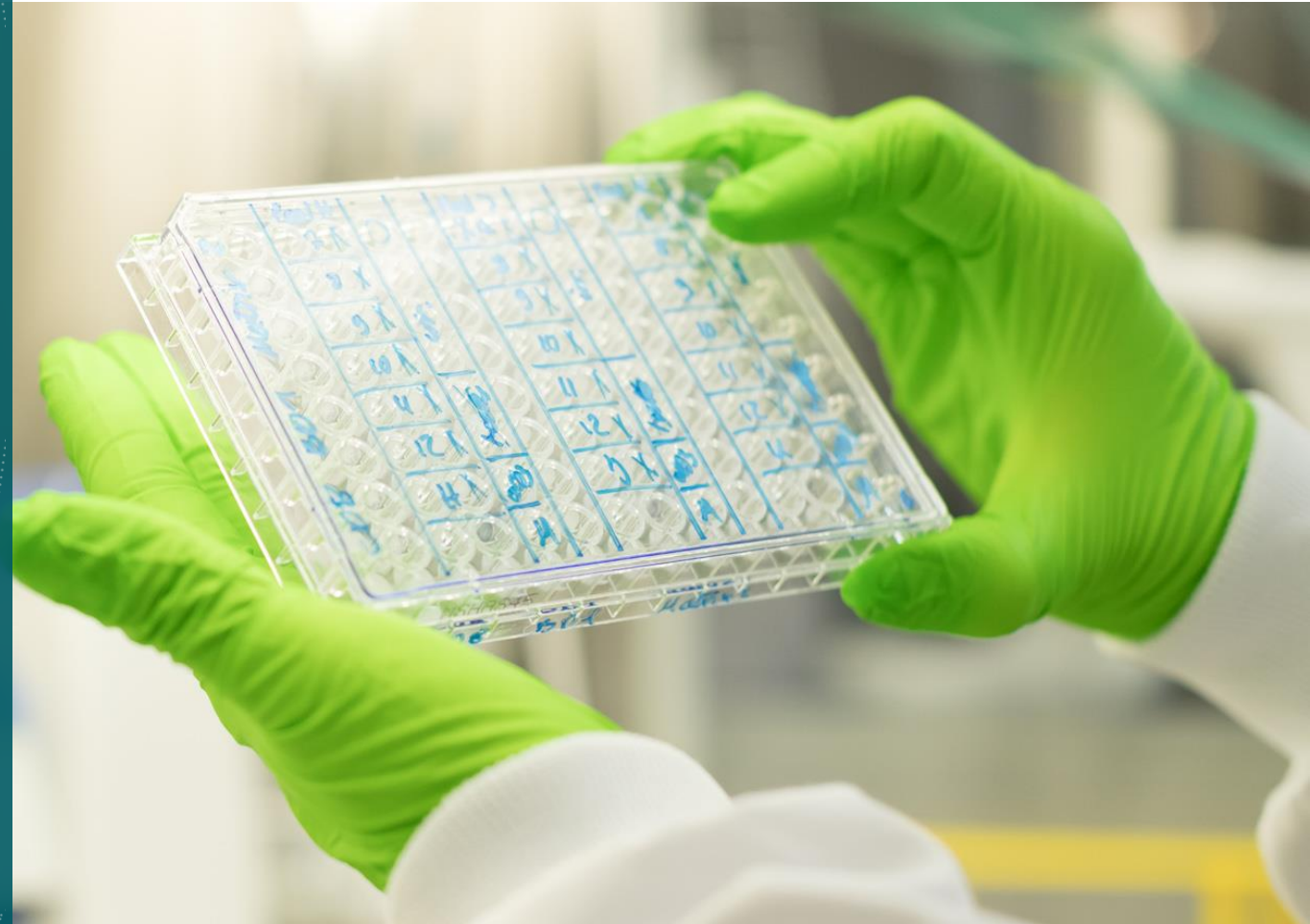


BIONTECH

Next Generation Immunotherapy

October 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, but not limited to, statements concerning: our expected revenues and net profit related to sales of our COVID-19 vaccine, referred to as COMIRNATY® in the United States and European Union as approved or authorized for use under conditional marketing approval, in territories controlled by our collaboration partners, particularly for those figures that are derived from preliminary estimates provided by our partners; our pricing and coverage negotiations with governmental authorities, private health insurers and other third-party payors after our initial sales to national governments; the extent to which a COVID-19 vaccine continues to be necessary in the future; competition from other COVID-19 vaccines or related to our 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 our COVID-19 vaccine and our investigational medicines, if approved; the initiation, timing, progress, results, and cost of our research and development programs and our 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 our research and development programs; the timing of and our ability to obtain and maintain regulatory approval for our 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; our ability to identify research opportunities and discover and develop investigational medicines; the ability and willingness of our third-party collaborators to continue research and development activities relating to our development candidates and investigational medicines; the impact of the COVID-19 pandemic on our development programs, supply chain, collaborators and financial performance; unforeseen safety issues and claims for personal injury or death arising from the use of our COVID-19 vaccine and other products and product candidates developed or manufactured by us; BioNTech's Malaria, Tuberculosis and HIV programs; 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; our estimates of research and development revenues, commercial revenues, cost of sales, research and development expenses, sales and marketing expenses, general and administrative expenses, other operating income less expenses, finance income less expenses, income taxes, shares outstanding and basic and diluted profit for the period per share and our needs for or ability to obtain additional financing; our ability to identify, recruit and retain key personnel; our and our collaborators' ability to protect and enforce our intellectual property protection for our proprietary and collaborative product candidates, and the scope of such protection; the development of and projections relating to our competitors or our industry; our ability and that of our collaborators to commercialize and market our product candidates, if approved, including our COVID-19 vaccine; the amount of and our ability to use net operating losses and research and development credits to offset future taxable income; our ability to manage our development and expansion; regulatory developments in the United States and foreign countries; our ability to effectively scale our production capabilities and manufacture our products, including our target COVID-19 vaccine production levels, and our product candidates; our ability to implement, maintain and improve effective internal controls; our plans for expansion in southeast Asia and China, including our planned regional headquarters and manufacturing facility in Singapore as well as the joint venture with Fosun Pharma; and other factors not known to us 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 this 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

Indication & Authorized Use:

COMIRNATY® (COVID-19 vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech.

- It is approved as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older
- It is also authorized under Emergency Use Authorization (EUA) to be administered for emergency use to: prevent COVID-19 in individuals 12 through 15 years, and provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise

The Pfizer-BioNTech COVID-19 vaccine has received EUA from FDA to:

- prevent COVID-19 in individuals 12 years of age and older, and
- provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise

The FDA-approved COMIRNATY® (COVID-19 vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series. An individual may be offered either COMIRNATY® (COVID-19 vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2.

Important Safety Information

- Individuals should not get the Pfizer-BioNTech COVID-19 vaccine if they: had a severe allergic reaction after a previous dose of this vaccine, had a severe allergic reaction to any ingredient of this vaccine
- Individuals should tell the vaccination provider about all of their medical conditions, including if they: have any allergies, have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart), have a fever, have a bleeding disorder or are on a blood thinner, are immunocompromised or are on a medicine that affects the immune system, are pregnant, plan to become pregnant, or are breastfeeding, have received another COVID-19 vaccine, have ever fainted in association with an injection
- The vaccine may not protect everyone.
- Side effects reported with the vaccine include:
 - There is a remote chance that the vaccine could cause a severe allergic reaction
 - A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the vaccine. For this reason, vaccination providers may ask individuals to stay at the place where they received the vaccine for monitoring after vaccination
 - Signs of a severe allergic reaction can include difficulty breathing, swelling of the face and throat, a fast heartbeat, a bad rash all over the body, dizziness, and weakness
 - If an individual experiences a severe allergic reaction, they should call 9-1-1 or go to the nearest hospital
 - Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of the vaccine. The chance of having this occur is very low. Individuals should seek medical attention right away if they have any of the following symptoms after receiving the vaccine: chest pain, shortness of breath, feelings of having a fast-beating, fluttering, or pounding heart
 - Side effects that have been reported with the vaccine include: severe allergic reactions; non-severe allergic reactions such as rash, itching, hives, or swelling of the face; myocarditis (inflammation of the heart muscle); pericarditis (inflammation of the lining outside the heart); injection site pain; tiredness; headache; muscle pain; chills; joint pain; fever; injection site swelling; injection site redness; nausea; feeling unwell; swollen lymph nodes (lymphadenopathy); diarrhea; vomiting; arm pain
- These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The vaccine is still being studied in clinical trials. Call the vaccination provider or healthcare provider about bothersome side effects or side effects that do not go away
- There is no information on the use of the vaccine with other vaccines.

Patients should always ask their healthcare providers for medical advice about adverse events. Individuals are encouraged to report negative side effects of vaccines to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Visit <http://www.vaers.hhs.gov> or call 1-800-822-7967. In addition, side effects can be reported to Pfizer Inc. at www.pfizersafetyreporting.com or by calling 1-800-438-1985.

Safety Information

COMIRNATY® ▼ (the Pfizer-BioNTech COVID-19 vaccine) has been granted conditional marketing authorisation by the by the European Commission to prevent coronavirus disease 2019 (COVID-19) in people from 12 years of age. The European Medicines Agency's (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.

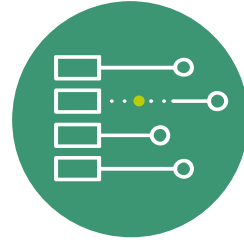
Important safety information

- 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. Available data suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis or pericarditis in general.
- 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. Stress-related reactions are temporary and resolve on their own. Individuals should be advised to bring symptoms to the attention of the vaccination provider for evaluation. It is important that precautions are in place to avoid injury from fainting.
- 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.
- 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.
- In clinical studies, adverse reactions in participants 16 years of age and older were injection site pain (> 80%), fatigue (> 60%), headache (> 50%), myalgia and 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.
- 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 clinical trial participants 12 to 15 years of age 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 fetus.
- 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.
- For complete information on the safety of COMIRNATY® always make reference to the approved Summary of Product Characteristics and Package Leaflet available in all the languages of the European Union on the EMA website.

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

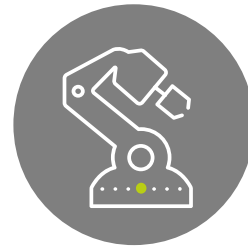
Harnessing the full
potential of the
immune system



**Building a fully integrated
biopharmaceutical company**



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

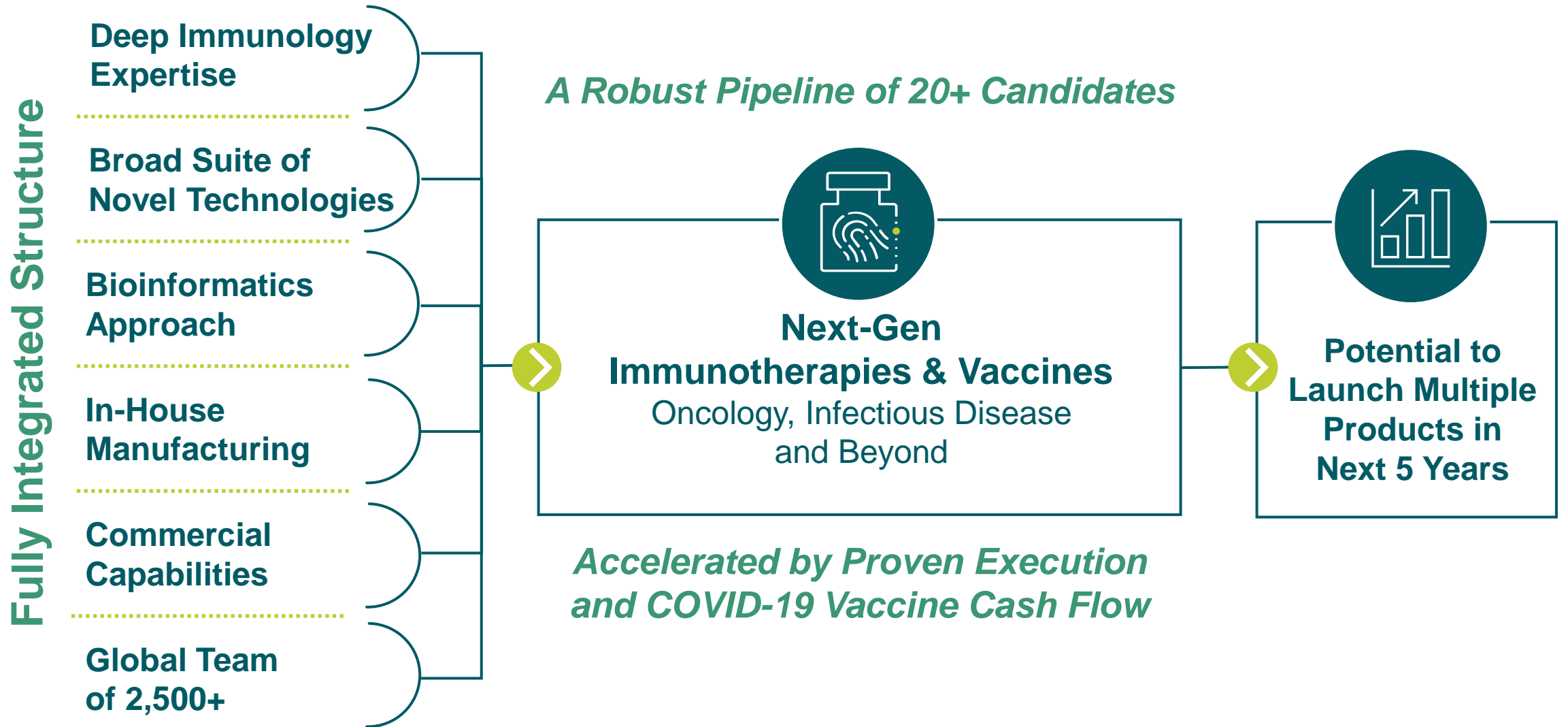


**Broad suite of novel
technologies**

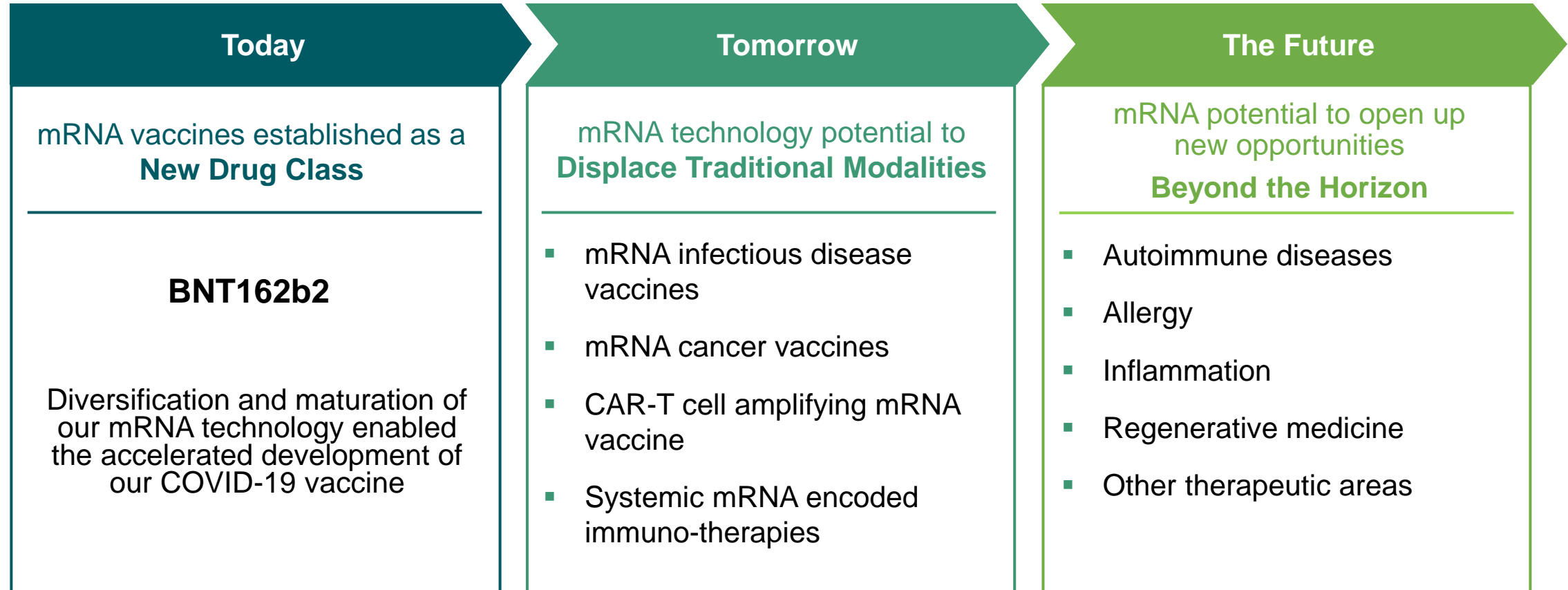


**Industry-leading global
collaborations**

Transformed Into a Fully Integrated, Global Immunotherapy Company



mRNA Technology Poised to Revolutionize Immunotherapy



uRNA

modRNA

saRNA

taRNA

**Broad IP portfolio covering technologies, targets and formulations.
Deep expertise and know-how built over the course of more than a decade.**

Infectious Diseases: A Long-term Growth Pillar

mRNA vaccines to combat major global health burden

Malaria¹:

- Development of first mRNA-based Malaria vaccine recently started
- Implementation of sustainable end-to-end vaccine supply solutions in Africa planned

HIV and tuberculosis²:

- Preclinical development of multiple product candidates ongoing

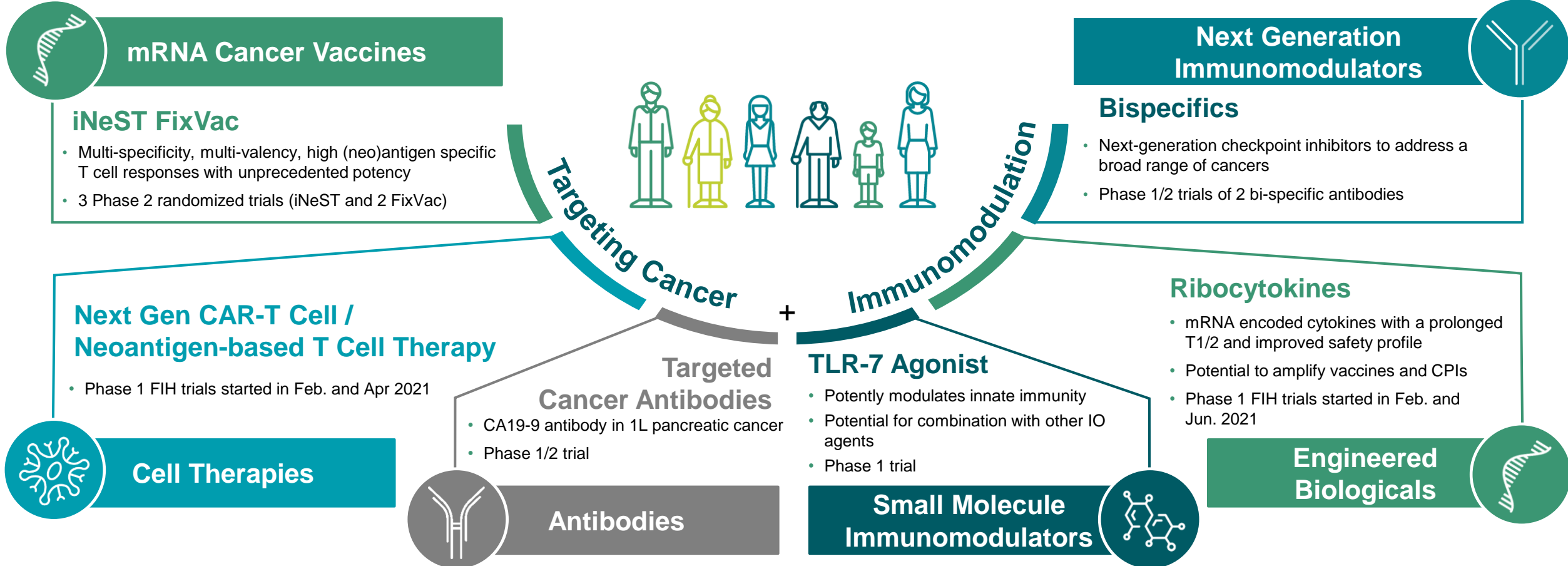
Opportunity to impact infectious diseases with high unmet need

- Up to 10 mRNA vaccine candidates in preclinical development³

BNT161 influenza vaccine candidate designed to improve traditional vaccines

- First patient dosed in Phase 1 trial
- Eligible for milestone payments and royalties through Pfizer agreement

Potential to Tackle Multiple Diseases with Different Therapeutic Modalities



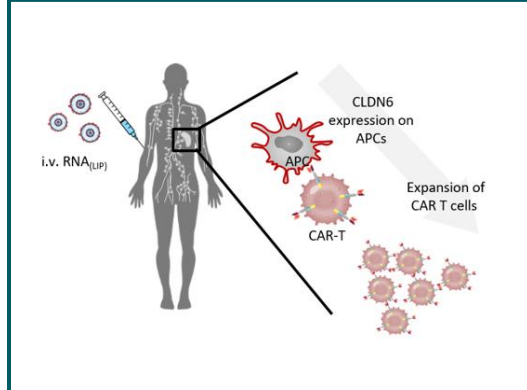
Oncology: Multiple product opportunities with unique combination potential in clinical testing

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"> • mRNA Neoantigen Immunotherapy (iNeST) |
| Low mutational burden cancers | >60% of cancers | Poor response to checkpoint inhibitors | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • Antibodies • CAR-Ts |
| Refractory tumors | Patients with large tumors and multiple resistance mechanisms | Few treatment options | <ul style="list-style-type: none"> • Cell Therapies • Combination Therapies |

Next Wave Oncology Advancing Innovation Beyond Current Boundaries

CARVac CAR-T cell amplifying mRNA therapy for solid tumors¹

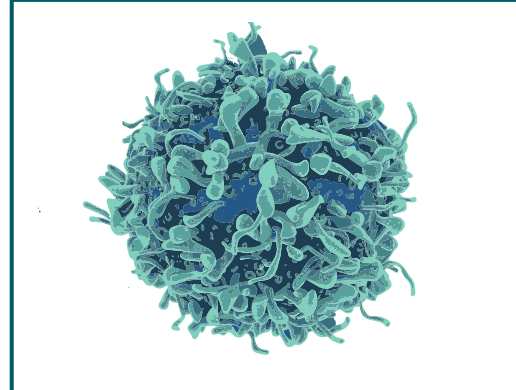


- **BNT211 (CLDN 6 CAR)**
Next generation CAR-T
targeting CLDN6 with
CARVac

Wholly owned:

FIH start: **FPD Feb. 2021**

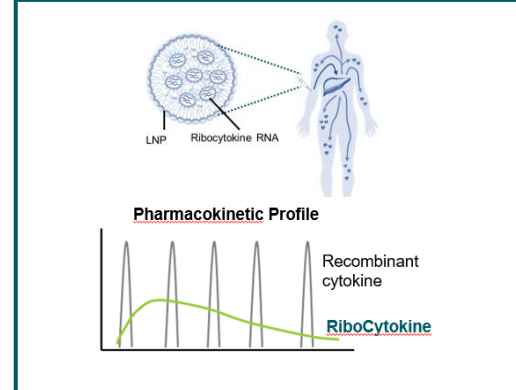
NEOSTIM T cell therapy Individualized Neoantigen specific T cell therapy



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

FPD Apr. 2021

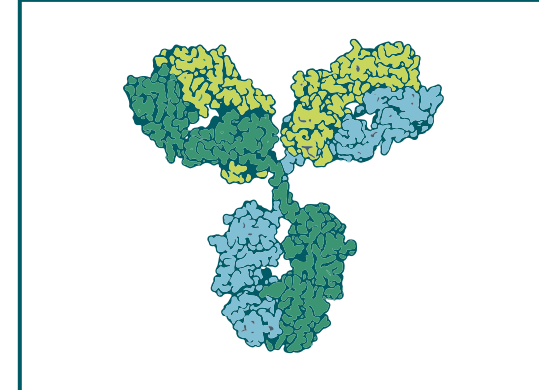
RiboCytokines mRNA encoded Cytokines



- **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)

2H 2021

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

On Track to Achieve Multiple Significant Data & Clinical Milestones in 2H 2021

Eight Clinical Trial Initiations in 2021, Including Three Randomized Phase 2



5+ Trial Updates

- ✓ **BNT162b2:** Multiple updates
- **BNT311:** Bi-specific CPI: PD-L1 x 4-1BB in solid tumors
- **BNT312:** Bi-specific CPI: 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 CPI-R/R melanoma
- ✓ **BNT113:** FixVac HPV16+ + CPI in 1L HNSCC
- ✓ **BNT122:** iNeST (autogene cevumeran) in adjuvant mCRC



7 First-in-human Phase 1 Trial Starts

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

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

- 15 product candidates in oncology in 18 ongoing clinical trials
- 3 potentially registrational phase 2 trials initiating in 2021
- Advance innovations into first-in-human studies
- Strategic in-licensing to complement internal R&D

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: 15 Product Candidates in 19 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 | |
| | | 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, IL-15sushi, GM-CSF, 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, IL-2</i>) | | | | | fully-owned | |
| Antibodies | Next-Gen CP ² Immunomodulators | GEN1046 (BNT311) | solid tumors (<i>PD-L1×4-1BB</i>) | | | | | Genmab (global 50:50 profit/loss) | Data update in 2H 2021 |
| | | GEN1042 (BNT312) | solid tumors (<i>CD40×4-1BB</i>) | | | | | | Data update in 2H 2021 |
| | 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 | Data update in 2H 2021 |
| Cell Therapies | CAR-T Cells | BNT211 | solid tumors (<i>CLDN6</i>) | | | | | fully-owned | Data update in 2H 2021 |
| | Neoantigen-based T cell therapy | BNT221 (NEO-PTC-01) | solid tumors | | | | | fully-owned | |

16 ¹BNT113 and BNT115 are currently being studied in investigator-initiated Phase 1 trials.
²Checkpoint Inhibitor.

³Small Molecule Immunomodulators.
⁴FPD = First Patient Dosed

Early-stage Oncology Pipeline: 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 2H 2021 |
| | | BNT142 | solid tumors (<i>CD3+CLDN6</i>) | fully-owned | Phase 1 start in 2H 2021 |
| 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

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Pipeline

Deeper dive on our key programs

COVID-19 vaccine program (project “Lightspeed”)

mRNA vaccines – FixVac and iNeST

Antibodies

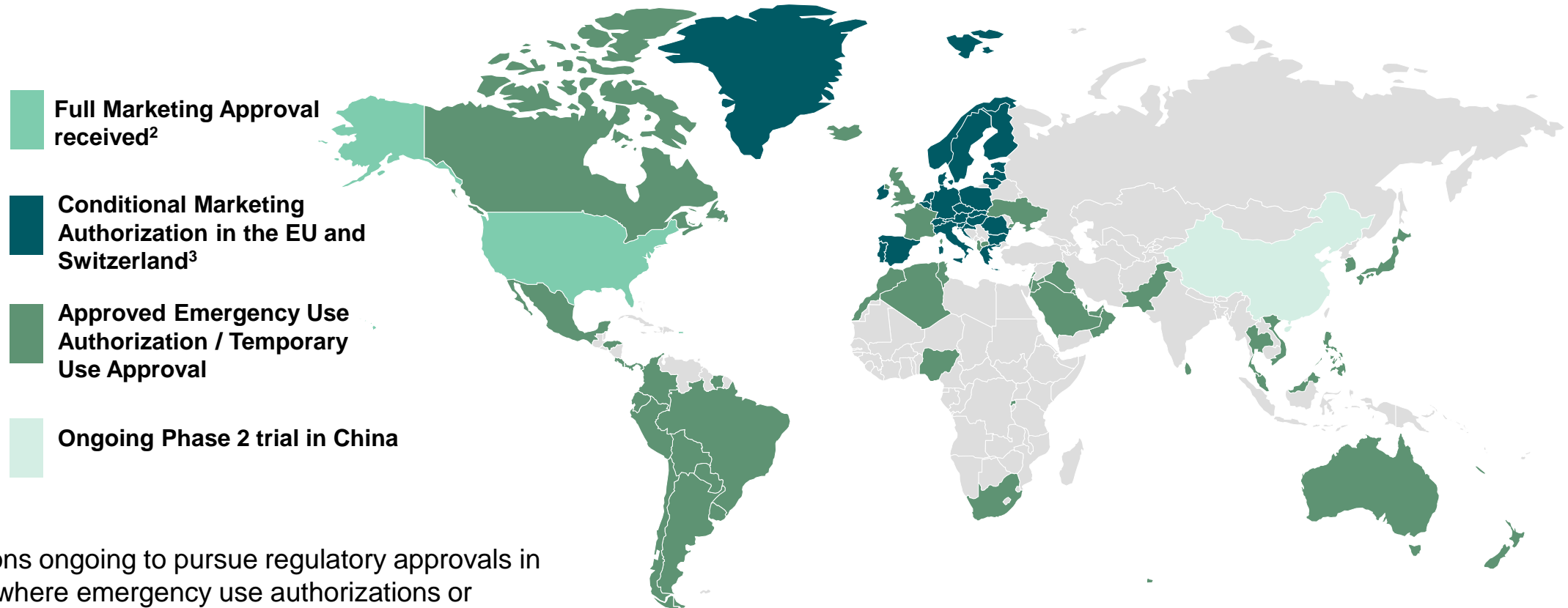
Cell Therapies – CARVac and NEO-STIM T cell therapy

Small Molecule Immunomodulators

RiboCytokines

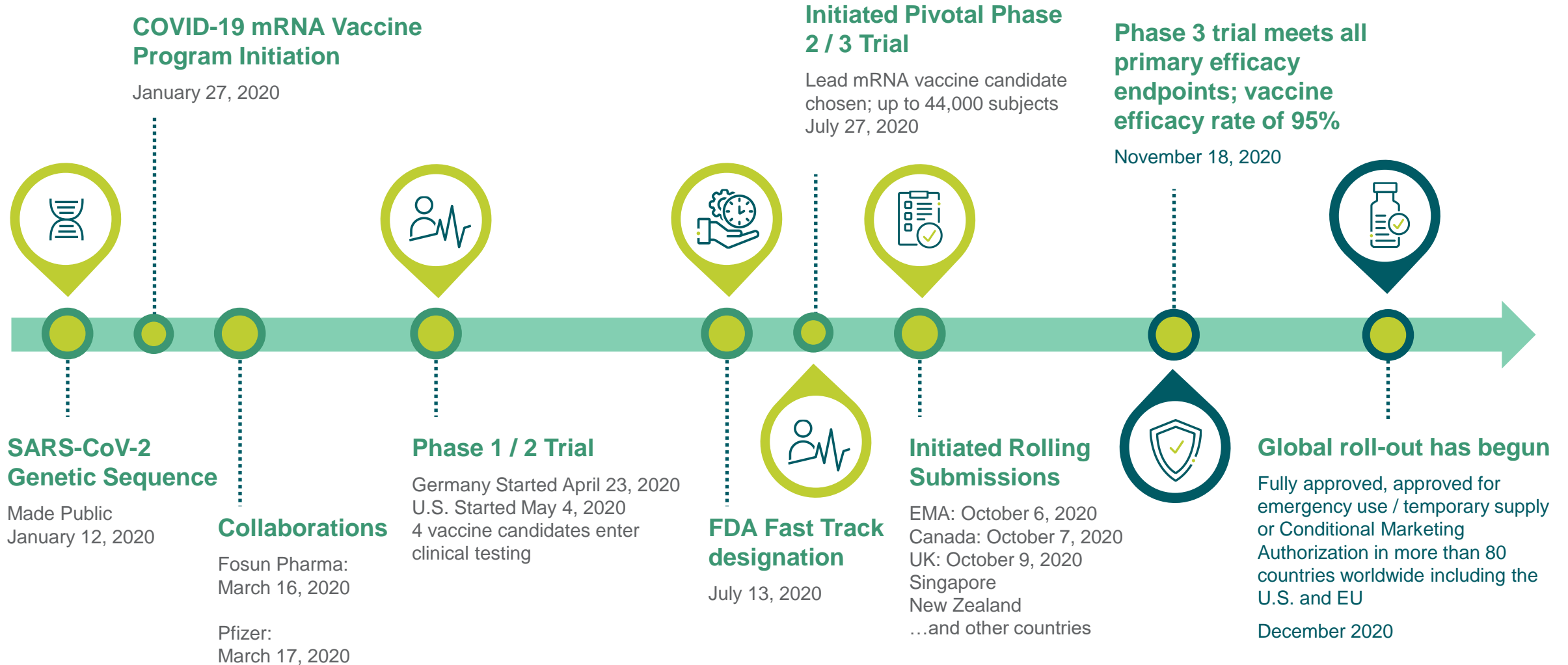
Shipped >1.5 Billion Doses to >130 Countries & Territories Worldwide¹

A concerted and large-scale global effort

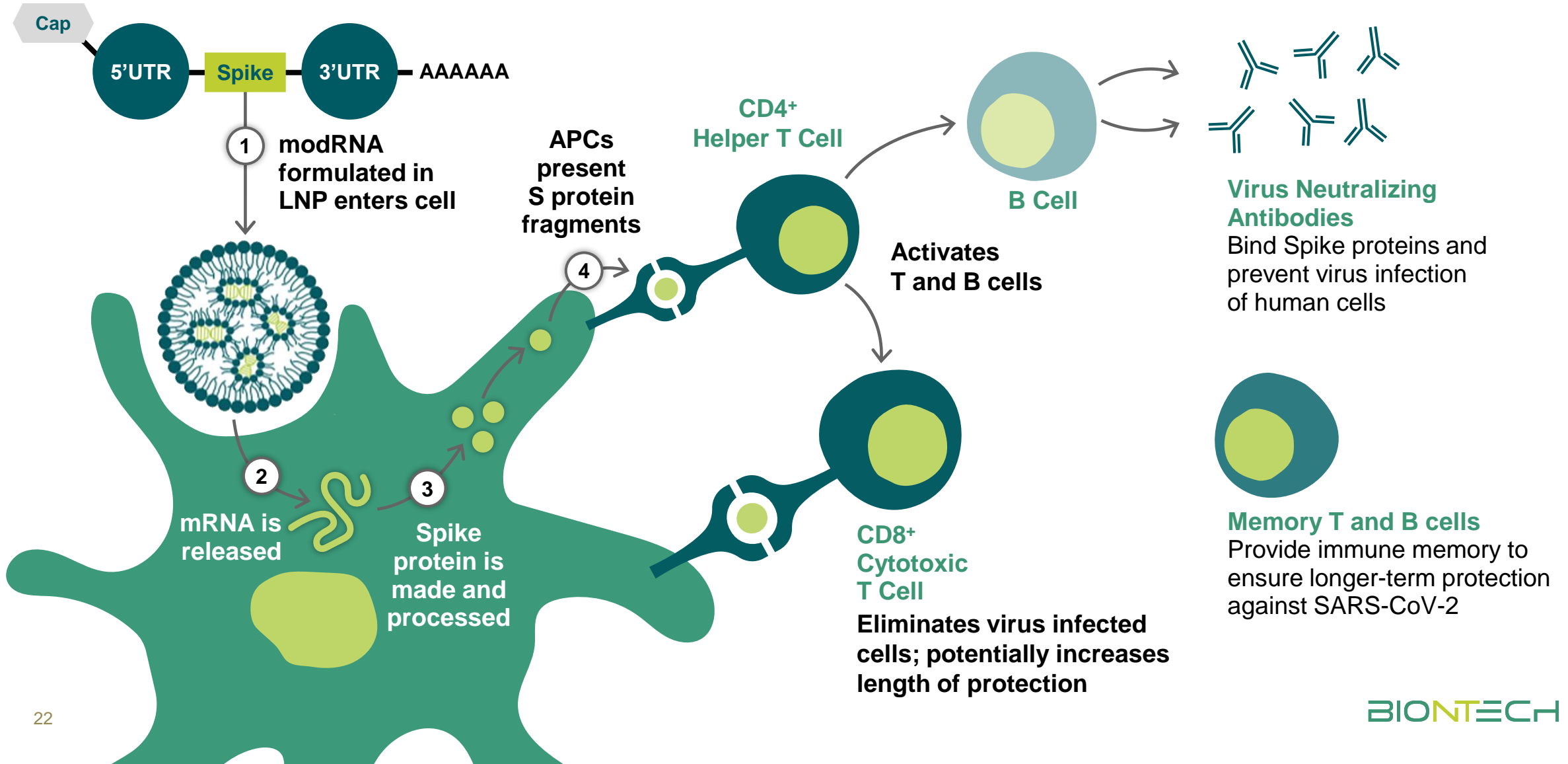


Submissions ongoing to pursue regulatory approvals in countries where emergency use authorizations or equivalents were initially granted are ongoing or planned.

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

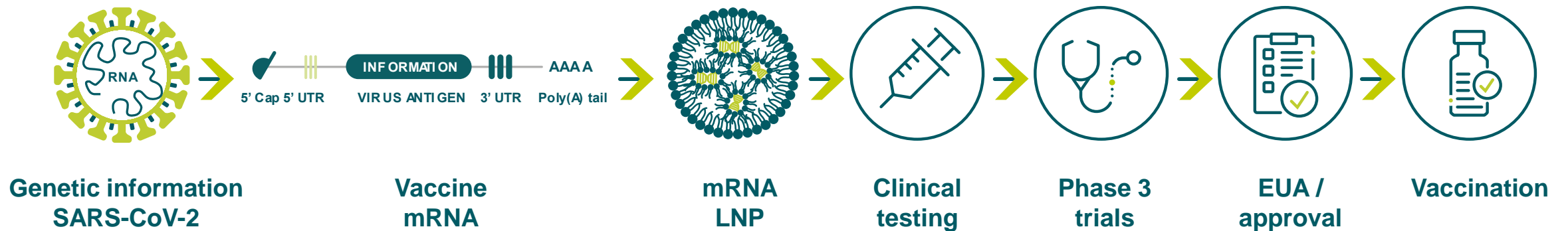
Natural molecule with well-characterized **bio-safety properties**

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



A Leading Provider Globally of COVID-19 Vaccines: ~2.2 Bn Doses Contracted for 2021*

| Selected Regions | 2021 Orders | 2022 and beyond |
|------------------|----------------|--|
| EU | 660 m | 900 m doses (plus option for additional 900 m) |
| U.S. | 410 m | 90 m |
| Other | ~1.150 m | Canada, Israel and others |
| TOTAL | ~2.2 bn | > 1 bn (excl. options) |

Ongoing discussions for additional doses in 2021/2022 and beyond

2 bn doses pledged over the next 18 months to ensure global equitable vaccine access

Targeting up to **3.0 bn doses** capacity in 2021 and up to **4.0 bn** in 2022*

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

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

Increased Manufacturing Capacity



- Continued efforts to establish multi-continent manufacturing capabilities to support global vaccine needs
- South Africa and Latin America collaborations to expand BNT/Pfizer manufacturing network

Label Expansion to Additional Populations



- Expansion of authorizations for adolescents 12 years of age and older in U.S., EU and other countries
- Submitted initial clinical data on children 5 to <12 years of age to FDA; EMA submission planned
- Ongoing trial in children 2 to 11 years and 6 months to 2 years of age: data expected Q4 2021
- Global Phase 2/3 trial in healthy pregnant women

Regulatory Advancement Across All Geographies



- First COVID-19 vaccine to receive full FDA approval¹
- Converting existing emergency use authorizations into regulatory approvals globally
- Regulatory submission for BLA in China underway

Optimize Formulations to Further Simplify Access Worldwide



- Storage at 2-8 °C for 31 days approved by multiple regulators, including EMA and FDA
- Phase 3 trial for ready-to-use and lyophilized formulations

Addressing Waning Immune Responses



- Booster dose granted EUA by FDA for 65+ years of age and certain high-risk groups 18 to 64 years of age
- Initial, preliminary booster data: ~6 months after dose 2 of BNT162b2 show overall consistent tolerability profile while eliciting SARS-CoV-2 neutralization titers against wild type, Beta and Delta variant
- Expanded trials for third booster dose of BNT162b2 and multiple variant-specific approaches in both vaccine-naive and previously vaccinated individuals 6-12 months post dose 2

Addressing SARS-CoV-2 Variants

Strong Clinical Results: Vaccine Efficacy Remains High up to 6 Months Following 2nd Dose^{1,2}



Clinical profile

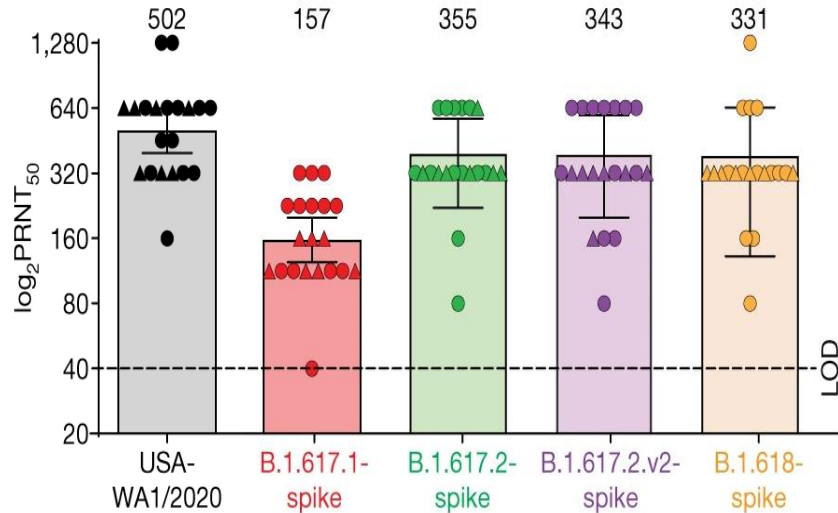
- 95% effective against symptomatic COVID-19¹
- Up to 6 months after dose 2²:
 - 91.2% effective against symptomatic disease
 - 95.7% effective against severe disease
- Well tolerated safety profile
- High titers of neutralizing antibodies
- Robust and poly-epitopic CD8+ and Th1 CD4+ T-cell responses³



Data Demonstrates Protection Against Circulating SARS-CoV-2 Variants Including Delta Variant

Neutralizing antibody titers

Reduced, yet preserved *in vitro* neutralizing activity of immune sera against several variants of concern, including: Alpha, Gamma, Beta, Eta, Delta^{1, 2, 3}



Poly-specific T cell responses

Vaccinated individuals generate a T cell response targeting epitopes conserved across a number of variants, including the Delta variant^{2,4}

| | 84 | 92 | 269 | 277 | 321 | 329 | 448 | 456 | 896 | 904 | 1000 | 1008 | 1208 | 1216 | 1211 | 1220 |
|-------------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|-----|-----|------|------|------|------|------|------|
| BNT162b2 | LPFNDGVYF | YLQPRTFLL | QPTESIVRF | NYNYLYRLF | IPFAMQMAY | RLQSLQTYV | QYIKWPWYI | KWPWYIWLGF | | | | | | | | |
| B.1.617.2 (Delta) | LPFNDGVYF | YLQPRTFLL | QPTESIVRF | NYNYRFRLF | IPFAMQMAY | RLQSLQTYV | QYIKWPWYI | KWPWYIWLGF | | | | | | | | |
| B.1.1.7 (Alpha) | LPFNDGVYF | YLQPRTFLL | QPTESIVRF | NYNYLYRLF | IPFAMQMAY | RLQSLQTYV | QYIKWPWYI | KWPWYIWLGF | | | | | | | | |
| B.1.351 (Beta) | LPFNDGVYF | YLQPRTFLL | QPTESIVRF | NYNYLYRLF | IPFAMQMAY | RLQSLQTYV | QYIKWPWYI | KWPWYIWLGF | | | | | | | | |
| P.1 (Gamma) | LPFNDGVYF | YLQPRTFLL | QPTESIVRF | NYNYLYRLF | IPFAMQMAY | RLQSLQTYV | QYIKWPWYI | KWPWYIWLGF | | | | | | | | |

Real world data

Observed effectiveness against variants of concern including Delta variant (95%CI)

| Real-World Study | Timepoint | Infection | Symptomatic | Hospitalization |
|--|---------------------------|------------|-------------|-----------------|
| Public Health England, NEJM July 2021 ⁵ ; preprint July 2021 ⁶ | ≥14d post 2d – up to 2-3m | 88 (78-93) | -- | 96 (86-99) |
| Public Health Ontario, Canada, preprint July 2021 ⁷ | ≥7d post 2d – up to 1-2m | -- | 87 (64-95) | 100 |
| Public Health Scotland, Lancet June 2021 ⁸ | ≥14d post 2d – up to 2-3m | 79 (75-82) | -- | -- |
| Israel, MoH ⁹ | ≥7d post 2d – up to 6m | 39 (9-59) | 41 (9-61) | 88 (79-93) |

1. Liu J et al Nature 2021 <https://www.nature.com/articles/s41586-021-03693-y>. 2. Xie X et al Nature Med <https://doi.org/10.1038/s41591-021-01270-4> 2021. 3. Liu J et al Nature Med 2021 <https://doi.org/10.1038/s41586-021-03693-y>. 4. Sahin U et al Nature 2021 <https://www.nature.com/articles/s41586-021-03653-6> 5. Bernal et al. NEJM 2021 <https://www.nejm.org/doi/pdf/10.1056/NEJMoa2108891?articleTools=true> 6. Stowe et al (preprint) available from https://media.tghn.org/articles/Effectiveness_of_COVID-19_vaccines_against_hospital_admission_with_the_Delta_B_G6gngqJ.pdf 7. Nasreen et al MedRxiv preprint 10.1101/2021.06.28.21259420 8. Sheikh et al. Lancet 2021 doi: 10.1016/s0140-6736(21)01358-1; 9. Press release Israel MoH https://www.gov.il/BlobFolder/reports/vaccine-efficacy-safety-follow-up-committee/he/files_publications_corona_two-dose-vaccination-data.pdf

BNT162b2 Booster Dose Results in a Broad, Robust Neutralisation Response

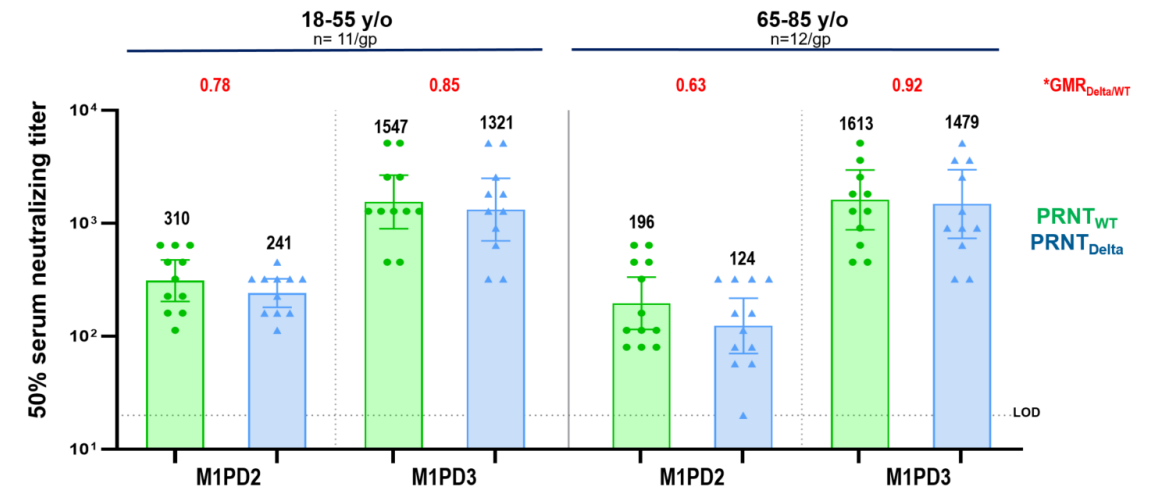
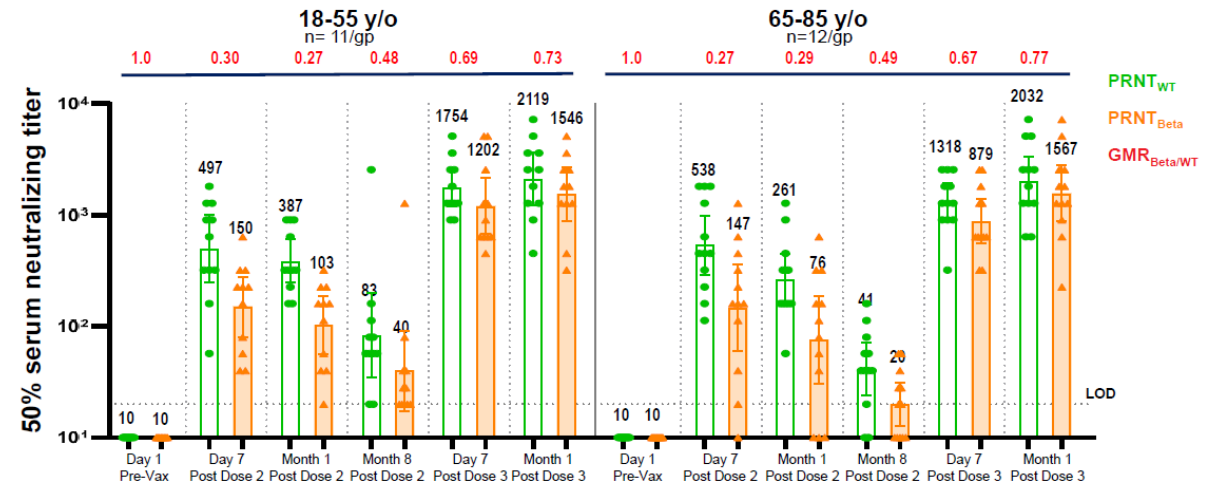
Booster dose could prolong protection and further increase breadth of protection against SARS-CoV-2 variants

- 3rd dose strongly boosts neutralizing titers both in younger and older adults against¹
 - Wild type > 5-8-fold
 - Delta variant > 5-11-fold
 - Beta variant > 15-21-fold

when comparing month 1 data after dose 2 or dose 3

- Wild type and Beta variant titers continue to increase comparing day 7/month 1 data after dose 2 versus dose 3
- Overall consistent tolerability profile

Data being prepared for submission to regulatory authorities globally.



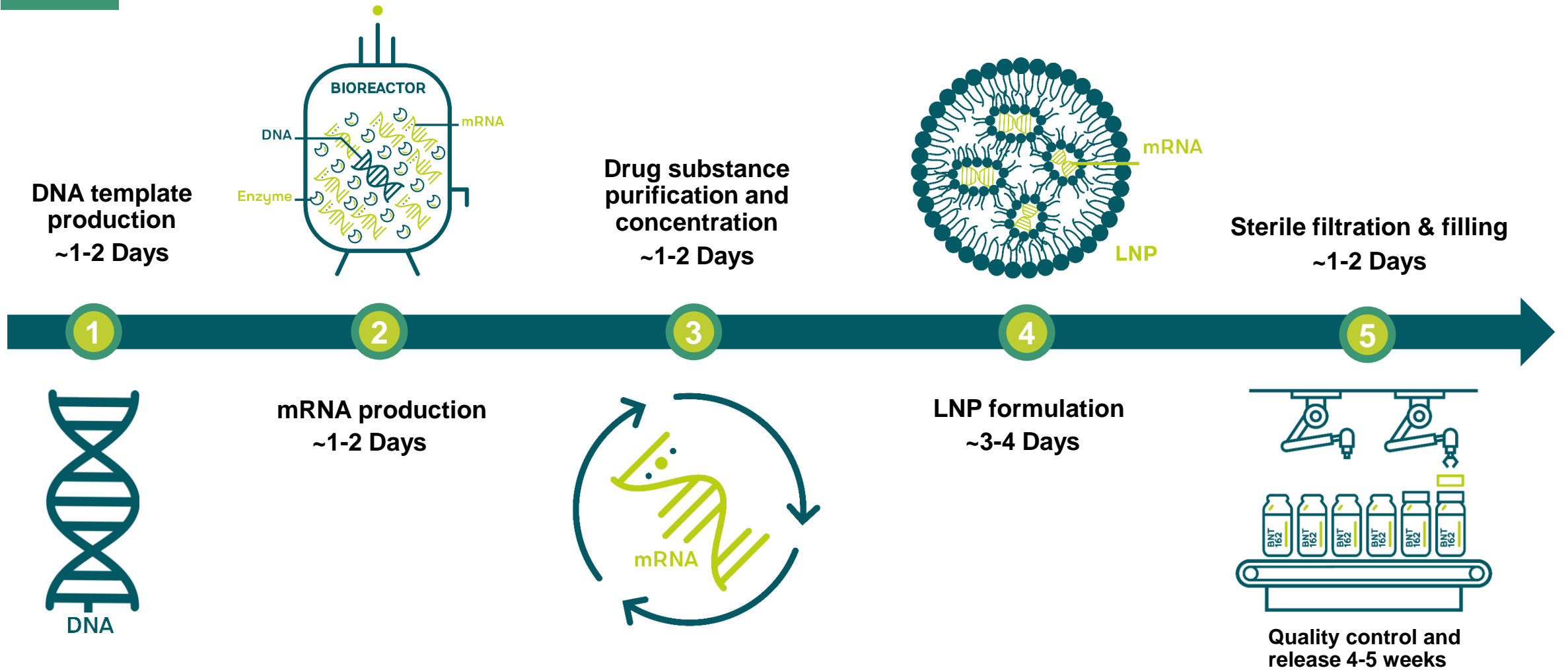
Preemptive Strategy to Address SARS-CoV-2 Variants

- Establishing development, manufacturing and regulatory pathway for variant-specific prototype approach

Prototype Approach substantiated by broad clinical data

| | 1 | 2 | 3 | 4 |
|----------------------------------|--|--|---|---|
| | BNT162b2: 3rd dose Safety & immunogenicity trial | BNT162b2: 3rd dose Safety & efficacy trial | Beta: 3 rd dose or naïve Safety & immunogenicity trial | Multivalent Delta + Alpha or Delta or Alpha: 3 rd dose or naïve: Safety & immunogenicity trial |
| Study Start | March 2021 | July 2021 | March 2021 | August 2021 |
| Nb of participants (trial phase) | <ul style="list-style-type: none"> N=23 (ph 1) N=~300 (ph 2/3) | <ul style="list-style-type: none"> N=~10,000 (ph 3) | <ul style="list-style-type: none"> N=~300 (ph 3) N=~300 (naïve) | <ul style="list-style-type: none"> N=~600 N=~300 (naïve) |
| Boosting post dose 2 | 6-12 months | 6 months | 5-7 months | >6 months |
| Data expected | First data published | Q4 2021 | Q3 2021 | Q4 2021 |

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

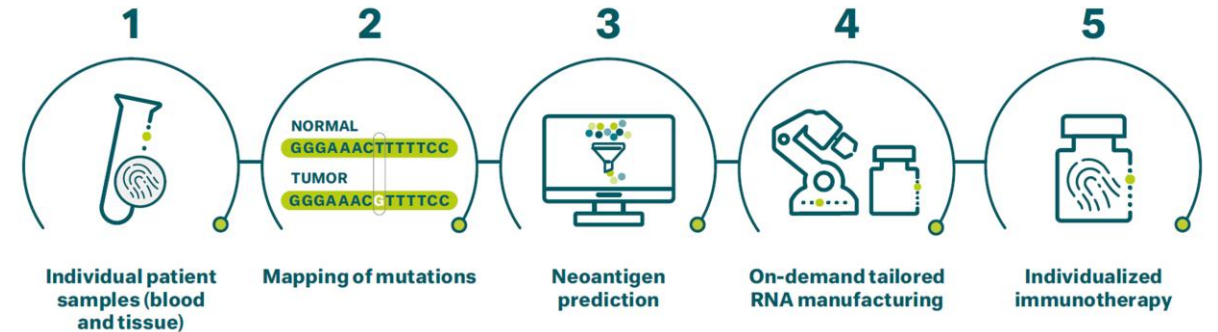
Our mRNA Vaccine Platforms: FixVac and iNeST

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

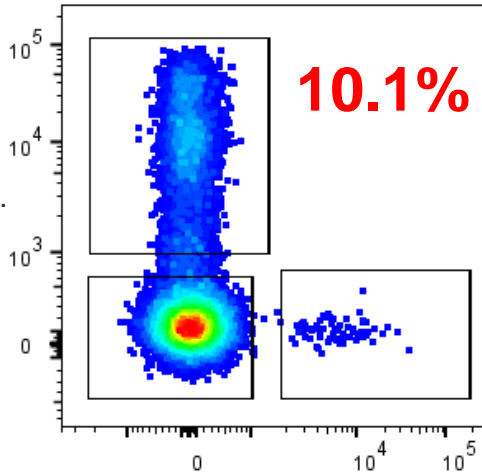
Proprietary RNA-LPX formulation for systemic dendritic cell targeting

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

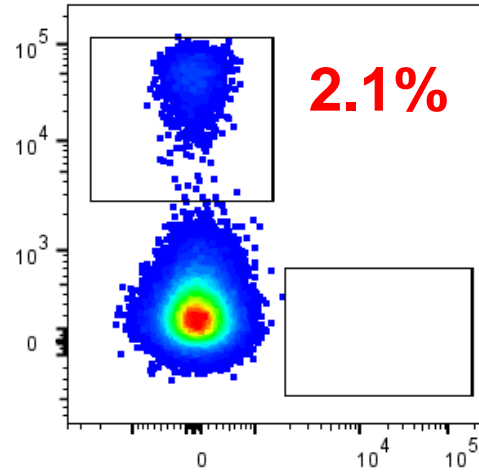
Potent induction of strong *ex vivo* CD4+ and CD8+ T cell responses

Our RNA-LPX Vaccine Approach

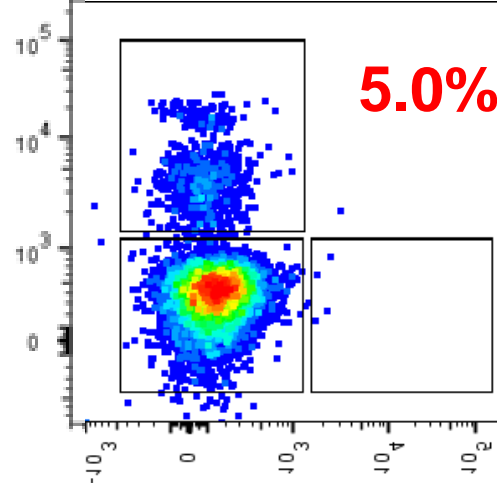
Strong vaccine-induced *ex vivo* CD8+ T cell responses¹ across different cancer types



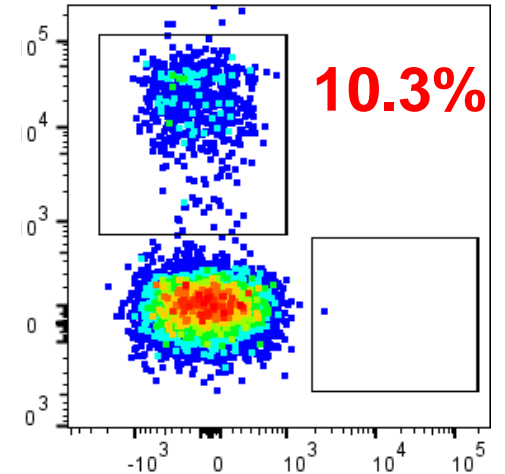
NY-ESO-1
Melanoma
BNT111, Lipo-MERIT trial



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 Antigens 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 | [Progress bars] | | |
| BNT112 | Prostate cancer | [Progress bars] | | |
| BNT113 | HPV16+ head and neck cancer | [Progress bars] | | |
| BNT116 | NSCLC | [Progress bars] | | |

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***

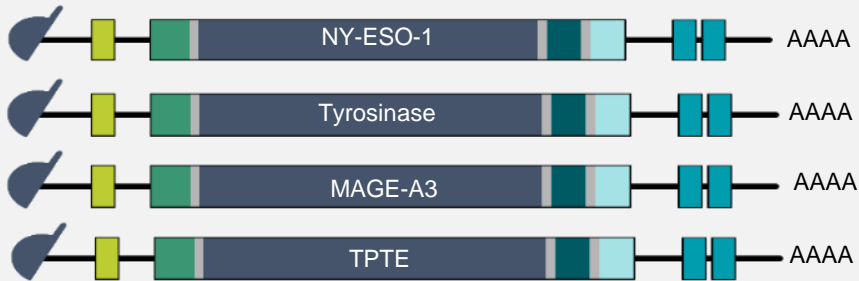
Regeneron strategic collaboration and ongoing Phase 2 trial

- 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

Incidence

↑ **50%**

Annual cases have increased by nearly 50% to over 287,000^{1,2}

Deaths

↑ **20%**

WHO predicts by 2025, number of deaths will increase by 20%³

CPI R/R patients

~ **55%**

patients refractory to or relapse on CPI treatment, leaving them with limited treatment options⁴

Significant Opportunity to Improve on Standard of Care

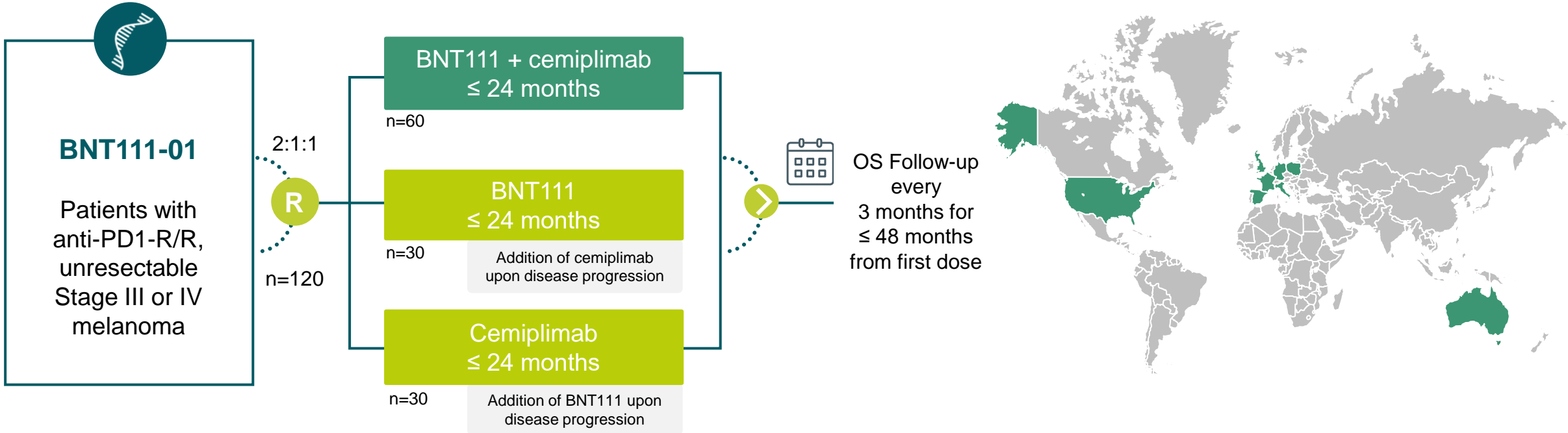
- 5-year survival for metastatic melanoma still only 29.8%⁵
- Frontline immunotherapy with CPI induces durable responses in max. 45-50% of patients but with relatively short PFS⁴
- CPI resistant/ refractory patients that fail to respond to CPI or relapse after CPI have an especially poor prognosis with 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';

38 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

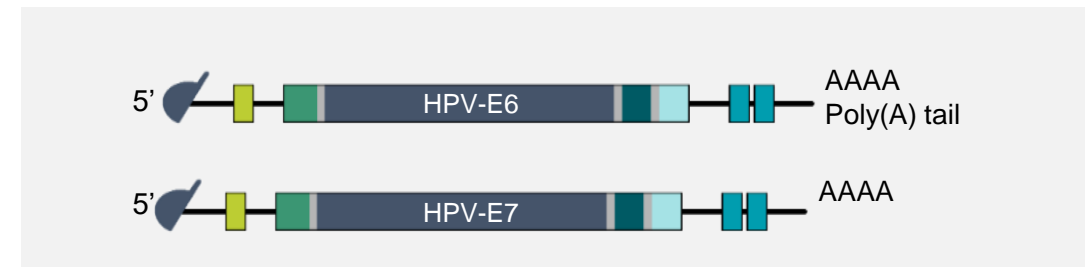
Secondary Endpoints

- 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}

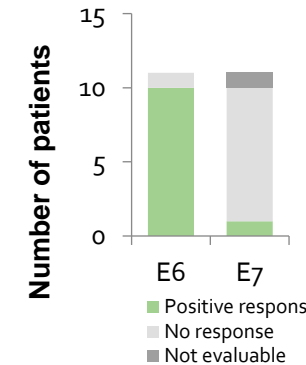
- CD4⁺ and CD8⁺ T cell responses
- Responses detectable ex vivo, implying high numbers of T cells
- Responses against multiple E6 or E7 epitopes

A

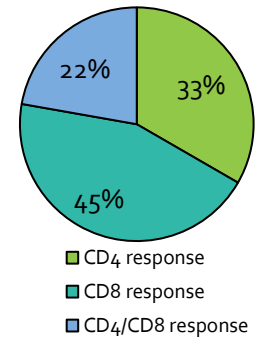
Overview of T cell responses Arm 1A

| 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

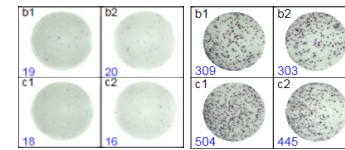


B

ELISPOTS³ Patient 7

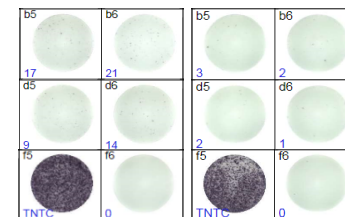
CD8 response to vaccine targets

Pre vaccination Post vaccination



Pepmix
E6

Pepmix
E7



PBMCs only

PBMCs only

Anti-CD3

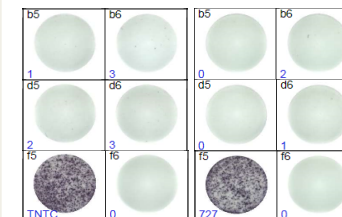
ELISPOTS³ Patient 6

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

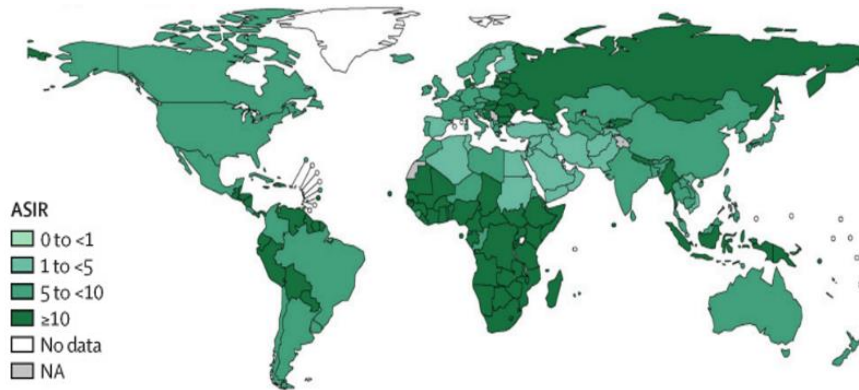
¹HARE-40 trial

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 |

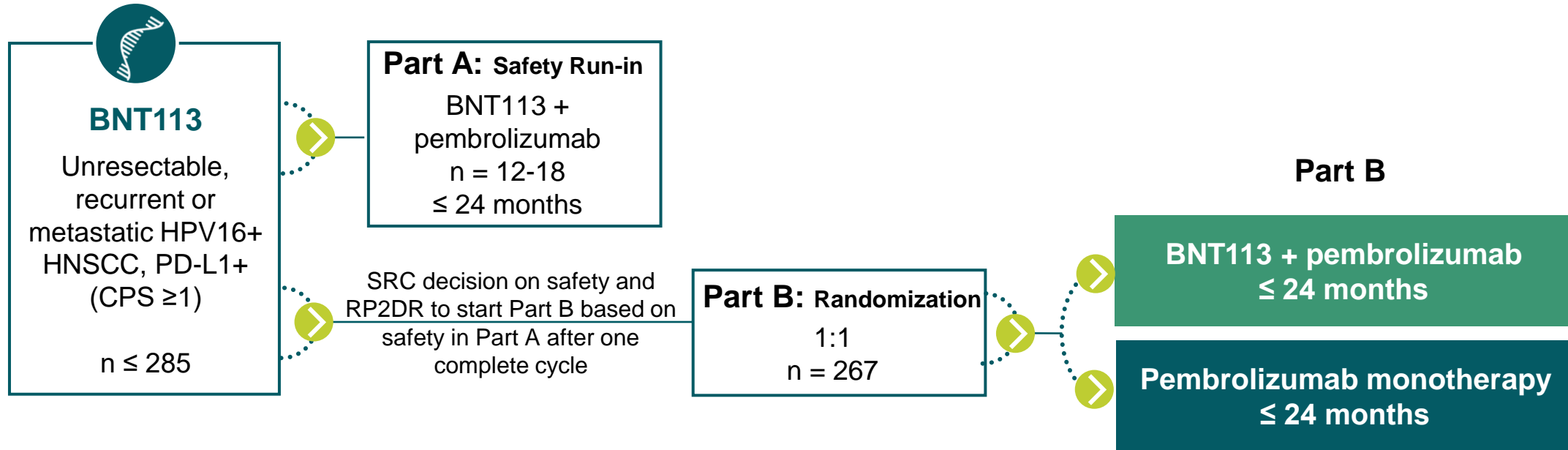
HPV, human papilloma virus; HNSCC, head and neck squamous cell carcinoma, CPI, check point inhibitor; R/R refractory/recurrent

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

42 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

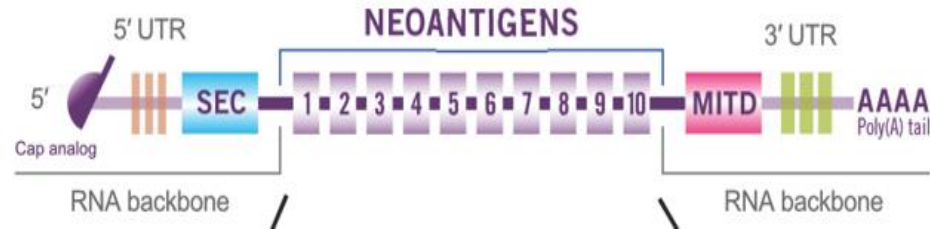
Secondary Endpoints

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

Success Measures for BNT113 Trial

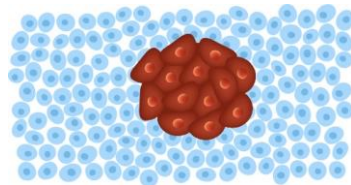
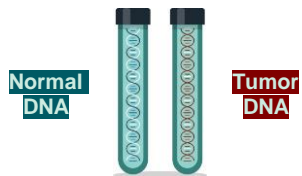
- mOS: 18 months (HR=0.667)
- ORR: 40%

iNeST¹: Tailored Treatment to Exploit Individual Targets



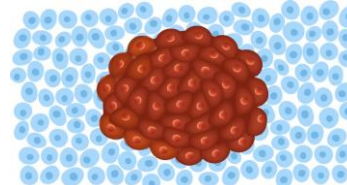
- Fully customized to the individual Patient
- Targeting 20 neo-antigens per patient

ADJUVANT



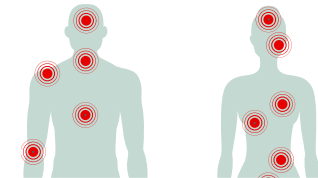
Residual cancer cells may remain – emphasis on recurrence free survival

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**

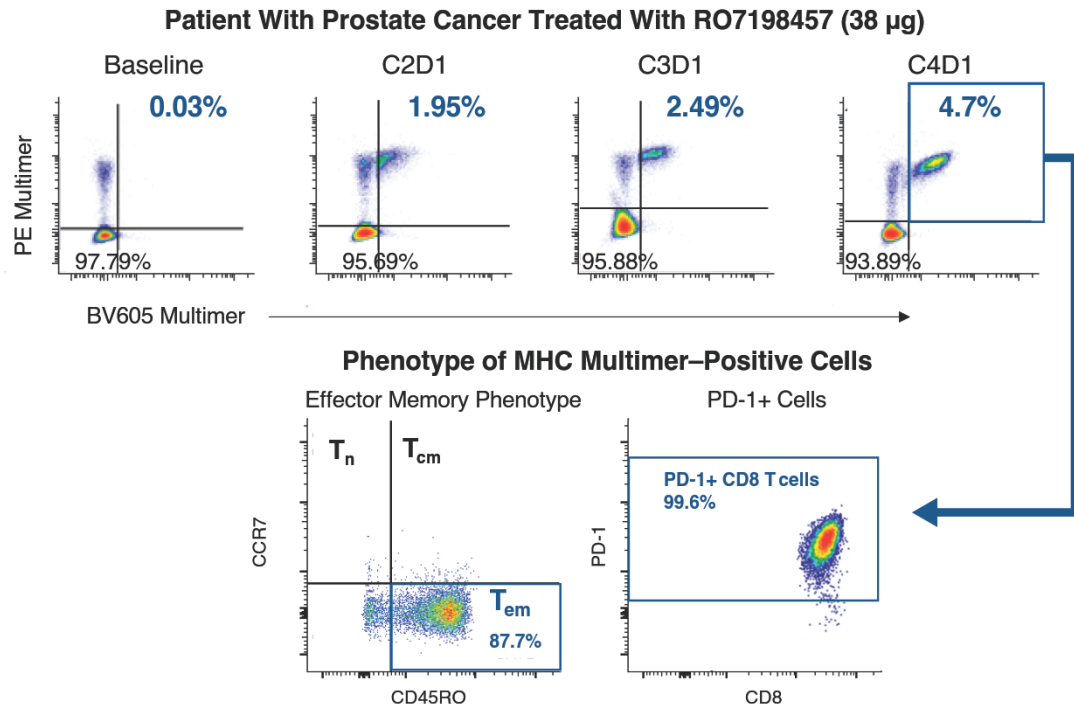
Phase 1b combination with atezolizumab demonstrated clinical activity in heavily pre-treated patients

- **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%)

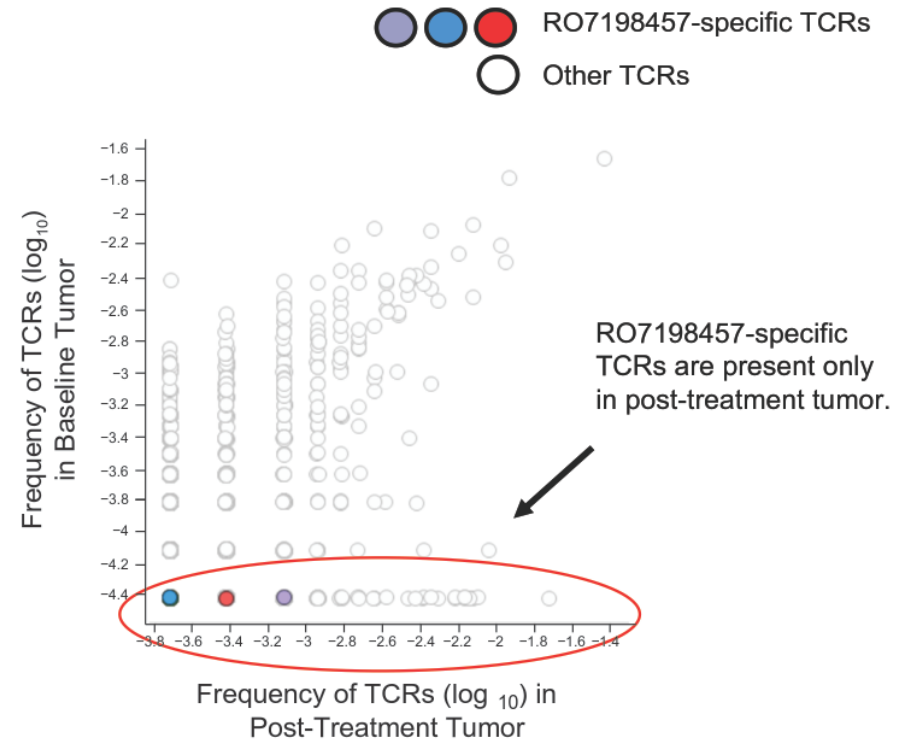
- **Demonstrates ability to elicit significant T cell responses of both effector and memory phenotype as monotherapy and in combination**
- **Treatment-related adverse events were primarily transient systemic reactions, manifesting as low grade CRS, IRR or flu-like symptoms**
- **Early evidence of clinical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



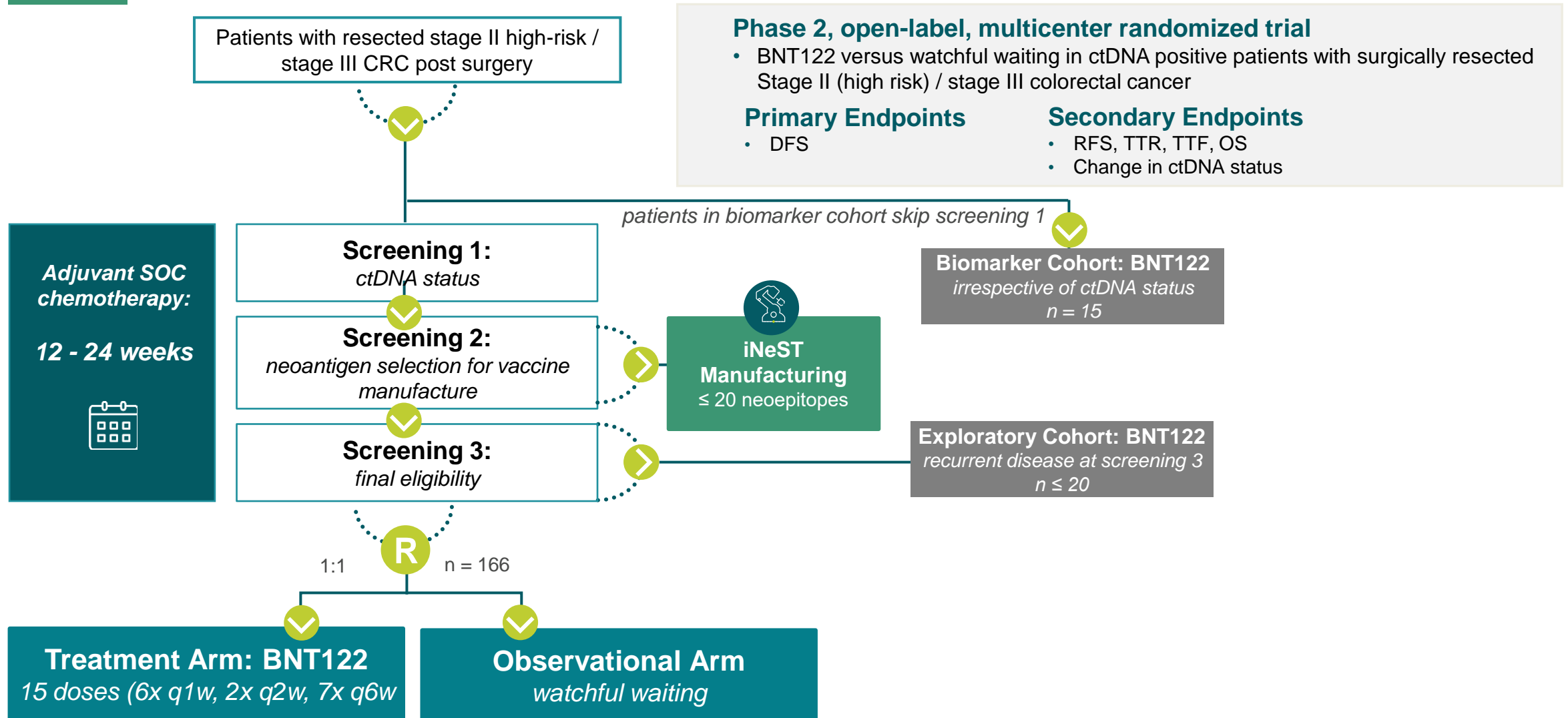
BNT122 induces CD8+ T cell infiltrates in tumors



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



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

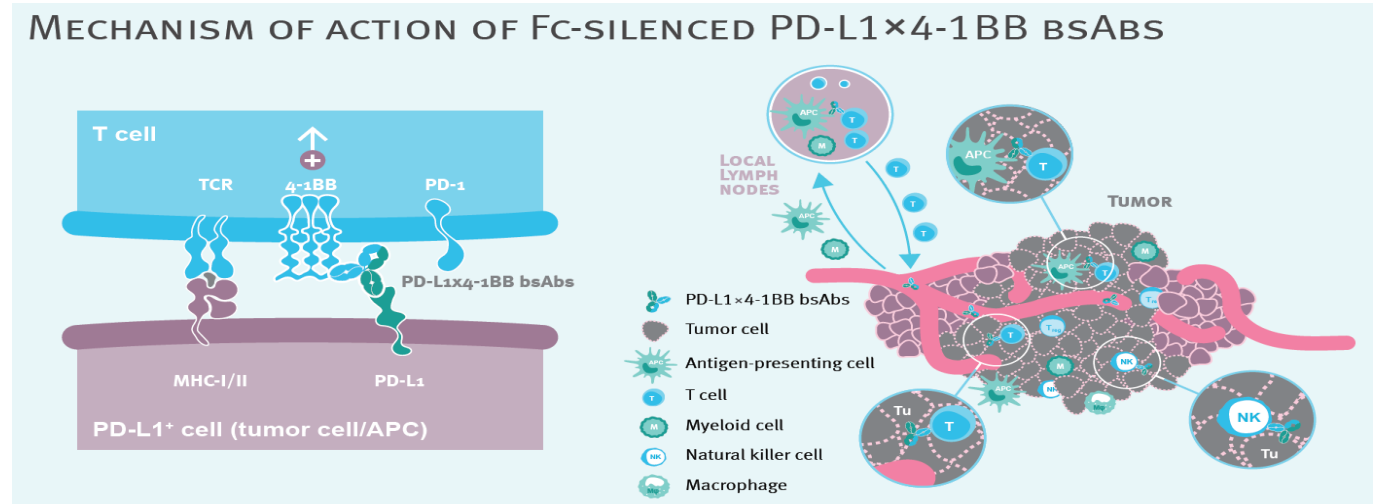
Cell Therapies – CARVac and NEO-STIM T cell therapy

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**

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



100 mg
RP2D

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

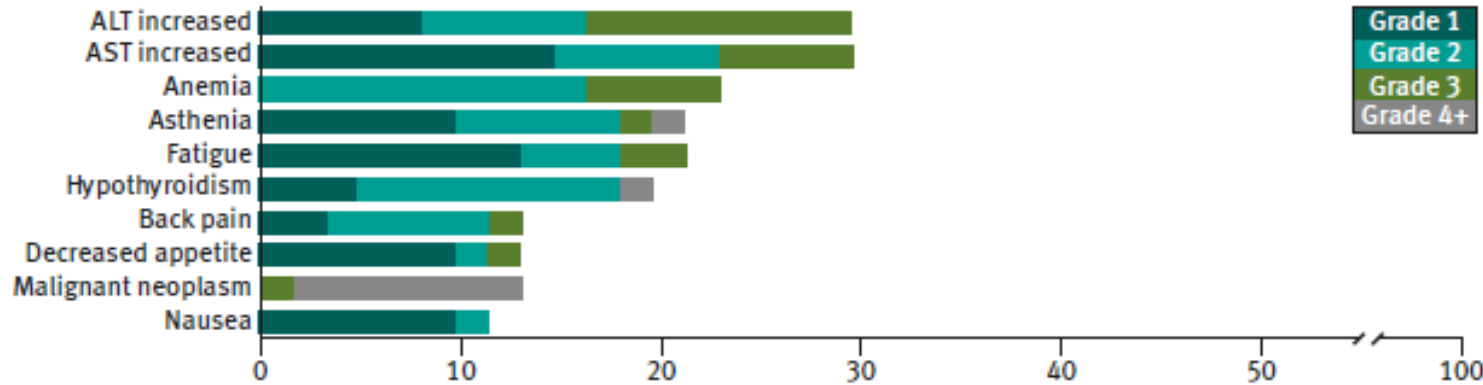
- Clinical benefit **across different dose levels and solid tumor types**
- Disease control in **65.6% of patients**
- **4 partial responses:**
 - TNBC (1), ovarian cancer (1), CPI* pre-treated NSCLC (2)
- Modulation of **circulating CD8+ T cells** and serum levels of interferon gamma and IP10 observed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



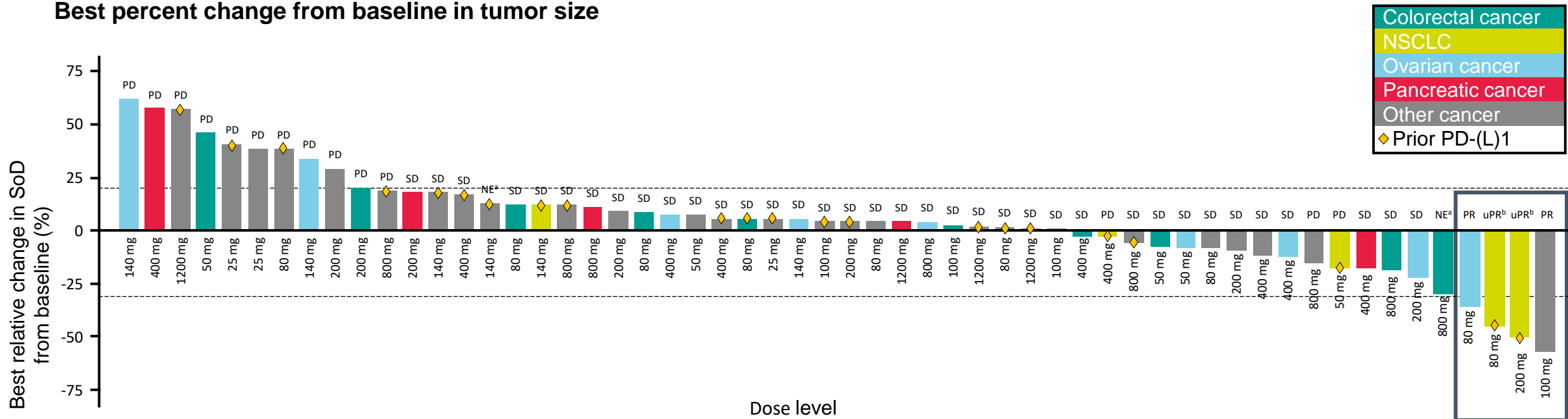
- The most common treatment-related adverse events were transaminase elevations, hypothyroidism and fatigue
- Treatment-related transaminase elevations occurred in 26.2% of patients (9.8% of patients had grade 3 transaminase elevations)
- There were no patients with Grade 4 transaminase, or treatment-related 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

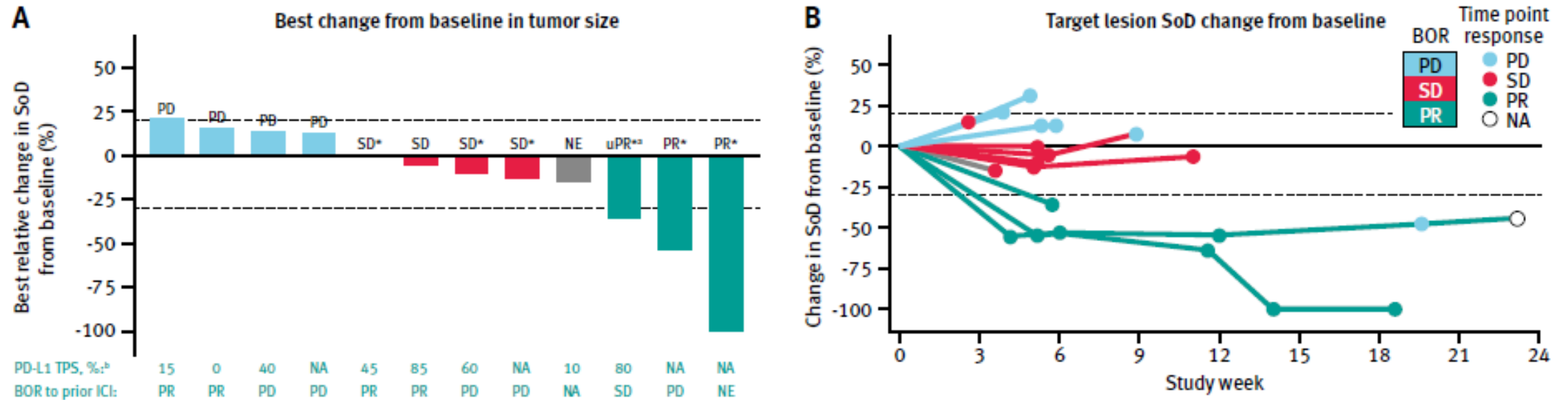
Data cut-off: September 29, 2020. Post-baseline scans were not conducted for five patients.

^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

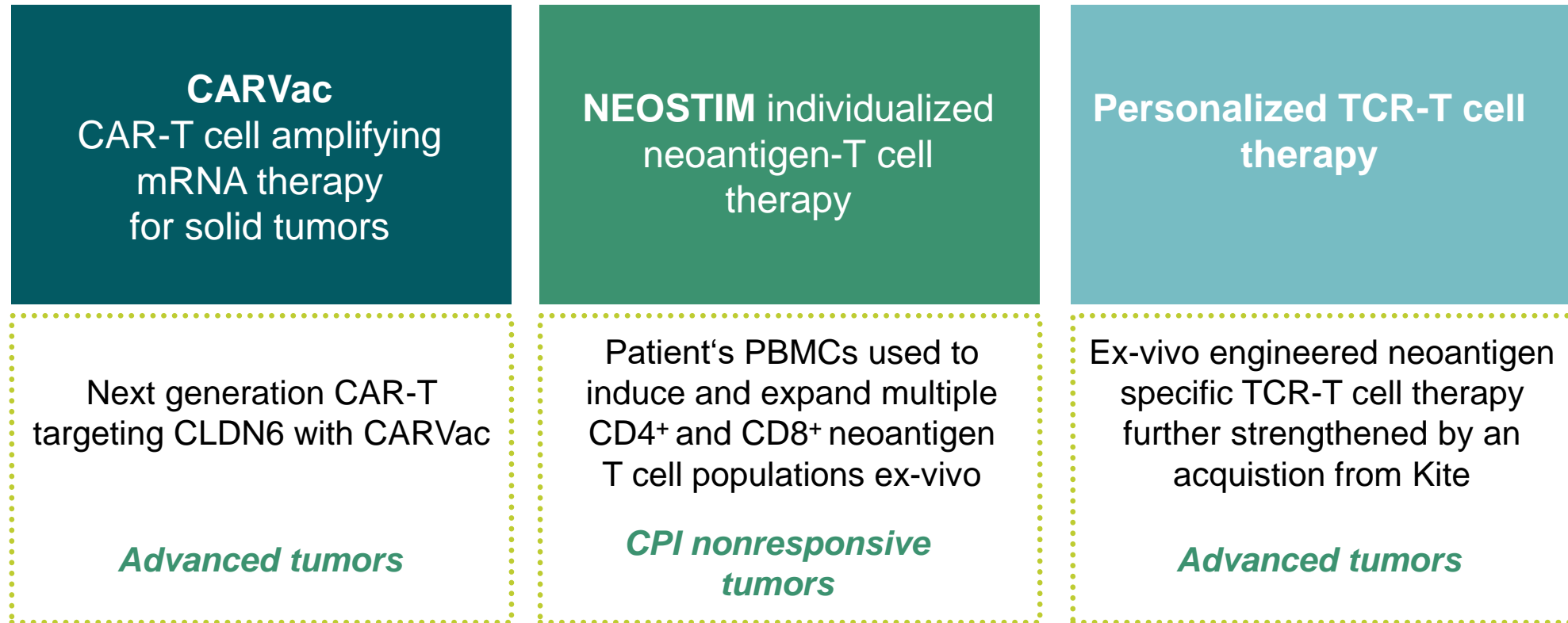
Cell Therapies – CARVac and NEO-STIM T cell therapy

Small Molecule Immunomodulators

RiboCytokines

Proprietary Cell Therapy Pipeline and Capabilities

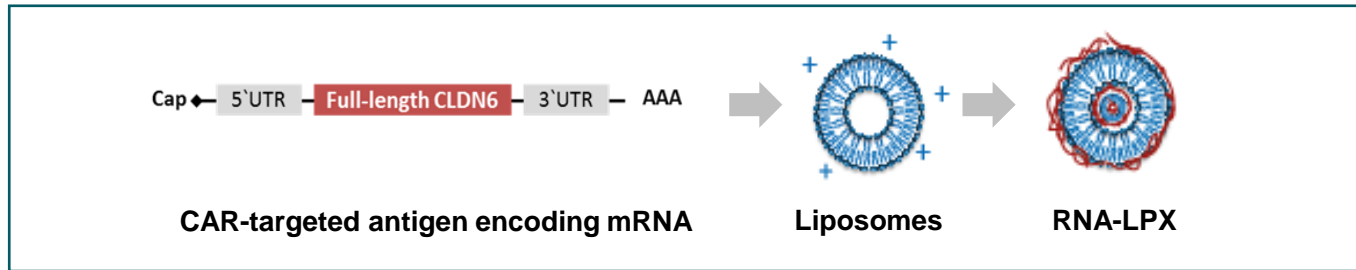
- Two cell therapy manufacturing facilities (Idar-Oberstein, Germany and Gaithersburg, U.S.)



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

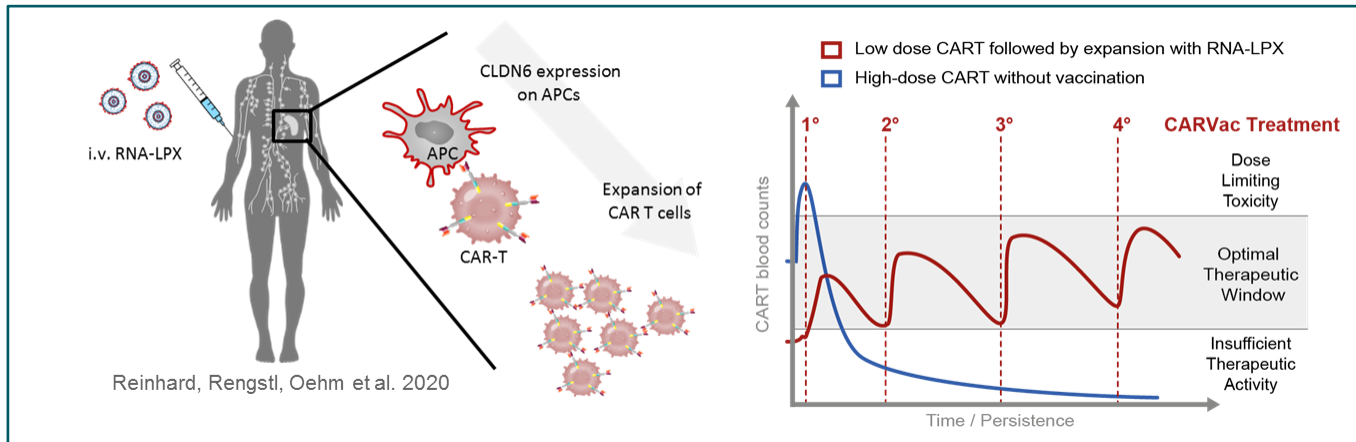
CAR-T cell Amplifying RNA Vaccine (CARVac) drives in vivo expansion and efficacy of CAR-T against solid tumors

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

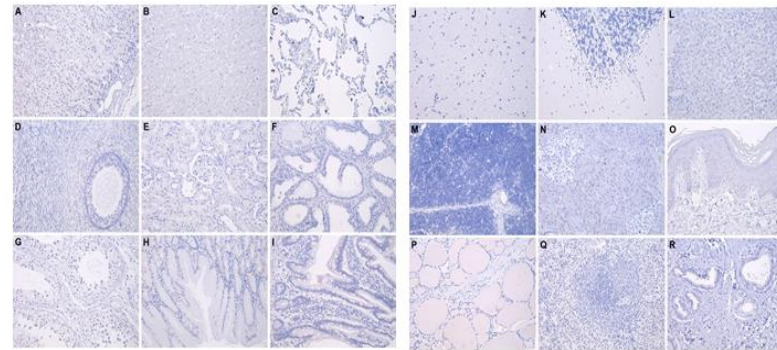
CANCER IMMUNOTHERAPY

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

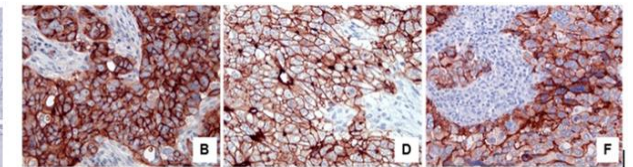
Katharina Reinhard^{1,*,} Benjamin Rengstl^{1,*,} Petra Oehm^{1,*,} Kristina Michel^{1,} Arne Billmeier^{1,} Nina Hayduk^{1,} Oliver Klein^{1,} Kathrin Kuna^{2,} Yasmina Ouchan^{1,} Stefan Wöll^{1,} Elmar Christ^{1,} David Weber^{2,} Martin Suchan^{2,} Thomas Bukur^{2,} Matthias Birtel^{1,} Veronika 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



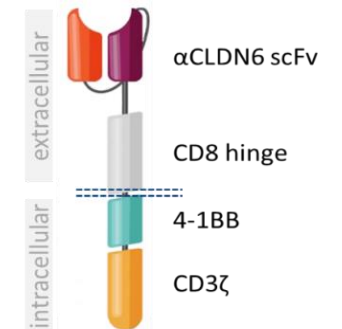
CLDN6 expressed in multiple cancers



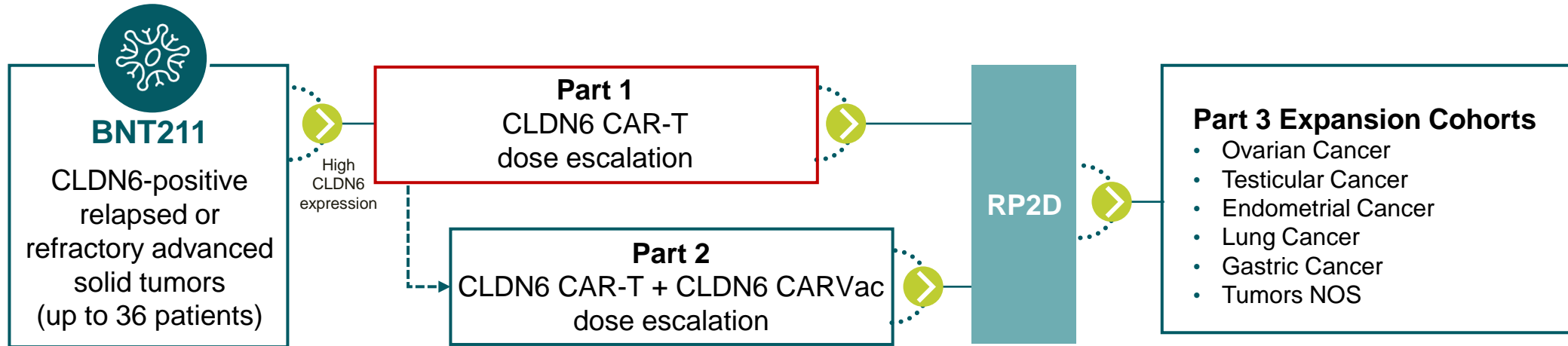
Ovarian Testicular Lung

- Directed against new carcino-embryonic antigen CLDN6
- 2nd generation CAR functionalized with antibody-derived CLDN6-binding domain (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

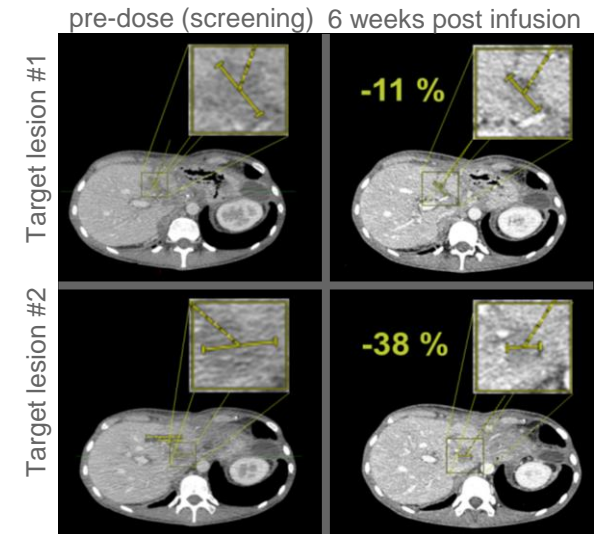
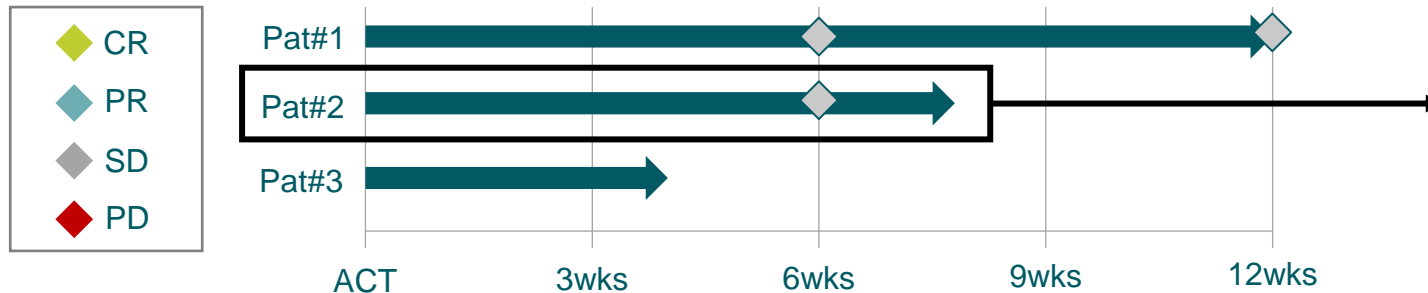
- AEs Mild to Moderate & Transient
 - No AEs ≥ grade 3 and no DLTs

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;

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

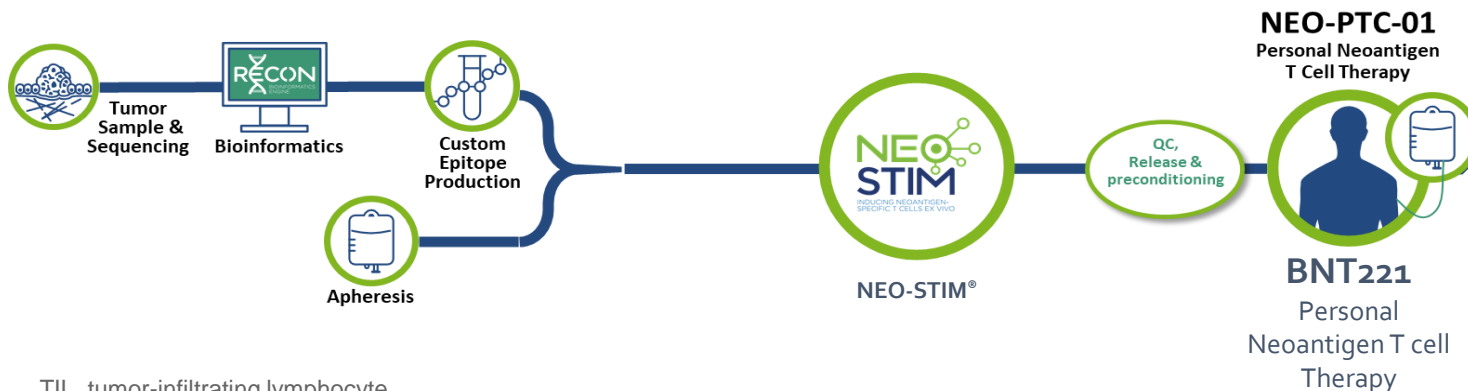
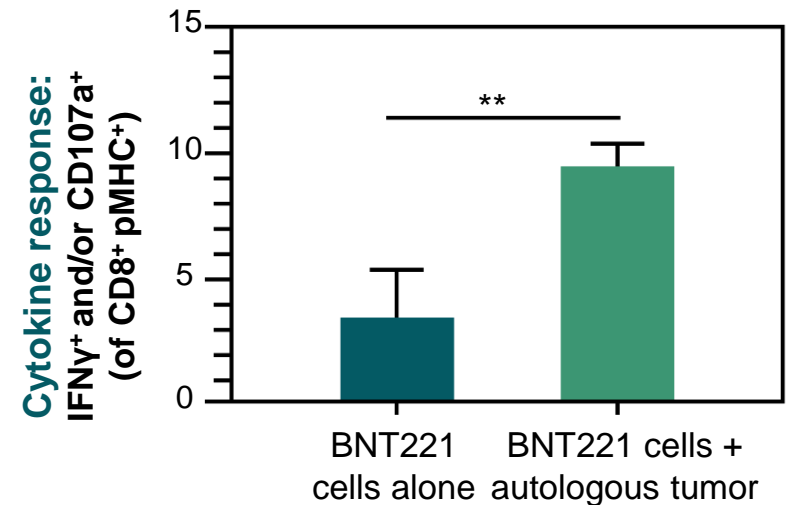
* Suspected to be related to drug product

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

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

RiboCytokines: Designed to Overcome Limitations of Recombinant Cytokine Therapy

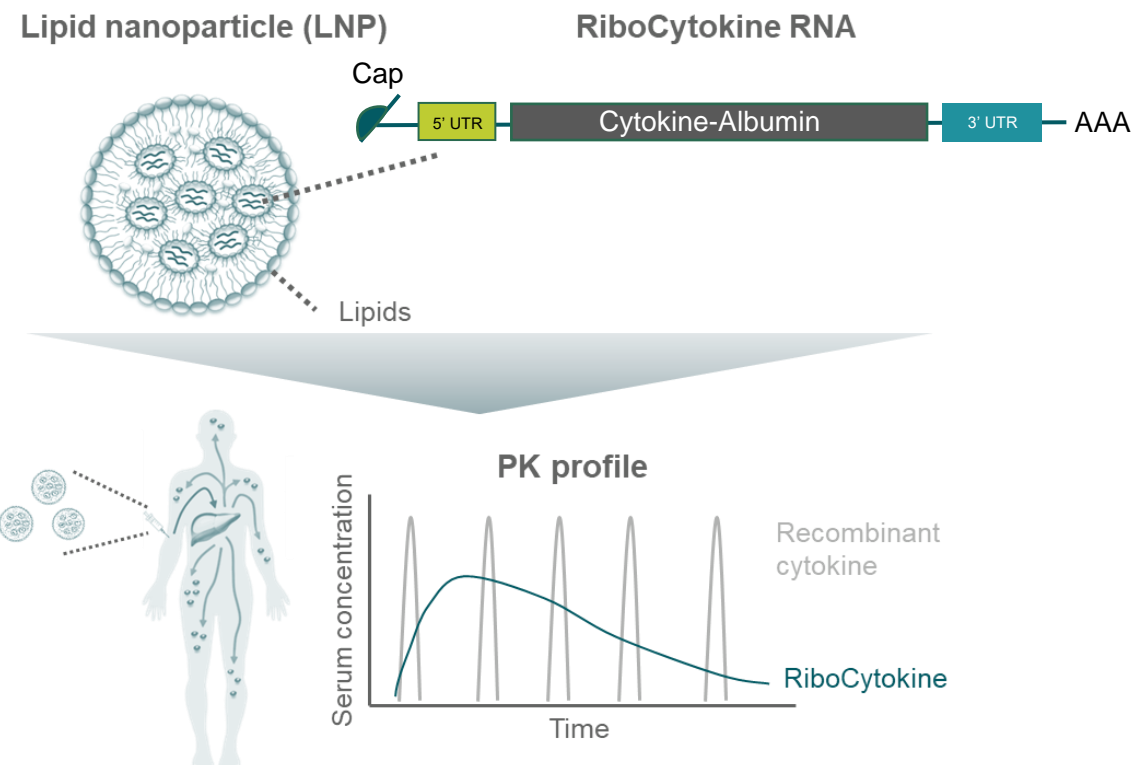
Cytokines encoded by mRNA: A novel therapeutic concept

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

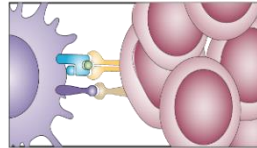


| Product Candidate | Indication | Pre-clinical | Phase 1 | Phase 2 |
|-----------------------------|--------------|--------------|------------|------------|
| BNT151 (modified IL-2) | Solid Tumors | ██████████ | ██████████ | ██████████ |
| BNT152+153 (IL-7 + IL-2) | Solid Tumors | ██████████ | ██████████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

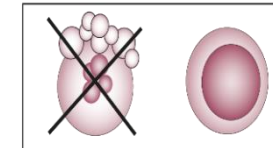
RiboCytokines: A Tailored Approach to T Cell Regulation and Stimulation

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

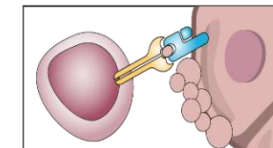
↑ T cell proliferation



↑ 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)

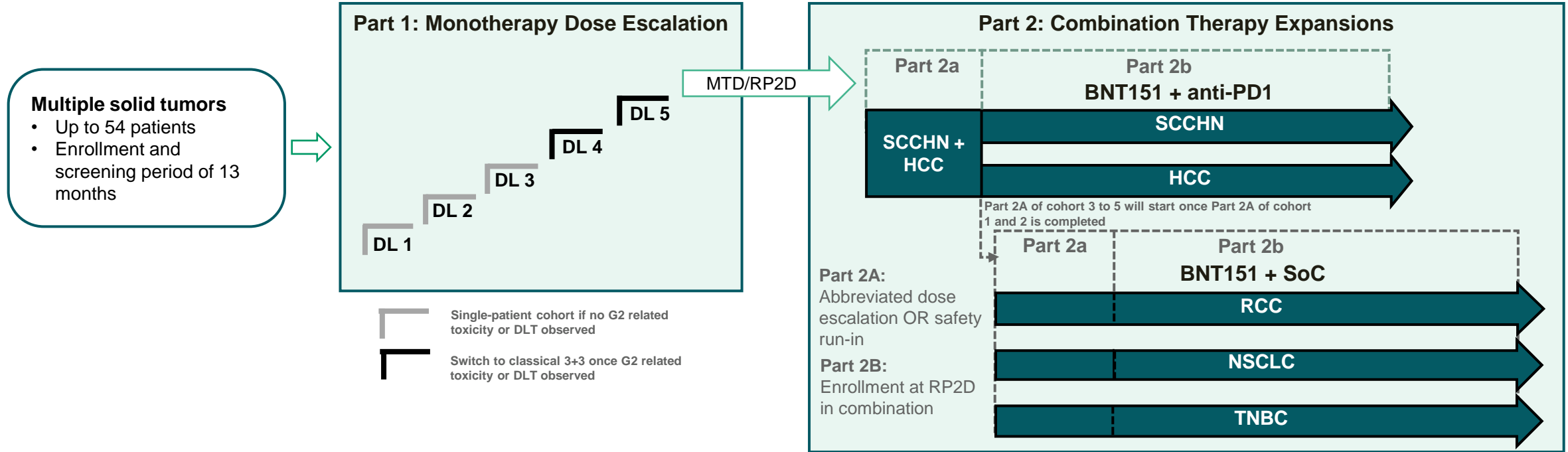
- Stimulates recently activated anti-tumor T cells and regulatory T cells

BNT152 (IL-7)

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

Combination with RNA vaccine

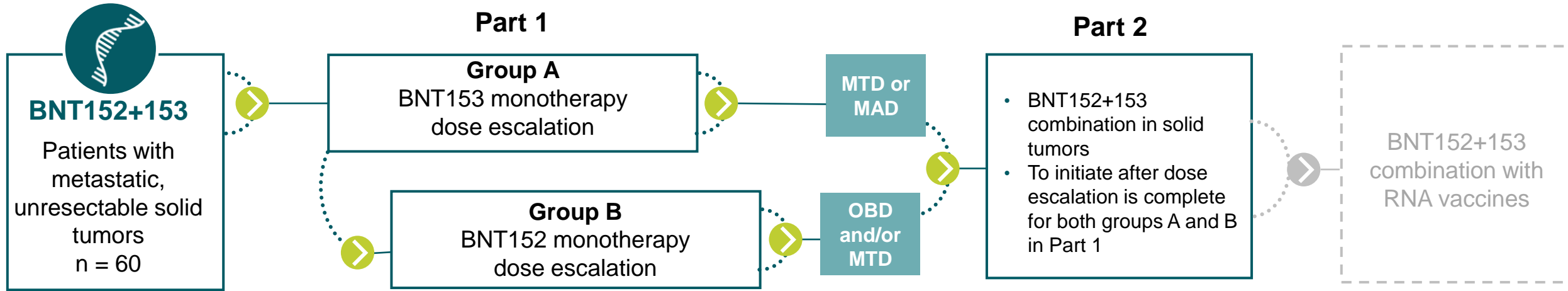
BNT151: Open-label, Multicenter Phase 1/2, First-in-human Trial



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 Biontech logo is displayed 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 on the left side of the slide.

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