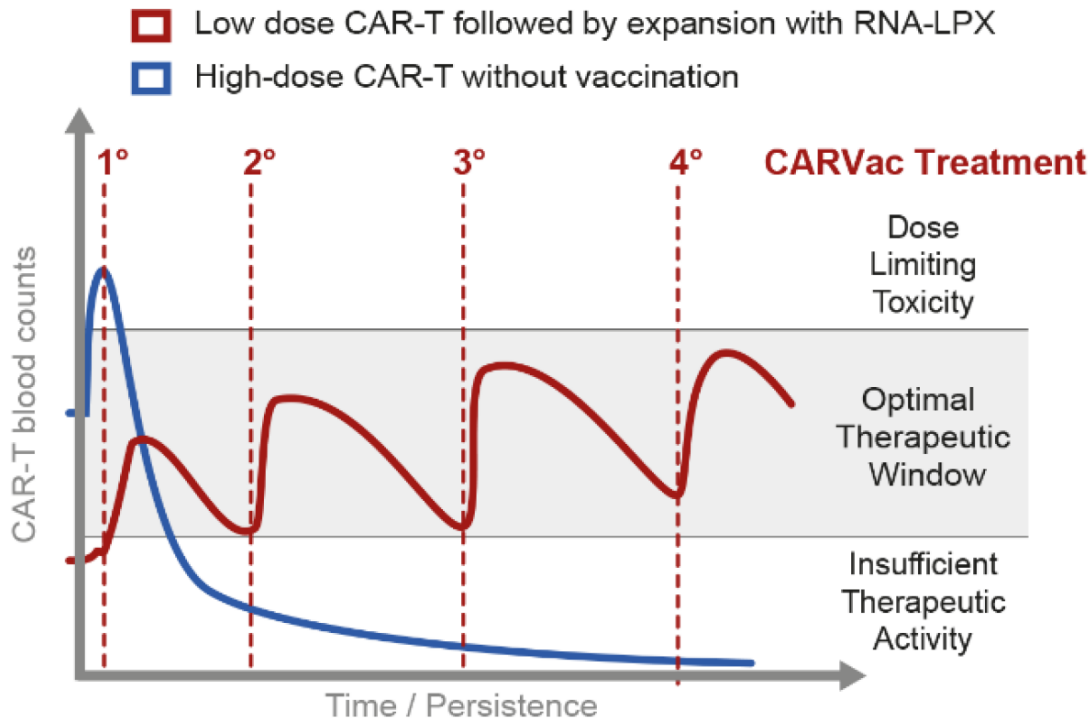
BNT211: Next generation CAR-T targeting CLDN6 with CARVac “primer”







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

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

[1]Reinhard et al, Science 2020: An RNA vaccine drives expansion and efficacy of claudin-CAR-T cells against solid tumors

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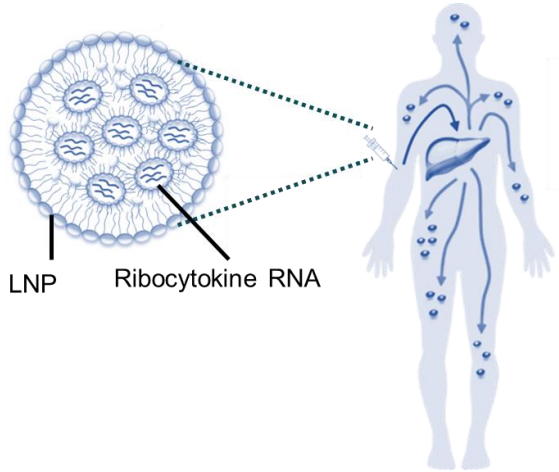
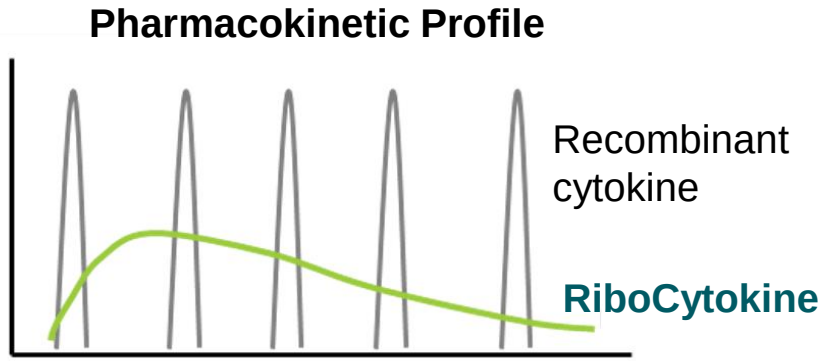
RiboCytokines: a novel therapeutic platform

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



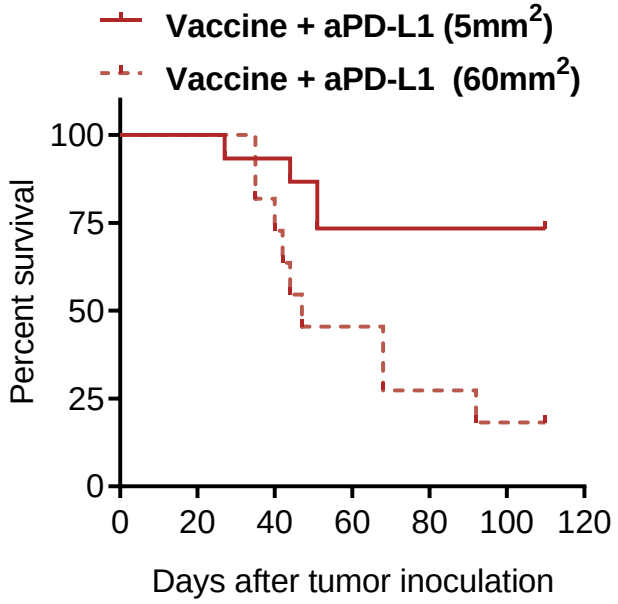


Therapeutic Goals

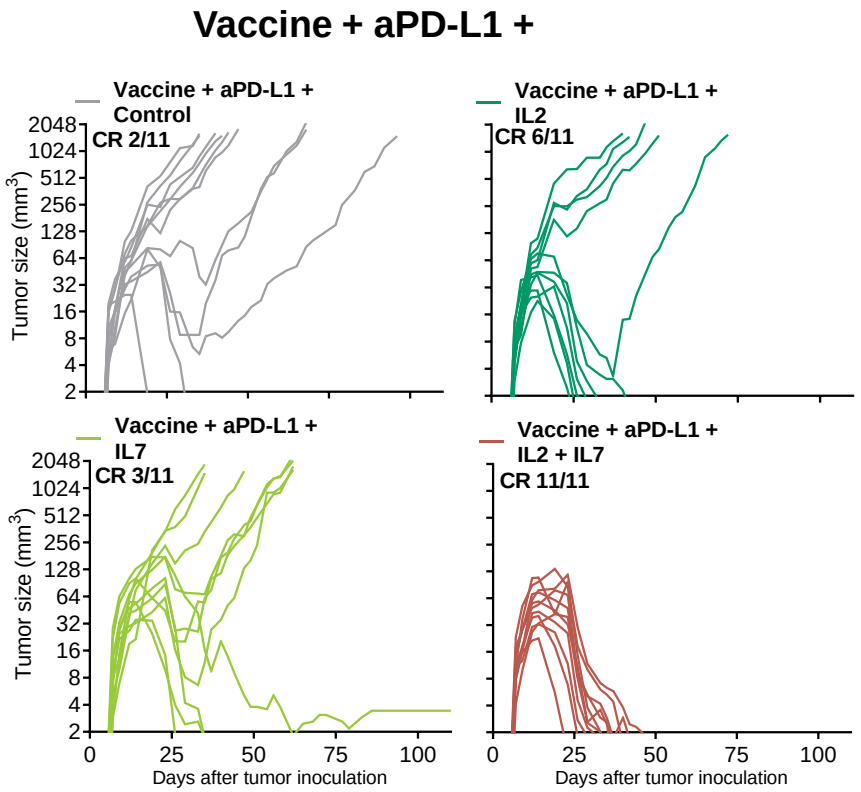
- Overcome resistance mechanisms by therapeutic synergy
- Improve activity of mRNA Vaccines

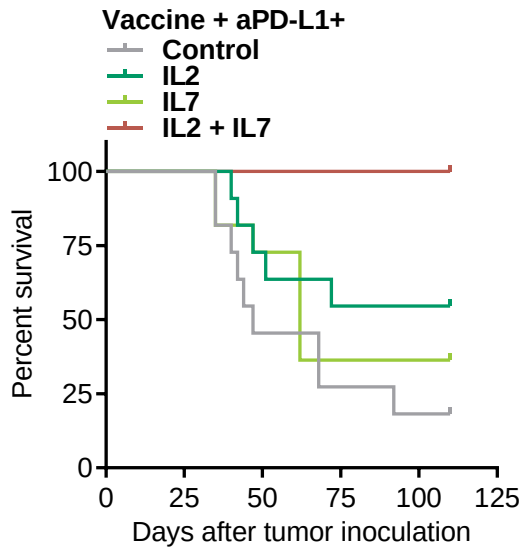
Worldwide rights; wholly owned

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



CT26 tumor model, vaccine antigen: gp70





CT26 tumor model, tumor size: 60mm^2
CR: complete response,
vaccine antigen:gp70

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

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

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Dr. Sylke Maas
Vice President Investor Relations & Business Strategy
An der Goldgrube 12
55131 Mainz
Germany

T: +49 6131 9084-1074
M: **investors@biontech.de**