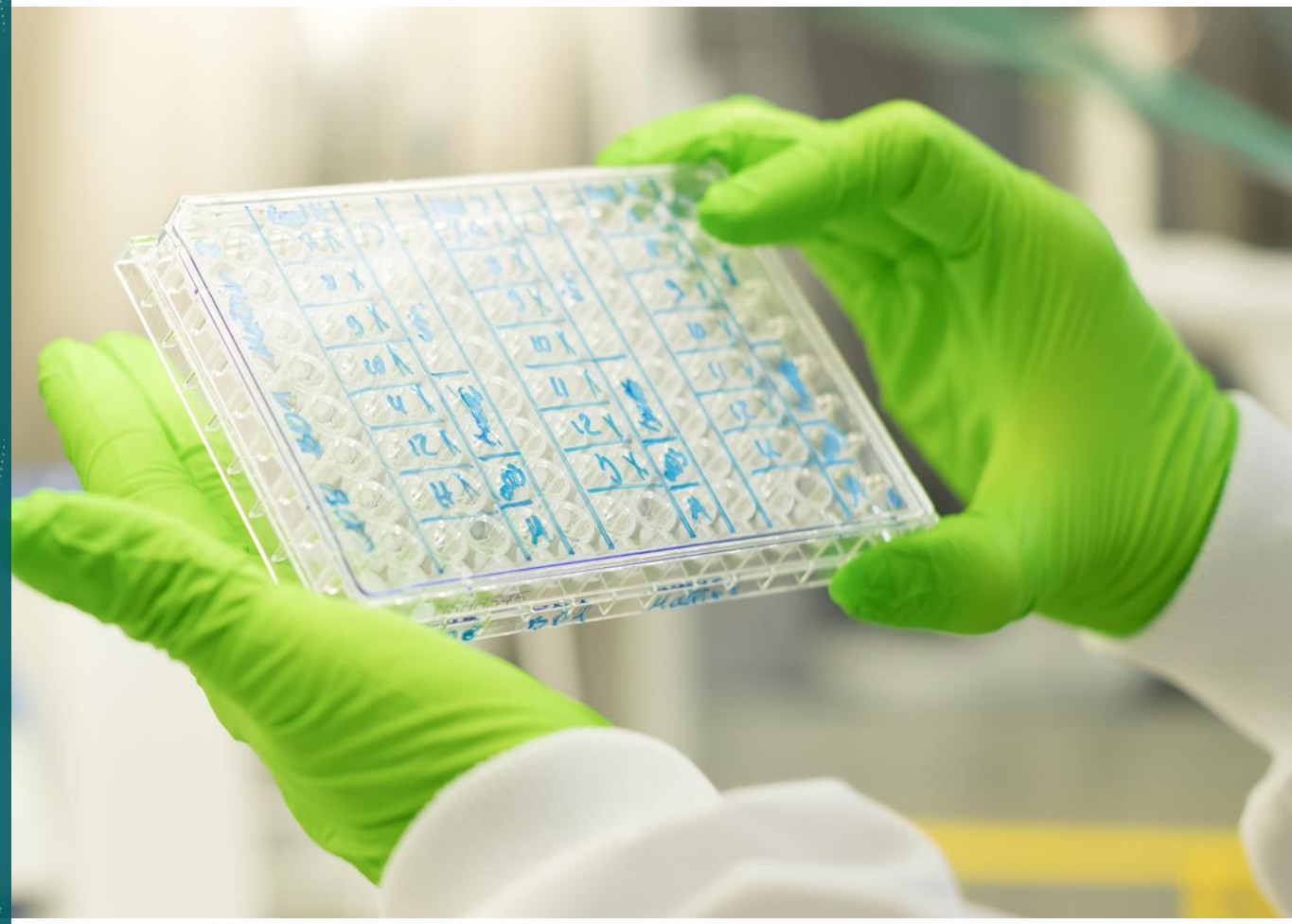
Next Generation Immunotherapy

June 2021



This slide presentation includes forward-looking statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended including BioNTech's efforts to combat COVID-19; the collaboration between BioNTech and Pfizer regarding a COVID-19 vaccine; our expectations regarding the potential characteristics of BNT162b2 in our continuing trials and/or in commercial use based on data observations to date, including real-world data gathered; the ability of BNT162b2 to prevent COVID-19 caused by emerging virus variants; the expected time point for additional readouts on trial data of BNT162b2 in our ongoing trials; the timing for submission of data for, or receipt of, any marketing approval or Emergency Use Authorization; our contemplated shipping and storage plan, including our estimated product shelf life at various temperatures; the ability of BioNTech to supply the quantities of BNT162 to support clinical development and market demand, including our production estimates and targets for 2021 and 2022;; BioNTech's target vaccine production for 2021; the planned next steps in BioNTech's pipeline programs and specifically including, but not limited to, statements regarding plans to initiate clinical trials of BioNTech's product candidates; BioNTech's plans for expansion in southeast Asia and China, including its planned regional headquarters and manufacturing facility in Singapore as well as the JV with Fosun Pharma; and expectations for data announcements with respect to BioNTech's clinical trials. 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 forward-looking statements contain these words. The forward-looking statements in this quarterly report 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 our quarterly report and in subsequent filings made by BioNTech with the SEC, which are available on the SEC’s website at https://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 quarterly report 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 12 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 should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series.
- Vaccination providers must report Adverse Events in accordance with the Fact Sheet to VAERS at https://vaers.hhs.gov/reportevent.html or by calling 1-800-822-7967. The reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report.
- Vaccination providers should review the Fact Sheet for Information to Provide to Vaccine Recipients/Caregivers and Mandatory Requirements for Pfizer-BioNTech COVID-19 Vaccine Administration Under Emergency Use Authorization.

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.

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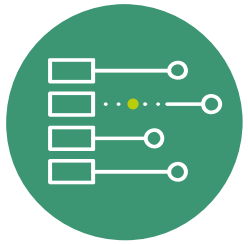
Next generation Immunotherapy

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

BIONTECH

Transformed into a fully integrated, global immunotherapy company

Fully Integrated Structure

- **Deep Immunology Expertise**
- **Broad Suite of Novel Technologies**
- **Bioinformatics Approach**
- **In-House Manufacturing**
- **Commercial Capabilities**
- **Global Team of 2,000+**

A Robust Pipeline of 20+ Candidates

Next-Gen Immunotherapies & Vaccines

Oncology, Infectious Disease and Beyond

Potential to Launch Multiple Products in Next 5 Years

Accelerated by Proven Execution and COVID-19 Vaccine Cash Flow

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We collaborate with global leaders in our industry

Collaborations for clinical stage programs

Covid-19 Vaccine	FixVac Melanoma	iNeST	Bispecific mABs	Intra-tumoral mRNA
50:50 gross profit share[1]	*Each company to keep 100% of rights to own product*	*50:50 cost & profit share*	*50:50 cost & profit share*	*cost & profit share*
Pfizer, FOSUNPHARMA	REGENERON	Genentech	Genmab	SANOFI

Pre-clinical collaborations

Seasonal Influenza	Up to 10 Infectious Disease Indications	HIV, Tuberculosis	5 Rare Disease Indications
royalties & milestones	*worldwide opt-in right*	*developed world rights*	*50:50 cost & profit share*
Pfizer	University of Pennsylvania	BILL & MELINDA GATES foundation	GENEVANT

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

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** **uRNA** **saRNA**

Broad IP portfolio covering technologies, targets and formulations.

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

Infectious diseases represent a long-term growth pillar

Unmet Medical Needs

- Increasing number of highly unaddressed indications
- Only **7** infectious disease vaccines approved by the FDA from 2017 to 2020
- Many high incident infections with **no vaccine or therapy approved**
- 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

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Oncology: Tackling multiple diseases with different therapeutic modalities

mRNA Cancer Vaccines

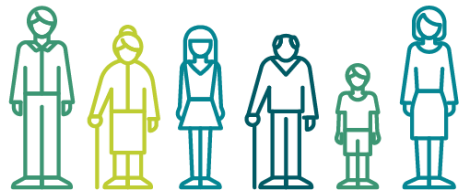
iNeST and FixVac

- Multi-specificity, multi-valency, high (neo)antigen specific T cell responses with unprecedented potency
- Ongoing Phase 2 randomized trial (iNeST)

Next Generation Immunomodulators

Bispecifics

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



Targeting Cancer + Immunomodulation

Next Gen CAR-T Cell Therapy
Neoantigen-based T Cell Therapy

- CARVac: Paired with mRNA vaccination to enhance PK and persistence
- Phase 1 FIH trials started in Feb. and Apr.

Cell Therapies

Targeted Cancer Antibodies

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

Antibodies

TLR-7 Agonist

- Potently modulates innate immunity
- Potential for combination with other IO agents
- Ongoing Phase 1 trial

Small Molecule Immunomodulators

Ribocytokines

- 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

PK, Pharmacokinetics; CA 19-9: Cancer antigen 19-9; IO, Immuno-oncology; CPI, Check-point Inhibitor

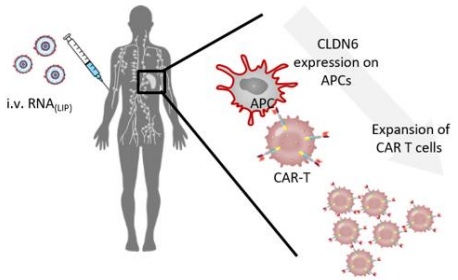
A technology agnostic approach targets a broader addressable cancer market

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

Next wave oncology advancing innovation beyond current boundaries

CARVac
CAR-T cell amplifying mRNA therapy for solid tumors[1]

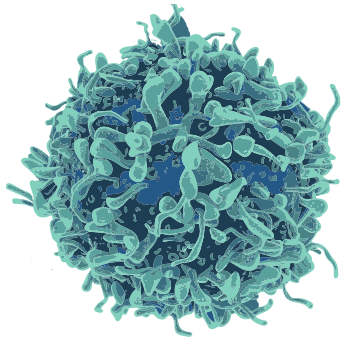


- **BNT211 (CLDN 6 CAR)**
  Next generation CAR-T targeting CLDN6 with CARVac

Wholly owned: ✓

FIH start: FPD Feb. 2021

NEOSTIM T cell therapy
Individualized Neoantigen specific T cell therapy

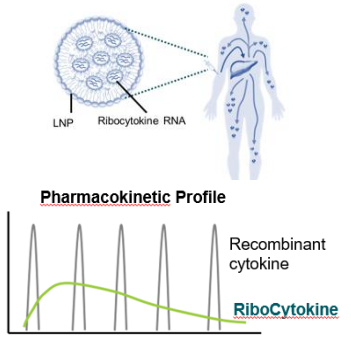


- **BNT221**
  PBMC derived ex vivo T cell therapy

Wholly owned: ✓

FIH start: FPD Apr. 2021

RiboCytokines
mRNA encoded Cytokines

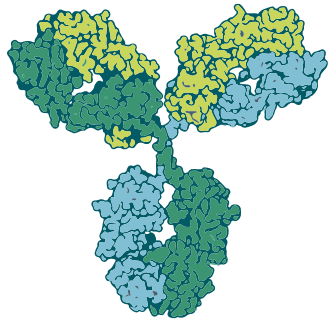


- **BNT151**
  (modified IL-2)
- **BNT152 + BNT153**
  (IL-2/IL-7)

Wholly owned: ✓

FIH start: BNT151: FPD Feb. 2021

RiboMabs[2]
mRNA encoded Antibodies



- **BNT141**
  (undisclosed)
- **BNT142**
  (CD3xCLDN6)

Wholly owned: ✓

FIH start: 2H 2021

FPD, first patient dosed; CLDN6, Claudin-6, CAR-T cells, chimeric antigen receptor T cells; IL-2, interleukin 2; IL-7, Interleukin 7; PBMC, peripheral blood mononuclear cells; FIH, first in human

[1] Reinhard K, et al. Cancer Immunotherapy 2020; 367:446-453; 2 Stadler et al, Oncoimmunology 2018

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Significant pipeline milestones expected in 2021

5+ Trial Updates

- **BNT162b2:** Multiple 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 + CPI in refractory melanoma
- **BNT113:** FixVac HPV16+ + CPI in 1L HNSCC
- **BNT122:** iNeST (autogene cevumeran) + CPI in adjuvant mCRC

7 First-in-human Phase 1 Trial Starts

- ✓ **BNT211:** CLDN-6 CAR-T + CARVac in solid tumors
- ✓ **BNT151:** Ribocytokine (modified IL-2)
- ✓ **BNT221:** NEOSTIM individualized neoantigen-T cell therapy in melanoma
  - **BNT152+153:** RiboCytokine IL-2 / IL-7 combo in solid tumors
  - **BNT141**: RiboMab (undisclosed)
  - **BNT142:** RiboMab bi-specific CPI in solid tumors (CD3xCLDN6)
  - **BNT161:** Influenza vaccine

CLDN6, Claudin-6, CAR-T cells, chimeric antigen receptor T cells; IL-2, interleukin 2; IL-7, Interleukin 7; CPI, check-point inhibitor; HNSCC, head and neck squamous cell carcinoma; mCRC, metastatic colorectal cancer

Building a 21st Century Global Immunotherapy Powerhouse

Increase global footprint

- New regional headquarters planned in Singapore
- Commercial subsidiaries established in Germany and Turkey
- Offices established in the United States

Expand integrated infrastructure

- Continue investment in innovation to support future product launches
- Invest in clinical, commercial and manufacturing, and digital capabilities
- Attract and retain top talent

Rapidly advance pipeline

- 14 product candidates in 15 ongoing clinical trials
- 3 potentially registrational phase 2 trials initiating this year
- Advance innovations into first-in-human studies
- Strategic in-licensing to complement internal R&D

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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
- Cell Therapies – CARVac and NEO-STIM T cell therapy
- RiboCytokines

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Oncology pipeline: 14 product candidates in 15 ongoing clinical trials

Drug class	Platform	Product Candidate	Indication (Targets)	Preclinical / Phase 1 / Phase 2 / Phase 3	Rights Collaborator	Milestones
mRNA	FixVac (fixed combination of shared cancer antigens)	BNT111	advanced melanoma		fully-owned	FPD[4] phase 2: 1H 2021
		BNT112	prostate cancer		fully-owned	
		BNT113	HPV16+ head and neck cancer[1]		fully-owned	FPD[4] phase 2: 1H 2021
		BNT114	triple negative breast cancer		fully-owned	
		BNT115	ovarian cancer[1]		fully-owned	
	iNeST (patient specific cancer antigen therapy)	autogene cevumeran (BNT122)	1L melanoma		Genentech (global 50:50 profit/loss)	
			solid tumors			Phase 2 trial planned in adjuvant CRC: FPD[4] in 2H 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	
Antibodies	Next-Gen CP[2] Immunomodulators	GEN1046 (BNT311)	solid tumors *(PD-L1×4-1BB)*		Genmab (global 50:50 profit/loss)	Data update 2H 2021
		GEN1042 (BNT312)	solid tumors *(CD40×4-1BB)*			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 Therapies	CAR-T Cells	BNT211	solid tumors (CLDN6)		fully-owned	Data update 2H 2021
	Neoantigen-based T cell therapy	BNT221 (NEO-PTC-01)	solid tumors		fully-owned	

[1]BNT113 and BNT115 are currently being studied in investigator-initiated Phase 1 trials.
[2]Checkpoint Inhibitor.
[3]Small Molecule Immunomodulators.
[4]FPD = First Patient Dosed

Early-stage oncology pipeline: 3 additional FIH[1] trials to begin in 2021

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

[1]first-in-human

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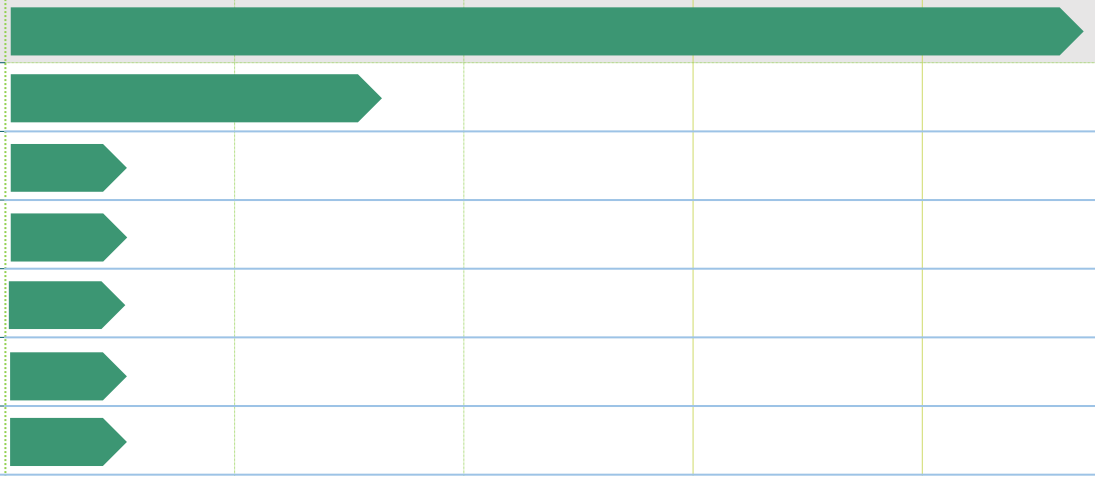
Broad infectious disease pipeline

Drug Class	Product Candidate	Indication (Targets)	Pre-clinical	Phase 1	Phase 2	Phase 3	Commercial	Rights / Collaborator
mRNA Vaccine	COMIRNATY	COVID-19						Pfizer/Fosun
	BNT162b3 (modRNA)	COVID-19						Pfizer/Fosun
	BNT161	Seasonal Influenza						Pfizer
	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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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
  - Cell Therapies – CARVac and NEO-STIM T cell therapy
  - RiboCytokines

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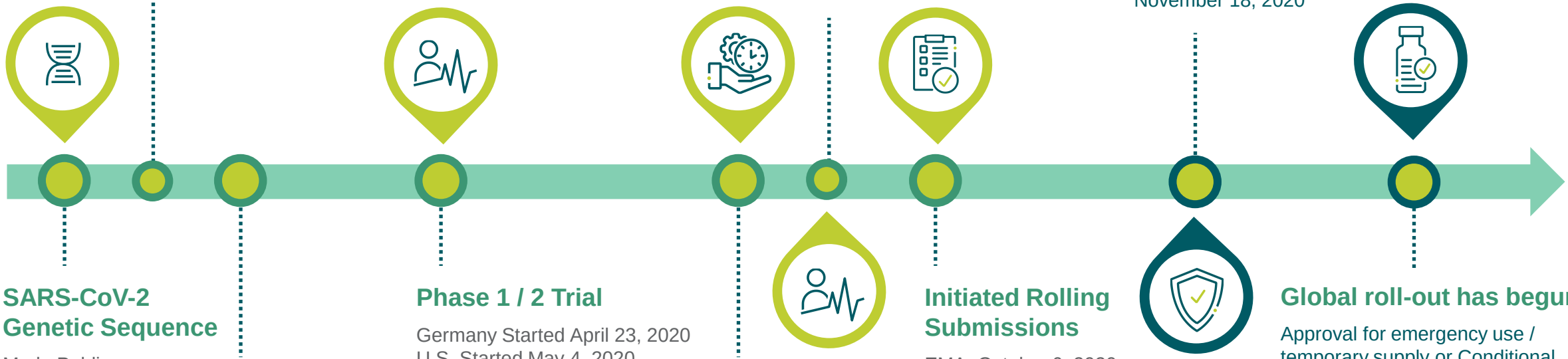
Project Lightspeed – a 10-month journey to an effective and safe vaccine



SARS-CoV-2 Genetic Sequence

Made Public
January 12, 2020

COVID-19 mRNA Vaccine Program Initiation

January 27, 2020

Collaborations

Fosun Pharma:
March 16, 2020

Pfizer:
March 17, 2020

Phase 1 / 2 Trial

Germany Started April 23, 2020
U.S. Started May 4, 2020
4 vaccine candidates enter clinical testing

FDA Fast Track designation

July 13, 2020

Initiated Pivotal Phase 2 / 3 Trial

Lead mRNA vaccine candidate chosen; up to 44,000 subjects
July 27, 2020

Initiated Rolling Submissions

EMA: October 6, 2020
Canada: October 7, 2020
UK: October 9, 2020
Singapore
New Zealand
…and other countries

Phase 3 trial meets all primary efficacy endpoints; vaccine efficacy rate of 95%

November 18, 2020

Global roll-out has begun

Approval for emergency use / temporary supply or Conditional Marketing Authorization in more than 70 countries worldwide including the U.S. and E.U.

December 2020

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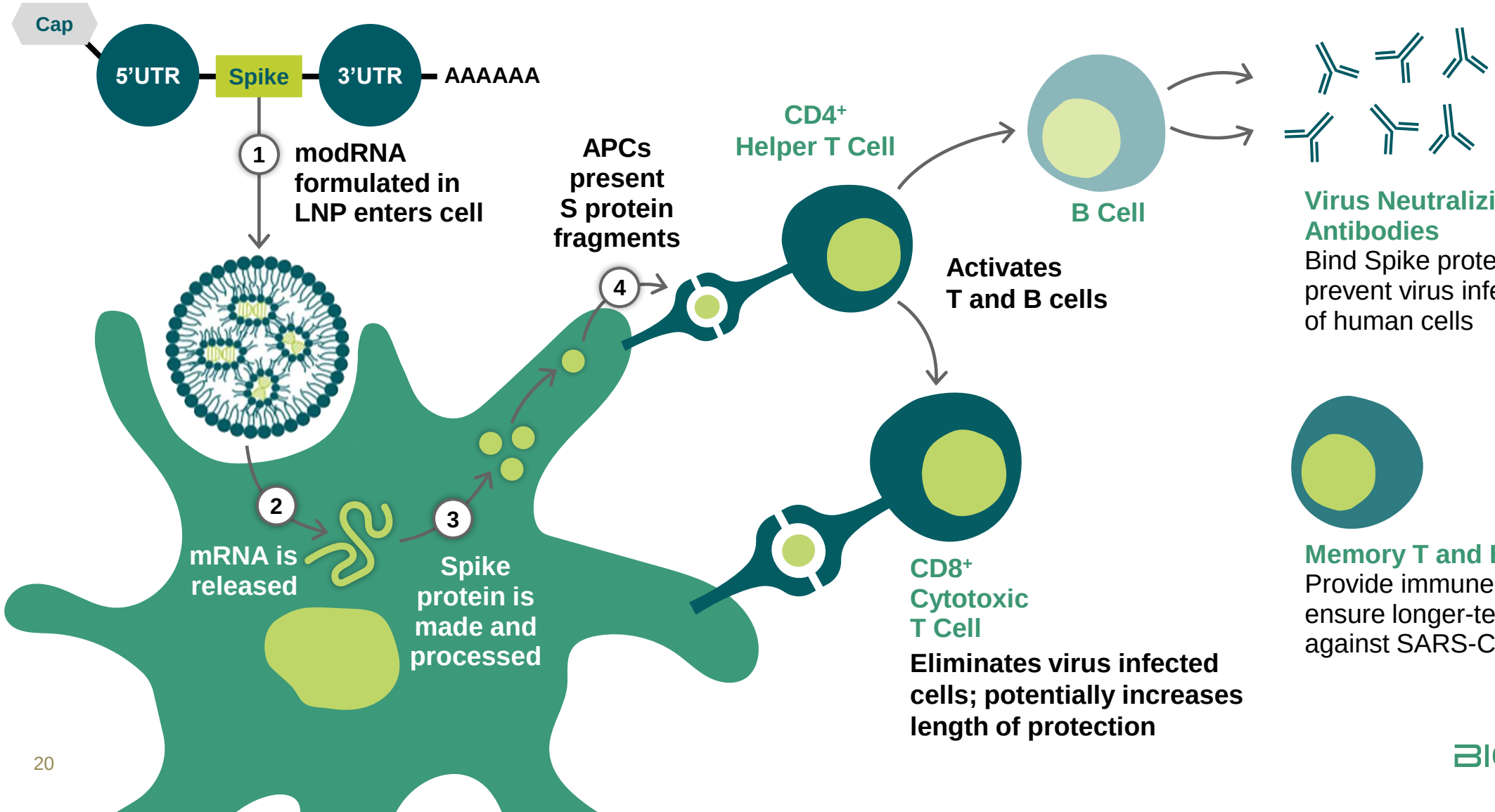
How mRNA vaccines work – training the immune system for a real infection



Virus Neutralizing Antibodies
Bind Spike proteins and prevent virus infection of human cells

Memory T and B cells
Provide immune memory to ensure longer-term protection against SARS-CoV-2

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mRNA is a natural solution for vaccines especially in a pandemic

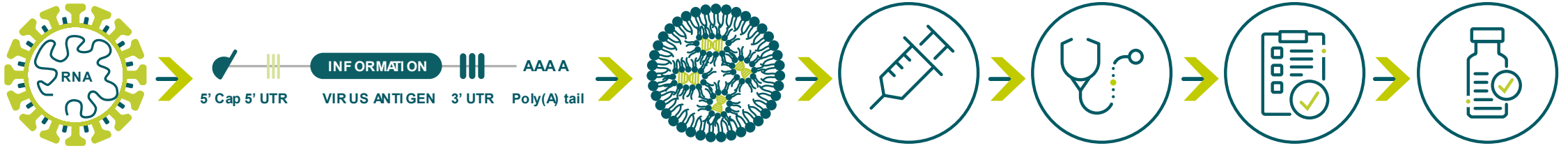
Natural molecule with well-characterized **bio-safety properties**

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

Highly scalable production

High purity and animal free

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



Genetic information SARS-CoV-2 | **Vaccine mRNA** | **mRNA LNP** | **Clinical testing** | **Phase 3 trials** | **EUA / approval** | **Vaccination**

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Strong clinical results

Clinical profile

- 95% effective against symptomatic COVID-19 infections[1]
- 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 responses[2]

[1]Polack FP, et al. NEJM 2020, 383:2603-2615
[2]Sahin U, et al. preprint 2020 (https://www.medrxiv.org/content/10.1101/2020.12.09.20245175v1)

Compelling real-world evidence

Real-world data from observational study conducted by Israel Ministry of Health

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

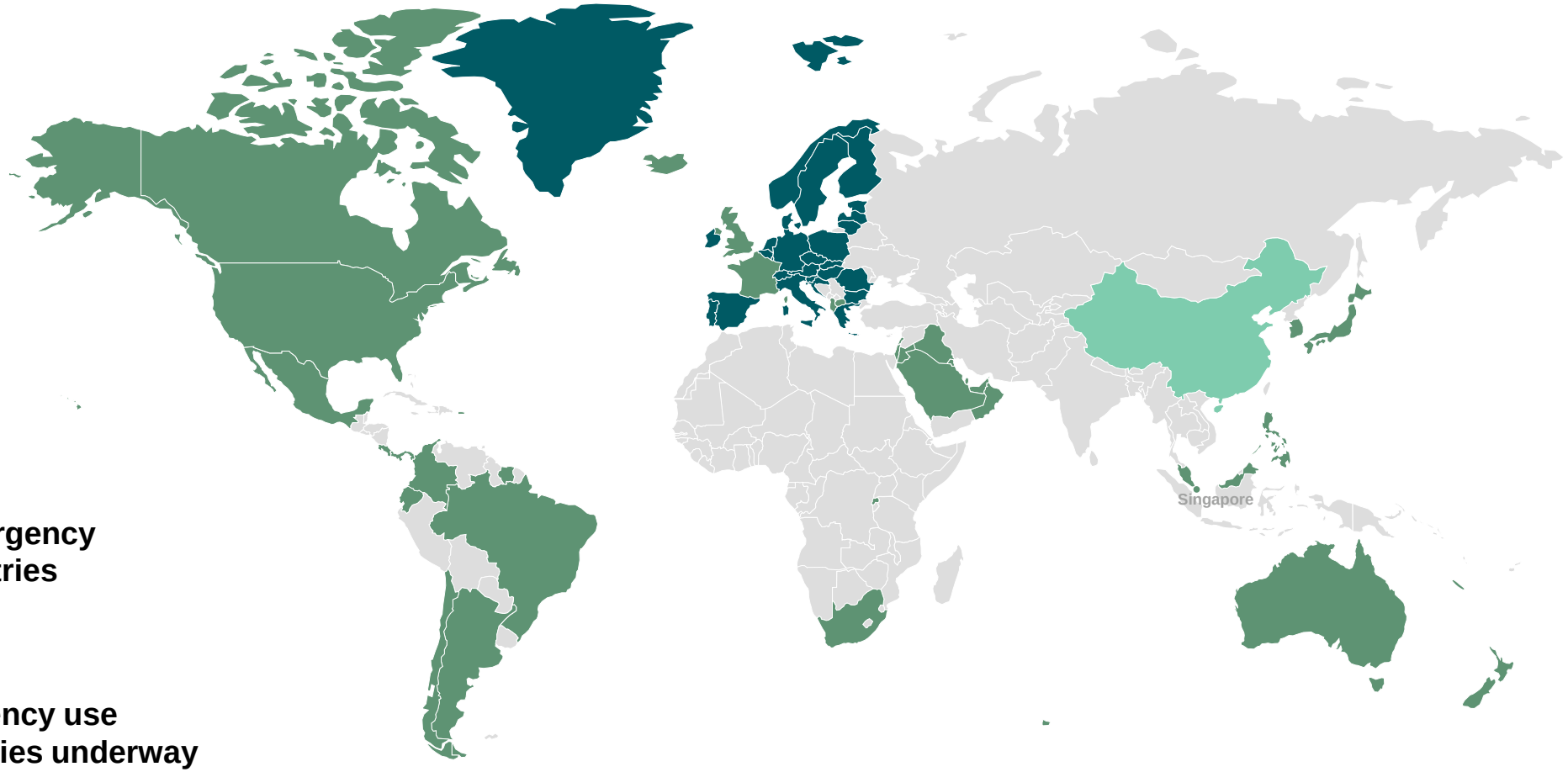
Real-World-Data announced by The Israel Ministry of Health (MoH) on March 11, 2021: https://www.businesswire.com/news/home/20210311005482/en/
Haas EJ, et al. preprint 2021; https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3811387

Project Lightspeed: A concerted and large-scale global effort

Conditional Marketing Authorization in the EU and Switzerland[1]

Approved Emergency Use Authorization / Temporary Use Approval

Ongoing Phase 2 trial in China



Conditional marketing or emergency use authorization in >70 countries with >450M doses delivered[2]

Rolling application for emergency use authorization in further countries underway

[1]The vaccine is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 16 years of age and older.
[2]As of May 10, 2021.

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

	Observation	*Implication*
1	Waning immune responses	Re-boostings may be required
2	Variants are driving new infections	Variant-specific vaccines may be needed
3	New mRNA vaccines can be rapidly designed and produced at scale	mRNA vaccines are well suited for long-term challenge

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

Increased Manufacturing Capacity

- Up to 3 billion doses by end of 2021; more than 3 billion doses in 2022
- First shipments from Marburg facility delivered mid April
- New regional headquarters in Singapore to house mRNA manufacturing facility

Additional Populations

- FDA amended EUA to include adolescents 12 to 15 years
- EMA expanded label to include adolescents 12 to 15 years
- Ongoing study in children 6 months to 11 years of age; first data expected in Q3

Additional Geographies

- Authorized or approved for emergency authorization in more than 70 countries worldwide
- Shipped to 91 counties and territories
- Regulatory submission for BLA in China underway

Broadened & Decentralized Vaccine Access

- U.S. rolling BLA submission initiated
- Initiated Phase 3 trial to evaluate lyophilized and a ready-to use formulation; data expected in Q3
- FDA and EMA updated storage conditions to include 4-week storage at 2°C to 8°C

Addressing SARS-CoV-2 Variants

Addressing Waning Immune Responses

- Ongoing trial to evaluate variant-specific version BNT162b2SA in naïve and vaccinated individuals as well as third dose of BNT162b2 at 6 – 12 months post dose 2
  - Effect on waning immune response against original strain
  - Effect on immune response against variant strains

In March 2021, BioNTech announced its Full Year 2020 Financial Results and Corporate Update as a part of the Annual Report filed in Form 20-F, highlighting developments relating to its COVID-19 vaccine program between January 1 and March 30, 2021. This slide focuses on developments that occurred after March 30, 2021.

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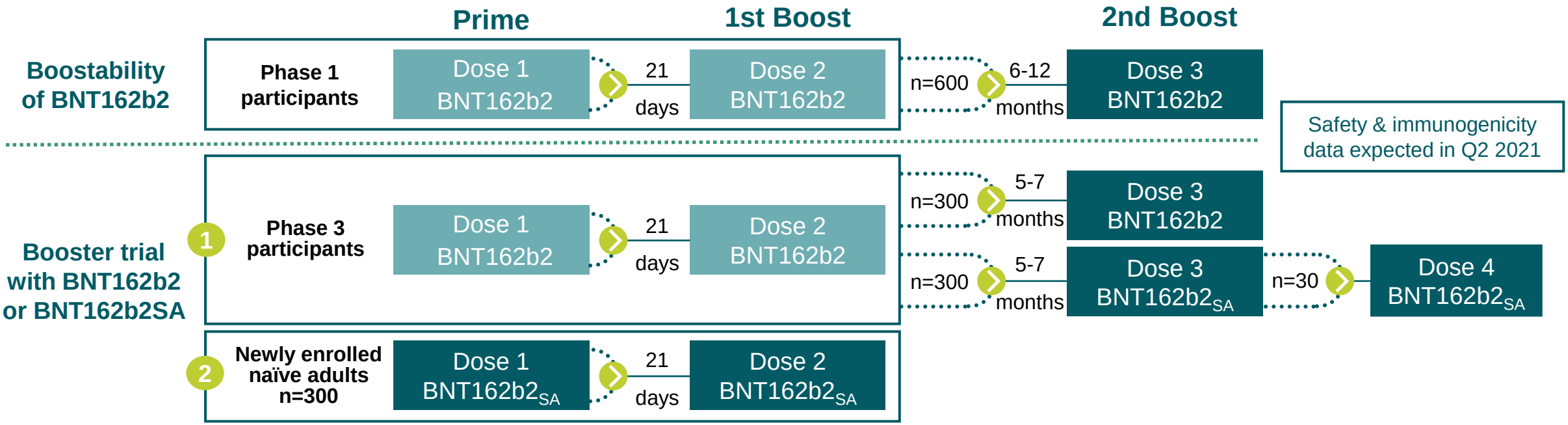
Preemptive strategy to be prepared for addressing SARS-CoV-2 variants

- **No evidence that adaptation of BNT162b2 is needed to date**
  - Sera of BNT162b2 vaccinated individuals neutralize B.1.1.7 (UK), B.1.351 (SA), and P.1 (brazilian) lineage* in *in vitro* studies
- **Expansion of global Phase 1/2/3 trials:**
  - 3rd dose to evaluate safety, magnitude and duration of immunity and variant protection
  - Variant specific booster to evaluate safety and immunogenicity of B.1.351 Spike version of BNT162b2 ($BNT162b2_{SA}$)
  - **"Blueprint" approach informs regulatory path and manufacturing**



*B.117 (UK variant), B.1.351 (South African variant), and P.1 lineage (Brazilian variant)
Liu et al., NEJM, Mar. 8, 2021

BIONTECH

Scaling up manufacturing capacity to address pandemic demand

1.8 billion doses contracted to date for 2021[1]

Selected Regions	Current Orders 2021
EU	600 million
US	300 million
Japan	194 million
UK	90 million
Other	~680 million

First orders contracted for 2022 and beyond

900 million doses for the EU in 2022/2023 with option for an additional 900 million

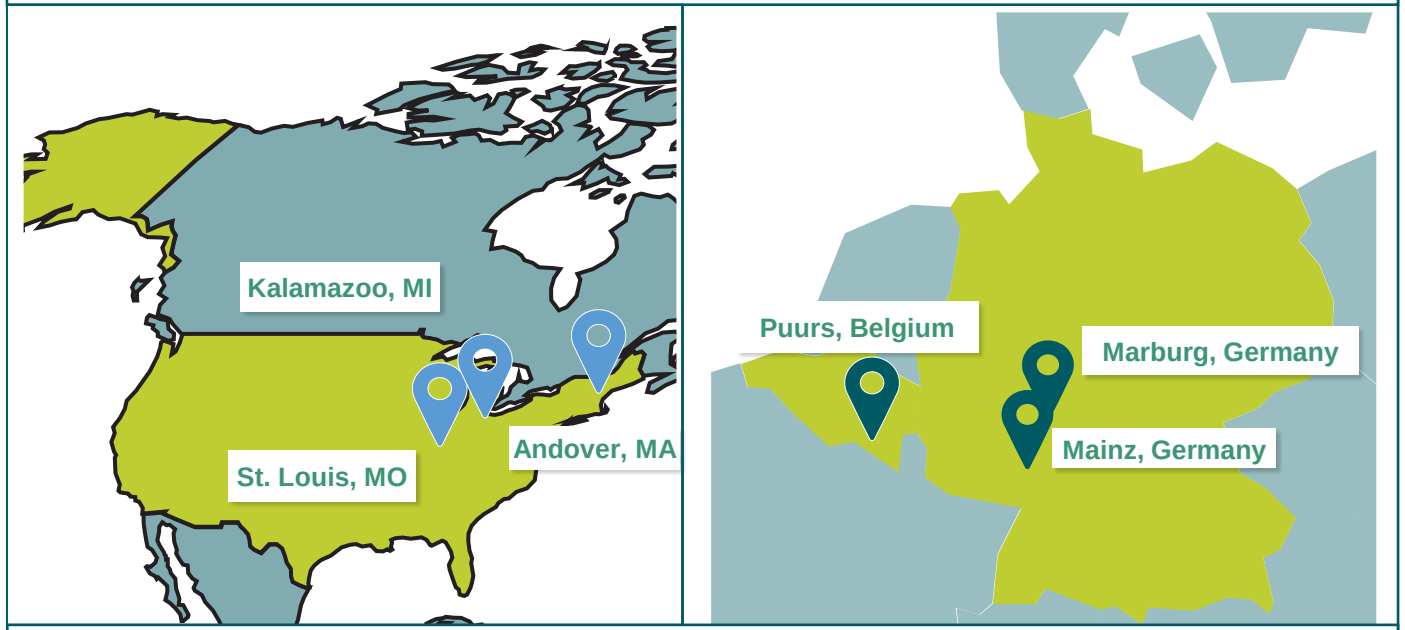
125 million doses for Canada in 2022/2023 with option for 60 million in 2024

Millions of doses to be supplied to Israel in 2022

Ongoing discussions in other regions for additional doses in 2021 and beyond

Targeting up to **3.0 billion doses** capacity in 2021*

Targeting more than **3.0 billion doses** capacity in 2022



Marburg facility

- Up to **1 billion doses** in annual run-rate capacity
- First site batch of vaccine delivered in April

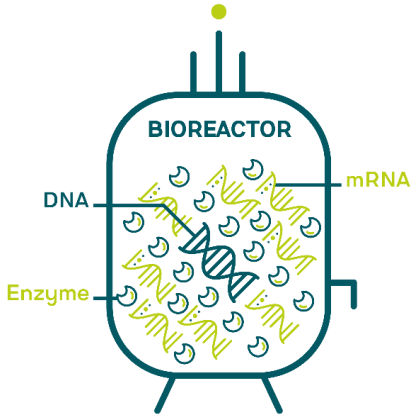
[1]As of May 10, 2021.

*This assumes continuous process improvements and expansion at our current facilities and contingent upon adding more suppliers and contract manufacturers.

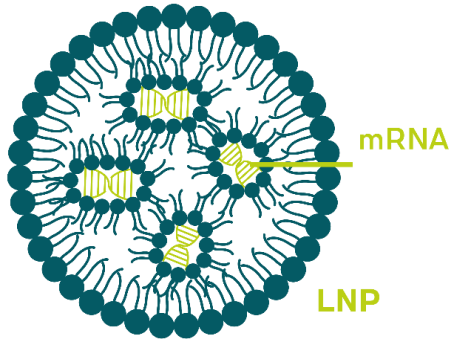
BIONTECH

Flexible manufacturing allows rapid adaptation to variants

DNA template production
~1-2 Days



Drug substance purification and concentration
~1-2 Days



Sterile filtration & filling
~1-2 Days

1 2 3 4 5

mRNA production
~1-2 Days

LNP formulation
~3-4 Days

Quality control and release 4-5 weeks

BIONTECH

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

- 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

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
  - Cell Therapies – CARVac and NEO-STIM T cell therapy
  - RiboCytokines

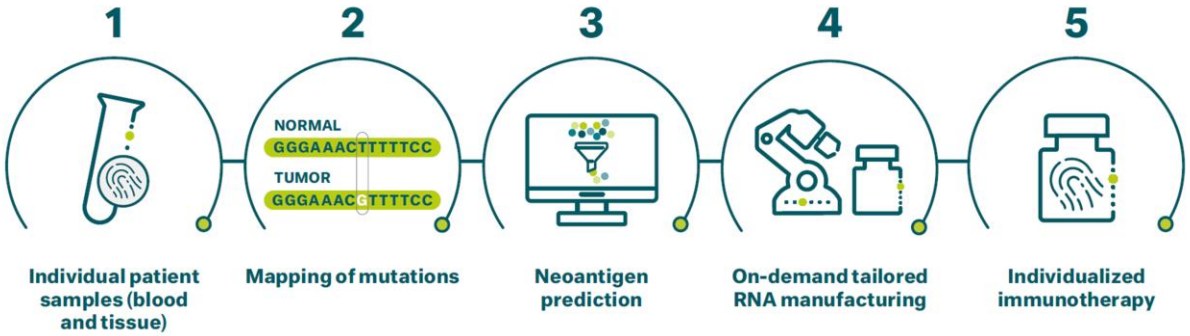
BIONTECH

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

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

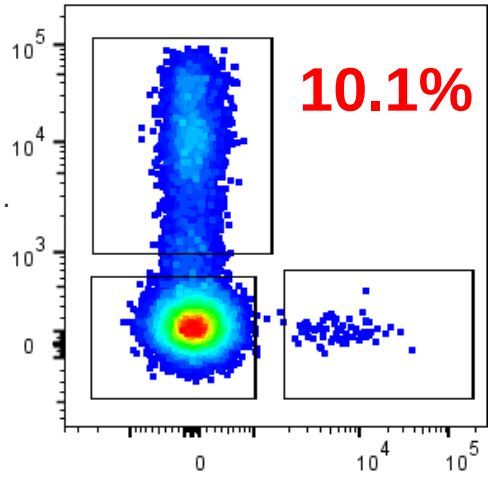
Strong immunogenicity observed *in vivo* via TLR7-driven adjuvant effect

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

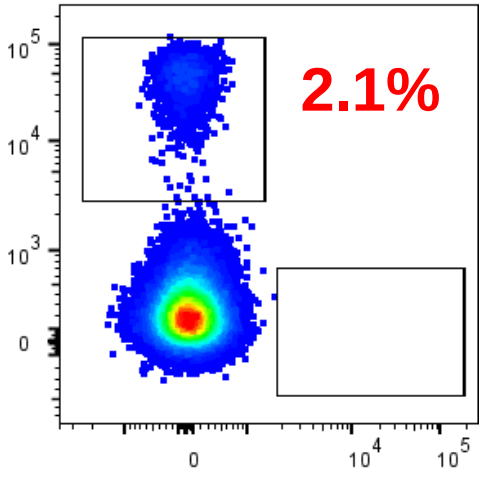
Kranz et al., Nature 2016

Our RNA-LPX vaccine approach

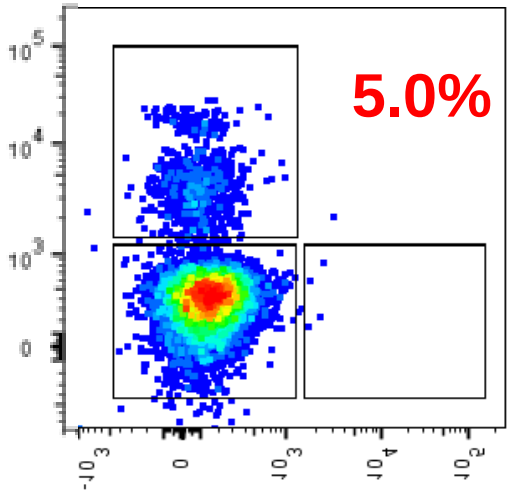
Strong vaccine-induced *ex vivo* CD8+ T cell responses[1] across different cancer types



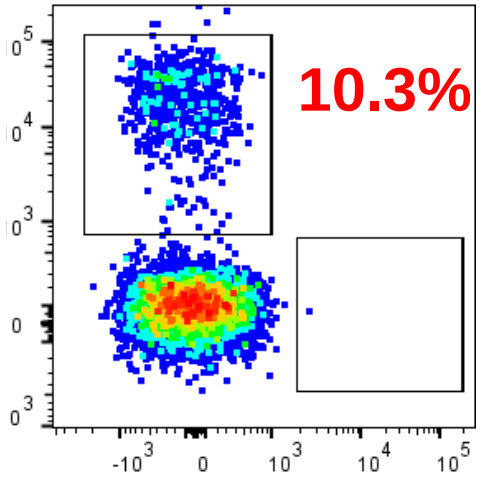
NY-ESO-1
Melanoma
BNT111, Lipo-MERIT trial



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

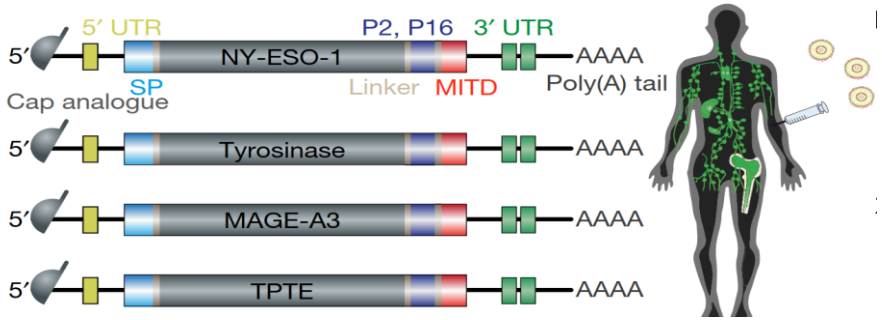
BIONTECH

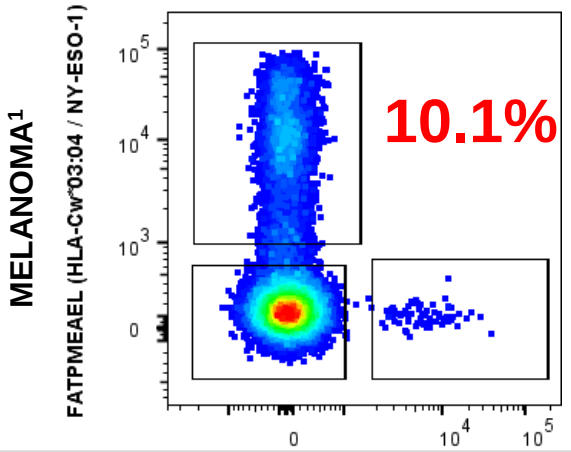
FixVac: Leveraging shared antigens to break immune tolerance

Novel Structure

FixVac

- Multi-valency + Off-the-shelf
- Applicable for almost all types of tumor antigens





Product candidate[2]	Preclinical	Phase 1	Phase 2
BNT111	**Advanced melanoma** *NY-ESO-1, MAGE-A3, Tyrosinase, TPTE*		
BNT113	**HPV+ head & neck cancer** *HPV E6 and E7 oncoproteins*		
BNT112	**Prostate cancer** *PSA, PAP, 3 addition undisclosed antigens*		
BNT116	**NSCLC**		

[1]Sahin et al, Nature 2020
[2]Additional exploratory indications: TNBC, Ovarian Cancer

BIONTECH

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

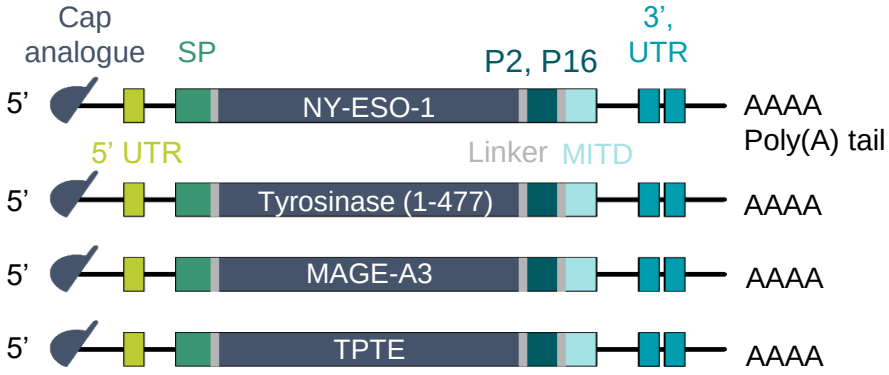
- Signed strategic collaboration to jointly conduct randomized Phase 2 trial with BNT111 and Libtayo® (cemiplimab anti-PD-1 therapy)
- Targeting patients with anti-PD1-refractory/relapsed, unresectable Stage III or IV cutaneous melanoma
- Companies to share development costs equally and keep full commercial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

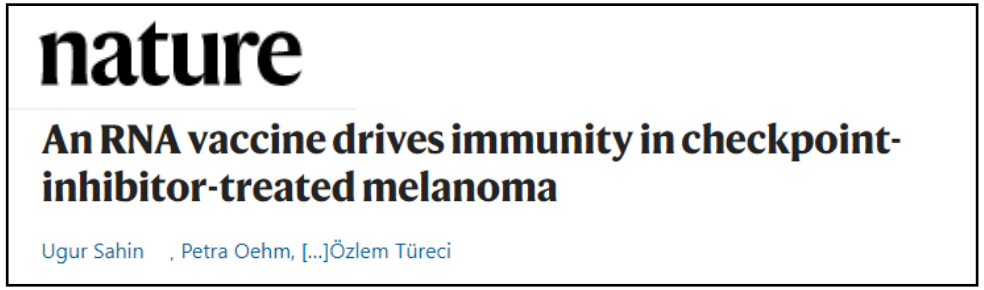
BIONTECH

BNT111: FixVac Melanoma Compelling Preliminary Data

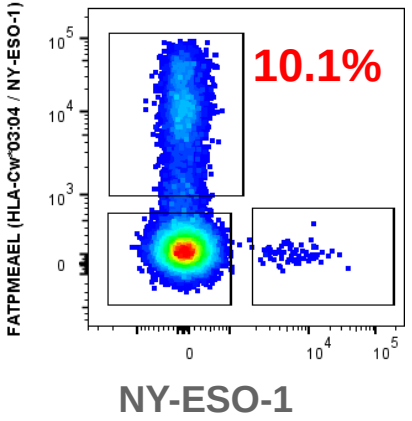
Off-the-shelf mRNA Immunotherapy

- Fixed combination of non-nucleoside modified mRNA
- Encodes 4 tumor-associated antigens (TAA) covering ~95% of melanoma patients
- Intravenous formulation targets antigen presenting cells bodywide to stimulate antigen-specific T cell responses

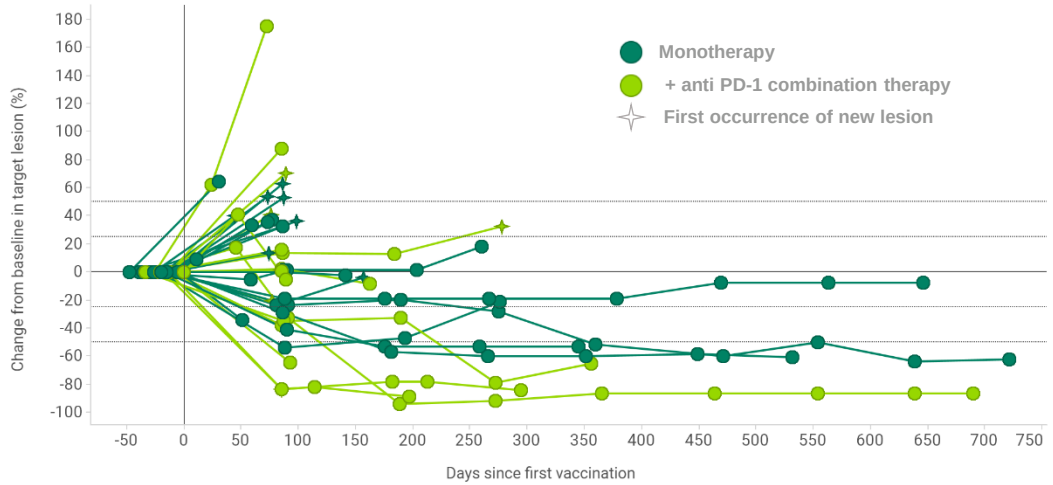




Phase 1 trial in Advanced Melanoma published in Nature



- Tolerable safety as monotherapy and in combination with CPI
- Durable Objective Responses in CPI-experienced patients with evaluable disease at baseline
  - ORR 35% for combination therapy (BNT111 + anti-PD1): 6/17 patients
- High-magnitude and persistent CD4+ and CD8+ T cell responses

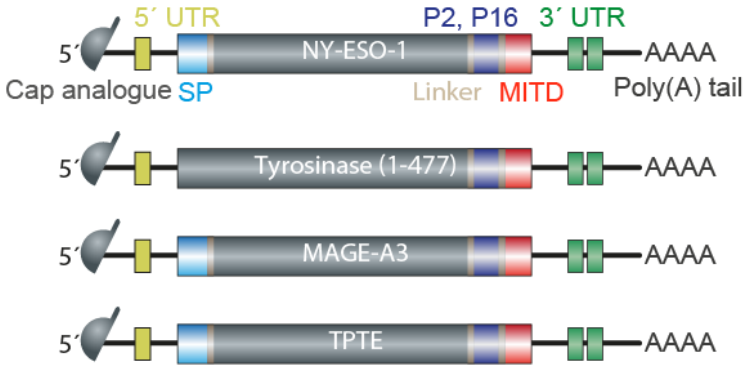


TPTE, trans-membrane phosphatase with tensin homology; SP, surfactant protein; UTR, untranslated region; MITD, MHC I-targeting domain; PD1, programmed death-ligand 1; CPI, checkpoint inhibitor; ORR, overall response rate
https://www.nature.com/articles/s41586-020-2537-9

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%

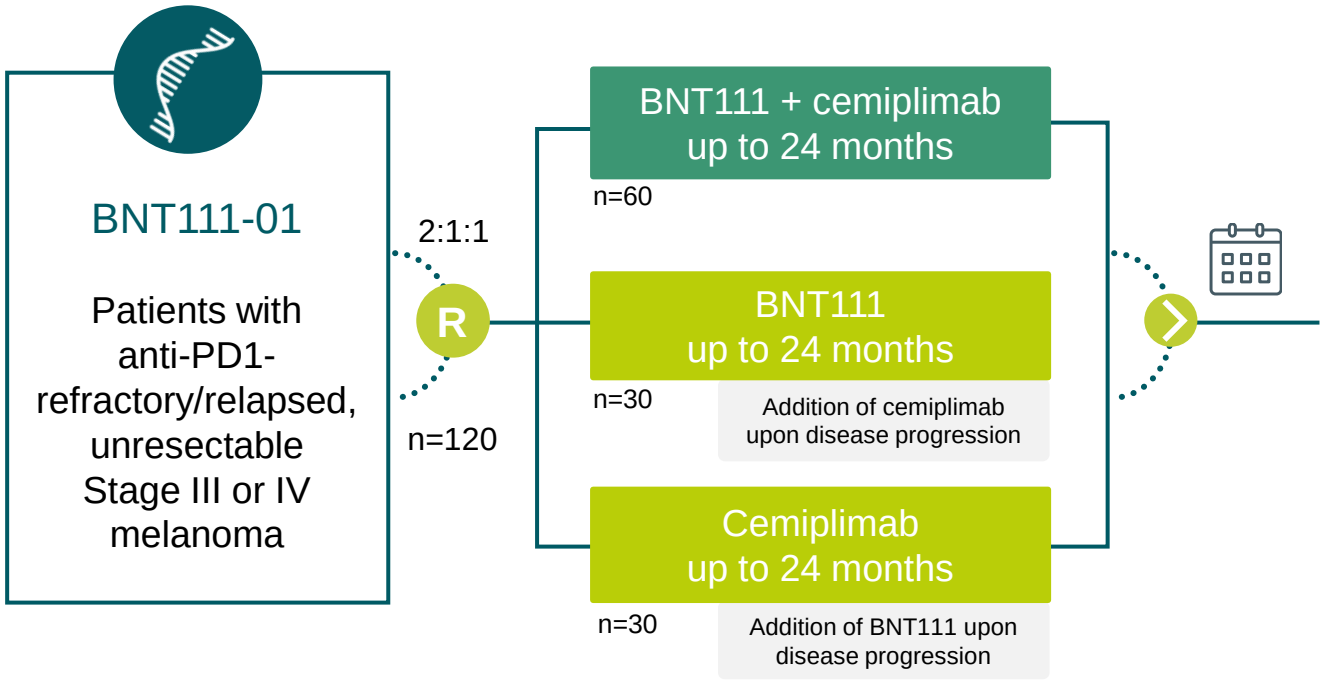
Report phase 1 data 1H 2020

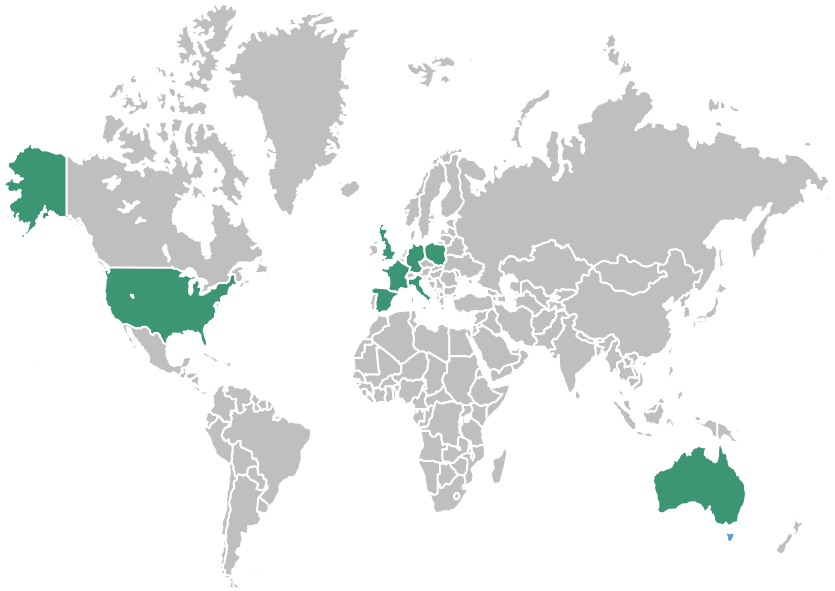
Start randomized phase 2 trial in 1H 2021

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

BIONTECH

BNT111: FixVac phase 2 clinical trial in anti-PD1 r/r melanoma patients





Open-label, randomized Phase 2 trial with BNT111 and cemiplimab in combination or as single agents

- Collaboration with Regeneron

Primary EP

- Arm 1: ORR by RECIST 1.1

Secondary EP

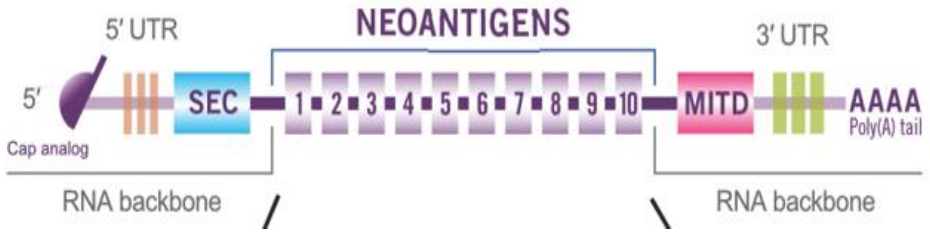
- ORR (key secondary endpoint arms 2, 3) DOR, DCR, TTR , PFS, by RECIST 1.1
- OS, safety, tolerability, PRO

main treatment arm

calibrator arm

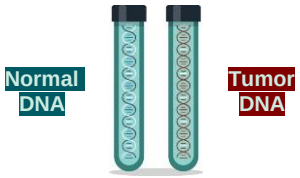
PD1, programmed death-ligand 1; EP, endpoint; ORR, overall response rate; DOR, duration of response; DCR, disease control rate; TTR, time to response; PFS, progression free survival; OS, overall survival; PR, patient reported outcomes; R/R, refractory, relapsed
https://clinicaltrials.gov/ct2/show/record/NCT04526899

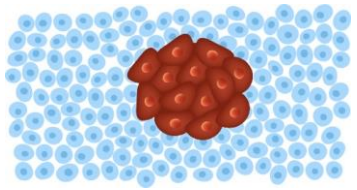
iNeST[1]: Tailored treatment to exploit individual targets



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

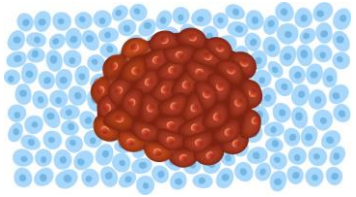
ADJUVANT





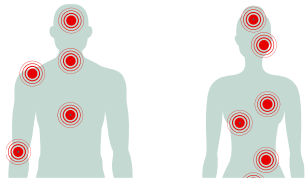
Residual cancer cells may remain – emphasis on recurrence free survival

1L METASTATIC



Rapidly growing but often still in early phase of metastases

LATE-LINE METASTATIC



Bulky tumors with multiple organs involved

iNeST

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

- **Single agent activity** in melanoma[2] and gastric[3] cancer
- **Encouraging efficacy signal validates iNeST potential in early settings**

[1] iNeST is partnered with Genentech/Roche in a 50:50 cost/profit split
[2] Sahin et. al. Nature 20
[3] AACR 2020

BIONTECH

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

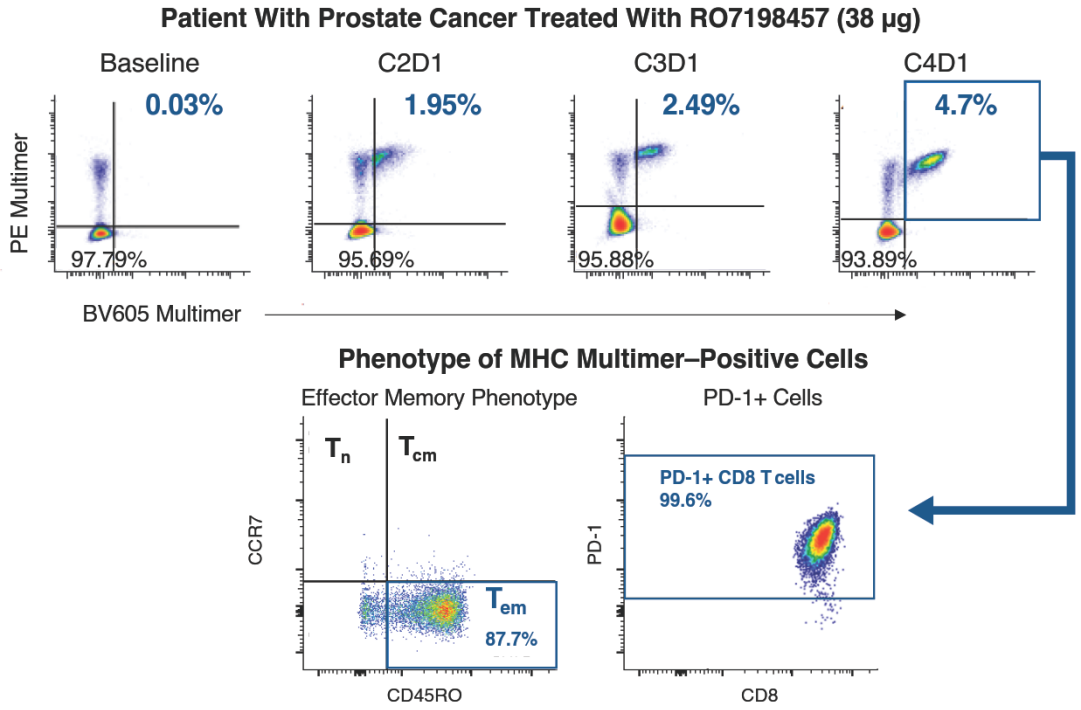
- **132 patients** enrolled, cohorts with **doses ranging from 15-50µg**
- Heavily pre-treated patient population
  - Both CPI experienced and inexperienced
  - **Most patients with low PD-1**
- Clinical responses associated with T cell response, correlating immune profiling of patients' T cells to cancer-specific 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 both effector and memory phenotype as monotherapy and in combination**
- **Treatment-related adverse events were primarily transient systemic reactions, manifesting as low grade CRS, IRR or flu-like symptoms**
- **Early evidence of clinical activity in highly refractory patient population**

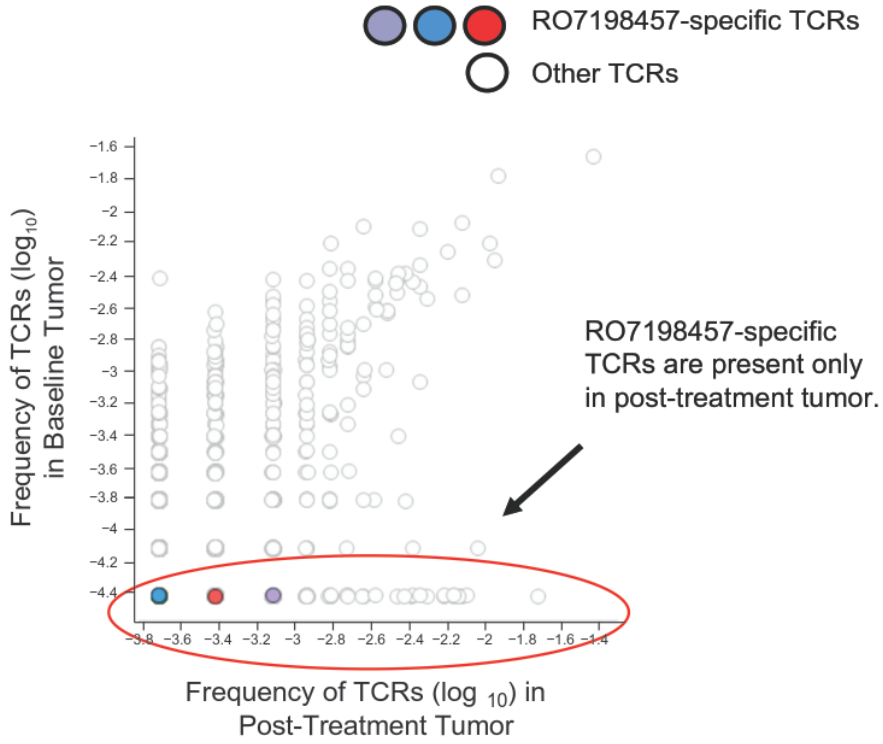
Note: Patients in both cohorts received personalized product manufactured on per patient basis with **up to 20 patient-specific neoantigens, in both cohorts majority of AEs were Grad 1 or Grade 2**

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 2H 2021***

BIONTECH

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

SIEMENS

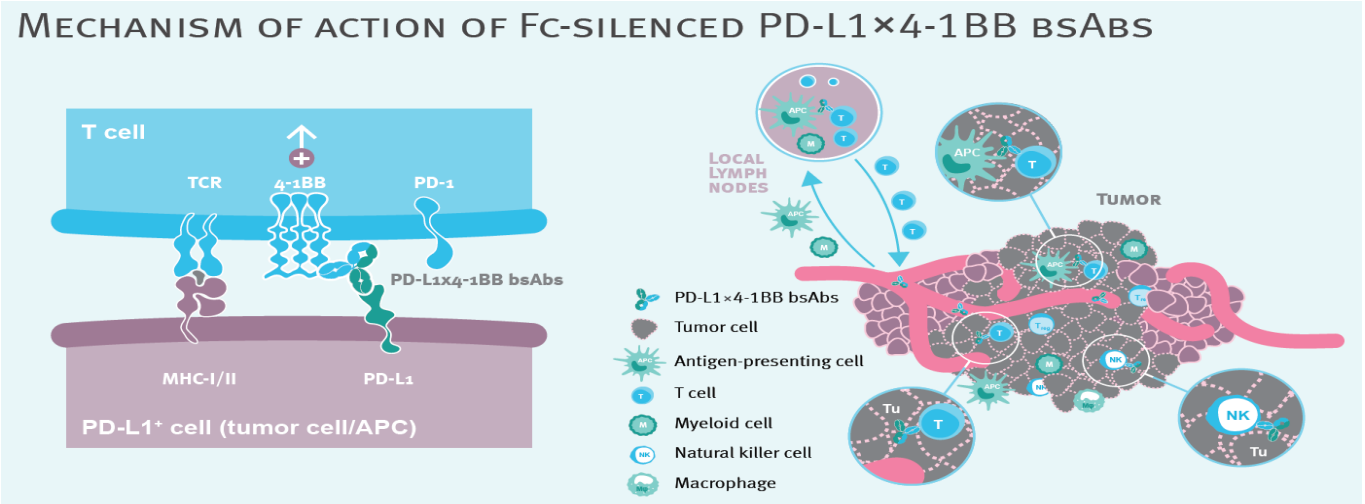
BIONTECH

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
  - Cell Therapies – CARVac and NEO-STIM T cell therapy
  - 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**

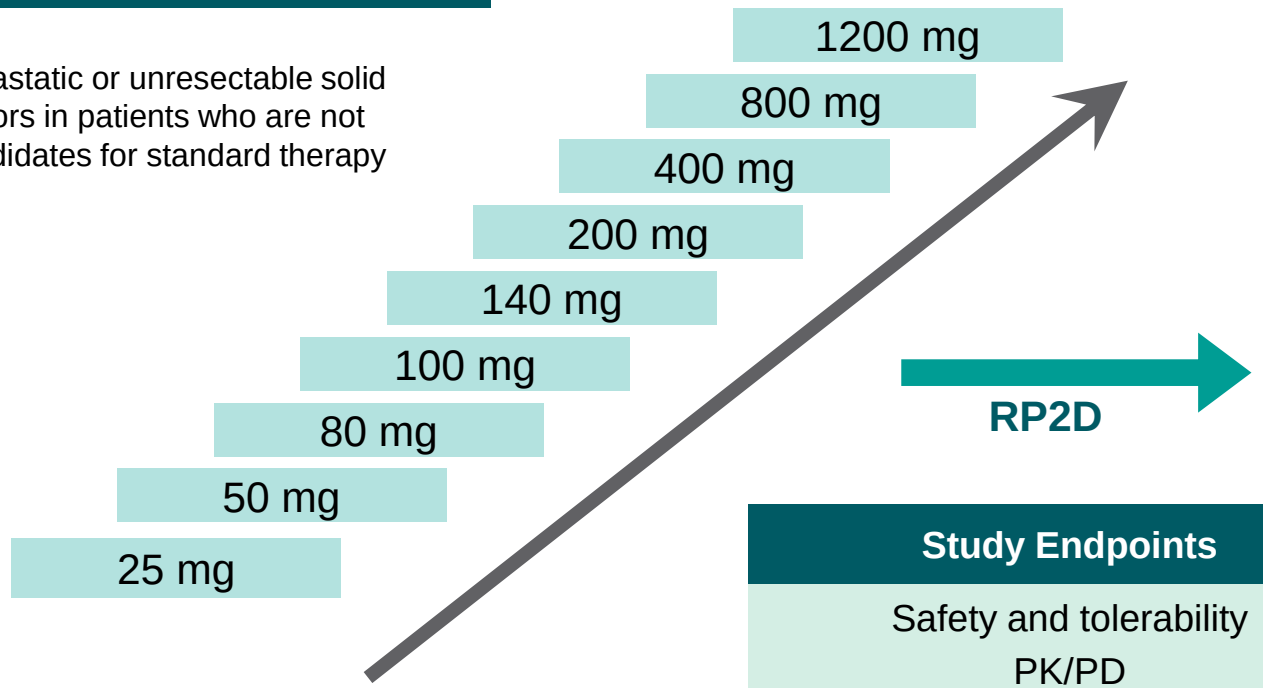
SITC 2020, Muik et al. and SITC 2020, Garralda et al.

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

Phase 1
Dose Escalation
N = 61

Metastatic or unresectable solid tumors in patients who are not candidates for standard therapy

Cycle
Q3W



BNT311/GEN1046: intravenous flat dose every 3 weeks until disease progression or unacceptable toxicity

Study Endpoints

Safety and tolerability
PK/PD
Anti-tumor activity
Biomarkers

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

BIONTECH

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

Safety

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

Dose escalation

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

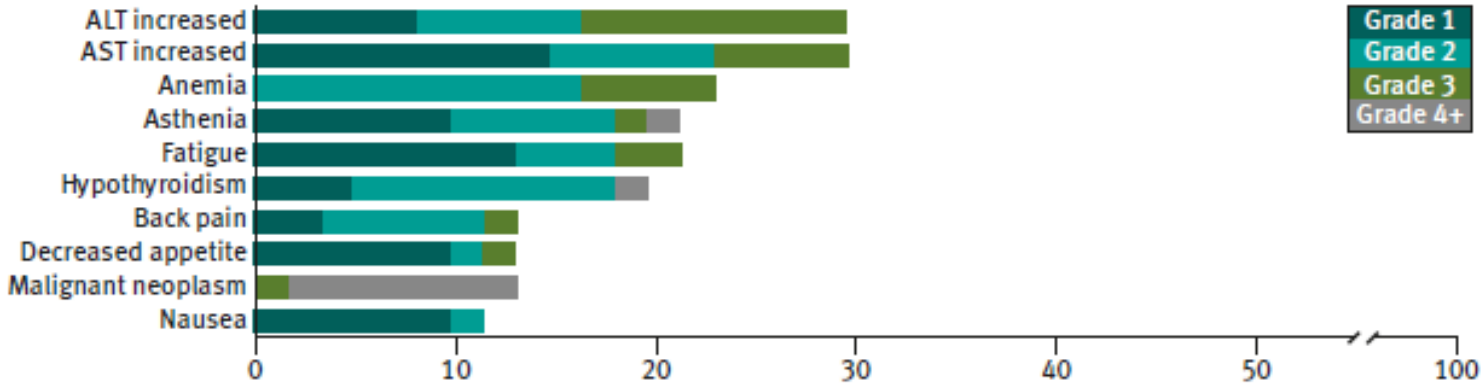
Dose expansion

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

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

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

TEAEs occurring in ≥10% of patients



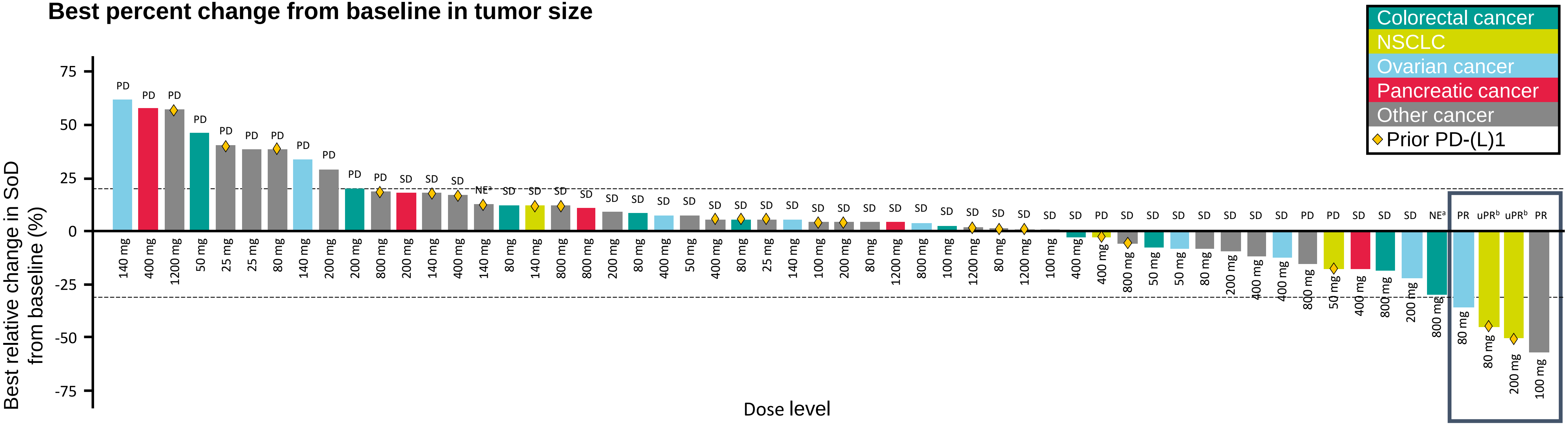
TRAEs occurring in ≥10% of patients

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

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

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

Best percent change from baseline in tumor size

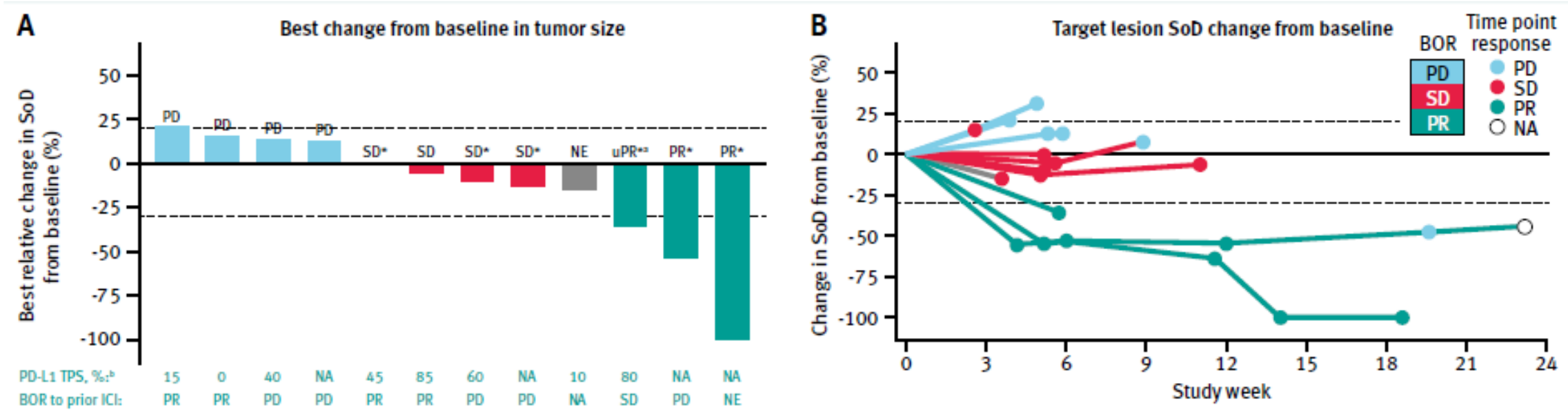


Disease control achieved in 65.6% of patients; four patients with PR
Includes 4 early partial responses in TNBC (1), ovarian cancer (1), and ICI-pre treated NSCLC (2) patients

Data cut-off: September 29, 2020. Post-baseline scans were not conducted for five patients.
[a]Minimum duration of response (5 weeks) per RECIST v1.1 not reached.
[b]PR 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.

BIONTECH

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.
*Denotes patients with ongoing treatment.
aPR was not confirmed by a subsequent scan.
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.

Agenda

Overview and business outlook

Deeper dive on our key programs

- COVID-19 vaccine program (project “Lightspeed”)
- mRNA vaccines – FixVac and iNeST
- Antibodies
- **Small Molecule Immunomodulators**
- Cell Therapies – CARVac and NEO-STIM T cell therapy
- RiboCytokines

BIONTECH

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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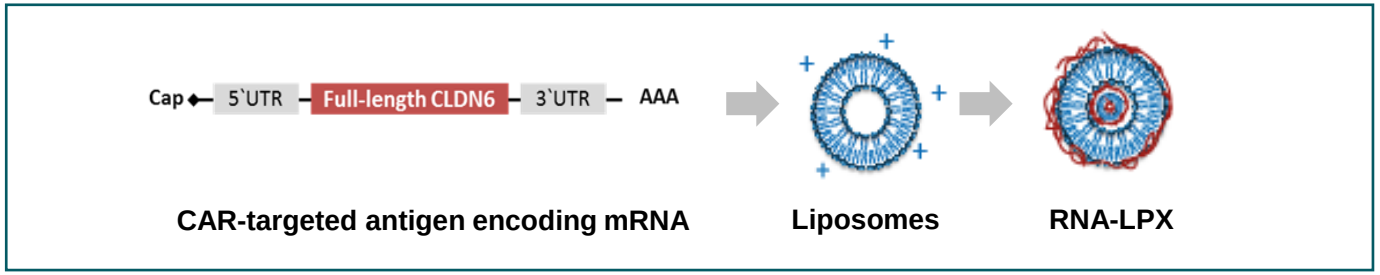
- **Cell Therapies – CARVac and NEO-STIM T cell therapy**
- RiboCytokines

BIONTECH

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

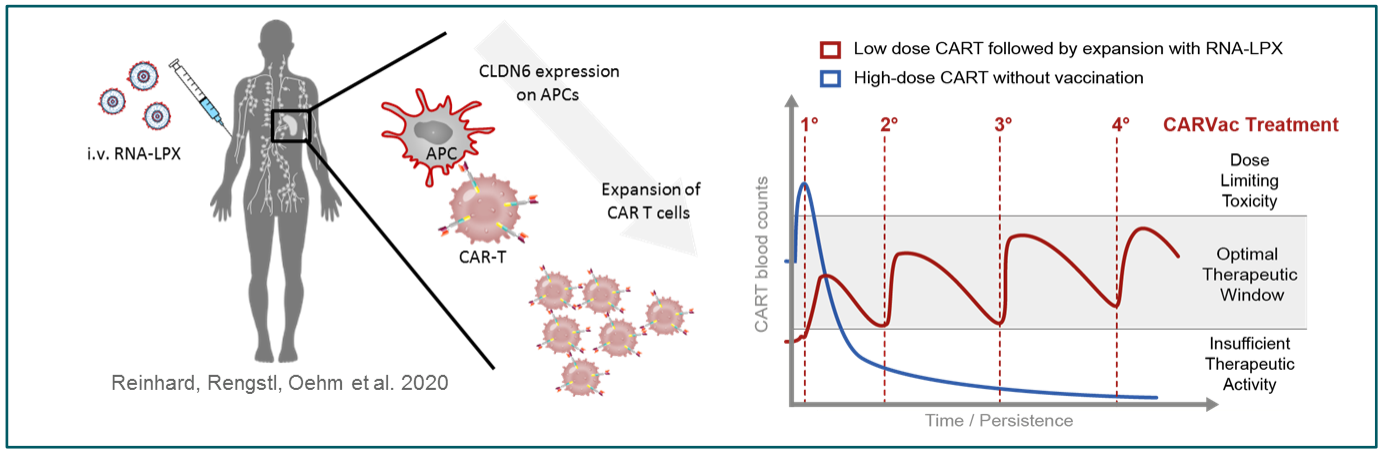
CAR-T cell Amplifying RNA Vaccine (CARVac) drives in vivo expansion and efficacy of CAR-T against solid tumors

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**

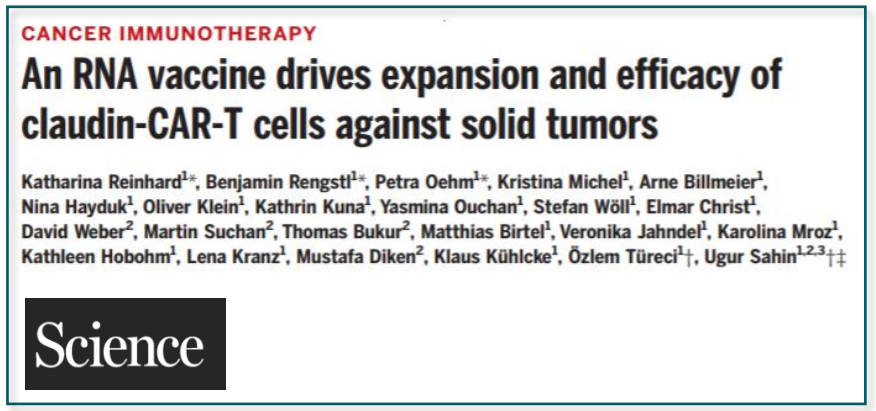
CARVac based CAR-T expansion



- 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**

CLDN6, Claudin-6; CAR-T cells, chimeric antigen receptor engineered T cells; RNA-LPX, RNA-lipoplex; APCs, antigen presenting cells
Reinhard K, et al. Science 2020; 367:446-453

BNT211: CLDN6-CAR demonstrates potent and robust target recognition

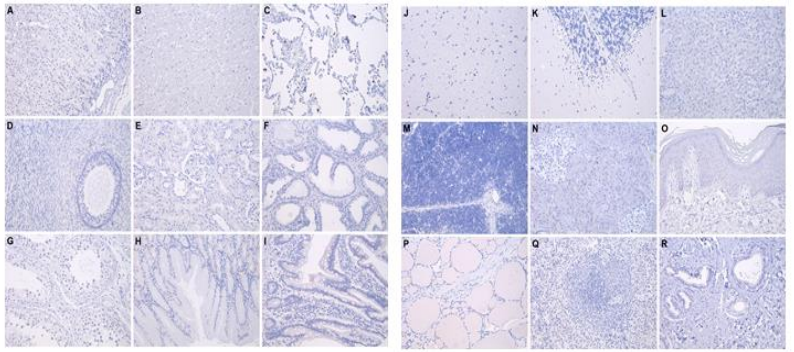

CANCER IMMUNOTHERAPY

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

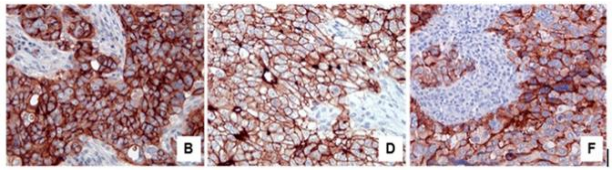
Katharina Reinhard[1]*, Benjamin Rengstl[1]*, Petra Oehm[1]*, Kristina Michel[1], Arne Billmeier[1], Nina Hayduk[1], Oliver Klein[1], Kathrin Kuna[1], Yasmina Ouchan[1], Stefan Wöll[1], Elmar Christ[1], David Weber[2], Martin Suchan[2], Thomas Bukur[2], Matthias Birtel[1], Veronika Jahndel[1], Karolina Mroz[1], Kathleen Hobohm[1], Lena Kranz[1], Mustafa Diken[2], Klaus Kühlcke[1], Özlem Türeci[1]†, Ugur Sahin[1,2,3]†‡

Science

CLDN6 not present in healthy tissues



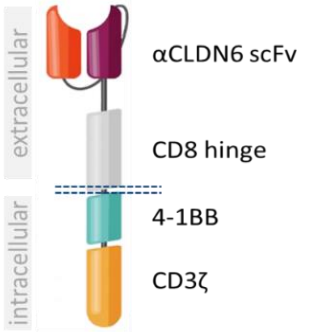
CLDN6 expressed in multiple cancers



Ovarian 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

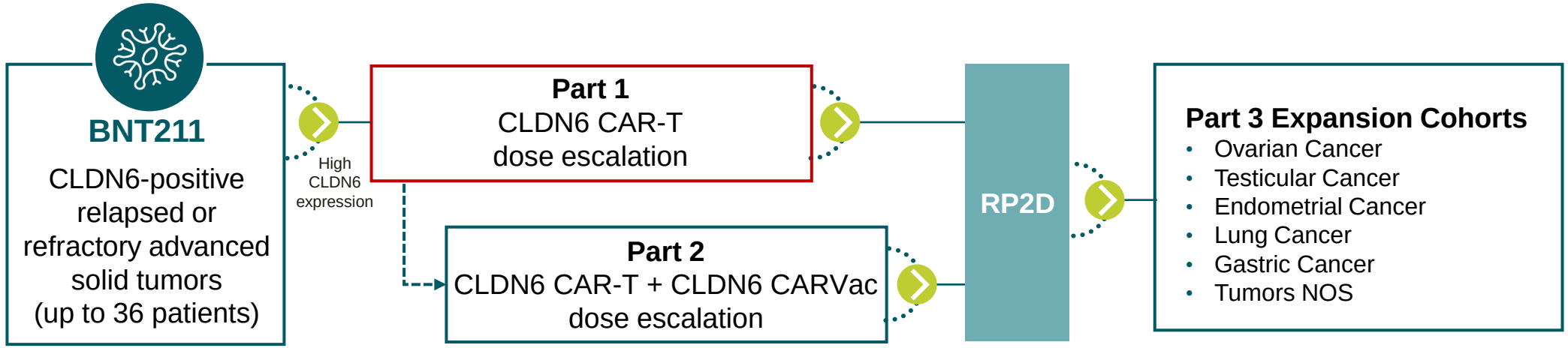


CLDN6, Claudin-6; CAR-T cells, chimeric antigen receptor engineered T cells; scFv, single chain variable fragment

Reinhard K, et al. Science 2020; 367:446-453

BIONTECH

BNT211: Next generation CAR-T therapy in solid tumors



An open-label Phase 1/2a study of BNT211 in patients with advanced solid tumors

- Evaluation of safety and tolerability
- Ongoing Phase 1/2a study
- Monotherapy dose level 1 completed (3 patients)

CLDN6, Claudin-6; CAR-T cells, chimeric antigen receptor engineered T cells; RP2D, recommended Phase 2 dose; NOS, not otherwise specified
NCT04503278, https://clinicaltrials.gov/ct2/show/NCT04503278

BNT211: CAR-T engraftment and stable disease in first 2 patients

Patient #	1	2	3
Age, gender	68 y, female	25 y, male	33 y, male
Tumor entity	Ovarian CA	Sarcoma	Testicular CA
CLDN6 II/III+	60%	80%	60%
Stage	FIGO IIIc	unknown	IIIc
Prior treatment lines	5	3	4
CAR-T infusion	FEB2021	MAR2021	MAR2021
DLTs	**0**	**0**	**0**
AEs ≥ grade 3*	**0**	**0**	**0**
CAR-T engraftment	**9x (days 3-17)**	**>700x (days 3-24)**	**90x (days 3-10)**

First dose level was well tolerated

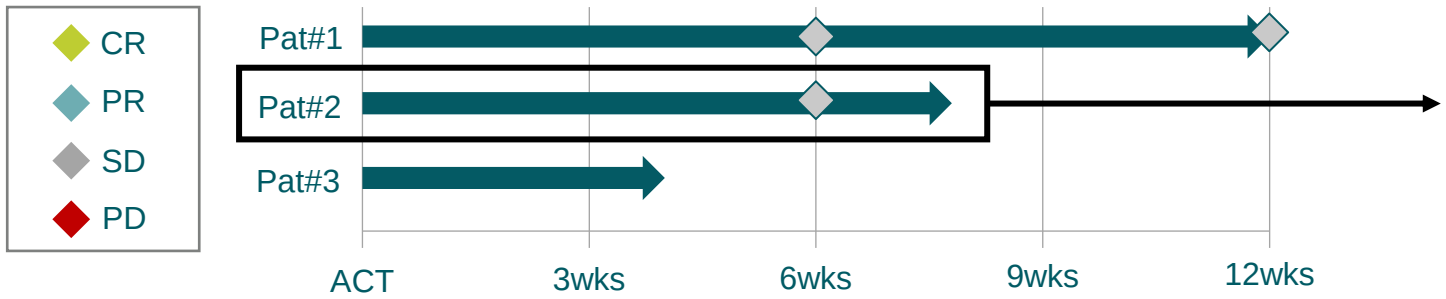
- AEs Mild to Moderate & Transient
  - No AEs ≥ grade 3 and no DLTs

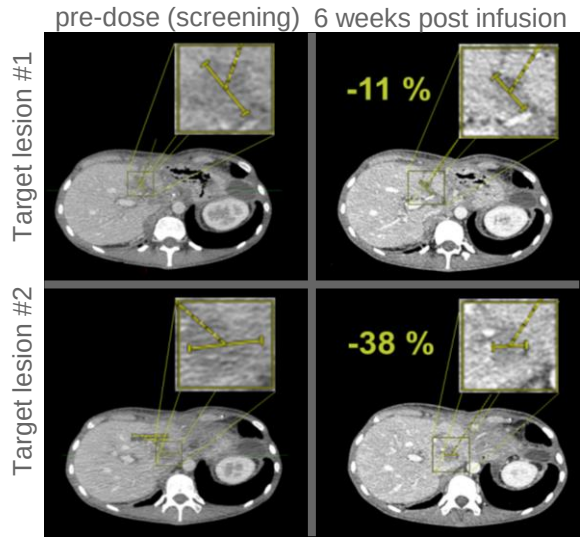
CAR-T detectable across different tumor types

- Robust engraftment in all patients,
  - Follow-up days 3-24 for patient #1 and #2, and days 3-10 for patient #3 post CAR-T cell transfer

Tumor Reduction in Patient #2:

- 19.7% shrinkage of tumor (RECIST 1.1)





DLT, dose limiting toxicity; Pat, patient; CR, complete response; PR, partial response; SD, stable disease; PD, progressive disease; LD, lymphodepletion; FIGO, International Federation of Gynecology and Obstetrics; CLDN6, Claudin-6; AE, adverse event; CAR-T, chimeric antigen receptor engineered T cells

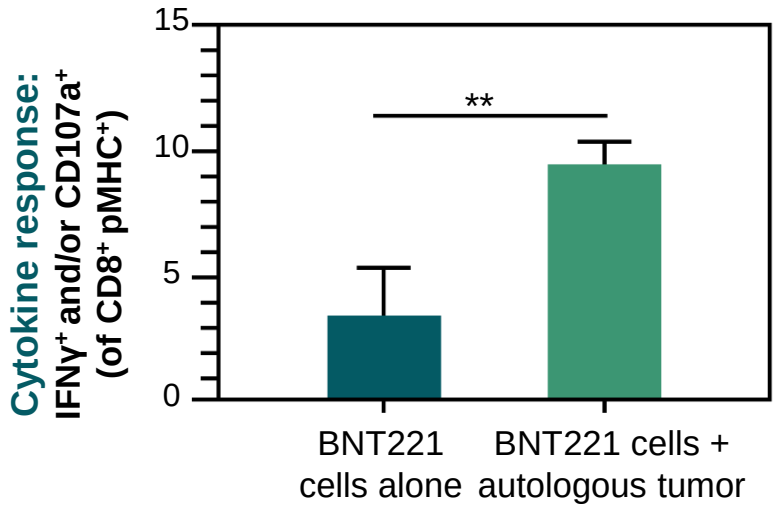
* Suspected to be related to drug product

BNT221: NEO-STIM® personalized neoantigen-targeted adoptive cell therapy

Addresses limitations of TIL cell therapy approaches

- T cells induced from peripheral blood (NEO-STIM)
  - No gene engineering or viral vectors
- Targets each patient´s personal tumor neoantigens
- Multiple specific CD8+ and CD4+ T cell populations that are functional and have a favorable phenotype
- First patient dosed in Phase 1 trial in anti-PD-1 experienced unresectable stage III or IV melanoma

BNT221 cells specifically recognize autologous tumor



TIL, tumor-infiltrating lymphocyte

Lenkala D, et al. J Immunother Cancer 2020; 8(Suppl 3) A153

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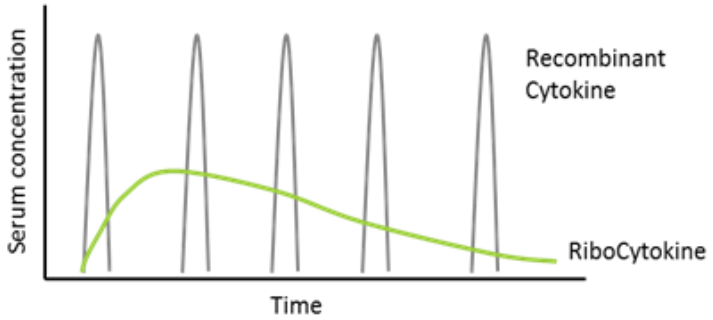
- RiboCytokines

BIONTECH

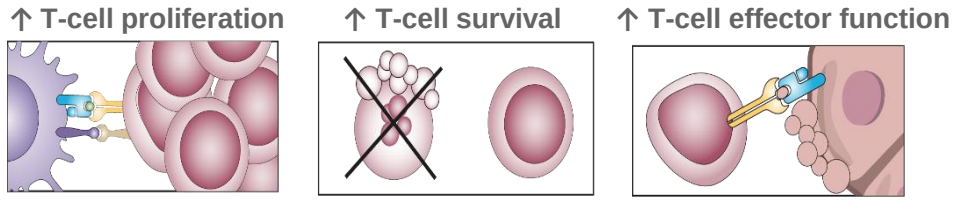
BNT151: Designed to overcome limitations of recombinant cytokine therapy

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

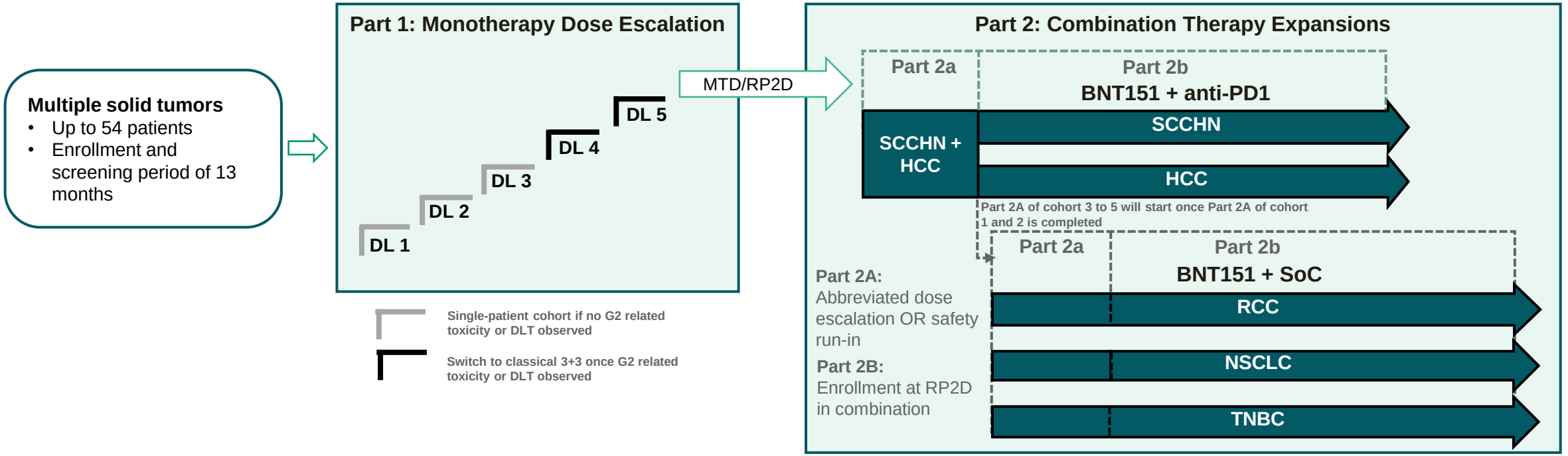


- **BNT151** is nucleoside-modified mRNA encoding human **IL-2 variant fused to human albumin**
- **IL-2 is a key cytokine** in T cell immunity, supporting differentiation, proliferation, survival and effector functions of T cells
- **BNT151 stimulates anti-tumoral T cells without extensively triggering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

IL-2, interleukin-2

Vormehr, M. et al. SITC Poster Sess. (2019); Vormehr, M. et al. CICON Poster Sess. (2019)

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

NSCLC, Non-small Cell Lung Cancer; DL, dose level; MTD, maximum tolerated dose; RP2D, recommended Phase 2 dose; G2, grade 2; DLT, dose limiting toxicity; SoC, Standard of Care; SCCHN, Squamous cell carcinoma of the head and neck; HCC, Hepatocellular carcinoma; RCC, Renal cell carcinoma; TNBC, Triple-negative breast cancer; CPI; checkpoint inhibitor

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