

Next Generation Immunotherapy

.....●.....
November 15, 2021



BIONTECH

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, but not limited to, statements concerning: BioNTech's expected revenues and net profit related to sales of BioNTech's COVID-19 vaccine, referred to as COMIRNATY® where approved for use under full or conditional marketing authorization, in territories controlled by BioNTech's collaboration partners, particularly for those figures that are derived from preliminary estimates provided by BioNTech's partners; BioNTech's pricing and coverage negotiations with governmental authorities, private health insurers and other third-party payors after BioNTech's initial sales to national governments; the extent to which initial or booster doses of a COVID-19 vaccine continue to be necessary in the future; competition from other COVID-19 vaccines or related to BioNTech's other product candidates, including those with different mechanisms of action and different manufacturing and distribution constraints, on the basis of, among other things, efficacy, cost, convenience of storage and distribution, breadth of approved use, side-effect profile and durability of immune response; the rate and degree of market acceptance of BioNTech's COVID-19 vaccine and, if approved, BioNTech's investigational medicines; the initiation, timing, progress, results, and cost of BioNTech's research and development programs and BioNTech's current and future preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and BioNTech's research and development programs; the timing of and BioNTech's ability to obtain and maintain regulatory approval for BioNTech's product candidates; the collaboration between BioNTech and Pfizer to develop a COVID-19 vaccine (including a potential booster dose of BNT162b2 and/or a potential booster dose of a variation of BNT162b2 having a modified mRNA sequence); the ability of BNT162b2 to prevent COVID-19 caused by emerging virus variants; BioNTech's ability to identify research opportunities and discover and develop investigational medicines; the ability and willingness of BioNTech's third-party collaborators to continue research and development activities relating to BioNTech's development candidates and investigational medicines; the impact of the COVID-19 pandemic on BioNTech's development programs, supply chain, collaborators and financial performance; unforeseen safety issues and claims for personal injury or death arising from the use of BioNTech's COVID-19 vaccine and other products and product candidates developed or manufactured by us; BioNTech's ability to progress BioNTech's Malaria, Tuberculosis and HIV programs, including timing for selecting clinical candidates for these programs and the commencement of a clinical trial, as well as any data readouts; the nature of the collaboration with the African Union and the Africa CDC; the nature and duration of support from WHO, the European Commission and other organizations with establishing infrastructure; the development of sustainable vaccine production and supply solutions on the African continent and the nature and feasibility of these solutions; BioNTech's estimates of research and development revenues, commercial revenues, cost of sales, research and development expenses, sales and marketing expenses, general and administrative expenses, capital expenditures, income taxes, shares outstanding; BioNTech's ability and that of BioNTech's collaborators to commercialize and market BioNTech's product candidates, if approved, including BioNTech's COVID-19 vaccine; BioNTech's ability to manage BioNTech's development and expansion; regulatory developments in the United States and foreign countries; BioNTech's ability to effectively scale BioNTech's production capabilities and manufacture BioNTech's products, including BioNTech's target COVID-19 vaccine production levels, and oBioNTech'sur product candidates; and other factors not known to BioNTech at this time. 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 BioNTech's quarterly report for the three and nine months ended September 30, 2021 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 COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 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 (eg, 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/clinical-considerations/managing-anaphylaxis.html>)
- Reports of adverse events following use of the Pfizer-BioNTech COVID-19 Vaccine under EUA suggest increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The decision to administer the Pfizer-BioNTech COVID-19 Vaccine to an individual with a history of myocarditis or pericarditis should take into account the individual's clinical circumstances
- Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting
- 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%), following administration of the primary series
- In a clinical study, adverse reactions in adolescents 12 through 15 years of age included pain at the injection site (90.5%), fatigue (77.5%), headache (75.5%), chills (49.2%), muscle pain (42.2%), fever (24.3%), joint pain (20.2%), injection site swelling (9.2%), injection site redness (8.6%), lymphadenopathy (0.8%), and nausea (0.4%), following administration of primary series
- In a clinical study, adverse reactions in adults 18 through 55 years of age following administration of a booster dose were pain at the injection site (83.0%), fatigue (63.7%), headache (48.4%), muscle pain (39.1%), chills (29.1%), joint pain (25.3%), lymphadenopathy (5.2%), nausea (0.7%), decreased appetite (0.3%), rash (0.3%), and pain in extremity (0.3%)
- Following administration of the Pfizer-BioNTech COVID-19 Vaccine, the following have been reported outside of clinical trials:
 - severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions, diarrhea, vomiting, and pain in extremity (arm) and syncope
 - myocarditis and pericarditis
- 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 is no information on the co-administration of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.
- An overall review of adverse reactions reported in the study following the Pfizer-BioNTech COVID-19 Vaccine heterologous booster dose did not identify any new safety concerns, as compared with adverse reactions reported following a Pfizer-BioNTech COVID-19 Vaccine primary series doses or homologous booster dose
- Vaccination providers must report Adverse Events in accordance with the Fact Sheet to VAERS online at <https://vaers.hhs.gov/reportevent.html>. For further assistance with reporting to VAERS call 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
- Before administration of Pfizer-BioNTech COVID-19 Vaccine, 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

Safety Information

COMIRNATY® ▼ (COVID-19 mRNA Vaccine) has been granted conditional marketing authorisation by the European Medicines Agency to prevent coronavirus disease 2019 (COVID-19) in people from 12 years of age. EMA's human medicines committee (CHMP) has completed its rigorous evaluation of COMIRNATY®, concluding by consensus that sufficiently robust data on the quality, safety and efficacy of the vaccine are now available.

Important safety information

Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with a known hypersensitivity to the active substance or to any of the excipients listed

Events of anaphylaxis have been reported. Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of the vaccine

Very rare cases of myocarditis and pericarditis have been observed following vaccination with Comirnaty. These cases have primarily occurred within 14 days following vaccination, more often after the second vaccination, and more often in younger men. Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis

Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions (e.g. dizziness, palpitations, increases in heart rate, alterations in blood pressure, tingling sensations and sweating) may occur in association with the vaccination process itself. It is important that precautions are in place to avoid injury from fainting

Vaccination should be postponed in individuals suffering from acute severe febrile illness or acute infection. The presence of a minor infection and/or low-grade fever should not delay vaccination

As with other intramuscular injections, the vaccine should be given with caution in individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following an intramuscular administration in these individuals

The efficacy, safety and immunogenicity of the vaccine has not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy. The efficacy of COMIRNATY® may be lower in immunosuppressed individuals.

The duration of protection afforded by the vaccine is unknown as it is still being determined by ongoing clinical trials

As with any vaccine, vaccination with COMIRNATY® may not protect all vaccine recipients. Individuals may not be fully protected until 7 days after their second dose of vaccine.

Comirnaty has no or negligible influence on the ability to drive and use machines. However, some of the side effects mentioned below, may temporarily affect the ability to drive or use machines.

In clinical studies, the most frequent adverse reactions in participants 16 years of age and older that received 2 doses were injection site pain (> 80%), fatigue (> 60%), headache (> 50%), myalgia (> 40%), chills (> 30%), arthralgia (> 20%), pyrexia and injection site swelling (> 10%) and were usually mild or moderate in intensity and resolved within a few days after vaccination. A slightly lower frequency of reactogenicity events was associated with greater age

In clinical trials, the most frequent adverse reactions in participants 18 to 55 years of age who received a booster were injection site pain (> 80%), fatigue (> 60%), headache (> 40%), myalgia (> 30%), chills and arthralgia (> 20%).

The overall safety profile of COMIRNATY® in adolescents 12 to 15 years of age was similar to that seen in participants 16 years of age and older. The most frequent adverse reactions in adolescents 12 to 15 years of age that received 2 doses were injection site pain (> 90%), fatigue and headache (> 70%), myalgia and chills (> 40%), arthralgia and pyrexia (> 20%)

There is limited experience with use of COMIRNATY® in pregnant women. Administration of COMIRNATY® in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and foetus.

It is unknown whether COMIRNATY® is excreted in human milk.

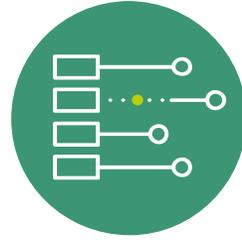
Interactions with other medicinal products or concomitant administration of COMIRNATY® with other vaccines has not been studied.

Very rare cases of myocarditis and pericarditis have been observed following vaccination with COMIRNATY® primarily in younger males, after the second dose, within 14 days following vaccination

The black equilateral triangle denotes that additional monitoring is required to capture any adverse reactions. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. Side effects can be reported to EudraVigilance [<http://www.adrreports.eu/>] or directly to BioNTech using email medinfo@biontech.de, telephone +49 6131 9084 0, or our website <https://medicalinformation.biontech.de/>

Next generation Immunotherapy

Harnessing the full
potential of the
immune system



**Building a fully integrated
biopharmaceutical company**



**Immunotherapies for cancer &
infectious diseases and beyond**

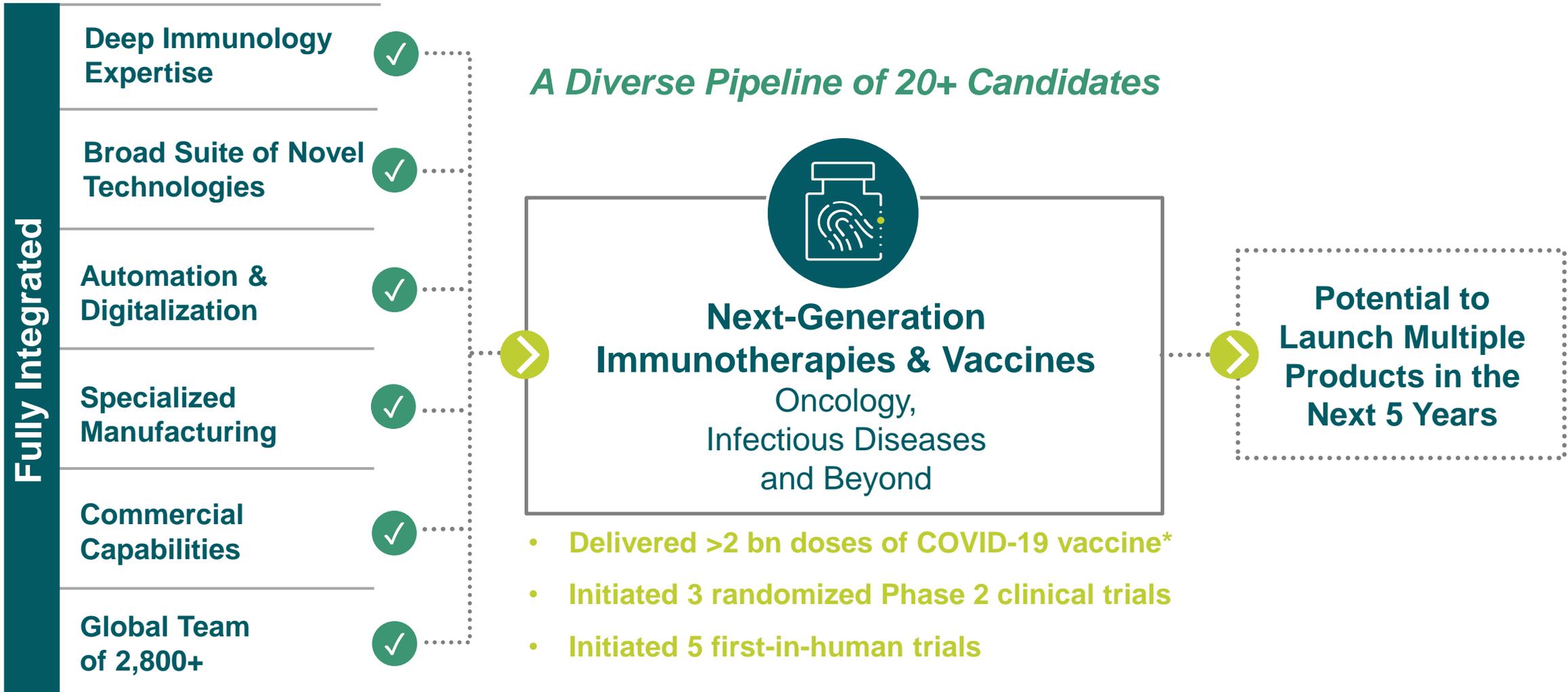


**Broad suite of novel
technologies**



**Industry-leading global
collaborations**

BioNTech: A Global Immunotherapy Powerhouse



Harnessing the Power of the Immune System to Address Serious Diseases



Infectious Disease

1 MARKETED
VACCINE

1 PHASE 1
PROGRAM

9 PRECLINICAL
PROGRAMS

- Validated mRNA technology
- Flexible & adaptable platform
- Speed in clinical development
- Global manufacturing network
- Large safety database with proven path to regulatory approval

Focus on significant global health needs, including COVID-19¹, malaria², HIV³, TB³, influenza¹



Oncology

15 PROGRAMS IN
19 CLINICAL TRIALS

4 RANDOMIZED
PHASE 2 PROGRAMS

- Sophisticated toolbox of technologies across 4 drug classes
- Diverse and complementary modes of action
- Novel therapeutic targets
- Potential for synergistic combinations
- Single agent objective responses in multiple Phase 1 trials

Focus on broad range of solid tumors with the potential to improve treatment paradigms



Broaden Disease Horizon:

Autoimmune and inflammatory diseases, regenerative medicine

Expanding our Capabilities and Pipeline in Infectious Diseases

Addressing Infectious Diseases with Significant Global Impact



COVID-19

- mRNA COVID-19 vaccine
- More than 2 billion doses shipped world-wide



Influenza

- Seasonal Flu vaccine: Phase 1 trial initiated Q3
- Licensed to Pfizer
- Eligible for milestone payments and royalties through Pfizer agreement



Malaria

- mRNA-based Malaria vaccine candidate
- Expected Phase 1 start: 2H 2022
- Sustainable end-to-end vaccine supply solutions in Africa planned



Tuberculosis

- Tuberculosis vaccine candidate
- Expected Phase 1 start: 2H 2022
- Collaboration with Bill & Melinda Gates Foundation



HIV

- Multiple product candidates in Preclinical development
- Vaccines and Ribologicals
- Collaboration with Bill & Melinda Gates Foundation



5 Additional Non-disclosed Programs

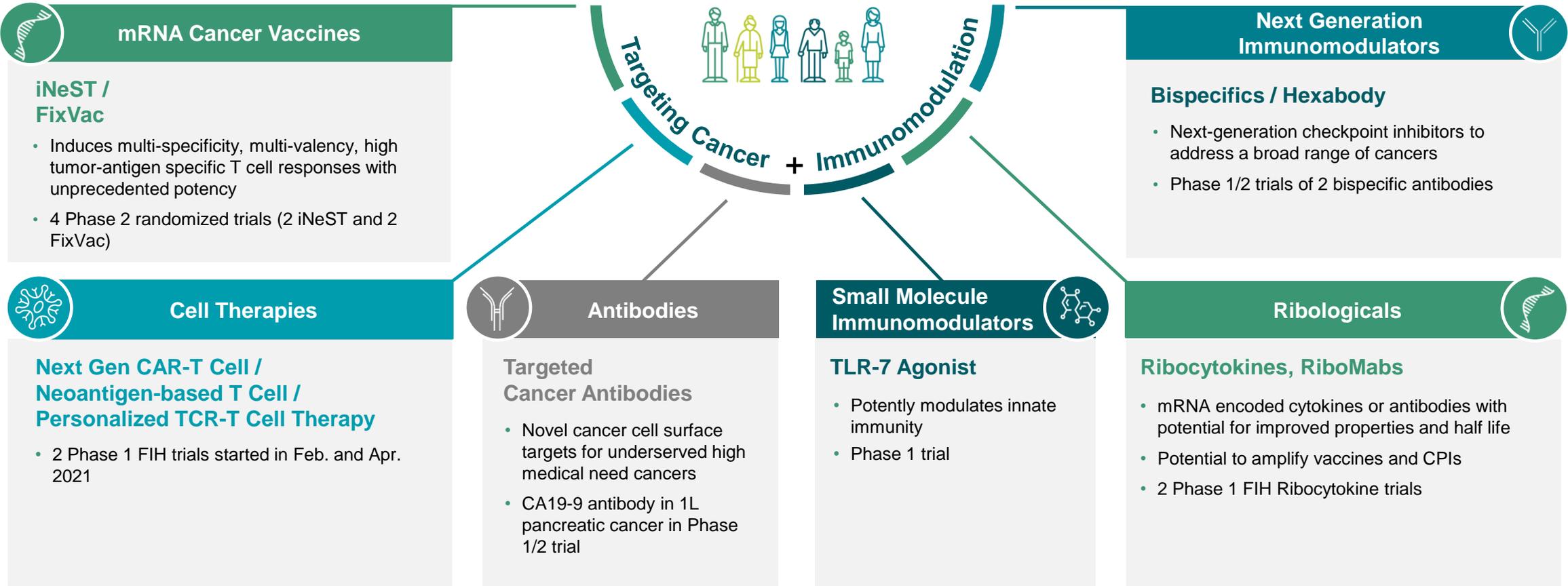
- Multiple product candidates in preclinical development
- Vaccines and Ribologicals



Bacterial Infections

- New class of precision antibacterials in the form of synthetic lysins
- Potential to address wide range of pathogens

Oncology: Potential To Tackle Multiple Diseases With Different Therapeutic Modalities



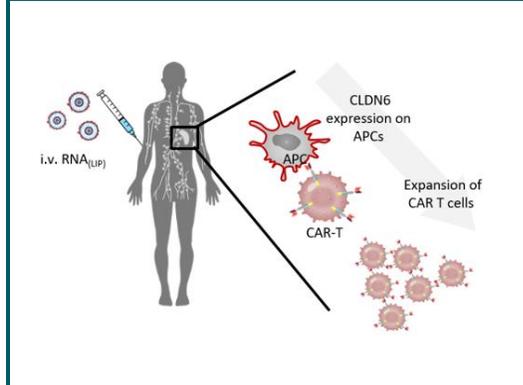
Oncology: Multiple product opportunities with unique combination potential in clinical testing

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	<ul style="list-style-type: none"> • <i>mRNA Neoantigen Immunotherapy (iNeST)</i>
Low mutational burden cancers	>60% of cancers	Poor response to checkpoint inhibitors	<ul style="list-style-type: none"> • <i>Shared Antigens (FixVac, CAR-T cells, Neoantigen-targeted T cells, Antibodies)</i>
“Immune desert” cancers	>40% of high-mutational cancers	Poor infiltration and activation of T-cells in TME ¹	<ul style="list-style-type: none"> • <i>RNA Immunotherapy</i> • <i>Immunostimulatory Compounds (intratumoral, RiboCytokines)</i>
Cancers with MHC / B2M loss	20-30% of CPI-experienced advanced cancers	Failure of immune system to recognize tumor cells	<ul style="list-style-type: none"> • <i>Antibodies</i> • <i>CAR-Ts</i>
Refractory tumors	Patients with large tumors and multiple resistance mechanisms	Few treatment options	<ul style="list-style-type: none"> • <i>Cell Therapies</i> • <i>Combination Therapies</i>

Next Wave Oncology Advancing Innovation Beyond Current Boundaries

CARVac CAR-T cell amplifying mRNA therapy for solid tumors¹

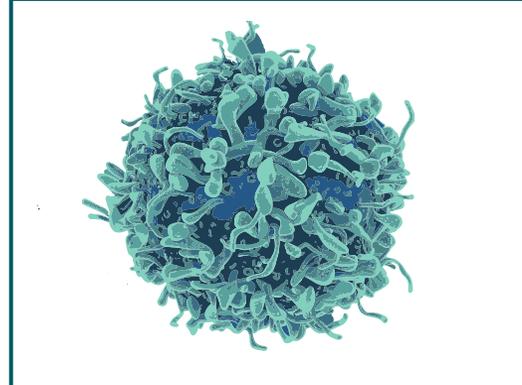


- **BNT211 (CLDN 6 CAR)**
Next generation CAR-T targeting CLDN6 with CARVac

Wholly owned:

FIH start: **FPD Feb. 2021**

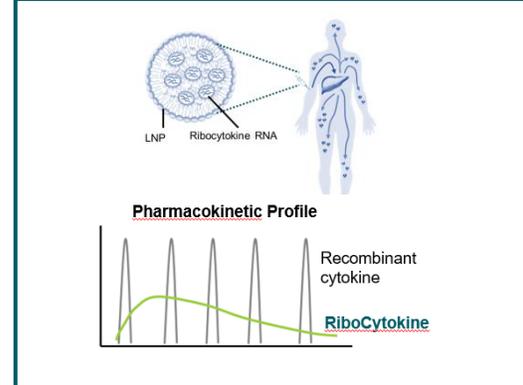
NEOSTIM T cell therapy Individualized Neoantigen specific T cell therapy



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

FPD Apr. 2021

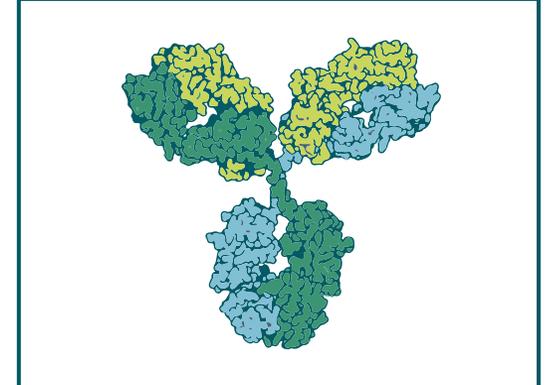
RiboCytokines mRNA encoded Cytokines



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

BNT151: FPD Feb. 2021
BNT152+BNT153: FPD June 2021

RiboMabs² mRNA encoded Antibodies



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

BNT141: 4Q 2021
BNT142: 1H 2022

11 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

Strong Clinical Execution: On Track To Achieve 2021 Corporate Milestones

Eight clinical trial initiations in 2021, including three Phase 2 and five first-in-human studies

5+ Trial Updates



- ✓ **BNT162b2: Multiple updates**
- ✓ **Corporate Milestones - SITC*:**
 - BNT311
 - BNT312
 - BNT211
 - BNT411
- ✓ **Additional data disclosures at SITC*:**
 - BNT111
 - BNT112
 - BNT221 (pre-clinical)

4 Randomized Phase 2 Trial Starts



- ✓ **BNT111**
- ✓ **BNT113**
- ✓ **BNT122**
- **BNT311 – Q4 2021** **NEW**

6 First-in-human Phase 1 Trial Starts



- ✓ **BNT211 – CARVac (Cell Therapy)**
- ✓ **BNT221 – NEOSTIM (Cell Therapy)**
- ✓ **BNT151 – Ribocytokine (mRNA)**
- ✓ **BNT152+153 – Ribocytokine (mRNA)**
- ✓ **BNT161: Influenza vaccine (license Pfizer)**
 - **BNT141 – Ribomab (mRNA) – Q4 2021**
 - **BNT142 – Ribomab (mRNA) – 1H 2022**

Poised to Accelerate Our Transformation



Rapidly advance pipeline

- 15 Oncology product candidates in 19 ongoing clinical trials
- 3 Phase 2 trials started in 2021
- 5 First-in-human trial starts in 2021
- 6 program updates at SITC
- Expansion into new class of Precision Antibacterials



Expand integrated infrastructure

- Expansion of team to more than 2,800 professionals globally
- Significant investments in digital
- Further scale-up of Marburg mRNA manufacturing site
- Planning further mRNA manufacturing sites in Africa and Singapore



Increase global footprint

- Continued expansion in U.S. with acquisition of cGMP Kite Cell Therapy manufacturing facility
- Planning to establish Southeast Asia headquarters in Singapore
- BioNTech R&D Austria established through PhagoMed acquisition

Building long-term value for patients, investors and and society as we advance our vision of harnessing the immune system's full potential to fight human disease

We Collaborate with Global Leaders in Our Industry

Collaborations for clinical stage programs

COVID-19 Vaccine
50:50 gross profit share¹



FixVac Melanoma
Companies keep full rights to own product



iNeST
50:50 cost & profit share



Bispecific mABs
50:50 cost & profit share



Intra-tumoral mRNA
cost & profit share



Seasonal Influenza
royalties & milestones



Pre-clinical collaborations

Up to 10 Infectious Disease Indications
worldwide opt-in right

University of Pennsylvania

HIV, Tuberculosis
developed world rights



5 Rare Disease Indications
50:50 cost & profit share



Agenda

Overview and business outlook



Pipeline

Deeper dive on our key programs

COVID-19 vaccine program (project “Lightspeed”)

mRNA vaccines – FixVac and iNeST

Antibodies

Cell Therapies – CARVac and NEO-STIM T cell therapy

Small Molecule Immunomodulators

RiboCytokines

Oncology Pipeline: 15 Product Candidates in 19 Ongoing Clinical Trials

Drug class	Platform	Product Candidate	Indication (Targets)	Preclinical	Phase 1	Phase 2	Phase 3	Rights Collaborator
mRNA	FixVac (fixed combination of shared cancer antigens)	BNT111	advanced melanoma	▶				fully-owned
		BNT112	prostate cancer	▶				fully-owned
		BNT113	HPV16+ head and neck cancer ¹	▶				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)
			adjuvant colorectal cancer	▶				
			solid tumors	▶				
	Intratumoral Immunotherapy	SAR441000 (BNT131)	solid tumors (<i>IL-12sc</i> , <i>IL-15sushi</i> , <i>GM-CSF</i> , <i>IFNα</i>)	▶				Sanofi (global profit/loss share)
	RiboCytokines (mRNA-encoded Cytokines)	BNT151	solid tumors (optimized IL-2)	▶				fully-owned
		BNT152 + BNT153	solid tumors (<i>IL-7</i> , <i>IL-2</i>)	▶				fully-owned
Antibodies	Next-Gen CP ² Immunomodulators	GEN1046 (BNT311)	solid tumors (<i>PD-L1</i> × <i>4-1BB</i>)	▶				Genmab (global 50:50 profit/loss)
		GEN1042 (BNT312)	solid tumors (<i>CD40</i> × <i>4-1BB</i>)	▶				
	Targeted Cancer Antibodies	BNT321 (MVT-5873)	pancreatic cancer (sLea)	▶				fully-owned
SMIM ³	Toll-Like Receptor Binding	BNT411	solid tumors (<i>TLR7</i>)	▶				fully-owned
Cell Therapies	CAR-T Cells	BNT211	solid tumors (<i>CLDN6</i>)	▶				fully-owned
	Neoantigen-based T cell therapy	BNT221 (NEO-PTC-01)	solid tumors	▶				fully-owned

Early-stage Oncology Pipeline: 2 Additional FIH¹ 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 Q4 2021
		BNT142	solid tumors (<i>CD3+CLDN6</i>)	fully-owned	Phase 1 start in 1H 2022
Cell Therapies	CAR-T Cells	BNT212	pancreatic, other cancers (<i>CLDN18.2</i>)	fully-owned	
	TCRs	to be selected	all tumors	fully-owned	

¹first-in-human

Broad Infectious Disease Pipeline

Drug Class	Product Candidate	Indication (Targets)	Pre-clinical	Phase 1	Phase 2	Phase 3	Commercial	Rights / Collaborator
mRNA Vaccine	BNT162b2	COVID-19						Pfizer/Fosun
	BNT161	Seasonal Influenza						Pfizer
	Un-named program	Malaria						Fully-owned
	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

Agenda

Overview and business outlook

Pipeline

Deeper dive on our key programs

COVID-19 vaccine program (project “Lightspeed”)

mRNA vaccines – FixVac and iNeST

Antibodies

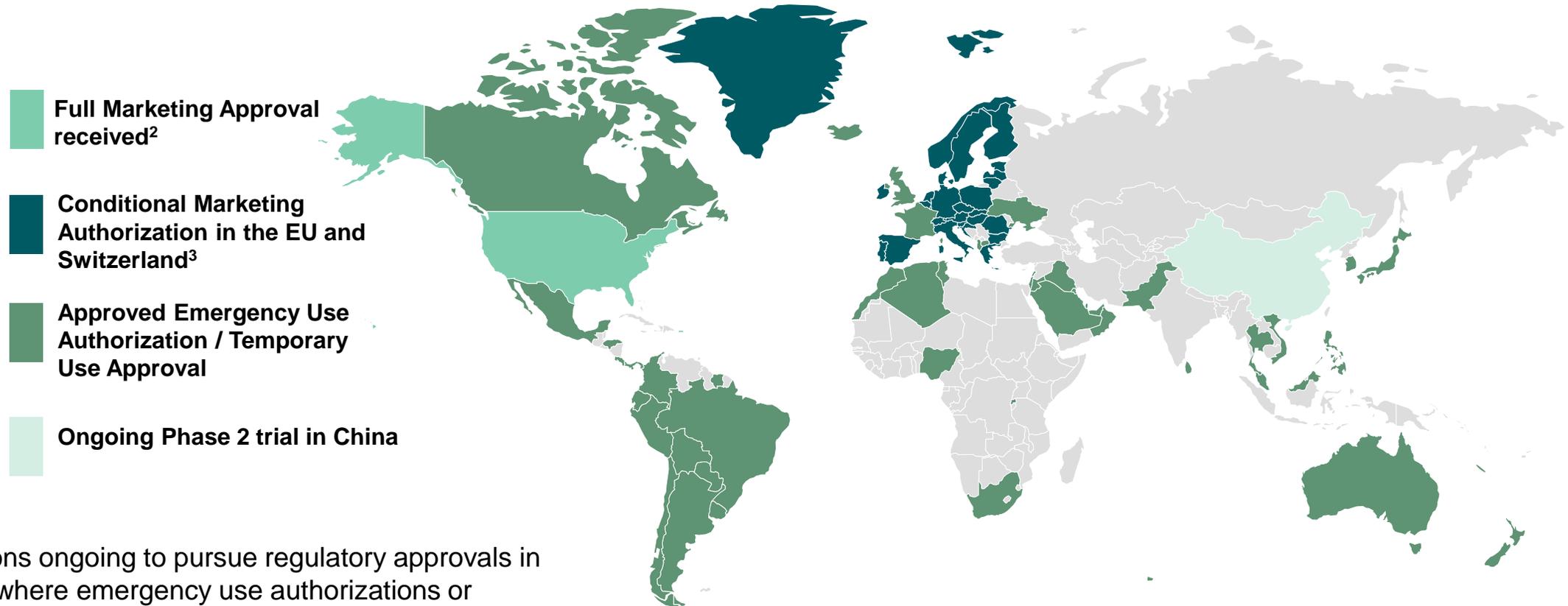
Cell Therapies – CARVac and NEO-STIM T cell therapy

Small Molecule Immunomodulators

RiboCytokines

Delivered >2 Billion Doses to >152 Countries & Territories Worldwide¹

A concerted and large-scale global effort



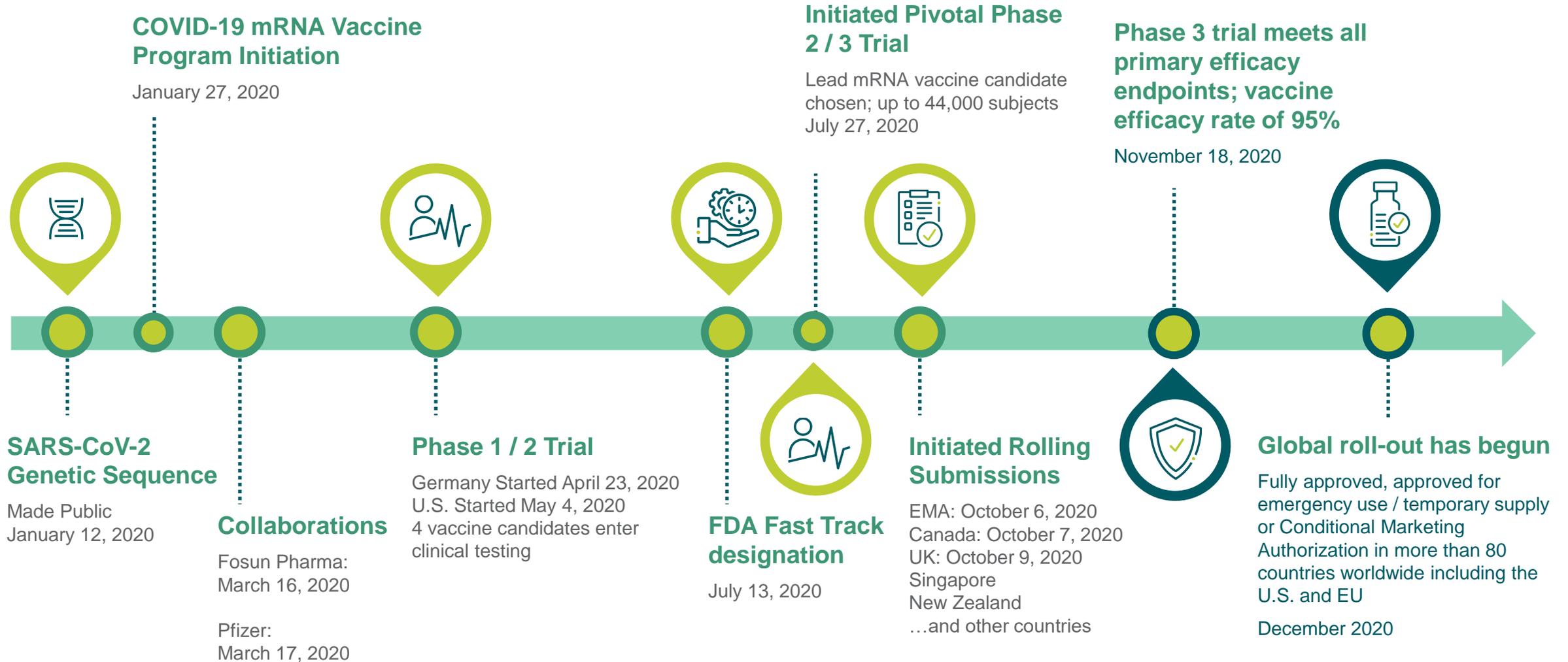
Submissions ongoing to pursue regulatory approvals in countries where emergency use authorizations or equivalents were initially granted are ongoing or planned.

¹As of September 22, 2021

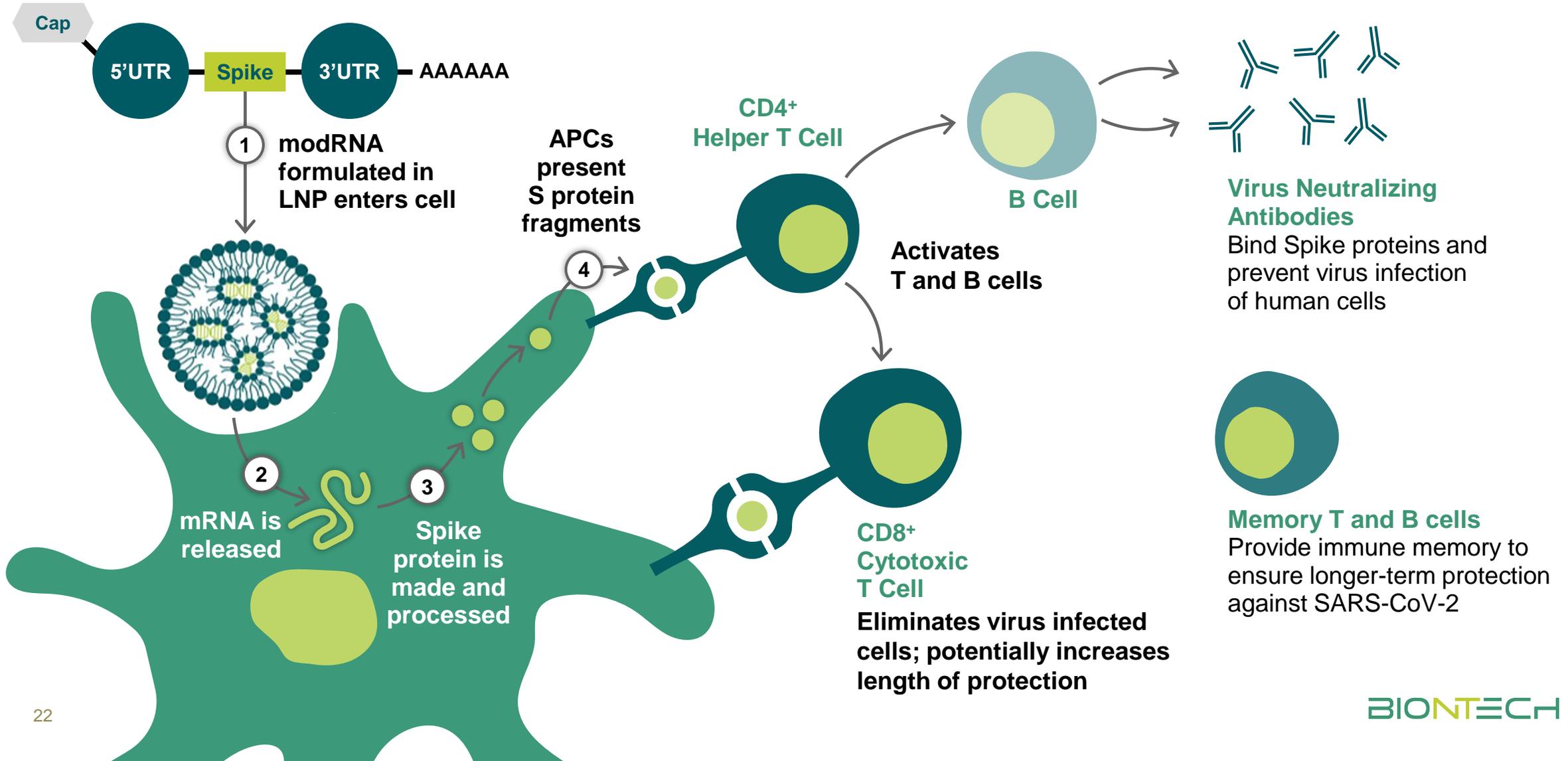
²Approved as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older; 2-dose series under Emergency Use Authorization for individuals 12-15 years old

³The vaccine is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 12 years of age and older.

Project Lightspeed – a 10-month Journey to an Effective and Safe Vaccine



How mRNA Vaccines Work – Training the Immune System for a Real Infection



mRNA is a Natural Solution for Vaccines Especially in a Pandemic

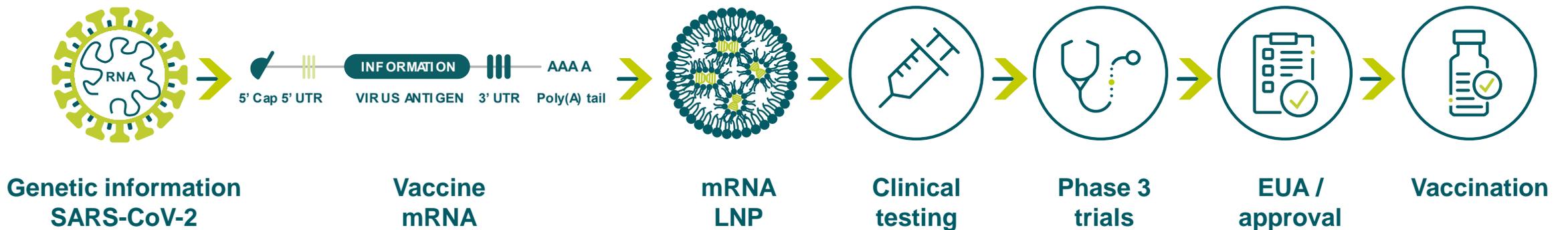
Natural molecule with well-characterized **bio-safety properties**

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

Highly scalable production

High purity and animal free

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



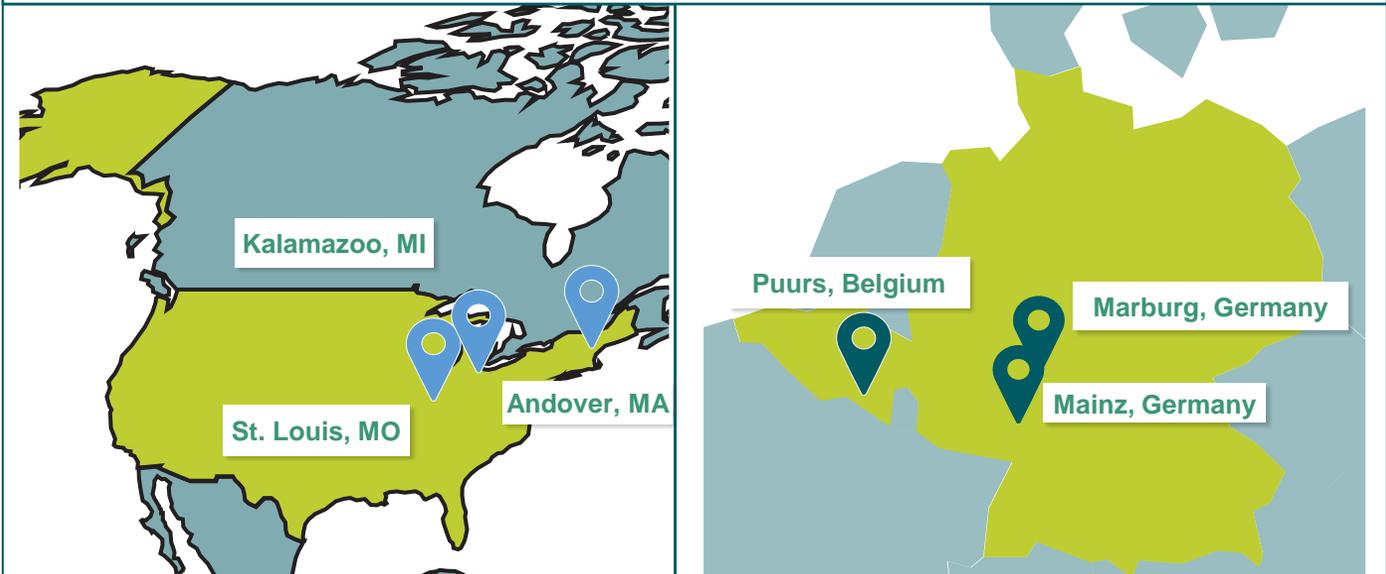
Global COVID-19 vaccine supply chain and manufacturing network

Delivered **>2 billion doses** to **153 countries and territories** worldwide¹

Global COVID-19 vaccine supply chain and manufacturing network with more than 20 facilities across four continents

- Regional headquarters and mRNA manufacturing facility planned for in Singapore
- Expanding manufacturing network to Africa and South America
- Plan to initiate construction of state-of-the-art mRNA vaccine manufacturing site in Africa in mid-2022 with capacity of several 100m vaccine doses

Targeting up to **3.0 bn doses** capacity in 2021
and up to **4.0 bn** in 2022²



Marburg facility:

Targeting **1 bn dose** annual run-rate capacity once fully operational

A Leading Provider of COVID-19 Vaccines Globally

Ensuring Equitable Vaccine Access to Children and Low & Lower Middle-Income Countries

Expect to deliver up to 2.5 billion doses in 2021*

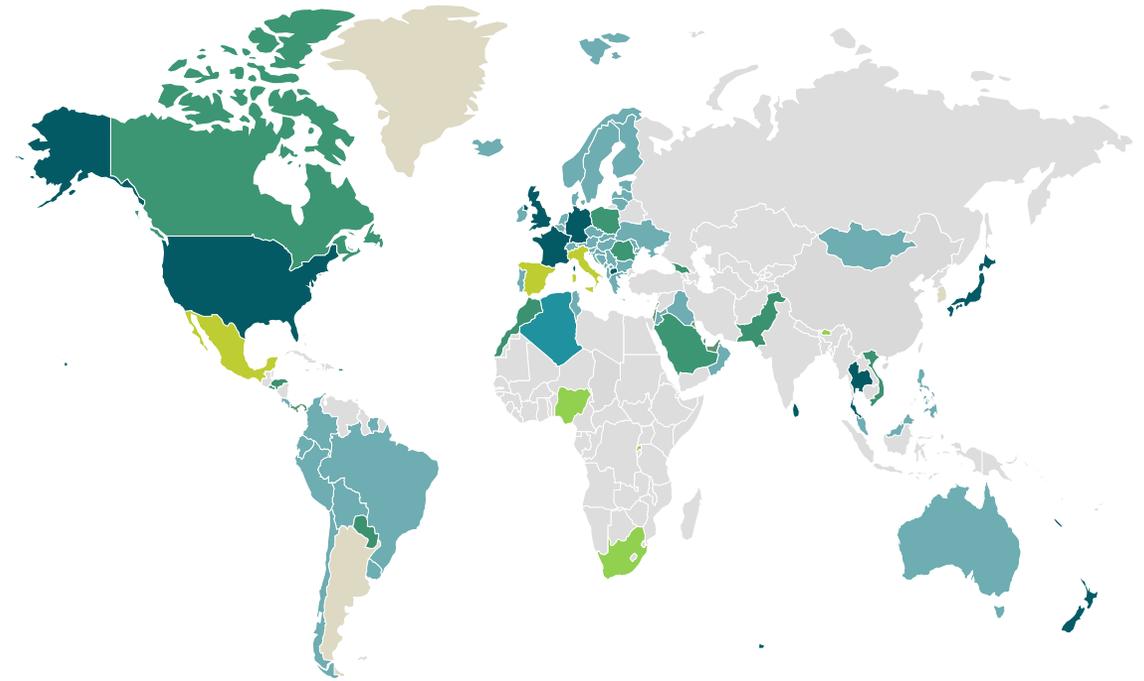
- Discussions with regard to additional contracts for 2022 and beyond remain ongoing

U.S. exercised final purchase option under existing contract with purchase of 50 m pediatric doses

- Includes vaccines for children under 5 years of age
- Brings total U.S. vaccine doses secured to 600 m

2 bn doses pledged through end of 2022 to ensure global equitable vaccine access*

- Agreement with U.S. government to provide 1 bn doses for donation via COVAX to ~100 countries, including those in African Union



Continued Progress Across Six Key Levers to Expand COVID-19 Vaccine Reach

Increased Manufacturing Capacity



- Expect to manufacture 2.7 bn to 3 bn doses by end of 2021
- Global COVID-19 vaccine supply chain and manufacturing network with more than 20 manufacturing facilities across four continents

Global Clinical Program to Generate Data and Support Label Expansion to Additional Populations



- Positive safety and efficacy data reported in children aged 5 to <12
- Children cohorts 2-5 years and 6 months to 2 years of age: data expected late Q4 2021 or early Q1 2022
- Global Phase 2/3 trial in healthy pregnant women ongoing

Regulatory Advancement Across All Geographies



- BLA approval in the United States for BNT162b2 to prevent COVID-19 in individuals 16 and older

Booster dose

- U.S. FDA authorization for emergency use in individuals 65 and older, individuals 18-64 at high risk of severe COVID-19, or with frequent exposure, and for third dose in severely immunocompromised individuals
- EC approval in individuals ≥ 18 years of age and for third dose in severely immunocompromised people following positive opinion from EMA CHMP

Label extension

- Submitted for variation of CMA to EMA in children 5 to <12
- EUA granted in U.S. for children 5 to <12

Optimize Formulations to Further Simplify Access Worldwide



- FDA and EMA authorized storage of current vaccine for up to 9 months at -90 to -60 °C
- New formulation with further simplified handling and optimized storage – up to 10 weeks at 2 to 8 °C – approved by EC, following positive opinion from EMA CHMP

Addressing Waning Immune Responses



- Multiple trials ongoing to address need for booster dose of BNT162b2, including a 10,000-participant efficacy study demonstrating 95.6% relative vaccine efficacy against disease after booster dose during period when Delta variant was prevalent strain

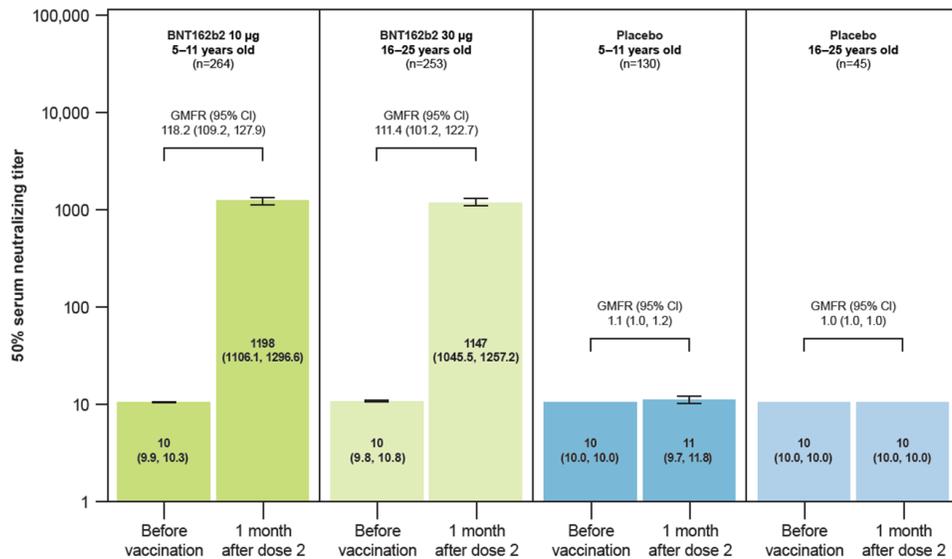
Preemptive Prototype Approach to Addressing SARS-CoV-2 Variants



- Generating data for variant-encoding vaccine candidates to support platform approach to emerging SARS-CoV-2 variants

Clinical Data Support Label Extension of BNT162b2 to Children 5 to 11 Years of Age¹

Robust immune response in children 5 to 11 years one month after the second dose of BNT162b2



- Two doses of 10µg administered 21 days apart
- Well tolerated with mainly transient mild-to-moderate side effects
- Robust neutralizing antibody responses similar (GMT of 1,197.6) compared to control group 16 to 25 years old (GMT of 1,146.5) at one month post dose two, meeting the predefined immunobridging success criterion

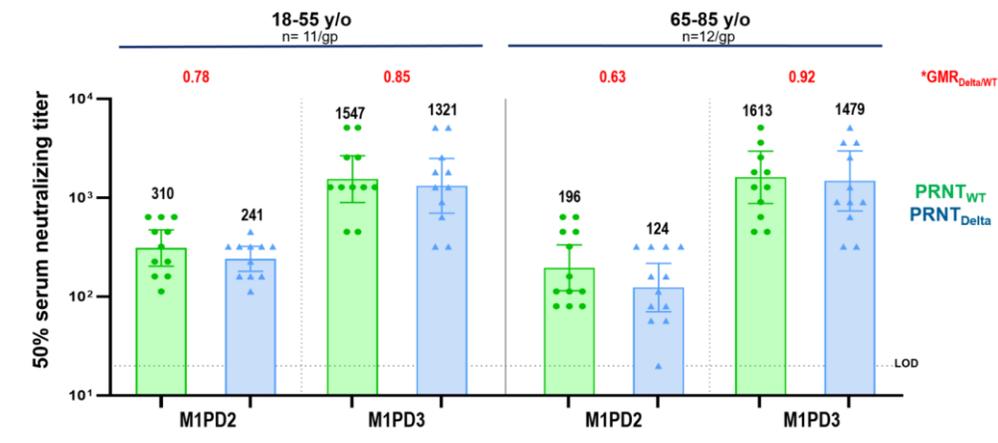
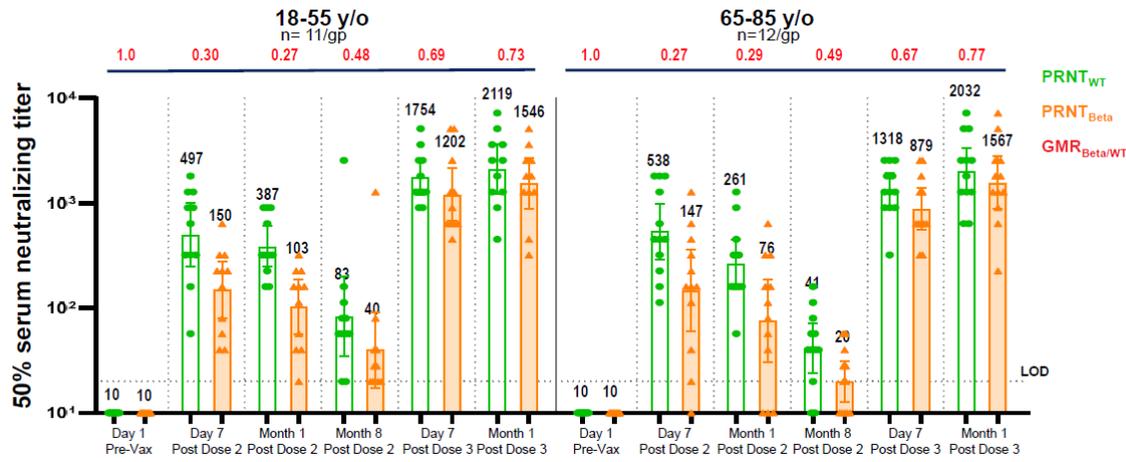
BNT162B2 efficacy across age groups

- 16 years and older: **95% efficacy** against symptomatic COVID-19 in Phase 3 pivotal trial with ~44,000 participants
- 16 years and older: **91% efficacy** against symptomatic COVID-19 and **95.3% efficacy** in preventing severe disease through to 6 months post second dose
- 12-15 year old children: **100% efficacy** against COVID-19 infection and 100% efficacy against severe disease
- 5-11 year old children: **90.7% efficacy** against symptomatic COVID-19 infection and no cases of severe COVID-19

- Well tolerated safety profile
- High titers of neutralizing antibodies
- Robust and poly-epitopic CD8+ and Th1 CD4+ T-cell responses²

Greater, Broader Neutralization and High Vaccine Efficacy Post Booster Dose for Protection Against Symptomatic Disease

Greater, Broader SARS-CoV-2 Neutralization with BNT162b2 Vaccine Dose 3¹



Booster Dose of BNT162b2 demonstrates High Relative Vaccine Efficacy in Phase 3 Trial with ~9,000 Subjects

Efficacy Endpoint	BNT162b2 (30µg) N=4695		Placebo N=4671		rVE	(95% CI)
	n	Surveillance Time (n)	n	Surveillance Time (n)		
First COVID-19 occurrence from ≥7 days after booster vaccination to <2 months after booster vaccination	5	0.623 (4659)	109	0.604 (4614)	95.6	(89.3, 98.6)

Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint

rVE = relative vaccine efficacy of the BNT162b2 booster group relative to the placebo group (nonbooster)

- Relative vaccine efficacy consistent irrespective of age, sex, race, ethnicity, or comorbid conditions
- Well tolerated with adverse events similar to those demonstrated in clinical development program. No further safety signals observed.

Booster Dose of BNT162b2 Restores High Levels of Vaccine Effectiveness and Prevents Against Severe Disease Across Diverse Population Groups, Globally

Real world vaccine effectiveness post primary dose schedule

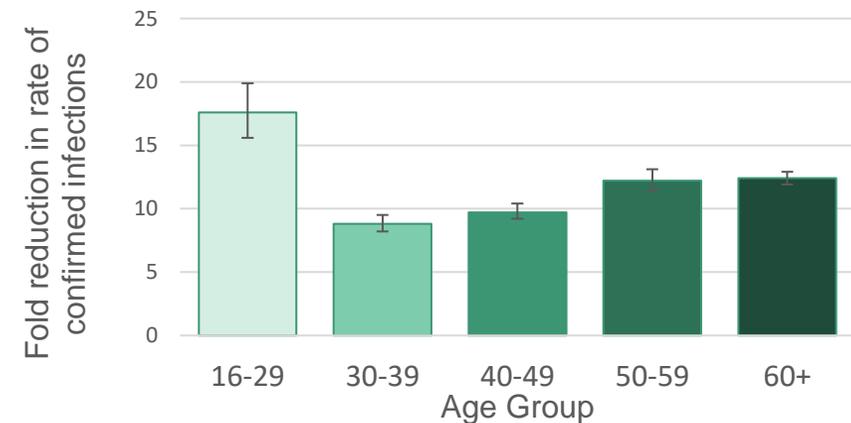
Global data reflecting high vaccine effectiveness post primary regimen.

Population analysis from the Israeli Ministry of Health data found BNT162b2 had a high level of VE across a range of outcomes¹:

- Asymptomatic disease: **91.5%** (95% CI: 90.7–92.2)
- Symptomatic disease: **97.0%** (95% CI: 96.7–97.2)
- COVID-19 hospitalizations: **97.2%** (95% CI: 96.8–97.5)
- Severe or critical hospitalization: **97.5%** (95% CI: 97.1–97.8)
- Death: **96.7%** (95% CI: 96.0–97.3)

Real world evidence that a booster dose restores high levels of vaccine effectiveness for confirmed infections and severe disease³

Risk Reduction at ≥12 days after 3rd Dose Booster Compared to Nonbooster by Age Group

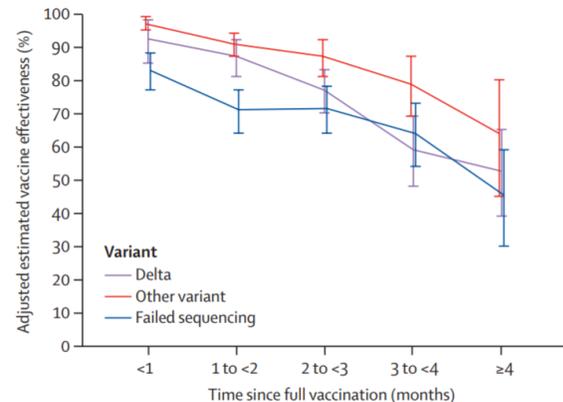


At ≥12 days post booster dose vs non-booster cohort:

- **~10-fold** risk reduction of **confirmed infection (8.8-17.6)** across all age groups
- **18.7-fold** risk reduction in **severe illness** for ages 60+
- **22.0-fold** risk reduction for **severe illness** for ages 40-60
- **14.7-fold** risk reduction in **COVID-19 associated deaths** for ages 60+

Vaccine effectiveness wanes with time post second dose regardless of variant of concern but vaccine efficacy preventing hospitalizations is maintained

Analysis of more than three million US healthcare records² demonstrated that BNT162b2 was **90% (95%CI 89-92) effective** against hospitalization



Clinical Strategy Supports Boosters and Platform Approach to Variants

Clinical data supports a booster dose of the vaccine in adults or high risk populations to augment vaccine protection over time

Clinical Trials Evaluating Booster Dose For Immunogenicity, Reactogenicity and Vaccine Efficacy

1

BNT162b2:
3rd dose

Safety & immunogenicity trial
N=23 (Ph 1); N=~300 (Ph 2/3)

First data published¹

2

BNT162b2:
3rd Dose

Safety & Vaccine Efficacy trial
N=~10,000 (Ph 3)

Data in Q4 2021

To date, no clinical evidence to advocate need to change vaccine to variant-specific version of vaccine. Platform approach preemptively prepares for the need, should it arise with a more severe/transmissible variant of concern.

3

Beta Variant-Encoding Vaccine:
3rd dose or naïve

Safety & immunogenicity trial
N=~300 (Ph 3); N=~300 (naïve)

Data in Q1 2022

4

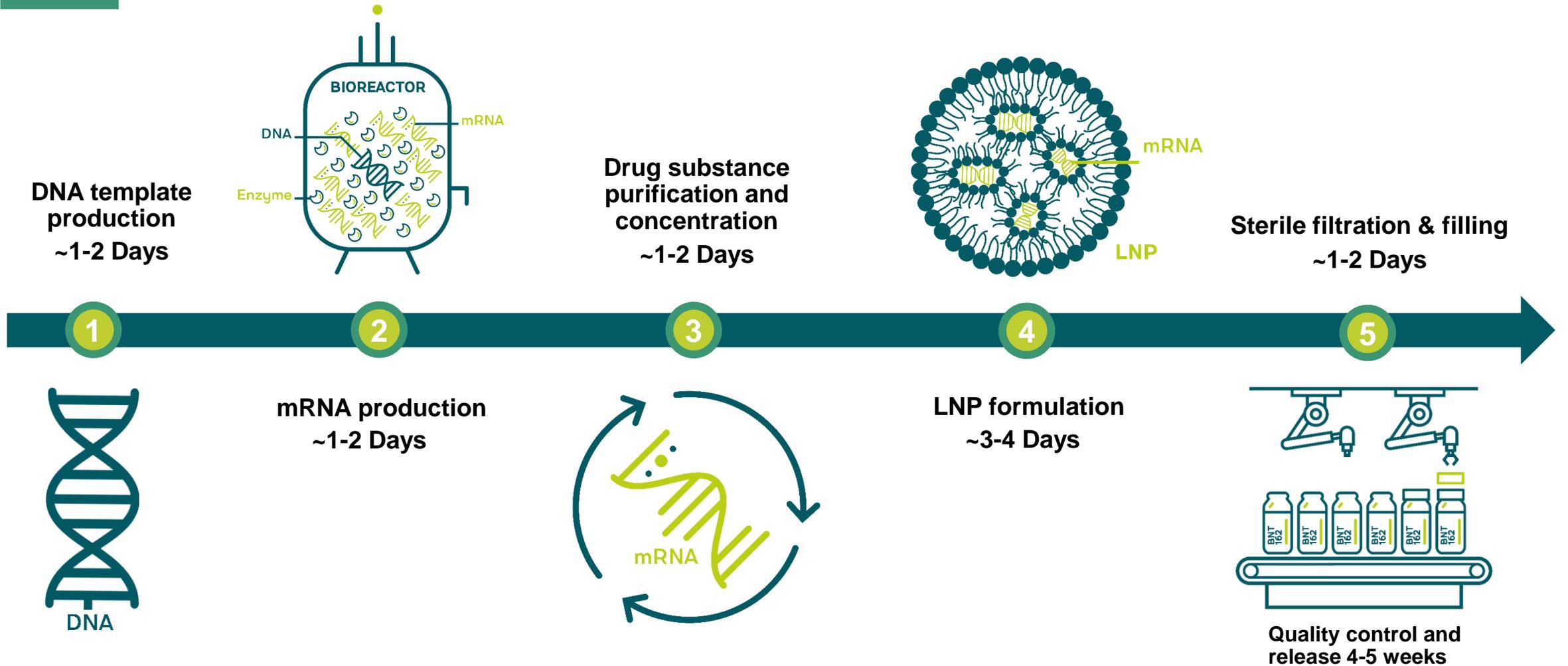
Multivalent Delta + Alpha
or Delta or Alpha
Variant-Encoding Vaccines as
3rd dose or in naïve subjects

Safety & immunogenicity trial
N=~600; N=~300 (naïve)

Data in Q4 2021

Trials Evaluating Variant-Encoding Vaccines Support Flexible Platform Approach to Product Adaptation

Flexible Manufacturing Allows Rapid Adaptation to Variants



Global Consortium to Address Pandemic - BNT162 Global Collaborations



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



- 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

Cell Therapies – CARVac and NEO-STIM T cell therapy

Small Molecule Immunomodulators

RiboCytokines

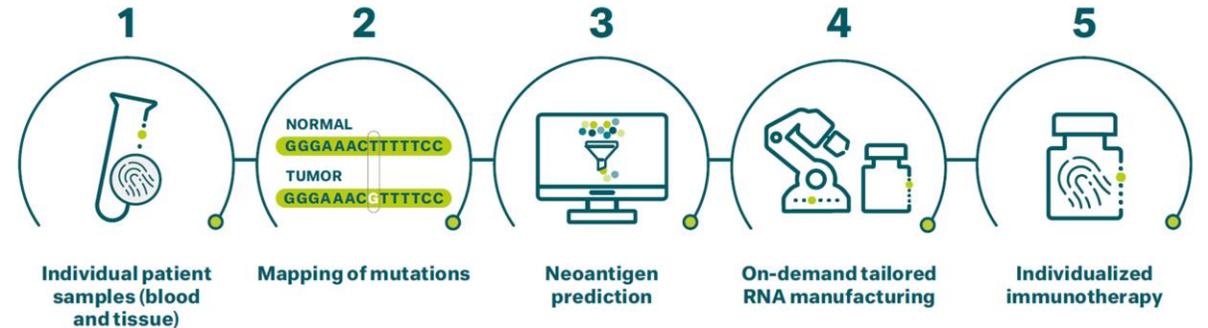
Our mRNA Vaccine Platforms: FixVac and iNeST

FixVac



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

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

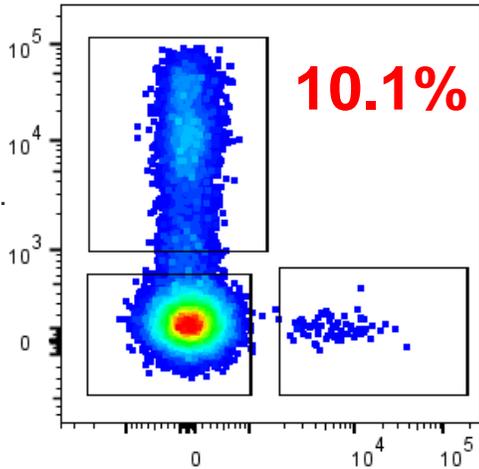
Proprietary RNA-LPX formulation for systemic dendritic cell targeting

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

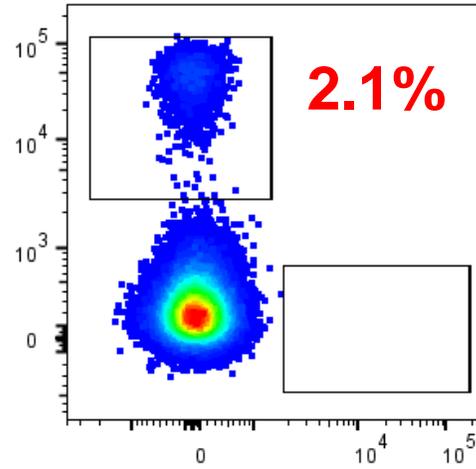
Potent induction of strong *ex vivo* CD4+ and CD8+ T cell responses

Our RNA-LPX Vaccine Approach

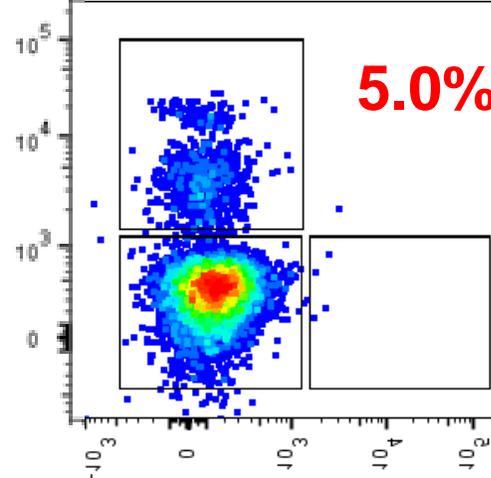
Strong vaccine-induced *ex vivo* CD8+ T cell responses¹ across different cancer types



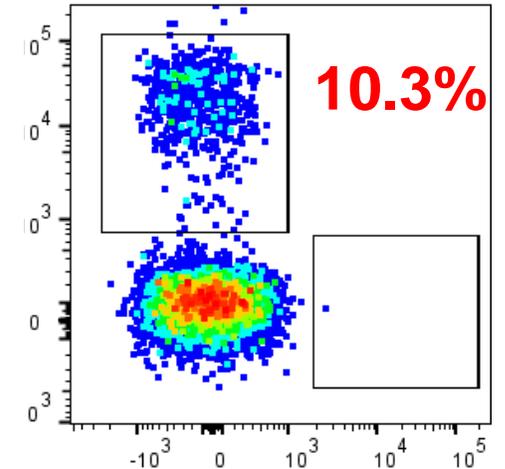
NY-ESO-1
Melanoma
BNT111, Lipo-MERIT trial



MAGE-A3
Melanoma
BNT111, Lipo-MERIT trial



HPV16-E7
Head Neck Cancer
BNT113, HARE40 trial



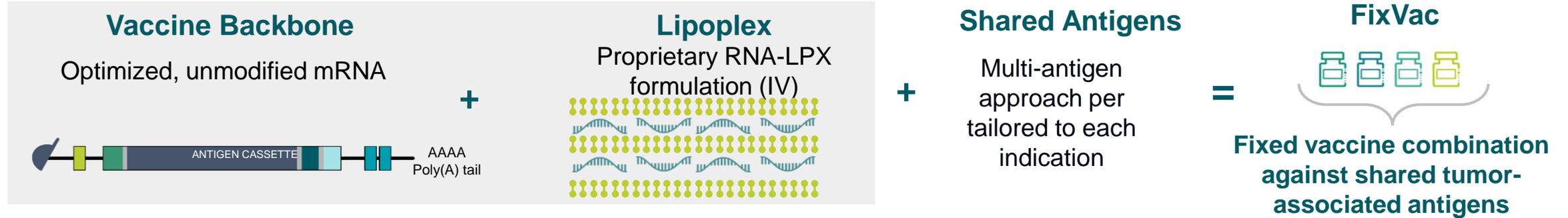
Mutant Neoantigen
TNBC
BNT114, TNBC MERIT trial

FixVac

iNeST

FixVac: Leveraging Shared Antigen to Break Immune Tolerance

Off-the Shelf Concept: Scalable for multiple indications



Targeting antigen presenting cells to stimulate antigen-specific T cell responses

- Strong immunogenicity observed *in vivo* via TLR-driven adjuvant effect¹
- Potent induction of strong *ex vivo* CD4⁺ and CD8⁺ T cell responses¹

Product Candidate ³	Indication (Targets)	Preclinical	Phase 1	Phase 2
BNT111	Advanced melanoma	Progressing	Completed	Completed
BNT112	Prostate cancer	Progressing	Completed	Completed
BNT113	HPV16+ head and neck cancer	Progressing	Completed	Completed
BNT116	NSCLC	Progressing	Completed	Completed

BNT111 FixVac Melanoma: Started 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 ongoing Phase 2 trial

- 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
- **First patient was dosed in June 2021**

BNT111: Off-the Shelf Therapeutic Vaccine for Melanoma

Potential to Improve Outcomes in Combination with Anti-PD1 by Rescuing from T Cell Exhaustion

BNT111 encodes 4 tumor-associated antigens covering >90% of cutaneous melanoma patients ¹



nature

An RNA vaccine drives immunity in checkpoint-inhibitor-treated melanoma

Ugur Sahin , Petra Oehm, [...]Özlem Türeci

Phase 1 trial data published in Nature²:

- Tolerable safety as monotherapy and in combination with anti-PD1
- Durable objective responses in CPI-experienced patients with unresectable melanoma
 - ORR: BNT111 monotherapy: 3/25 PR; 8/25 SD
 - ORR: 35% in combination with anti-PD1: 6/17 PR; 2/17 SD
- Clinical responses accompanied by strong CD4⁺ and CD8⁺ T cell immunity

BNT111: Treatment Options Needed to Address CPI Failure in Advanced Melanoma Patients

Melanoma Remains the Deadliest Skin Cancer



Significant Opportunity to Improve on Standard of Care

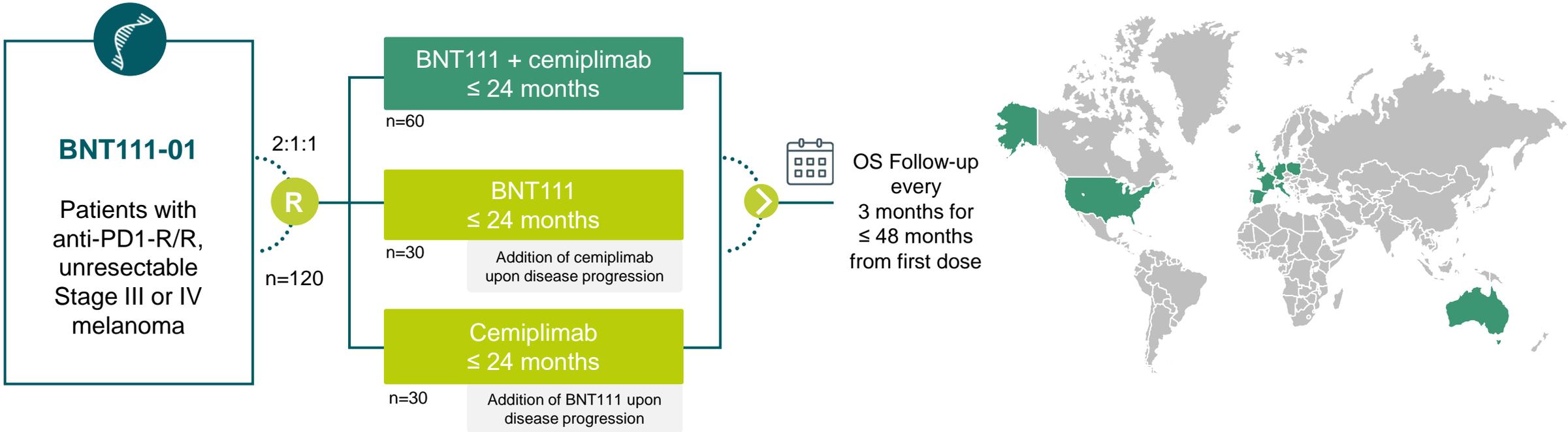
- 5-year survival for metastatic melanoma still only 29.8%⁵
- Frontline immunotherapy with CPI induces durable responses in max. 45-50% of patients but with relatively short PFS⁴
- CPI resistant/ refractory patients that fail to respond to CPI or relapse after CPI have an especially poor prognosis with survival as short as 6 months depending on risk factors
- Advanced CPI R/R melanoma is a high medical need population with highly unfavorable prognosis

WHO, World Health Organization; CPI, check point inhibitor; R/R, refractory/resistant; mPFS, median progression free survival; ORR, Overall Response Rate; DoR, Duration of Response

¹<https://www.melanomauk.org.uk/2020-melanoma-skin-cancer-report>; ²Global Cancer Observatory – 2018 data from 'Cancer Today';

³Global Cancer Observatory – projected 2025 data from 'Cancer Tomorrow'; ⁴Larkin J. et al. NEJM 2019;381(16):1535-1546; ⁵<https://seer.cancer.gov/statfacts/html/melan.html> Accessed August 06, 2021

BNT111: Global Phase 2 Clinical Trial in Anti-PD1 R/R Melanoma Patients



Open-label, randomized Phase 2 trial

- BNT111 and cemiplimab in combination or as single agents
- Collaboration with Regeneron

Success Measures for BNT111 Trial

ORR 30%

Primary Endpoints

- Arm 1: ORR by RECIST 1.1

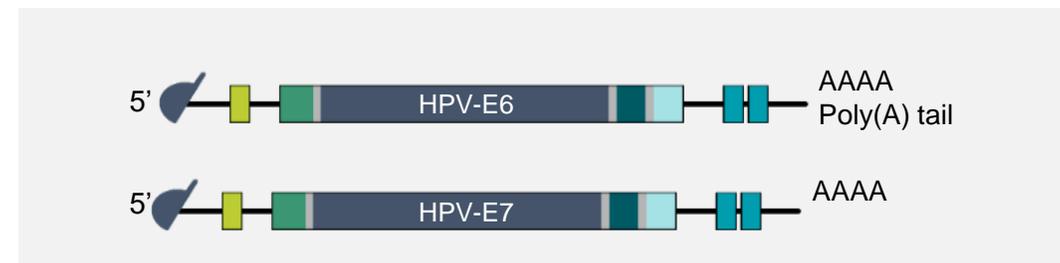
Secondary Endpoints

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

BNT113: Potential to Increase Response Rate and DoR to CPI by Stimulating Immune Response Against HPV16 Proteins

BNT113 encodes HPV16 oncoproteins E6 & E7

- E6 and E7 proven to be well-suited for immunotherapy intervention
- Exclusively expressed in pre-malignant and malignant tissue
- Maintain the transformed state of infected malignant cells
- Demonstrated immunogenicity
- Not affected by central tolerance mechanisms



BNT113 combination with anti-PD1: Potential for synergistic anti-tumor effect delaying escalation to toxic chemo

BNT113: Potent Antigen-Specific T Cell Responses in Phase 1 Trial^{1,2}

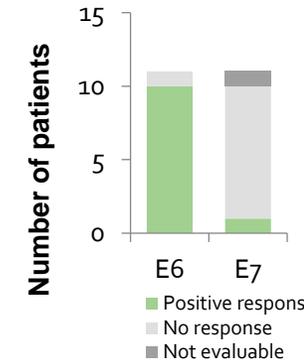
- CD4⁺ and CD8⁺ T cell responses
- Responses detectable ex vivo, implying high numbers of T cells
- Responses against multiple E6 or E7 epitopes

A

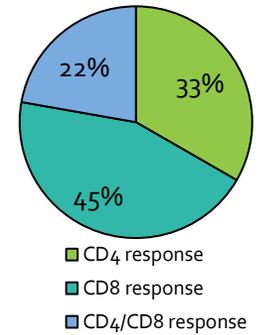
Overview of T cell responses Arm 1A

Arm 1A, adjuvantX	Antigen	Cohort 1 TD 29 µg						Cohort 2 TD 78.2 µg				
		Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7	Patient 8	Patient 9	Patient 10	Patient 11
E6		CD8	CD8	CD4	CD8	CD4	CD4/CD8	CD4/CD8	CD4	Bulk	CD8	NR
E7		NR	NR	NR	NR	NR	NR	CD8	NR	NE	NR	NR

Arm 1A patients



Type of response to E6

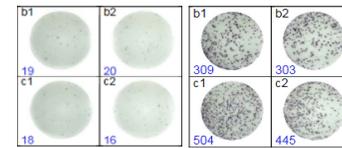


B

ELISPOTS³ Patient 7

CD8 response to vaccine targets

Pre vaccination Post vaccination



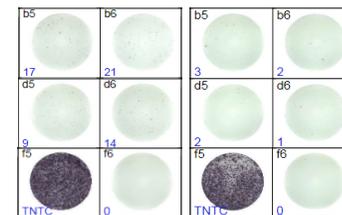
Pepmix E6

Pepmix E7

PBMCs only

PBMCs only

Anti-CD3



ELISPOTS³ Patient 6

CD4 response to vaccine targets

Pre vaccination Post vaccination

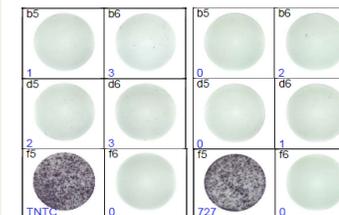


Pepmix E6

PBMCs only

PBMCs only

Anti-CD3



TD, total dose; CD, Cluster of Differentiation; NE, Not Evaluated; NR, Not Reported; PBMC, peripheral blood mononuclear cells

¹HARE-40 trial

²Presented at CIMT 2019; BNT113 is currently being studied in an investigator-initiated Phase 1 trial.

³ELISPOT (Enzyme Linked Immuno Spot Assay) data of selected patients. Data were generated using IFN- γ ELISPOT directly ex-vivo with overlapping peptides covering the whole length of vaccine antigens (PepMix).

BNT113: Unmet Medical Need for HPV-Associated HNSCC

HPV+ Cancer is a Growing Global Public Health Concern



Worldwide HPV-attributable cases (2018) = 690,000
(de Martel et al. 2020, Lancet Glob Health)

- Several types: HNSCC, Cervical, Anal, Vulvar, Vaginal, Penile
- HNSCC is the sixth most common cancer worldwide, with 890,000 new cases and 450,000 deaths in 2018²
- Oropharyngeal is most common HNSCC, accounting for 70% of cases, and 80-90% are HPV16+³

Limited treatment options for patients not responding to or relapse on CPI¹

- HPV16+ HNSCC typically occur in younger people and is not associated with tobacco or alcohol use
- >60% of patients diagnosed with late-stage HNSCC
- Current treatment options carry significant treatment burden or only work for some patients⁴:
 - Chemotherapy, surgery, radiation
 - CPI

Current SOC for recurrent/metastatic HNSCC	ORR	mOS (months)	mPFS (months)
pembrolizumab ⁵	17%	13.6	8.0
nivolumab ⁶	13.3%	7.7	2.0
chemotherapy ⁶	5.8%	5.1	2.3

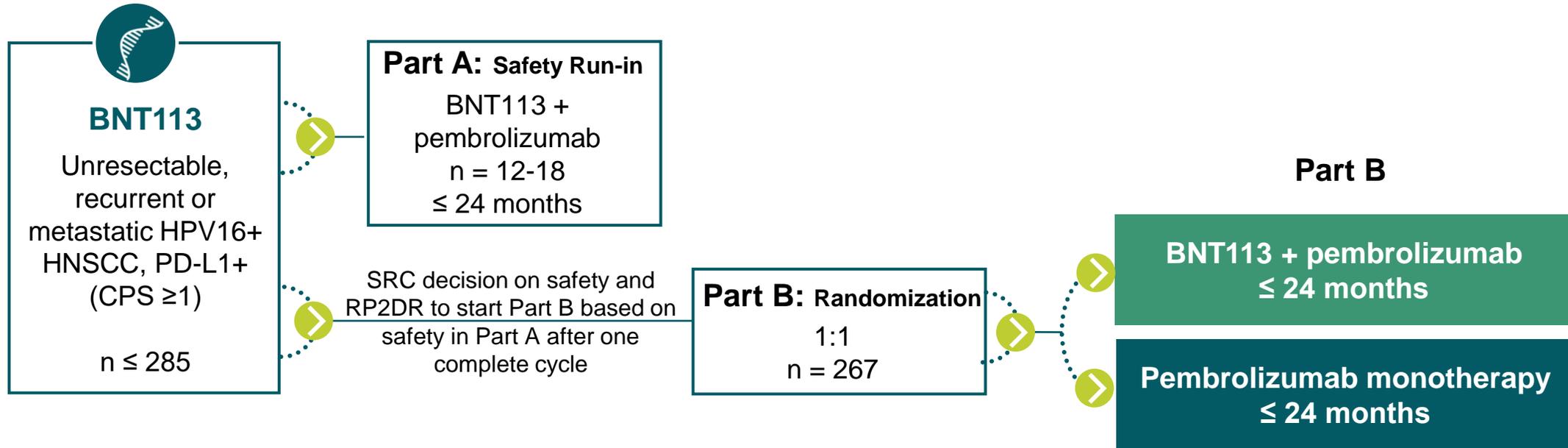
HPV, human papilloma virus; HNSCC, head and neck squamous cell carcinoma, CPI, check point inhibitor; R/R refractory/recurrent

¹Sabatini ME and Chiocca S. BJC 2020; 122:306-314, ²Johnson DE, et al., 2020, Nature Reviews Disease Primers 6:92

43 ³Saraiya et al. 2015, Vaccines; ⁴HNSCC NCCN Guidelines 2020, HNSCC ESMO Guidelines 2020; ⁵Burtress, et al. Lancet 2019 Nov 23; 394(10212):1915-28;

⁶<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6563923/pdf/nihms-1024161.pdf>

BNT113: First Patient Dosed in Potentially Registrational Phase 2 Trial in HPV16+ and PD-L1+ HNSCC



Open-label, controlled, Phase 2 study

- BNT113 in combination with pembrolizumab as frontline treatment for metastatic HPV16+ and PD-L1+ HNSCC
- HPV 16 companion diagnostic is being co-developed and will be clinically validated alongside the trial

Primary Endpoints

- Part A: Emergence of TEAEs
- Part B: OS, ORR

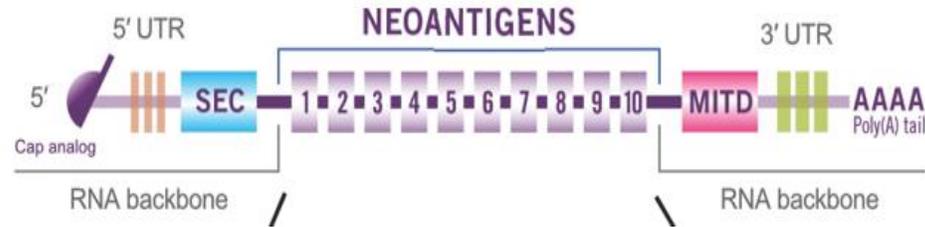
Secondary Endpoints

- PFS, DCR, DOR
- Safety
- Patient reported outcomes

Success Measures for BNT113 Trial

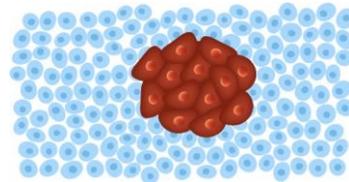
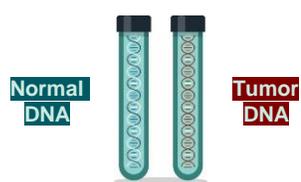
- mOS: 18 months (HR=0.667)
- ORR: 40%

iNeST¹: Tailored Treatment to Exploit Individual Targets



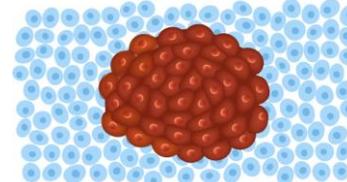
- Fully customized to the individual Patient
- Targeting 20 neo-antigens per patient

ADJUVANT



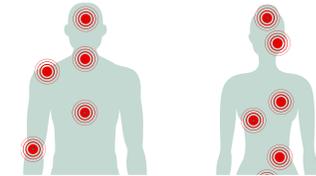
Residual cancer cells may remain – emphasis on recurrence free survival

1L METASTATIC



Rapidly growing but often still in early phase of metastases

LATE-LINE METASTATIC



Bulky tumors with multiple organs involved

iNeST

- Ongoing Phase 2 trial in adjuvant colorectal cancer
- Phase 1 trial data: 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 melanoma² and gastric³ cancer
- Encouraging efficacy signal validates iNeST potential in early settings

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**

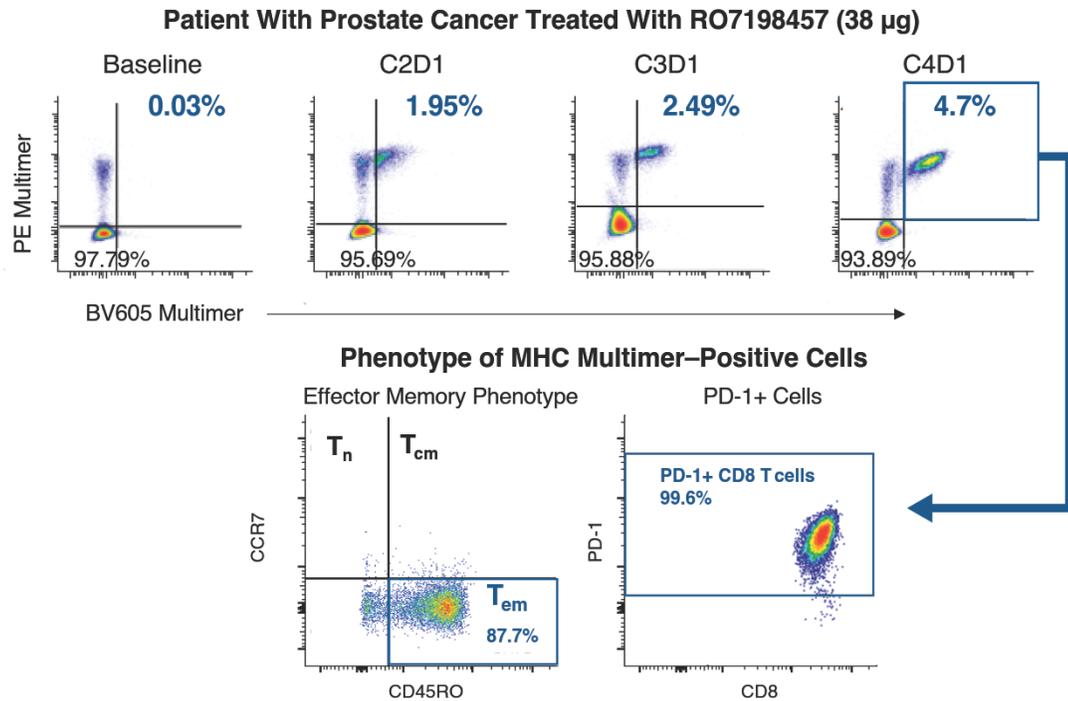
Phase 1b combination with atezolizumab demonstrated clinical activity in heavily pre-treated patients

- **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%)

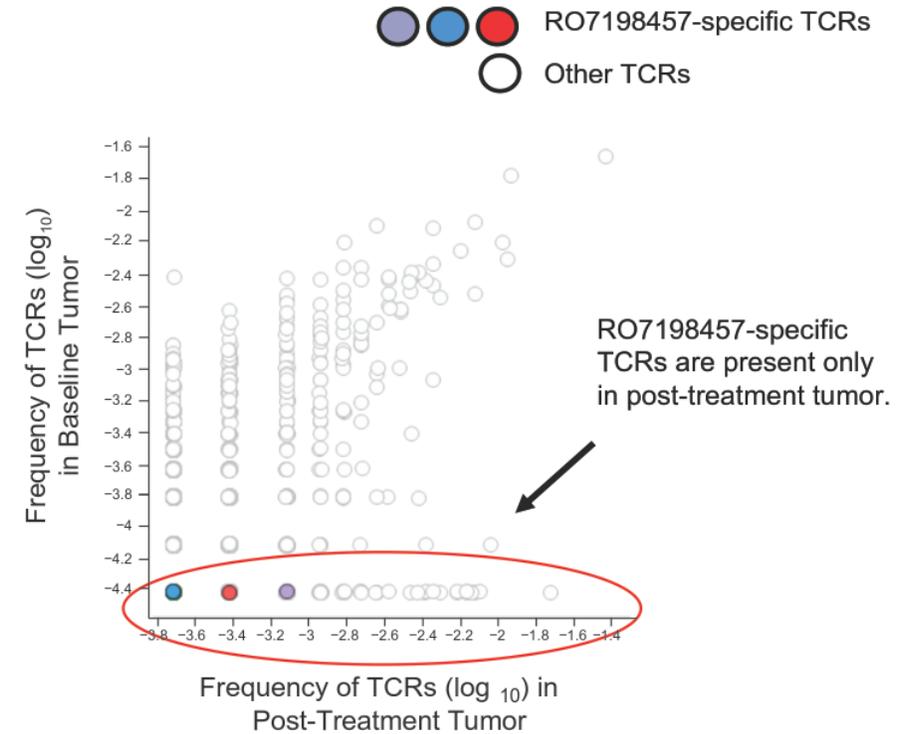
- **Demonstrates ability to elicit significant T cell responses of both effector and memory phenotype as monotherapy and in combination**
- **Treatment-related adverse events were primarily transient systemic reactions, manifesting as low grade CRS, IRR or flu-like symptoms**
- **Early evidence of clinical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

iNeST: Recent Update from BNT122 Reported at AACR (Cont'd)

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



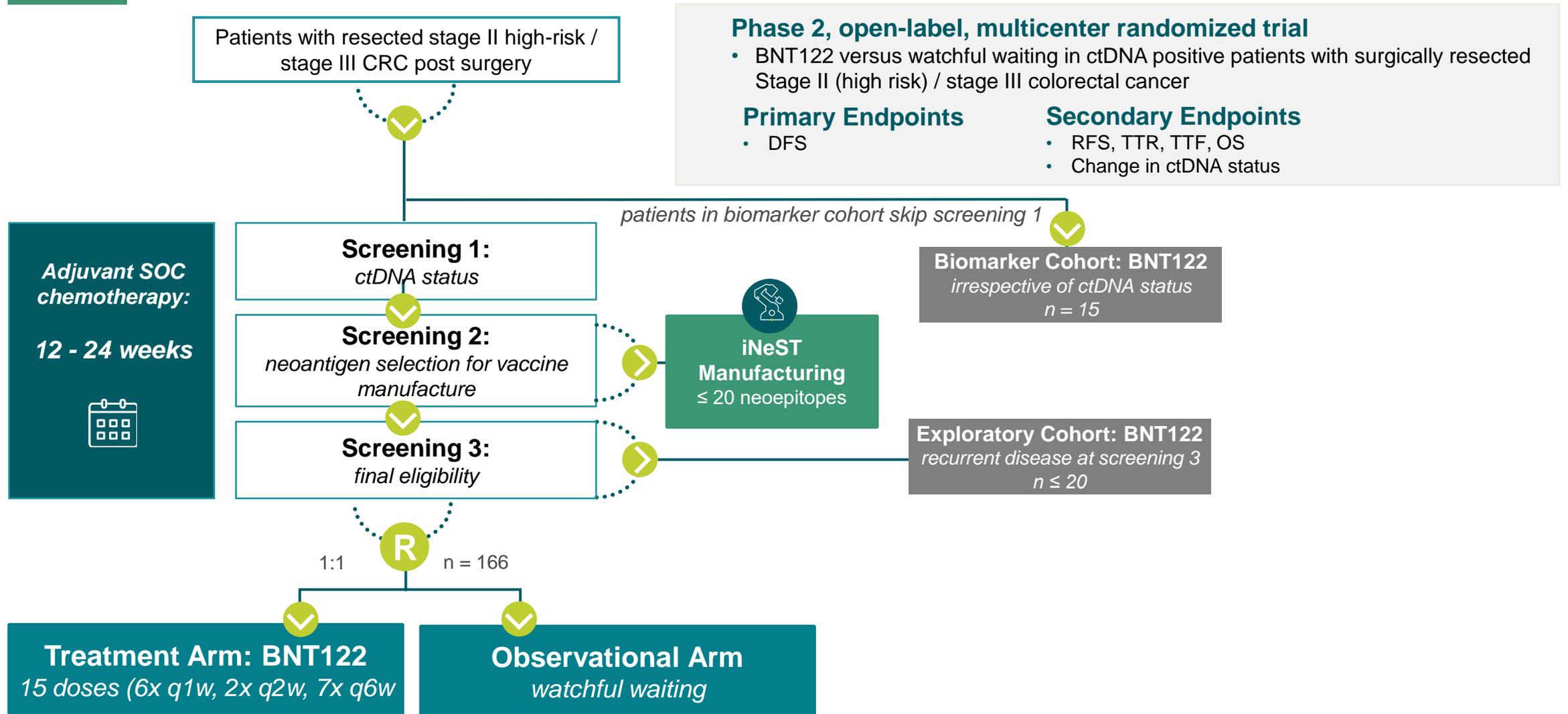
BNT122 induces CD8+ T cell infiltrates in tumors



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	<ul style="list-style-type: none">▪ Evaluate added benefit of 1L BNT122 in an advanced CPI-sensitive tumor (PFS, ORR)▪ Success may unlock 1L use of iNeST in CPI-sensitive advanced cancers for combination therapy	<ul style="list-style-type: none">▪ Evaluate added benefit of BNT122 in a micrometastatic CPI-insensitive tumor (RFS)▪ Success may unlock adjuvant use of iNeST for CPI-insensitive ctDNA+ cancer types
Status	<i>Currently enrolling</i>	<i>Currently enrolling</i>

BNT122: Randomized Phase 2 Trial in Adjuvant Colorectal Cancer



Autogene cevumeran (BNT122): First Patient Dosed in Phase 2 Clinical Trial in Adjuvant Colorectal Cancer

Randomized, Phase 2 trial evaluating autogene cevumeran* in the adjuvant treatment of circulating tumor DNA positive, surgically resected Stage II (high risk)/Stage III colorectal cancer

- Colorectal cancer is second deadliest cancer worldwide¹, 5 year OS in regional disease is 71%²
- SoC in Stage II (high risk) and Stage III CRC after removal of the primary tumor and adjuvant chemotherapy is watchful waiting
- ctDNA is a marker for minimal residual disease and thus can identify patients at high risk of disease recurrence^{3,4}
- In ctDNA-positive, Stage 2 (high risk) and Stage 3 CRC post AdCTx, duration of disease free survival is 6 months⁵

Challenge in Adjuvant Setting in Stage 2 (high risk) and Stage 3 Colorectal Cancer: Residual cancer cells may remain.



OS, Overall Survival; CRC, Colorectal Cancer; SoC, Standard of Care; ctDNA, circulating tumor DNA; AdCTx, adjuvant chemotherapy

Digitalization and Automation for Neo-antigen Vaccine Manufacturing



Paperless documentation



Semi-automatic manufacturing

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

Agenda

Overview and business outlook

Pipeline

Deeper dive on our key programs

COVID-19 vaccine program (project “Lightspeed”)

mRNA vaccines – FixVac and iNeST

Antibodies

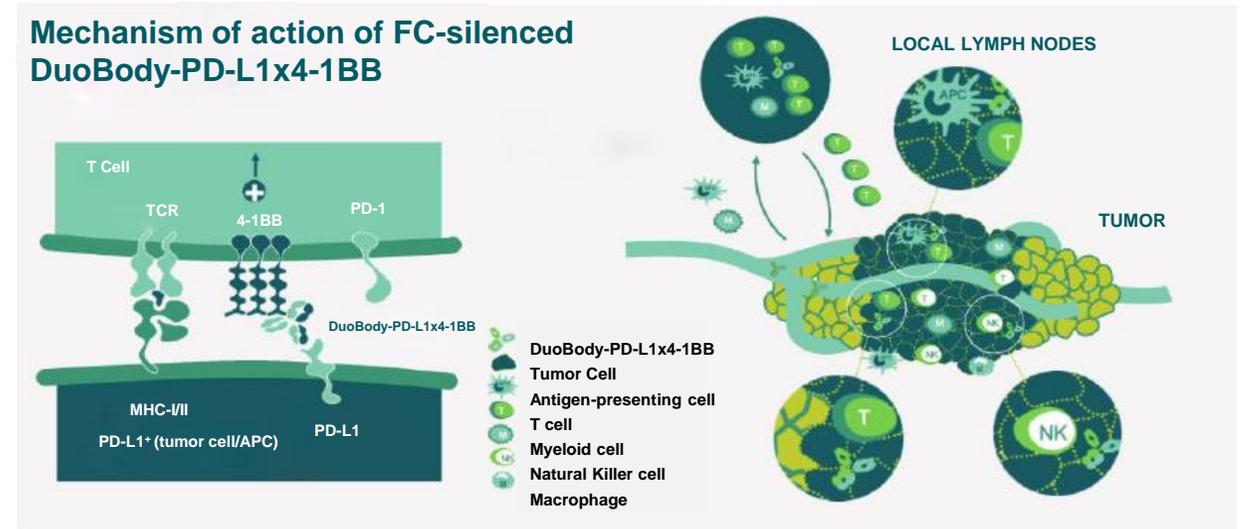
Cell Therapies – CARVac and NEO-STIM T cell therapy

Small Molecule Immunomodulators

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**

Phase 2 trial of BNT311 as monotherapy and in combination with pembrolizumab in R/R metastatic NSCLC expected to start in Q4 2021

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

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

8 expansion cohorts are currently recruiting

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

EC1: NSCLC ≤ 2-4L p. CPI

EC2: NSCLC ≤ 2-4L CPI n.

EC3: Urothelial Ca ≤ 2-4L p. CPI

EC4: Endometrial Ca ≤ 2-4L CPI n.

EC5: TNBC ≤ 2-4L CPI n./ p. CPI

EC6: SCCHN ≤ 2-4L CPI n./ p. CPI

EC7: Cervical Ca ≤ 2-4L CPI n.

EC9: Basket BNT311 + Docetaxel

BNT311: Interim Results of Ongoing Phase 1/2a Trial

Manageable Safety Profile and Initial Clinical Activity in FIH Trial

Safety

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

Dose escalation

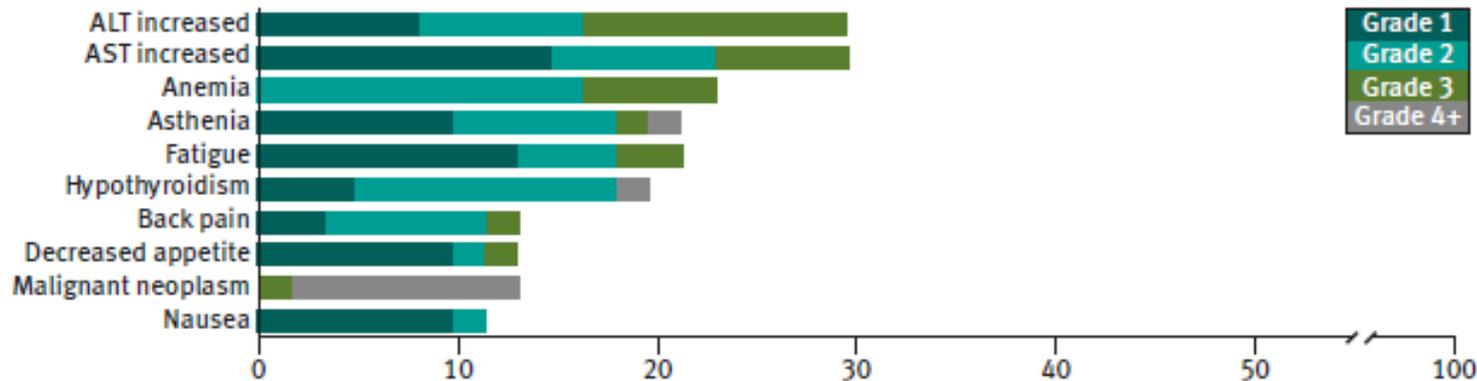
- Clinical benefit **across different dose levels and solid tumor types**
- Disease control in **65.6% of patients**
- **4 partial responses:**
 - TNBC (1), ovarian cancer (1), CPI* pre-treated NSCLC (2)
- Modulation of **circulating CD8+ T cells** and serum levels of interferon gamma and IP10 observed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

Dose expansion

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

BNT311: Interim Results of Ongoing Phase 1/2a – Safety Profile

TEAEs occurring in ≥10% of patients



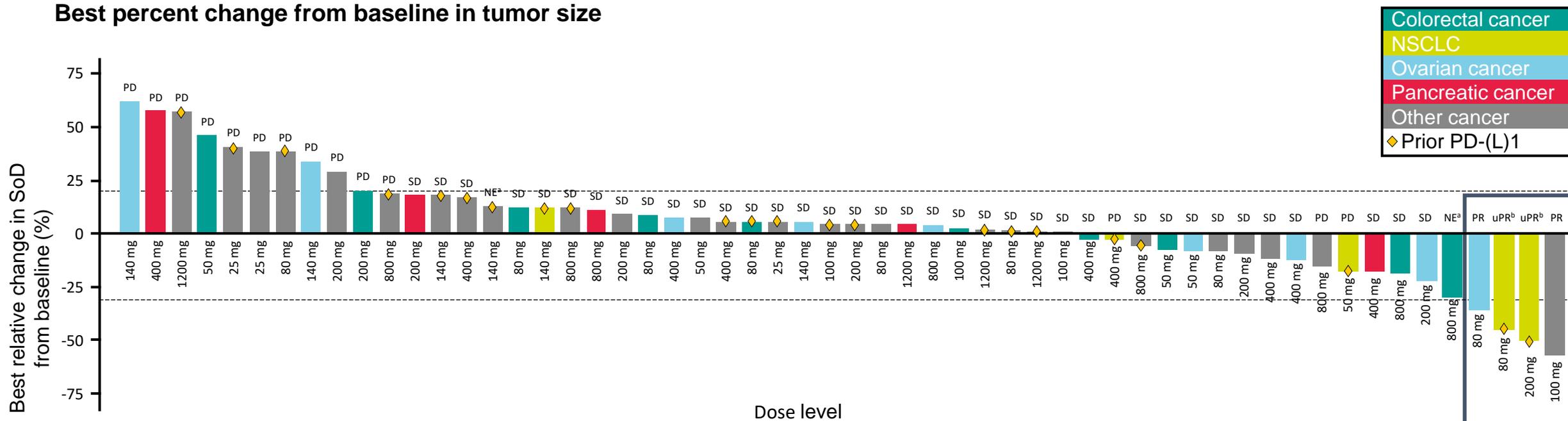
- The most common treatment-related adverse events were transaminase elevations, hypothyroidism and fatigue
- Treatment-related transaminase elevations occurred in 26.2% of patients (9.8% of patients had grade 3 transaminase elevations)
- There were no patients with Grade 4 transaminase, or treatment-related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

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

BNT311: Interim Results of Ongoing Phase 1/2a- Anti-tumor Activity Dose Escalation

Best percent change from baseline in tumor size



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

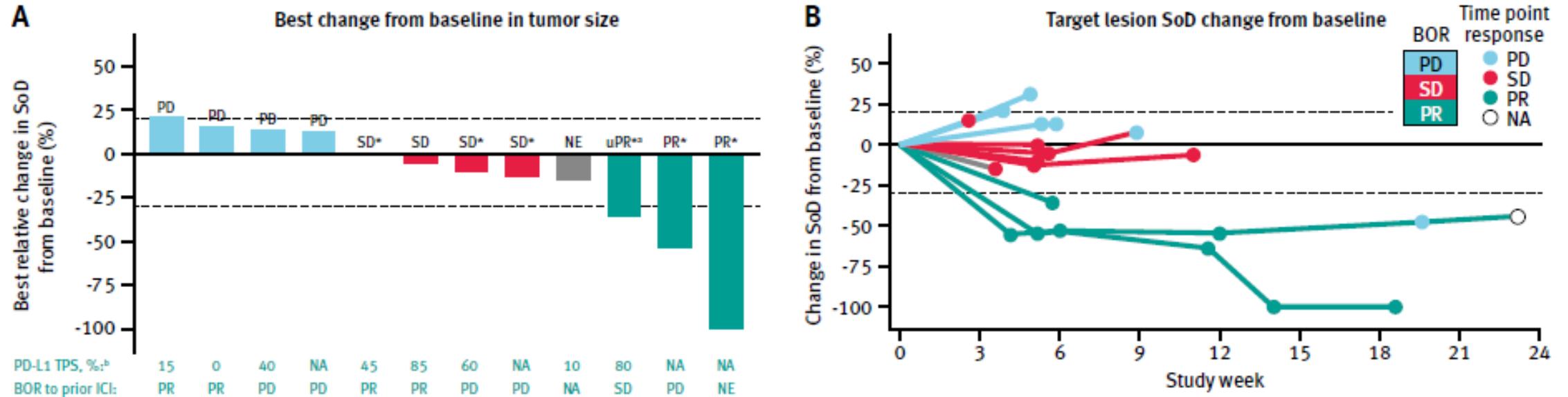
Data cut-off: September 29, 2020. Post-baseline scans were not conducted for five patients.

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

^bPR was not confirmed on a subsequent scan.

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

BNT311: Interim Results of Ongoing Phase 1/2a – Anti-tumor Activity in CPI Recurrent/Refractory NSCLC Expansion



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

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

Data cut-off: October 12, 2020.

*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

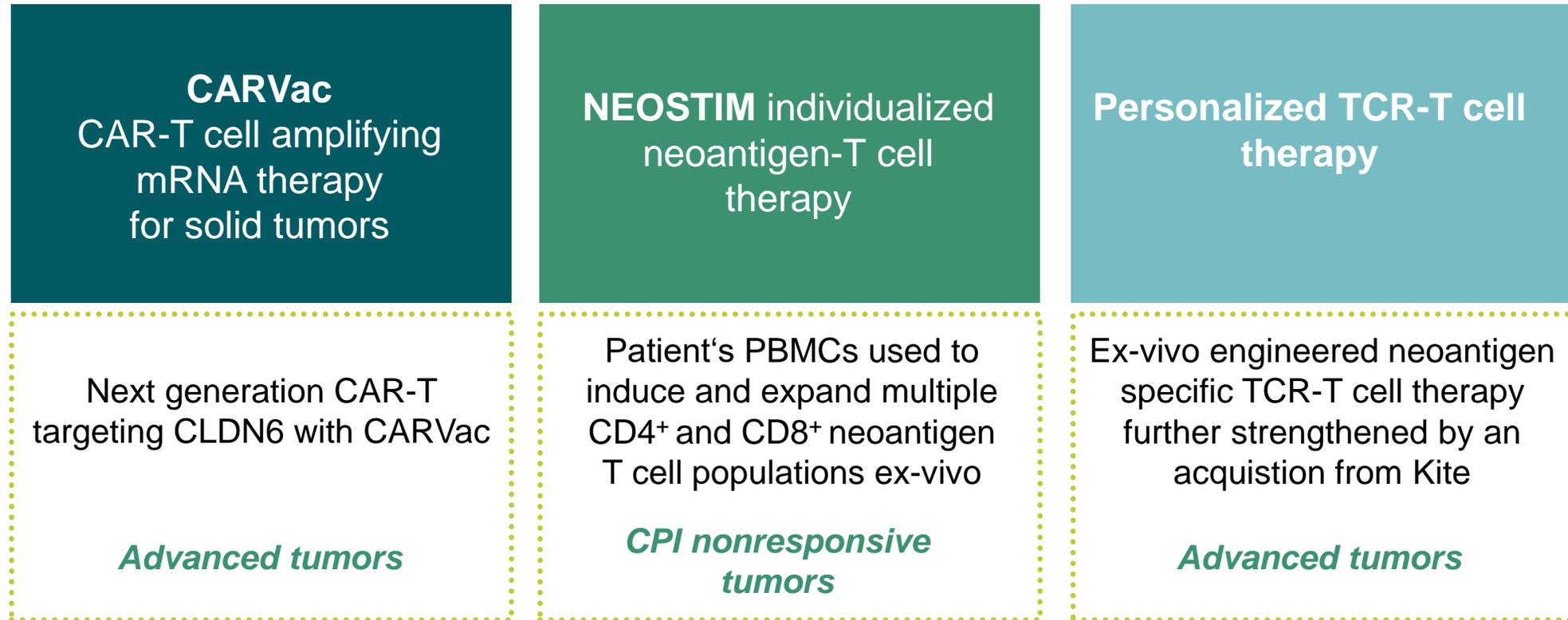
Cell Therapies – CARVac and NEO-STIM T cell therapy

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RiboCytokines

Proprietary Cell Therapy Pipeline and Capabilities

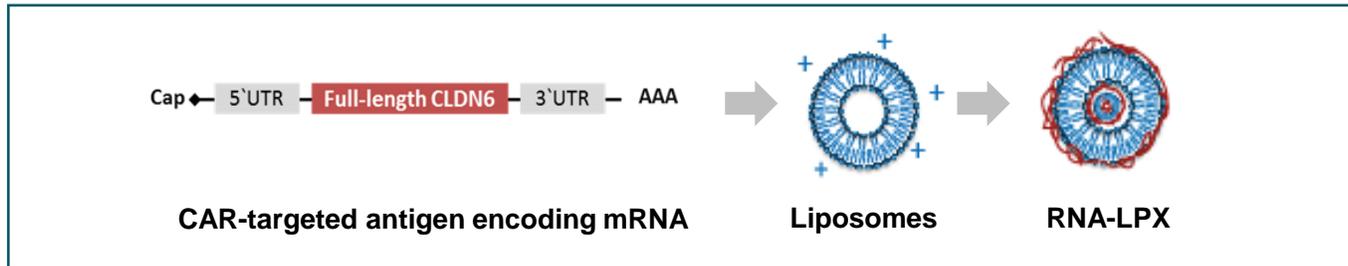
- Two cell therapy manufacturing facilities (Idar-Oberstein, Germany and Gaithersburg, U.S.)



BNT211: Repeated CARVac Dosing Enables Tunable Expansion of CAR-T Cells

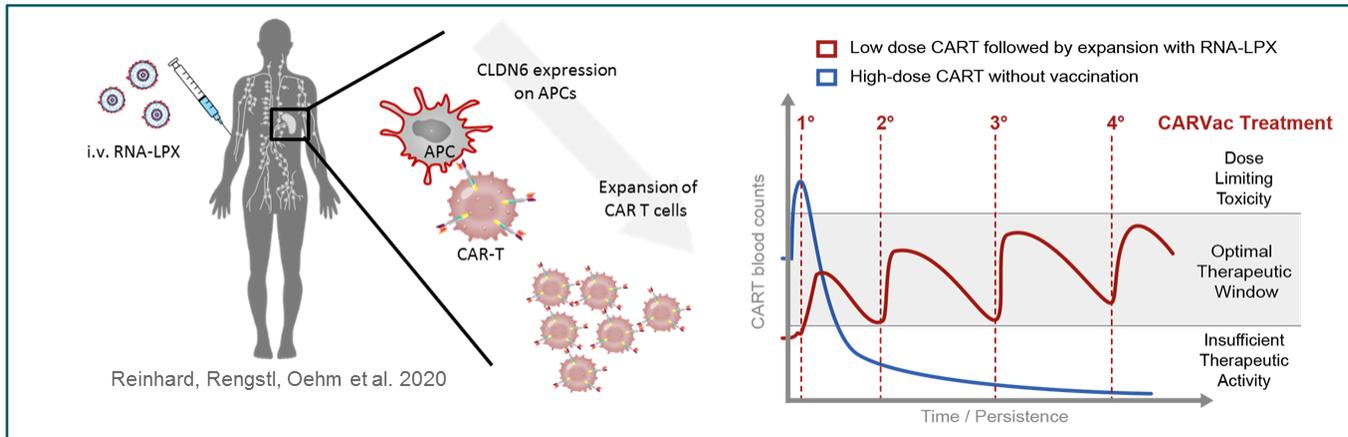
CAR-T cell Amplifying RNA Vaccine (CARVac) drives in vivo expansion and efficacy of CAR-T against solid tumors

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**

BNT211: CLDN6-CAR Demonstrates Potent and Robust Target Recognition

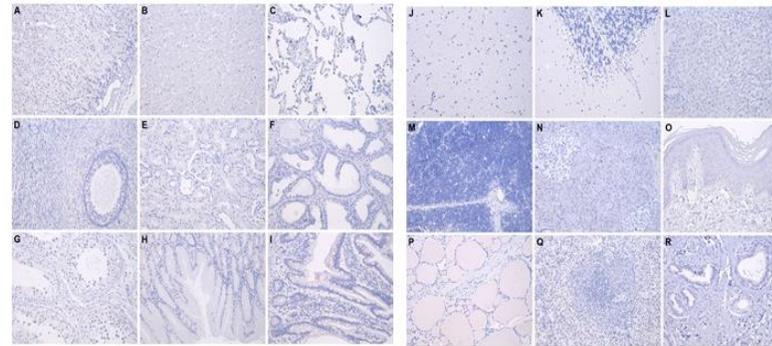
CANCER IMMUNOTHERAPY

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

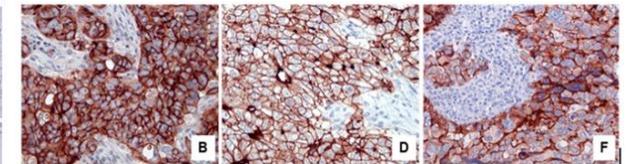
Katharina Reinhard^{1*}, Benjamin Rengstl^{1*}, Petra Oehm^{1*}, Kristina Michel¹, Arne Billmeier¹, Nina Hayduk¹, Oliver Klein¹, Kathrin Kuna², Yasmina Ouchan¹, Stefan Wöll¹, Elmar Christ¹, David Weber², Martin Suchan², Thomas Bukur², Matthias Birtel¹, Veronika Jahndel¹, Karolina Mroz¹, Kathleen Hobohm¹, Lena Kranz¹, Mustafa Diken², Klaus Kühlcke¹, Özlem Türeci^{1,†}, Ugur Sahin^{1,2,3,†,‡}

Science

CLDN6 not present in healthy tissues



CLDN6 expressed in multiple cancers



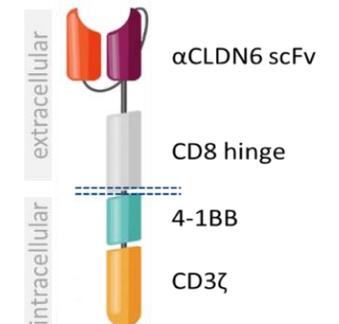
Ovarian

Testicular

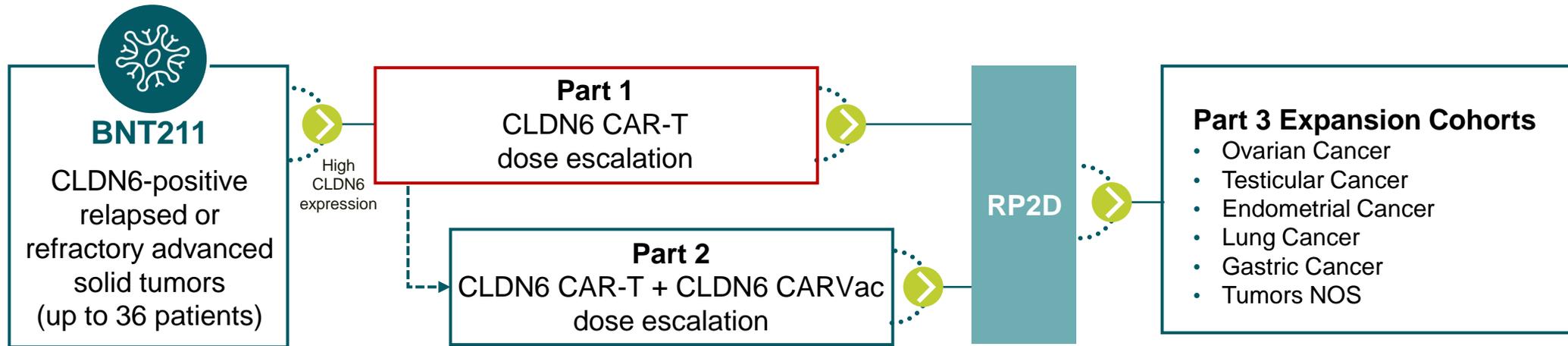
Lung

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

BNT211 CAR Structure



BNT211: 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)
- **Data update in 2H 2021**

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

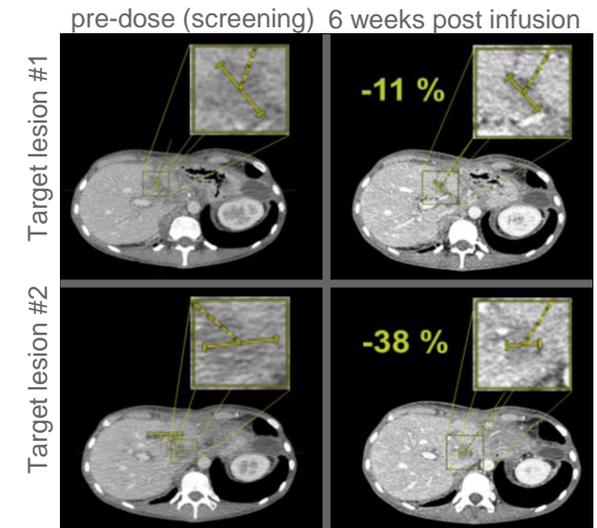
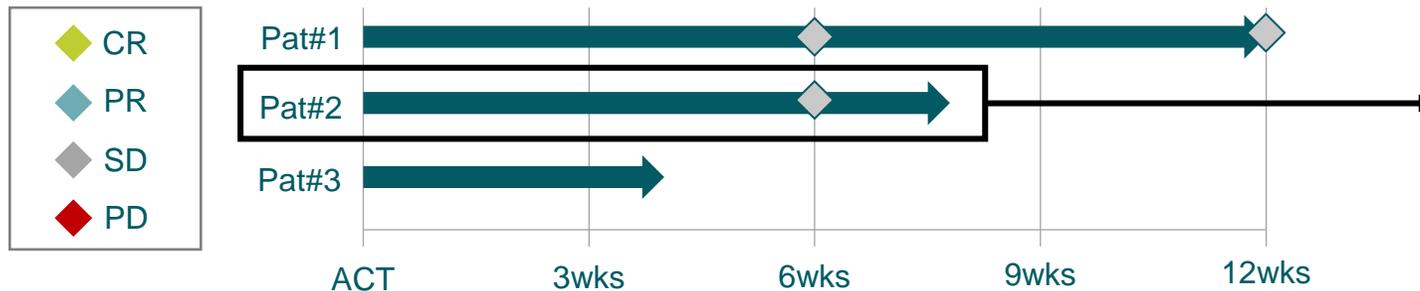
- AEs Mild to Moderate & Transient
 - No AEs ≥ grade 3 and no DLTs

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;

64 LD, lymphodepletion; FIGO, International Federation of Gynecology and Obstetrics; CLDN6, Claudin-6; AE, adverse event; CAR-T, chimeric antigen receptor engineered T cells

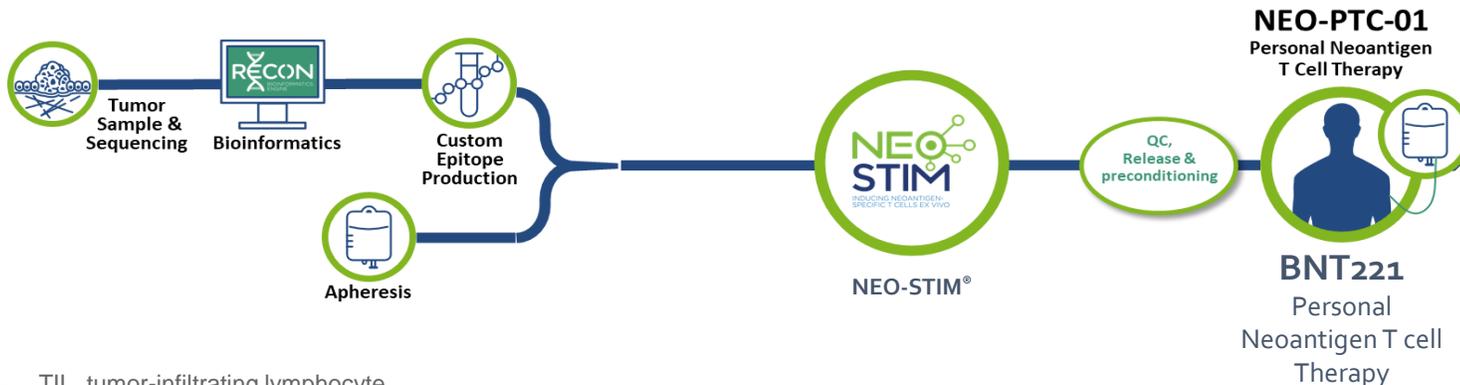
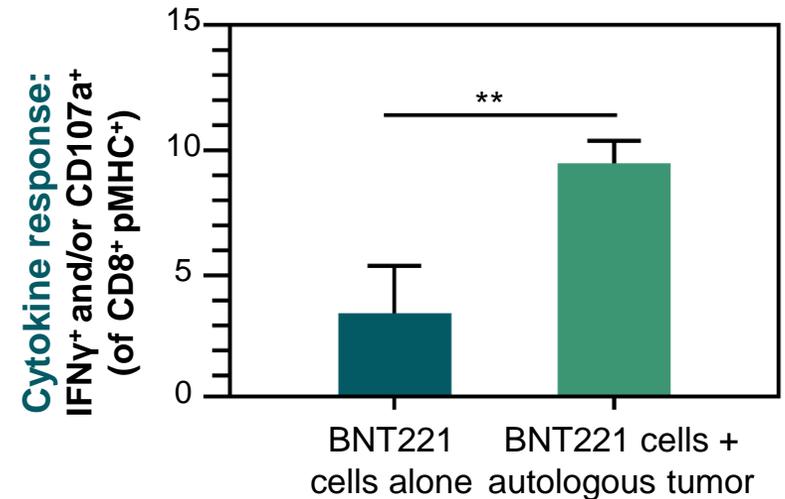
* Suspected to be related to drug product

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



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 – CARVac and NEO-STIM T cell therapy

Small Molecule Immunomodulators

RiboCytokines

BNT411: First Data Expected in 2H 2021

- 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 ongoing

Study design:

- Phase 1/2, 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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COVID-19 vaccine program (project “Lightspeed”)

mRNA vaccines – FixVac and iNeST

Antibodies

Cell Therapies – CARVac and NEO-STIM T cell therapy

Small Molecule Immunomodulators

RiboCytokines

RiboCytokines: Designed to Overcome Limitations of Recombinant Cytokine Therapy

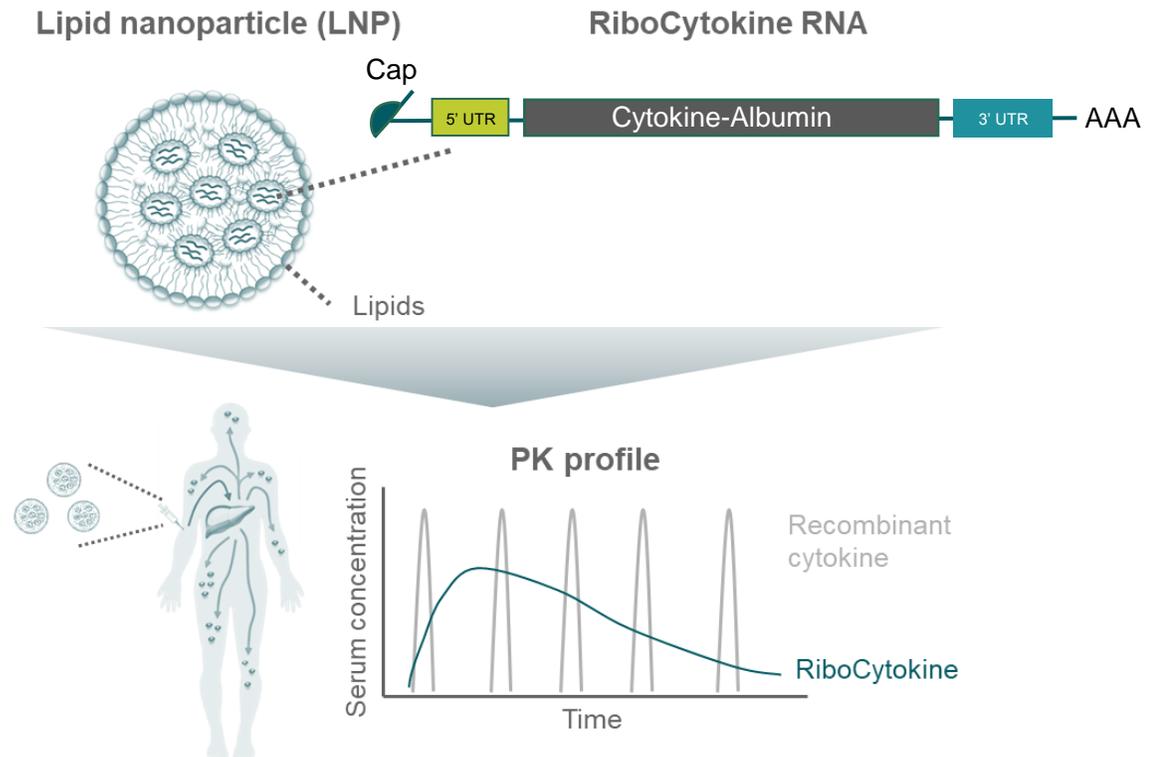
Cytokines encoded by mRNA: A novel therapeutic concept

Systemic delivery with minimal immunogenicity

- Backbone optimized and nucleoside-modified mRNA encoding cytokine fused to human albumin
- Liver-targeting LNP formulation with intravenous delivery
- Encoded cytokines translated within cells

Designed for optimized safety, tolerability and dosing

- Prolonged serum half-life
- High bioavailability
- Lower and less frequent dosing
- Lower toxicity

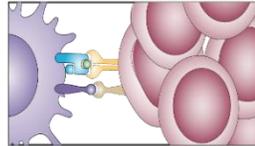


Product Candidate	Indication	Pre-clinical	Phase 1	Phase 2
BNT151 (modified IL-2)	Solid Tumors	████████████████████	████████████████████	████████████████████
BNT152+153 (IL-7 + IL-2)	Solid Tumors	████████████████████	████████████████████	████████████████████

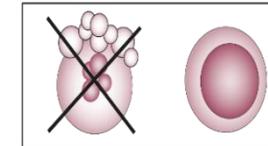
RiboCytokines: A Tailored Approach to T Cell Regulation and Stimulation

IL-2 supports differentiation, proliferation, survival and effector functions of T cells

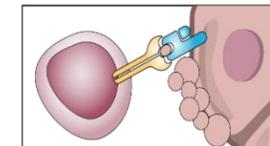
↑ T cell proliferation



↑ T cell survival



↑ T cell effector function



BNT151

mRNA encoding sequence-modified IL-2 variant

- Sequence modification that weakens binding to IL-2R α (CD25)
- Designed to stimulate naïve and effector T cells with low to no expression of IL-2R α (CD25^{low/neg})
- Stimulates anti-tumor effector cells without extensively triggering immunosuppressive regulatory T cells

Combination with anti-PD-1/PD-L1 therapy

BNT152 + 153

mRNAs encoding IL-2 and IL-7

BNT153 (IL-2)

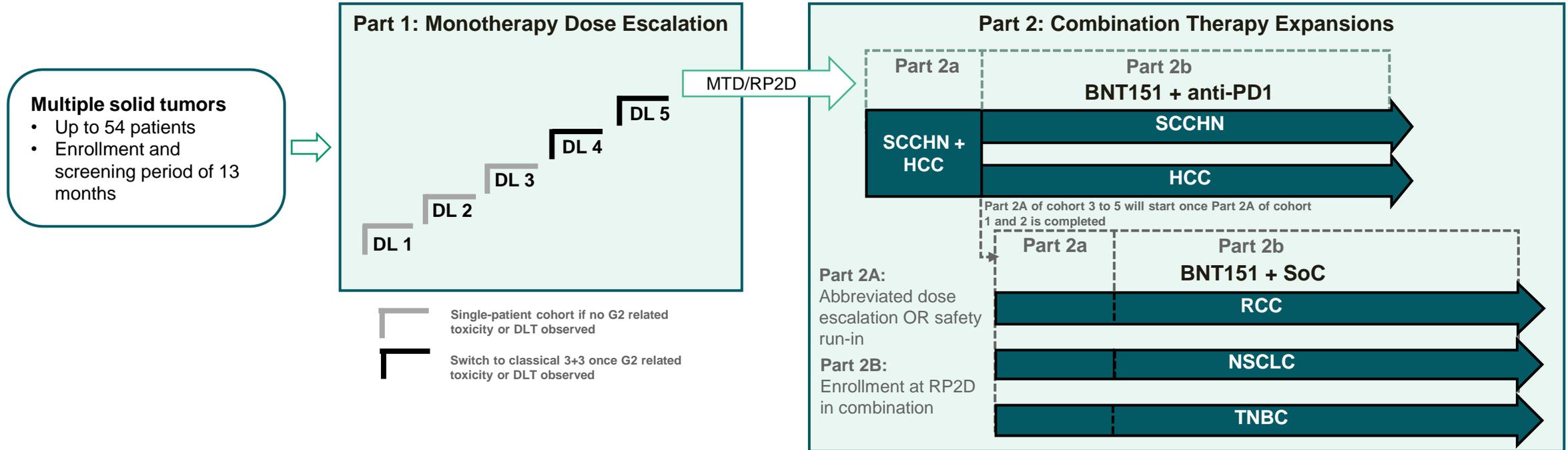
- Stimulates recently activated anti-tumor T cells and regulatory T cells

BNT152 (IL-7)

- Sensitizes effector T cells to IL2
- Controls fraction of immunosuppressive regulatory T cells

Combination with RNA vaccine

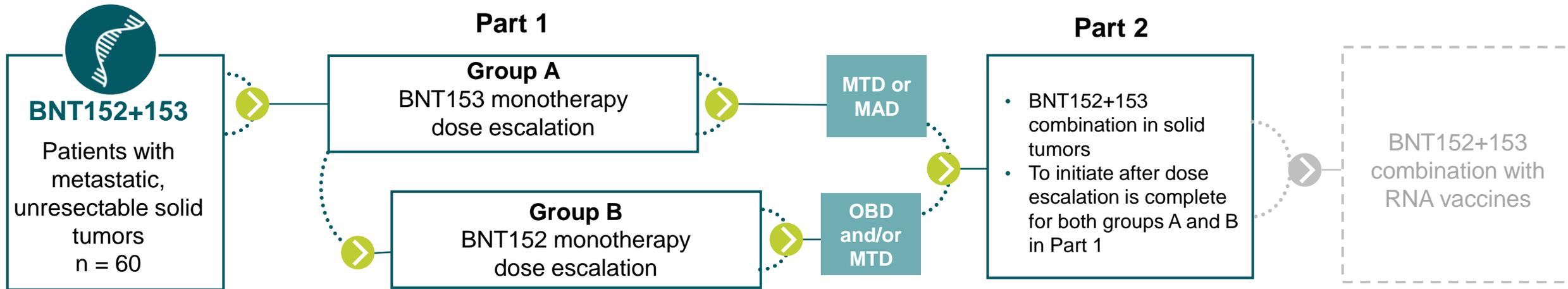
BNT151: Open-label, Multicenter Phase 1/2, First-in-human Trial



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

BNT152 + BNT153: Phase 1 Basket Trial in Patients with Solid Tumors

First-in-Human RiboCytokines Trial Evaluating mRNA-encoded IL-2 + IL-7 with Adaptive Trial Design Informs Dosing



Open-label, Phase 1 dose escalation study

Safety, PK, PD and anti-tumor activity of BNT152+153 in solid tumors

BNT152: IL-7
BNT153: IL-2

Primary Endpoints

- Occurrence of TEAEs
- Dose reduction or discontinuation due to TEAEs
- Occurrence of dose limiting toxicities

Secondary Endpoints

- ORR
- DCR
- DOR

The logo for Biontech, featuring the word "BIONTECH" in a bold, sans-serif font. The letters "B", "I", "O", "N", "T", "E", and "C" are in a light blue color, while the letters "H" and "H" are in a yellow color. The logo is positioned in the upper left quadrant of the page.

BIONTECH

An der Goldgrube 12
55131 Mainz
Germany

T: +49 6131 908-0

M: investors@biontech.de