Harnessing The Power Of The Immune System To Fight Human Diseases

May 13, 2022

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 BioNTech's 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 presentation are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond BioNTech’s control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. You should review the risks and uncertainties described under the heading “Risk Factors” in BioNTech's annual report on Form 20-F for the quarter and year ended December 31, 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 presentation 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

COMIRNATY® ▼(the Pfizer-BioNTech COVID-19 vaccine) has been granted conditional marketing authorization (CMA) by the European Commission to prevent coronavirus disease 2019 (COVID-19) in people from 5 years of age. The vaccine is administered as a primary course of 2 doses, 3 weeks apart. In addition, the CMA has been expanded to include a booster dose (third dose) at least 6 months after the second dose in individuals 12 years of age and older. For immunocompromised individuals, a third primary course dose may be given at least 28 days after the second dose. 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.
- There is an increased risk of myocarditis and pericarditis following vaccination with Comirnaty. These conditions can develop within just a few days after vaccination, and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males. 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, paraesthesia, hypoaesthesia 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.
- 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 and safety of the vaccine has not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy. The efficacy of Comirnaty may be lower in immunocompromised 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 participants 5 to 15 years of age was similar to that seen in participants 16 years of age and older.
- The most frequent adverse reactions in children 5 to 11 years of age were injection site pain (>80%), fatigue (>50%), headache (>30%), injection site redness and swelling (>20%), myalgia and chills (>10%).
- 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%).
- A large amount of observational data from pregnant women vaccinated with Comirnaty during the second and third trimester have not shown an increase in adverse pregnancy outcomes. While data on pregnancy outcomes following vaccination during the first trimester are presently limited, no increased risk for miscarriage has been seen. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, parturition or post-natal development. Comirnaty can be used during pregnancy.
- No effects on the breast fed newborn/infant are anticipated since the systemic exposure of breast feeding woman to Comirnaty is negligible. Observational data from women who were breast feeding after vaccination have not shown a risk for adverse effects in breast fed newborns/infants. Comirnaty can be used during breast feeding. 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. Individuals can help by reporting any side effects they may get. Side effects can be reported to EudraVigilance or directly to BioNTech using email medinfo@biontech.de, telephone +49 6131 9084 0, or via the website www.biontech.de

Safety Information

AUTHORIZED USE IN THE U.S.

COMIRNATY® (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. It is also authorized under EUA to provide a 2-dose primary series to individuals 5 years of age and older, a third primary series dose to individuals 5 years of age and older who have been determined to have certain kinds of immunocompromise, a single booster dose to individuals 12 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY®, a single booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized COVID-19 vaccine, a second booster dose to individuals 50 years of age and older who have received a first booster dose of any authorized COVID-19 vaccine; and a second booster dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise and who have received a first booster dose of any authorized COVID-19 vaccine.
The booster schedule is based on the labeling information of the vaccine used for the primary series.

IMPORTANT SAFETY INFORMATION

Individuals should not get the 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:

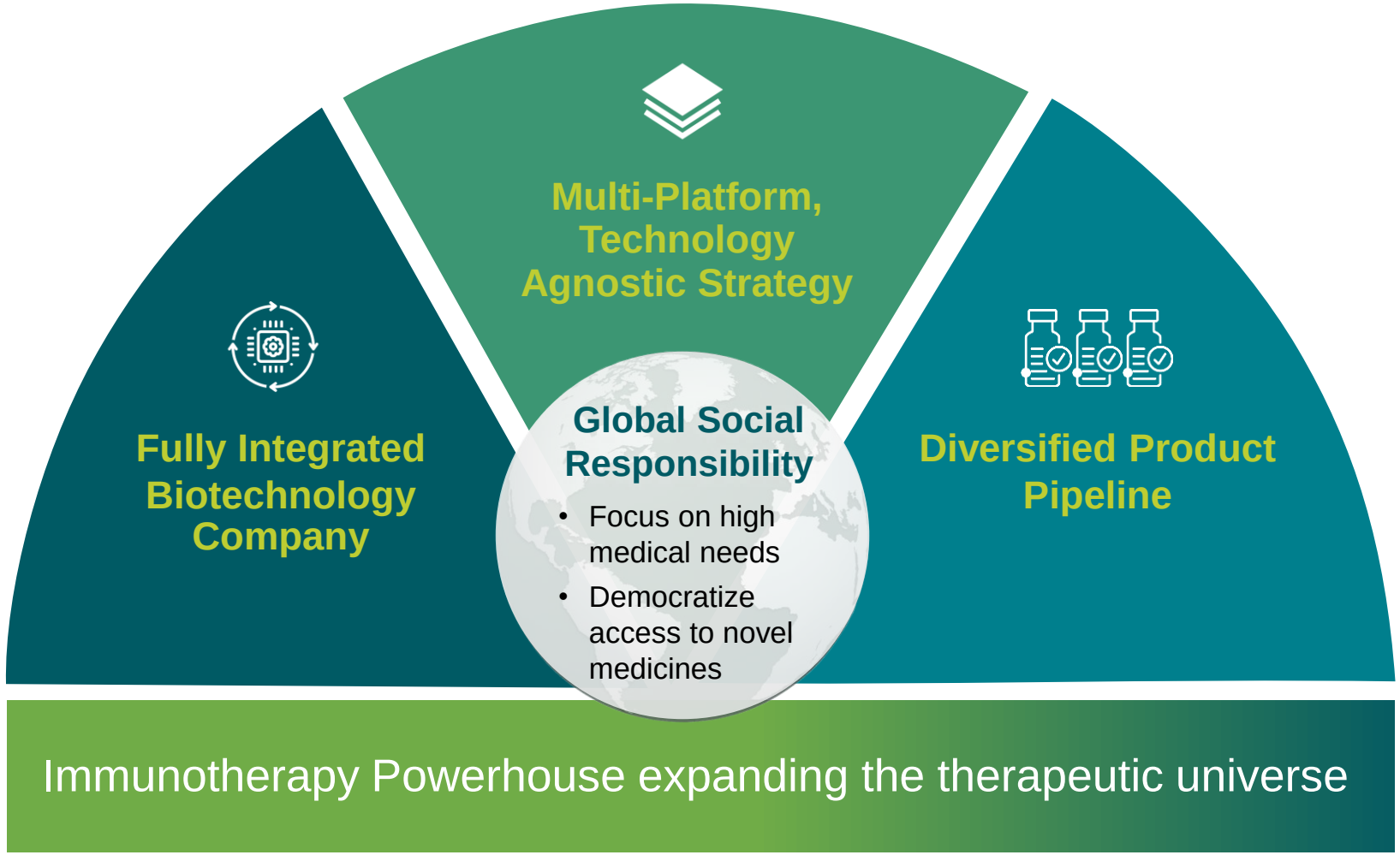
- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects the immune system
- are pregnant, 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 1 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, more commonly in males under 40 years of age than among females and older males. 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
- Additional side effects that have been reported with the vaccine include:
    - severe allergic reactions; non-severe allergic reactions such as injection site pain; tiredness; headache; muscle pain; chills; joint pain; fever; injection site swelling; injection site redness; nausea; feeling unwell; swollen lymph nodes (lymphadenopathy); decreased appetite; diarrhea; vomiting; arm pain; and fainting in association with injection of the vaccine
- These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are 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

Data on administration of this vaccine at the same time as other vaccines have not yet been submitted to FDA. Individuals considering receiving this vaccine with other vaccines should discuss their options with their healthcare provider. 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 https://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.

Our Vision: Harnessing The Power Of The Immune System To Fight Human Diseases



BIONTECH

BioNTech: A Global Immunotherapy Powerhouse

Fully Integrated

- **Deep Immunology Expertise**
- **Broad Suite of Novel Technologies**
- **Automation & Digitalization**
- **Specialized Manufacturing**
- **Commercial Capabilities**
- **Global Team of 3,000+**

A Diverse Pipeline of 17+ Clinical Candidates

Next-Generation Immunotherapies & Vaccines

Oncology,
Infectious Diseases
and Beyond

Potential to Launch Multiple Products in the Next 5 Years

1 as of end 2021: includes doses delivered by collaboration partner Pfizer
2 Includes updates through March 30, 2022

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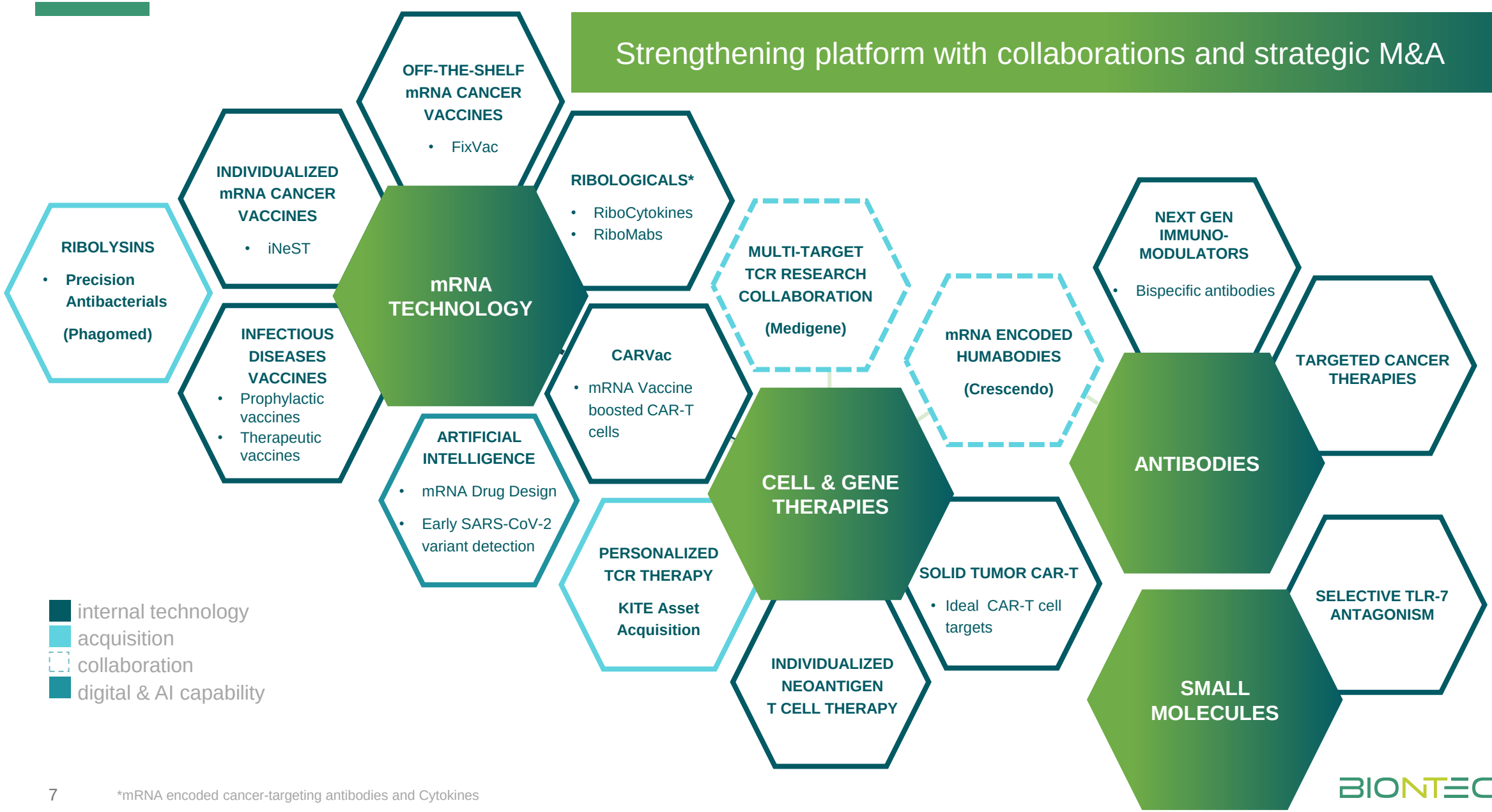
Multi-platform Strategy | Technology Agnostic Innovation Engine

Strengthening platform with collaborations and strategic M&A



*mRNA encoded cancer-targeting antibodies and Cytokines

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Waves of Innovation Propel Us Toward Our Vision

Potential for multiple product launches in next 3-5 years

PRESENT:

Driving Transformation TODAY…	Near- and Mid-Term…		Long-Term
1 MARKETED VACCINE	**16 PROGRAMS IN 20 CLINICAL TRIALS**	**1 PHASE 1 PROGRAM**	**MULTIPLE PROGRAMS IN LEAD-CANDIDATE SELECTION**
	5 RANDOMIZED PHASE 2 TRIALS	**10+ PRECLINICAL PROGRAMS**	
COVID-19 Vaccine	Oncology	Infectious Diseases	New Disease Areas

Once in a generation opportunity to transform medicine

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Diversified Product Pipeline Built on a Broad Suite of Technologies and Immunotherapeutic Expertise

Infectious Disease

- 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-19[1], shingles[1], malaria, HIV[2], TB[2], influenza[1], HSV 2[3]

Oncology

- 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

[1]Collaboration with Pfizer; [2]Collaboration with Bill & Melinda Gates Foundation; [3]Collaboration with University of Pennsylvania

Entering a New Era of mRNA Technology & Synthetic Biology

Impact poised to be comparable to introduction of recombinant technology

mRNA vaccines **validated** as a **new drug class** 〉 mRNA to **deliver** a variety of **biologically active molecules** 〉 mRNA poised to **broaden therapeutic horizons**

BNT162b2 success accelerates diversification & maturation of mRNA technology

mRNA vaccines	☑
CAR-T cell amplifying mRNA vaccines	☑
Systemic mRNA encoded immuno-therapies	☑
***In vivo* engineered cell therapies**	☑
Precision anti-bacterials	☑

Cancer	☑
Infectious diseases	☑
Autoimmune diseases	☑
Inflammatory diseases	☑
Cardiovascular & neuro-degenerative diseases	☑
Regenerative medicines	☑

We believe that in 15 years, one-third of all newly approved drugs will be based on mRNA

☑ Clinical programs ☑ Preclinical programs

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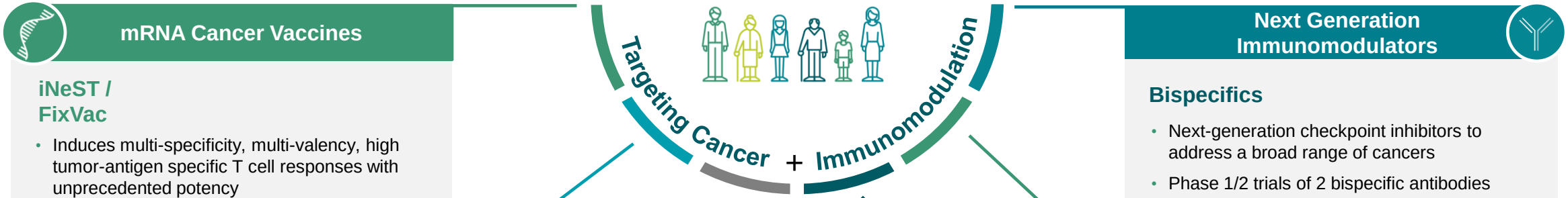
Oncology: Potential To Tackle Multiple Diseases With Different Therapeutic Modalities



mRNA Cancer Vaccines

iNeST / FixVac

- Induces multi-specificity, multi-valency, high tumor-antigen specific T cell responses with unprecedented potency
- 4 Phase 2 randomized trials (2 iNeST and 2 FixVac)

Next Generation Immunomodulators

Bispecifics

- Next-generation checkpoint inhibitors to address a broad range of cancers
- Phase 1/2 trials of 2 bispecific antibodies
- 1 Phase 2 randomized trial

Cell Therapies

Next Gen CAR-T Cell / Neoantigen-based T Cell / Personalized TCR-T Cell Therapy

- 2 Phase 1 FIH trials started in Feb. and Apr. 2021

Antibodies

Targeted Cancer Antibodies

- Novel cancer cell surface targets for underserved high medical need cancers
- CA19-9 antibody in 1L pancreatic cancer in Phase 1/2 trial

Small Molecule Immunomodulators

TLR-7 Agonist

- Potently modulates innate immunity
- Phase 1 trial

Ribologicals

Ribocytokines, RiboMabs

- mRNA encoded cytokines or antibodies with potential for improved properties and half life
- Potential to amplify vaccines and CPIs
- 2 Phase 1 FIH RiboCytokine trials
- 1 Phase 1 FIH RiboMab trial

Multiple product opportunities with unique combination potential in clinical testing

CAR, Chimeric antigen receptor; TCR, T Cell receptor; FIH, First-in-human; CA 19-9: Cancer antigen 19-9; 1L, first-line; TLR-7, Toll-like receptor 7; CPI, Check-point Inhibitor

Focused Execution Across 5 Phase 2 Programs in Various Solid Tumor Types

	FixVac		iNeST		Bispecific
Platform	Off-the-shelf mRNA vaccine		Individualized mRNA immunotherapy		Next-generation immunotherapy
Program	**BNT111** R/R Melanoma	**BNT113** HPV16+ HNSCC	Autogene cevumeran **BNT122**[1] 1L Melanoma	Autogene cevumeran **BNT122**[1] Adjuvant colorectal cancer	**BNT311**[2] R/R NSCLC
How	• Encodes 4 tumor-associated antigens covering >90% of cutaneous melanoma patients • U.S. Fast Track Designation and Orphan Drug Designation	• Encodes HPV16 oncoproteins E6 & E7	• Targets 20 neo-antigens unique to each patient • Data update expected 2H 2022	• Targets 20 neo-antigens unique to each patient	• Conditional 4-1BB co-stimulation while blocking PD(L)1 axis
Why	• Potential to improve outcomes in combo with anti-PD1	• Potential for synergistic anti-tumor effect in combination with anti-PD1	• Trial success may unlock 1L use of iNeST as combination therapy with anti-PD(L)1 in anti-PD1-naive advanced cancers	• Potential to address residual cancer cells that remain – focus on recurrence free survival	• Enhances T cell and NK cell function and targets them to tumor lesions

R/R, refractory/relapsed; HPV16+, human papilloma virus type 16 positive; HNSCC, head and neck squamous cell carcinoma; NK cell, Natural killer cell, CPI, checkpoint inhibitor
1 Collaboration with Genentech, 2 Collaboration with Genmab.

A Technology Agnostic Approach Targets a Broader Addressable Cancer Market

Cancer segment	Patient Population	Challenge	Our Therapeutic Strategies
High mutational burden/ adjuvant stage cancers	Significant portion of cancer patients	Poor risk-benefit profile of checkpoint inhibitors	• ***mRNA Neoantigen Immunotherapy*** *(iNeST)*
Low mutational burden cancers	>60% of cancers	Poor response to checkpoint inhibitors	• ***Shared Antigens*** *(FixVac, CAR-T cells, Neoantigen-targeted T cells, Antibodies)*
"Immune desert" cancers	>40% of high-mutational cancers	Poor infiltration and activation of T-cells in TME[1]	• ***RNA Immunotherapy*** • ***Immunostimulatory Compounds*** *(intratumoral, RiboCytokines)*
Cancers with MHC / B2M loss	20-30% of CPI-experienced advanced cancers	Failure of immune system to recognize tumor cells	• ***Antibodies*** • ***CAR-Ts***
Refractory tumors	Patients with large tumors and multiple resistance mechanisms	Few treatment options	• ***Cell Therapies*** • ***Combination Therapies***

[1]Tumor microenvironment

We Collaborate with Global Leaders in Our Industry

Collaborations for clinical stage programs

COVID-19 Vaccine	FixVac Melanoma	iNeST	Bispecific mABs	Intra-tumoral mRNA	Seasonal Influenza
50:50 gross profit share[1]	*Companies keep full rights to own product*	*50:50 cost & profit share*	*50:50 cost & profit share*	*cost & profit share*	*royalties & milestones*
Pfizer / FOSUNPHARMA	REGENERON	Genentech	Genmab	SANOFI	Pfizer

Pre-clinical collaborations

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

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

Significant Pipeline Expansion and Maturation Expected in 2022

Continue COVID-19 Vaccine Leadership

- Label & geographic expansion
- Next-generation vaccines
- Innovations for pandemic preparedness

Execute in Oncology

- First randomized Phase 2 readout
- Prepare for registrational trials
- POC data for CAR-T cell therapy

Expand in Infectious Disease

- Initiate 4 FIH vaccine trials
- 10+ additional mRNA vaccine programs
- Precision antibacterials

Advance into New Therapeutic Areas

- Autoimmune disease
- Regenerative medicine
- Cardiovascular disease

Invest in Foundation to Enable Accelerated Innovation and Expansion

Digital & AI Capabilities | Technologies | Development Team | Manufacturing | Global Footprint

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Agenda

Overview and business outlook

- Pipeline

Deeper dive on our key programs

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

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Oncology: Advancement Across Multiple Modalities and Indications

Drug class	Platform	Product candidate	Indication (targets)	Pre-clinical	Phase 1	Phase 2	Phase 3	Milestones 2022
mRNA	FixVac (fixed combination of shared cancer antigens)	BNT111	Advanced melanoma					
		BNT112	Prostate cancer					
		BNT113	HPV16+ head and neck cancer					
		BNT115[1]	Ovarian cancer[1]					
		BNT116	NSCLC					Phase 1 start: 2H 2022
	iNeST (patient specific cancer antigen immune therapy)	Autogene cevumeran (BNT122)[2]	1L melanoma					Data update: 2H 2022
			Adjuvant colorectal cancer					
			Solid tumors					
	Intratumoral Immunotherapy	SAR441000 (BNT131)[3]	Solid tumors (IL-12sc, IL15-sushi, GM-CSF, IFNα)					
	RiboMabs (mRNA-encoded antibodies)	BNT141	Multiple solid tumors (CLDN18.2)					
		BNT142	Multiple solid tumors (CD3+CLDN6)					Phase 1 start: 1H 2022
	RiboCytokines (mRNA-encoded cytokines)	BNT151	Multiple solid tumors (optimized IL-2)					
		BNT152, BNT153	Multiple solid tumors (IL-7, IL-2)					
Cell Therapies	CAR-T Cells + Carvac	BNT211	Multiple solid tumors (CLDN6)					Data update: 2H 2022
		BNT212	Pancreatic, other cancers (CLDN18.2)					
	Neoantigen-based T cells	BNT221 (NEO-PTC-01)	Multiple solid tumors					
	TCR engineered T cells	To be selected	All tumors					
Antibodies	Next-Gen CP Immunomodulators	GEN1046 (BNT311)[4]	Metastatic NSCLC (PD-L1x4-1BB)					
			Multiple solid tumors (PD-L1x4-1BB)					
		GEN1042 (BNT312)[4]	Multiple solid tumors (CD40x4-1BB)					
	Targeted Cancer Antibodies	BNT321 (MVT-5873)	Pancreatic cancer (sLea)					
SMIM	Toll-Like Receptor Binding	BNT411	Solid tumors (TLR7)					

[1]BNT115 is currently being studied in an investigator-initiated Phase 1 trial. [2]Collaboration with Genentech [3]Collaboration with Sanofi. [4]Collaboration with Genmab.
SMIM, Small Molecule Immunomodulators

Infectious Disease Pipeline: 4 mRNA Vaccine Trial Starts Expected in 2022

	Platform	Product candidate	Pre-clinical	Phase 1	Phase 2	Commercial	Milestones 2022
3 mRNA vaccines partnered w/Pfizer	COVID-19 Vaccine[1]	BNT162b2					Multiple updates
	Influenza[1]	BNT161					Data update: 2022
	Shingles[1]	Un-named program					Phase 1 start: 2H 2022
10+ other infectious disease programs	Malaria	Un-named program					Phase 1 start: 2H 2022
	Tuberculosis[2]	BNT164					Phase 1 start: 2H 2022
	HSV 2[3]	Un-named program					Phase 1 start: 2H 2022
	HIV[2]	Un-named program					
	Additional mRNA vaccine programs[3]	Un-named programs					
	Precision antibacterials	Un-named programs					

[1]Collaboration with Pfizer. [2]Collaboration with Bill & Melinda Gates Foundation. BioNTech holds worldwide distribution rights except developing countries where BMG holds distribution rights; [3]University of Pennsylvania collaboration

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- Antibodies
- Cell Therapies – CARVac and NEO-STIM T cell therapy
- Small Molecule Immunomodulators
- RiboCytokines

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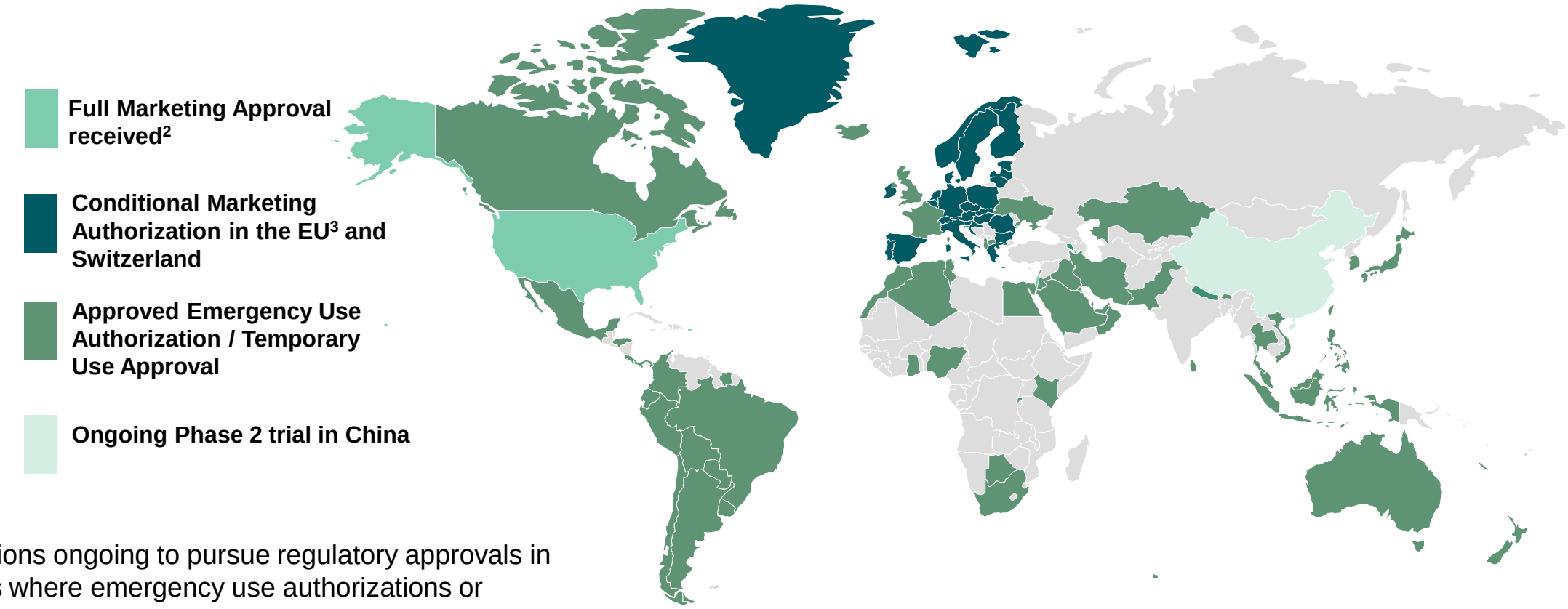
Regulatory Approvals in Over 100 Countries and Regions Around the World[1]

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.

[1]As of March 2022
[2]Approved 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 5-15 years old
[3]The vaccine is indicated for active immunization to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 5 years of age and older.

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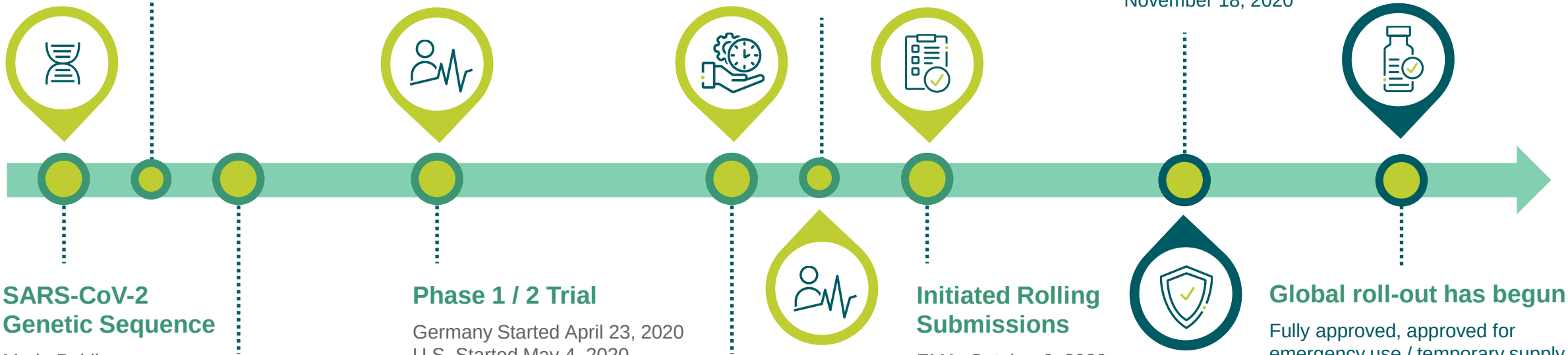
Project Lightspeed – a 10-month Journey to an Effective and Safe Vaccine



SARS-CoV-2 Genetic Sequence

Made Public
January 12, 2020

COVID-19 mRNA Vaccine Program Initiation

January 27, 2020

Collaborations

Fosun Pharma:
March 16, 2020

Pfizer:
March 17, 2020

Phase 1 / 2 Trial

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

FDA Fast Track designation

July 13, 2020

Initiated Pivotal Phase 2 / 3 Trial

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

Initiated Rolling Submissions

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

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

November 18, 2020

Global roll-out has begun

Fully approved, approved for emergency use / temporary supply or Conditional Marketing Authorization in more than 100 countries worldwide including the U.S. and EU

December 2020

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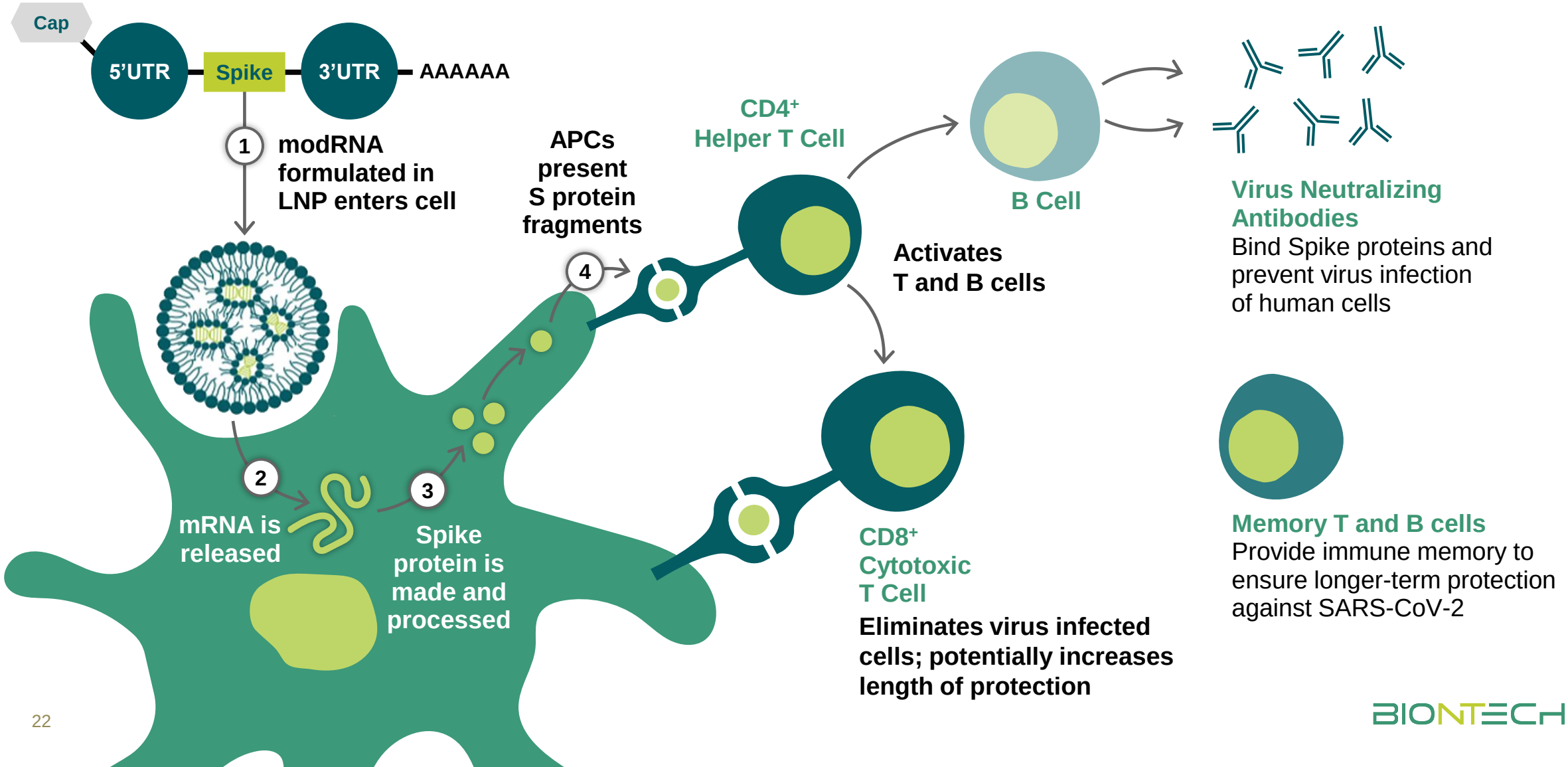
How mRNA Vaccines Work – Training the Immune System for a Real Infection



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mRNA is a Natural Solution for Vaccines Especially in a Pandemic

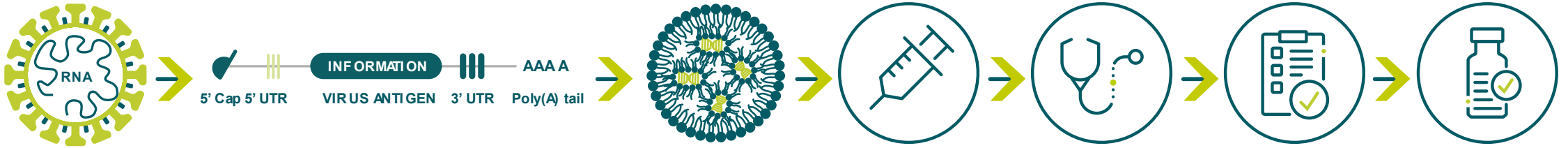
Natural molecule with well-characterized **bio-safety properties**

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

Highly scalable production

High purity and animal free

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



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

BIONTECH

Proactive Approach to Managing COVID-19 at a Global Scale

Strong global position to tackle COVID-19 pandemic

Delivered nearly **3.4 bn[1] doses** cumulatively to **>175 countries and regions**

On track to achieve pledge to deliver a total of **2 bn doses** to low- and middle-income countries by end of 2022

Innovation to stay ahead of COVID-19

- ✓ Optimized formulation
- ✓ Pediatric label expansion
  - Submission for boosters in children 5 to <12 yrs
  - Evaluating 3-dose primary regimen in children 6 months to <5 yrs; data expected in coming weeks
- ✓ Future pandemic preparedness
  - Monitoring of emerging variants
  - Rapid data-guided vaccine adaptation
- ✓ Pre-emptive approach to variants
  - Comprehensive variant-adapted and next-gen vaccine development program
  - Broad research program to study anti-SARS-CoV-2 immune profile after vaccinations, boosters, breakthrough infections to inform strategy

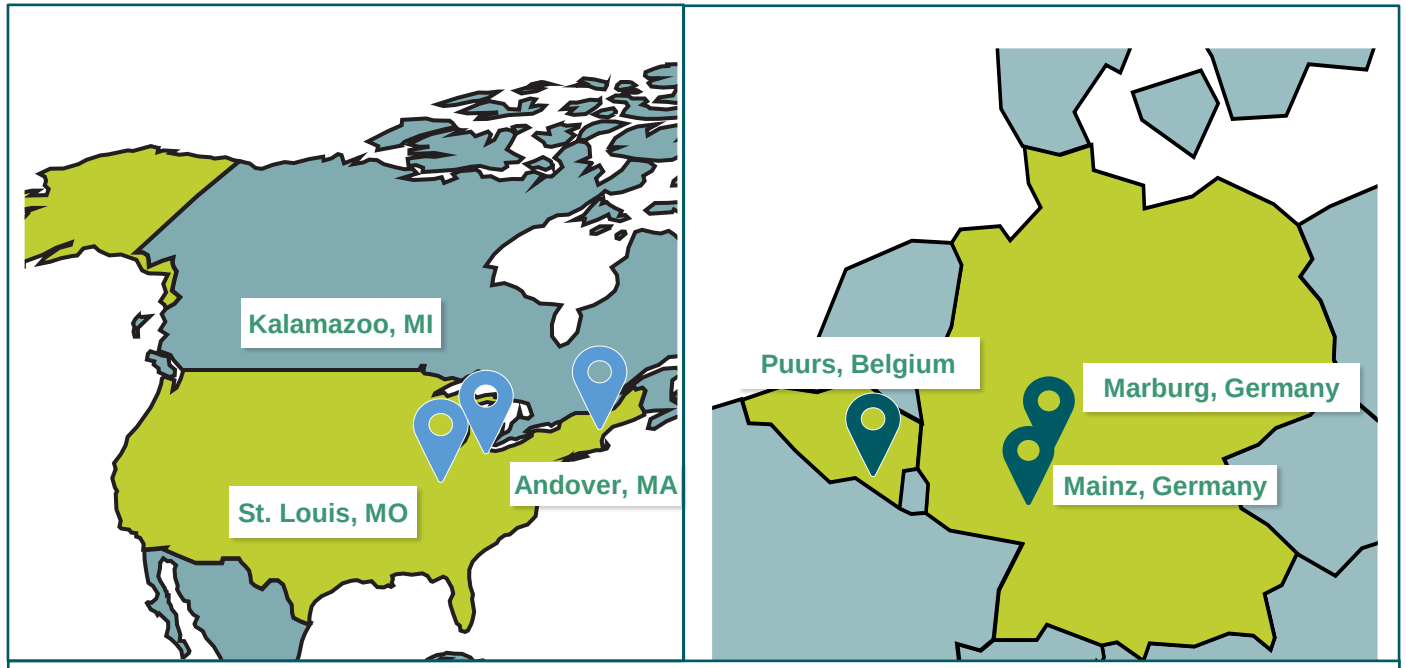
1 As of end-April 2022

This slide has been updated to remove an incorrect graphic regarding the countries to which the Pfizer-BioNTech COVID-19 vaccine has been delivered.

Global COVID-19 Vaccine Supply Chain and Manufacturing Network

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

- Launched BioNTainers as modular mRNA manufacturing facilities
- 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 100 m vaccine doses



Marburg facility:

One of the largest mRNA vaccine manufacturing sites worldwide

BNT162b2 Vaccine Shows High Efficacy and Safety Across Age Groups

16 years and older

- 95% efficacy against symptomatic COVID-19 in Phase 3 pivotal trial with ~44,000 participants
- 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

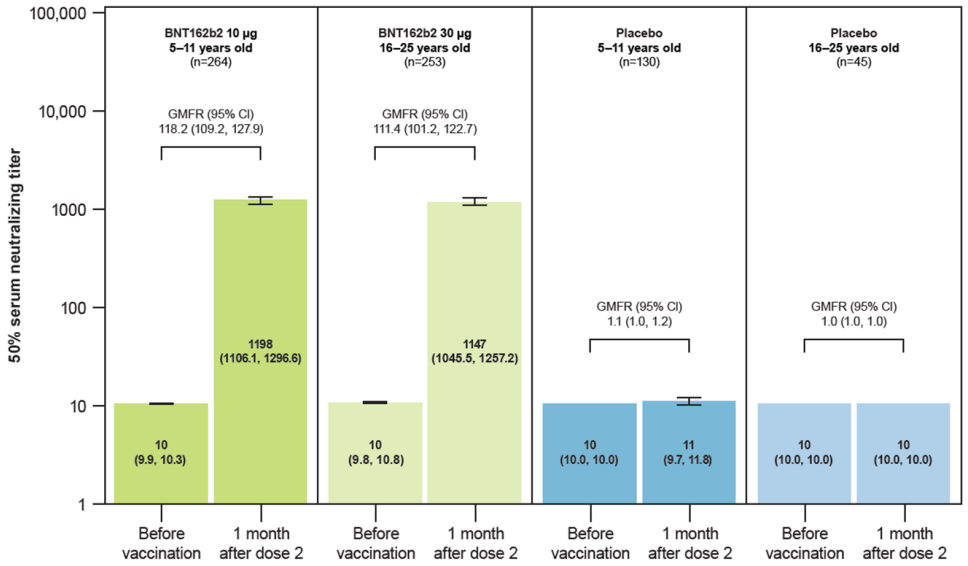
- 100% efficacy against COVID-19 infection and 100% efficacy against severe disease

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 responses[1]

Clinical data support vaccination of children 5 to 11 years of age[2]

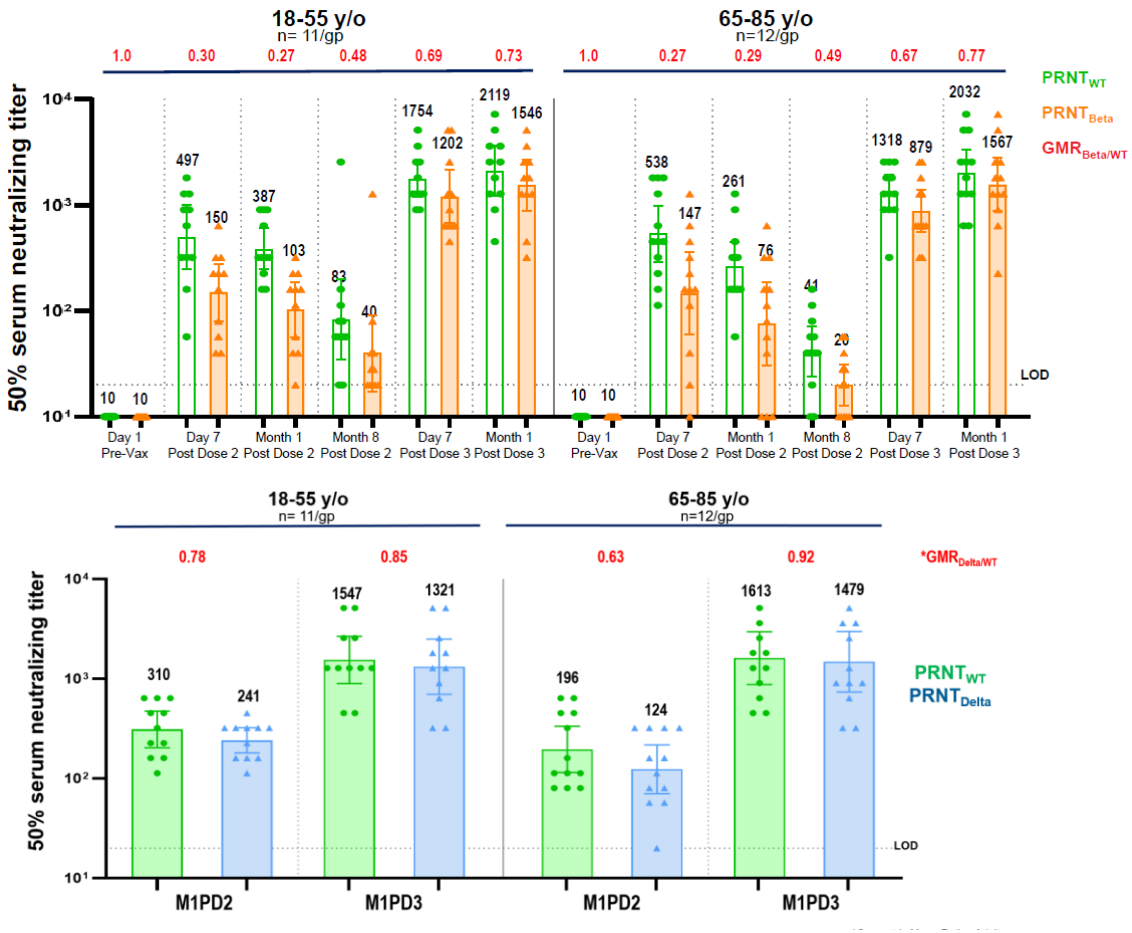


- Two doses of 10µg administered 21 days apart
- Well tolerated with mainly transient mild-to-moderate side effects
- Robust neutralizing antibody responses similar (GMT of 1,197.6) compared to control group 16 to 25 years old (GMT of 1,146.5) at one month post dose two, meeting the predefined immunobridging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

[1]Sahin U, et al. preprint 2020 (https://www.medrxiv.org/content/10.1101/2020.12.09.20245175v1)
[2] These data have been submitted for publication.
The vaccine has received U.S. EUA and CMA in the EU for 5 to <12 year olds.

Greater, Broader Neutralization and High Vaccine Efficacy Post 3rd Dose/Booster for Protection Against Symptomatic Disease

Greater, Broader SARS-CoV-2 Neutralization with BNT162b2 Vaccine Dose 3[1]



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

	BNT162b2 (30µg) N=4695		Placebo N=4671			
Efficacy Endpoint	n	Surveillance Time (n)	n	Surveillance Time (n)	rVE	(95% CI)
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.

[1] Falsey AR, et al, N Engl J Med 2021:doi: 10.1056/NEJMc2113468

Need for Vaccine-Adaptation to Omicron and Potentially Future Emerging Variants

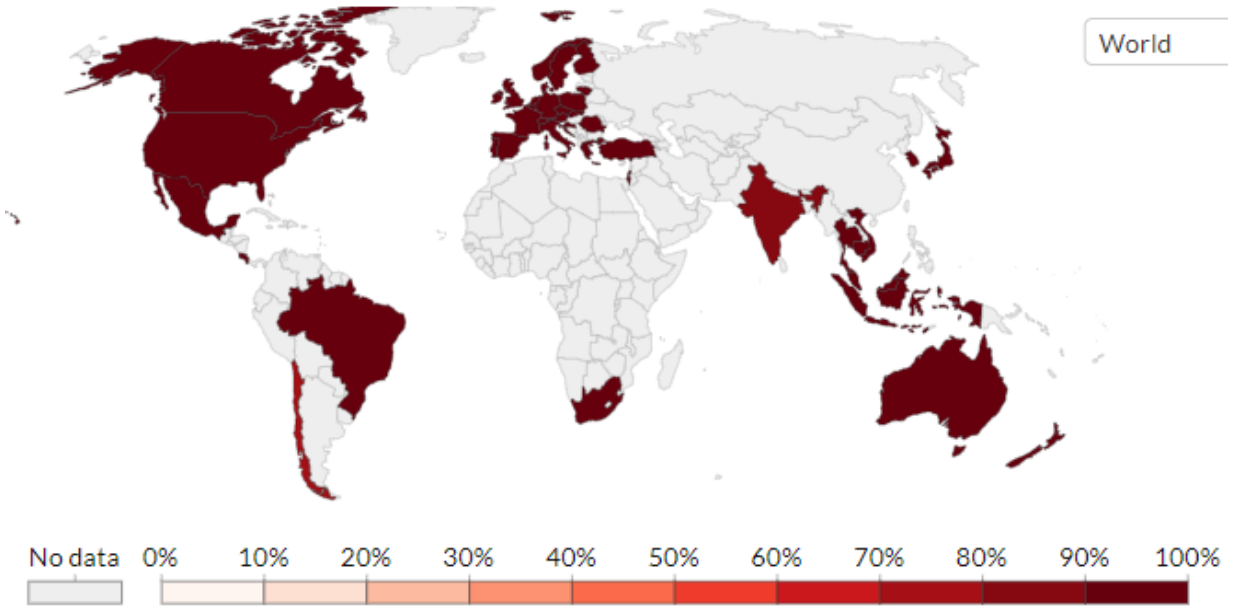
Omicron comprises almost 100% of sequenced genomes in most parts of the world[1]

New variants more likely to arise from variants that cause high infection rates[2,3]

Real-world data suggest that vaccine-induced immunity provides a higher degree of protection than natural immunity[4]

As natural immunity wanes, vaccination extends protection against reinfection[6-12]

Share of Omicron variant in all analyzed sequences in preceeding 2 weeks



Annual and/or seasonal boosters with variant adapted vaccines expected for the foreseeable future for pandemic preparedness[13]

1 Our World in Data. https://ourworldindata.org/grapher/covid-cases-omicron?country=GBR~FRA~BEL~DEU~ITA~ESP~USA~ZAF~BWA~AUS. Accessed 28/3/22; 2 Atlani-Duault L et al Lancet Public Health 6:e199-e200; DOI:https://doi.org/10.1016/S2468-2667(21)00036-0; 3 Otto SP, et al. Curr Biol, 2021; 31(14): R918-R929; 4 Shapira G, et al. Faseba 2022; 4: e22223. doi: 10.1096/fj.202101492R; 5 CDC https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/vaccine-induced-immunity.html. Accessed 28/3/22; 6 MRC Centre for Global infectious Disease Analysis Report 49 https://www.imperial.ac.uk/mrc-global-infectious-disease-analysis/covid-19/report-49-Omicron; 7 Hammerman A, et al. NEJM 2022; DOI: 10.1056/NEJMoa2119497; 5;
8 Yu, Y *et al. Sci Rep* **12,** 2628 (2022) https://doi.org/10.1038/s41598-022-06629-2; 9 Lombardi A, et al. Journ Infect Pub Health 2021; 14(8): 1120-1122; 7; 10 Mayo Clinic. https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/herd-immunity-and-coronavirus/art-20486808. . Accessed 22 March 2022; 11 Abu-Raddad et l EClinicalMedicine 2021 May;35:100861. doi: 10.1016/j.eclinm.2021.100861. Epub 2021 Apr 28; 12 MRC Centre for Global infectious Disease Analysis Report 49 https://http://www.imperial.ac.uk/mrc-global-infectious-disease-analysis/covid-19/report-49-Omicron/_6. Accessed 28/3/22; 13 Elliott P, et al [Preprint] https://spiral.imperial.ac.uk/handle/10044/1/93887

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BNT162b2 Boosters to Address Partial Immune Escape by Omicron

BNT162b2 3rd dose required to reinstall immunity and effectiveness against Omicron[1]

- Overall infections (~70-80%)[1-4]
- Symptomatic disease (~50-85%)[1-5]
- Hospitalizations (~75-90%)[2-6]

However: Vaccine effectiveness against Omicron starts waning after the first few months post booster[7,8]

Israel real-world data suggest a 4th dose increases immunogenicity and lowers rates of confirmed infections and severe illness in elderly population[9]

- In subjects >60 years of age, confirmed infection and severe disease after 4th dose[1] was lower compared to individuals who did not receive 4th dose[9]
- At 12 days+ post 4th dose, reduced risk was demonstrated compared to only 3 doses[9]:
  - **Infection** by a factor of **2.0** (95% CI 2.0 to 2.1)
  - **Severe disease** by a factor of **4.3** (95% CI 2.2 to 7.5)

Future pandemic preparedness:

Monitoring of emerging variants **Rapid data-guided vaccine adaptation**

1 Collie SH, et al. N Engl J Med 2022; 386:494-496 DOI: 10.1056/NEJMc2119270; 2 UK Health Security Agency. COVID-19 Vaccine Surveillance Report - Week 8. 24 February 2022; 3 Tartof SY, et al. Available at SSRN: https://ssrn.com/abstract=4011905; 4 Hansen CH, et al. MedRXiv. doi: https://doi.org/10.1101/2021.12.20.21267966; 5 Thompson MG, et al. MMWR Morb Mortal Wkly Rep 2022;71:139–145. DOI: http://dx.doi.org/10.15585/mmwr.mm7104e3external icon; 6 Lauring AS, et al. BMJ 2022; 376 doi: https://doi.org/10.1136/bmj-2021-069761; 7 Andrews N, et al. NEJM 2022. DOI: 10.1056/NEJMoa2119451; 8 Ferdinands JM, et al. MMWR Morb Mortal Wkly Rep 2022;71:255–263. DOI: http://dx.doi.org/10.15585/mmwr.mm7107e2external icon; 9 Bar-On YM, et al MedRxiv [Preprint] https://doi.org/10.1101/2022.02.01.22270232.

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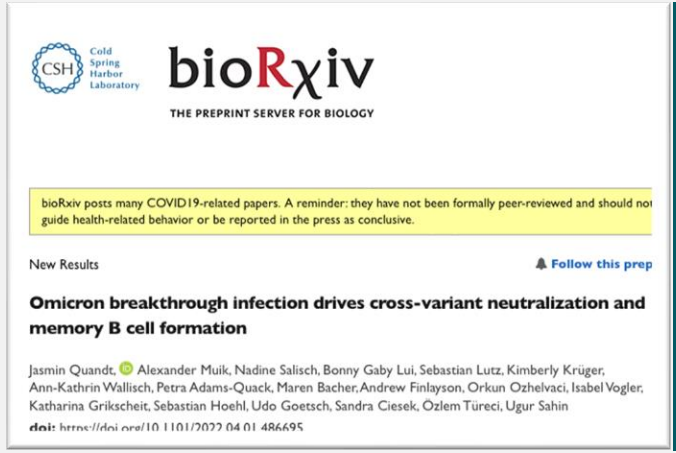
COVID-19 Vaccine R&D Strategy to Drive Pandemic Preparedness

	Purpose	Latest Developments
Landscape Research	Inform Understanding of Dynamic SARS-CoV-2 Immunity	 bioRxiv THE PREPRINT SERVER FOR BIOLOGY bioRxiv posts many COVID19-related papers. A reminder: they have not been formally peer-reviewed and should not guide health-related behavior or be reported in the press as conclusive. New Results Follow this prep **Omicron breakthrough infection drives cross-variant neutralization and memory B cell formation** Jasmin Quandt, Alexander Muik, Nadine Salisch, Bonny Gaby Lui, Sebastian Lutz, Kimberly Krüger, Ann-Kathrin Wallisch, Petra Adams-Quack, Maren Bacher, Andrew Finlayson, Orkun Ozhelvaci, Isabel Vogler, Katharina Grikscheit, Sebastian Hoehl, Udo Goetsch, Sandra Ciesek, Özlem Türeci, Ugur Sahin **Omicron Infection After Vaccination Drives Cross-Variant Neutralization and B Cell Immunity**[1] • Exposure to Omicron spike boosts strong and broad neutralizing activity against SARS-CoV-2 VOCs • Robust recall and expansion of preformed memory B cells that recognize epitopes shared across variants **Data suggest Omicron-adapted vaccination after COMIRNATY could provide similar cross-strain immunity**
Product Research	Explore Various Follow-On and Next-Gen Vaccine Approaches	COMIRNATY · **Omicron-Adapted** · **Mono-/ Multi-valent** · **T Cell Enhancing** · **Pan-Coronavirus covering**
Product Development	Assess Safety, Tolerability and Immunogenicity of Variant-Adapted Vaccines	Emerging data from ongoing clinical trials evaluating mono- or bivalent variant adapted vaccines will be reviewed and discussed with regulators

1 bioRxiv. Omicron breakthrough infection drives cross-variant neutralization and memory B cell formation; April 1, 2022. Available at: https://www.biorxiv.org/content/10.1101/2022.04.01.486695v1.full.pdf

VOC, variants of concern

Comprehensive Clinical Response Strategy to Omicron Variant

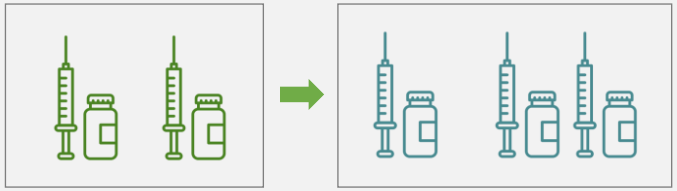
Assessing Safety, Tolerability and Immunogenicity of an Omicron-Adapted Vaccine

Evaluating different Omicron-adapted monovalent vaccine regimens

- N~1500, 18-55 years
- Vaccine experienced and naïve subjects

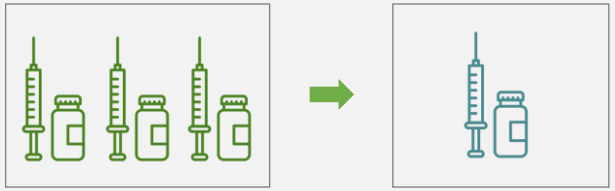
1 3rd dose or 3rd+4th dose

BNT162b2 → Omicron-adapted vaccine



2 4th dose

BNT162b2 → Omicron-adapted vaccine



3 3-dose primary regimen

Omicron-adapted vaccine

Vaccine naïve subjects

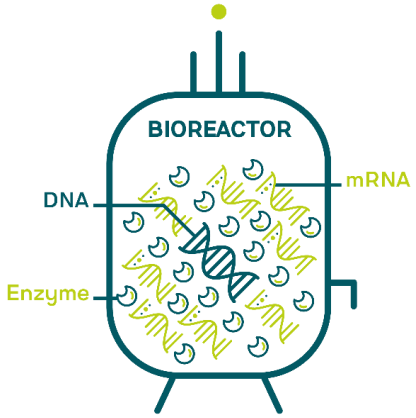
Evaluating bivalent Wild-Type/Omicron-adapted and Omicron-adapted vaccines

- N~650, >55 years
- Two dosages: 30 µg and 60 µg

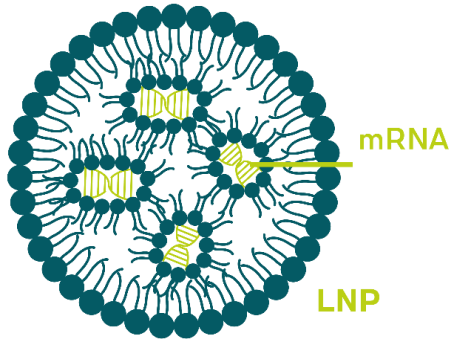
BioNTech. Available at: https://investors.biontech.de/news-releases/news-release-details/pfizer-and-biontech-initiate-study-evaluate-omicron-based-covid. Accessed January 2022;
ClinicalTrials.gov. Available at: https://www.clinicaltrials.gov/ct2/show/NCT04955626. Accessed March 2022.

Flexible Manufacturing Allows Rapid Adaptation to Variants

DNA template production
~1-2 Days



Drug substance purification and concentration
~1-2 Days



Sterile filtration & filling
~1-2 Days

1 2 3 4 5

mRNA production
~1-2 Days

LNP formulation
~3-4 Days

Quality control and release 4-5 weeks

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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 2020
- 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 2020
- 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

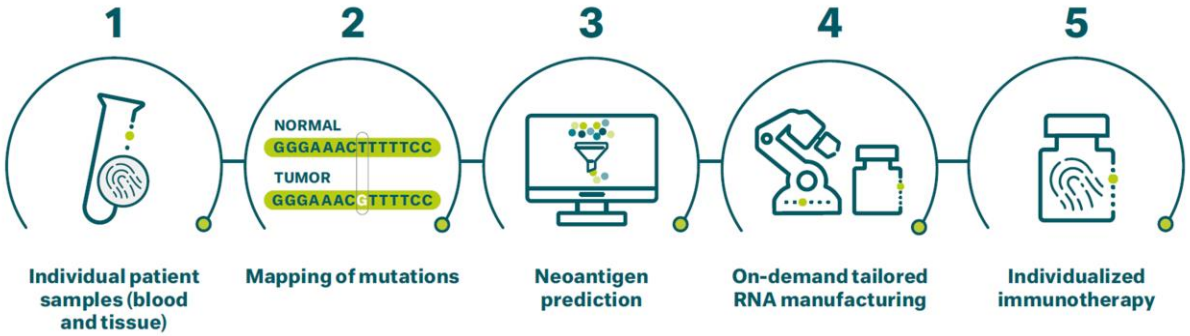
- **Overview and business outlook**
  - Pipeline
- **Deeper dive on our key programs**
  - COVID-19 vaccine program (project “Lightspeed”)
  - mRNA vaccines – FixVac and iNeST
  - Antibodies
  - Cell Therapies – CARVac and NEO-STIM T cell therapy
  - Small Molecule Immunomodulators
  - RiboCytokines

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

Kranz et al., Nature 2016

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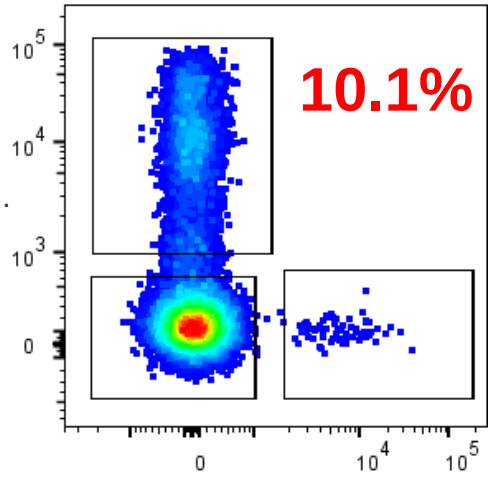
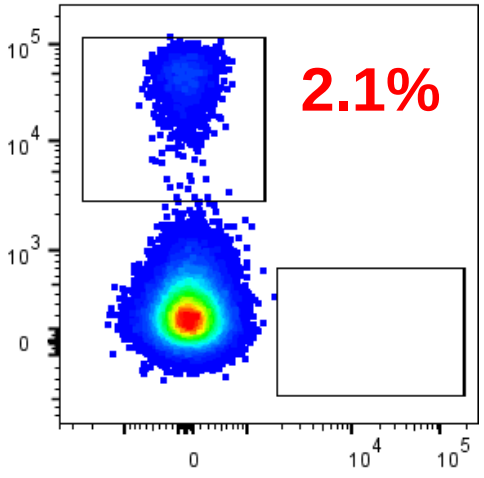
Our RNA-LPX Vaccine Approach

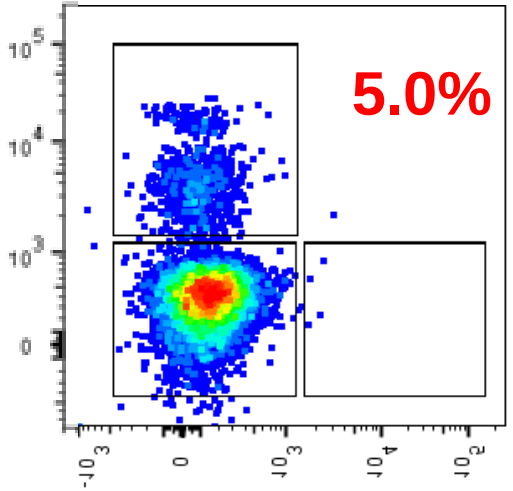
Strong vaccine-induced *ex vivo* CD8+ T cell responses[1] across different cancer types



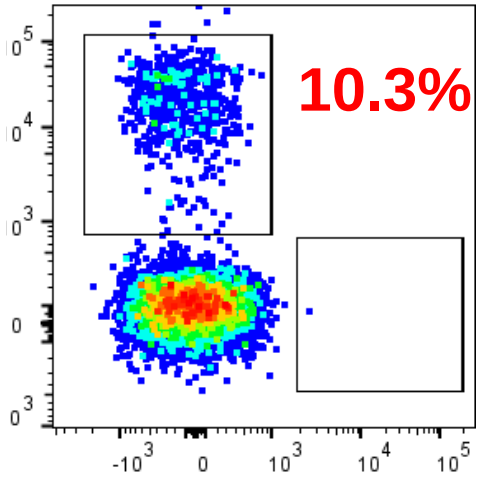
NY-ESO-1
Melanoma
BNT111, Lipo-MERIT trial



MAGE-A3
Melanoma
BNT111, Lipo-MERIT trial



HPV16-E7
Head Neck Cancer
BNT113, HARE40 trial



Mutant Neoantigen
TNBC
BNT114, TNBC MERIT trial

FixVac

iNeST

NY-ESO-1, New York esophageal squamous cell carcinoma-1; MAGE-A3, melanoma-associated antigen 3; HPV, human papilloma virus; TNBC, triple negative breast cancer.
[1]T cell responses analyzed by *ex vivo* multimer staining analysis in blood

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FixVac: Leveraging Shared Antigens to Break Immune Tolerance

Off-the-Shelf Concept: Scalable for multiple indications

Vaccine Backbone

Optimized, unmodified mRNA

\+

Lipoplex

Proprietary RNA-LPX formulation (IV)

\+

Shared Antigens

Multi-antigen approach tailored to each indication

=

FixVac

Fixed vaccine combination against shared tumor-associated antigens

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

- Strong immunogenicity observed *in vivo* via TLR-driven adjuvant effect[1]
- Potent induction of strong *ex vivo* $CD4^+$ and $CD8^+$ T cell responses[1]

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

RNA-LPX. RNA-Lipoplex; IV, intravenous; TLR7, Toll-like receptor; NY-ESO-1, New York esophageal squamous cell carcinoma-1; MAGE-A3, melanoma-associated antigen 3; HPV-E7, Human papillomavirus (type 16) E7 oncoprotein; HPV, Human papillomavirus; NSCLC, Non small cell lung cancer; HLA, human leukocyte antigen; CD, cluster of differentiation

[1]Sahin U, et al. Nature 2020; 585:107-112 ; [2]T cell responses analyzed by ex vivo multimer staining analysis in blood; [3]Additional exploratory indication: Ovarian Cancer

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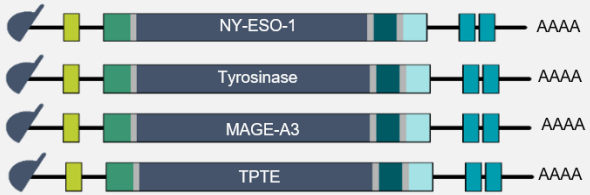
BNT111: Off-the-Shelf Therapeutic Vaccine for Melanoma

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



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

Phase 1 trial in Advanced Melanoma

- 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[2]
- ***Durable clinical responses in monotherapy and in combination with anti-PD1 accompanied by high magnitude CD4+ and CD8+ response***

Phase 2 trial, strategic collaboration with Regeneron*

- 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
- **FPD in June 2021**
- U.S. FDA Fast Track Designation and Orphan Drug Designation

NY-ESO-1, New York esophageal squamous cell carcinoma-1; MAGE-A3, melanoma-associated antigen 3; TPTE, transmembrane phosphatase with tensin homology; AAAA, Poly-A tail; PD1, Programmed cell death protein 1; FPD, First patient dosed; CPI, check point inhibitor;
[1]Data on file; [2]Sahin U, et al. Nature 2020; 585:107-112 (https://www.nature.com/articles/s41586-020-2537-9)
*Companies to share development costs equally and keep full commercial rights to own programs

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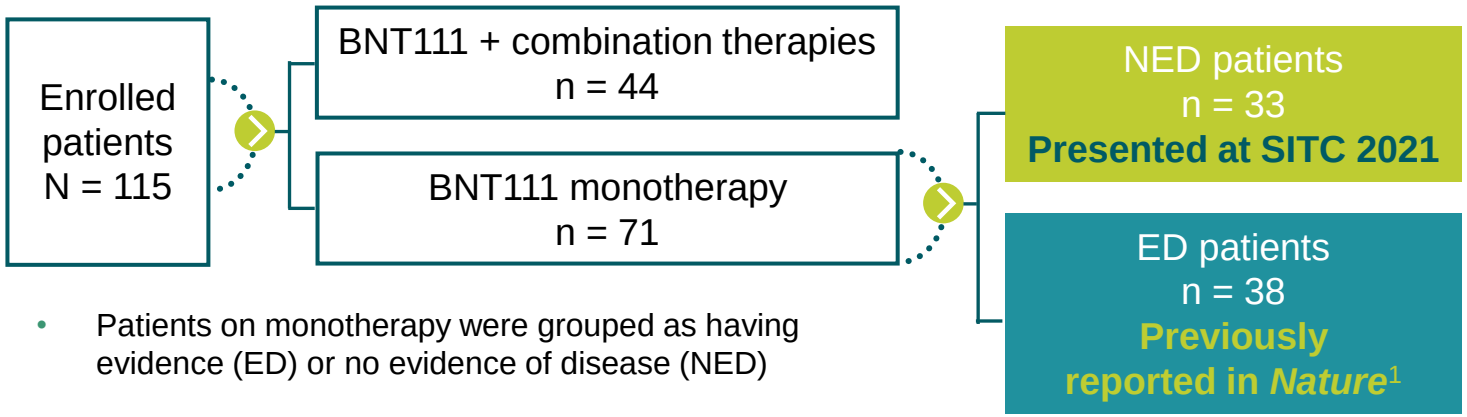
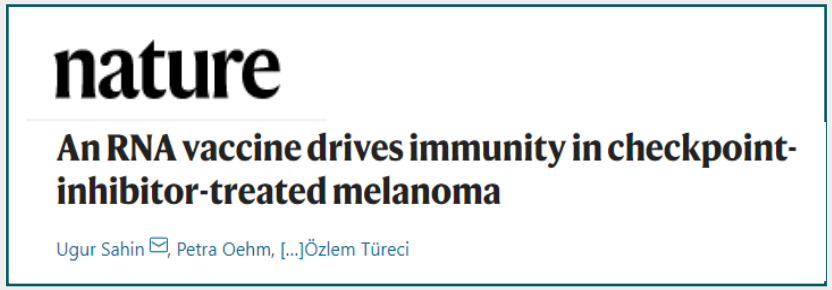
BNT111: Phase 1 Clinical Trial in Patients with Advanced Melanoma

Lipo-MERIT trial - Safety, tolerability and efficacy of BNT111 in patients with pretreated, Stage III or IV cutaneous melanoma



- Patients on monotherapy were grouped as having evidence (ED) or no evidence of disease (NED)

Phase 1 trial data published in Nature[1]:


nature

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

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

- Tolerable safety as monotherapy and in combination with anti-PD1
- Clinical responses accompanied by strong $CD4^+$ and $CD8^+$ T cell immunity
- All patients showed TAA specific T cell responses with in vitro stimulation, and > 75% of patients showed immune responses against ≥ 1 TAA on ex vivo basis
  - T cell responses ramped up over 4-8 weeks and increased or remained stable up to over one year with monthly maintenance therapy
- Durable objective responses in CPI-experienced patients with unresectable melanoma
  - BNT111 monotherapy: 3/25 PR; 8/25 SD
  - ORR 35% in combination with anti-PD1: 6/17 PR; 2/17 SD

PD1, Programmed cell death protein 1; TAA; tumor associated antigen; CPI, check point inhibitor; PR, partial response; SD, stable disease; ORR, Overall Response Rate; CD, Cluster of Differentiation;

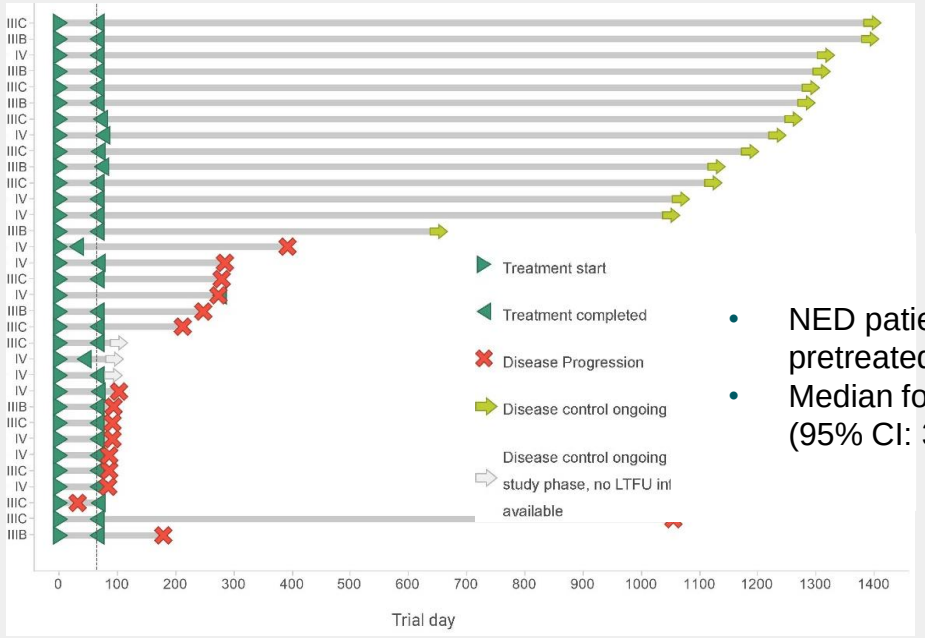
[1]Sahin U, et al. Nature 2020; 585:107-112 (https://www.nature.com/articles/s41586-020-2537-9)

SITC 2021 - BNT111 Phase 1: Monotherapy Shows Potential Immunogenicity and Extended Disease-free Survival in Patients with No Evidence of Disease

Favorable and tolerable Safety profile

- Most common treatment-related AEs: pyrexia, followed by mostly mild-to-moderate flu-like symptoms
- Similar safety profile between *evidence of disease* & *no evidence* of disease populations
- Low rate of related Serious AE
- Low rate of TEAE of Grade ≥3

Median DFS: 34.8 months (95% CI: 7.0–not reached)

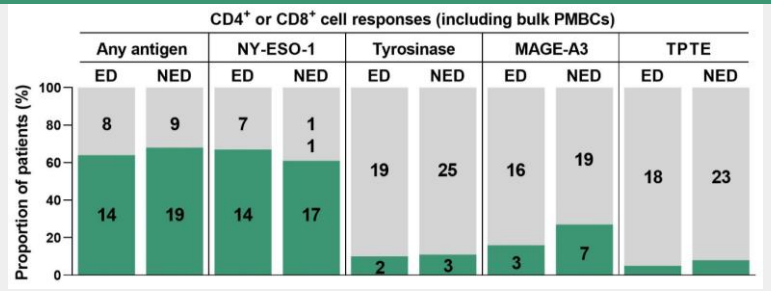


- NED patients (n=33), 27% CPI-pretreated
- Median follow-up of 40.7 months (95% CI: 35.3–42.7)

CD4+ and CD8+ T cell responses

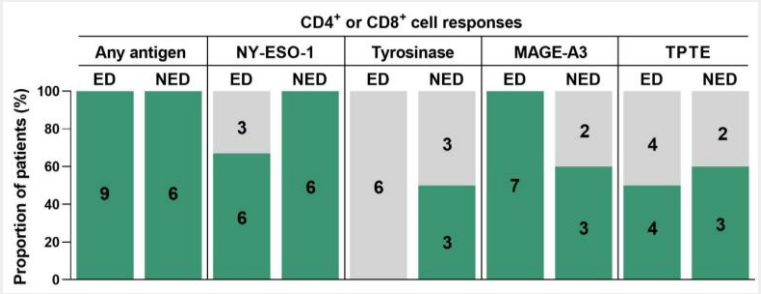
- Substantial fraction of *de novo* induced responses
- T-cell immunity irrespective of the presence of a clinically or radiologically detectable tumor
- All patients with T cell response against at least one TAA

Ex vivo ELISpot (ED, n=22; NED, n=28)



Response: ED 14/22 (63.6%) , NED 19/28 (67.7%)

Post-IVS ELISpot (ED, n=9; NED, n=6)



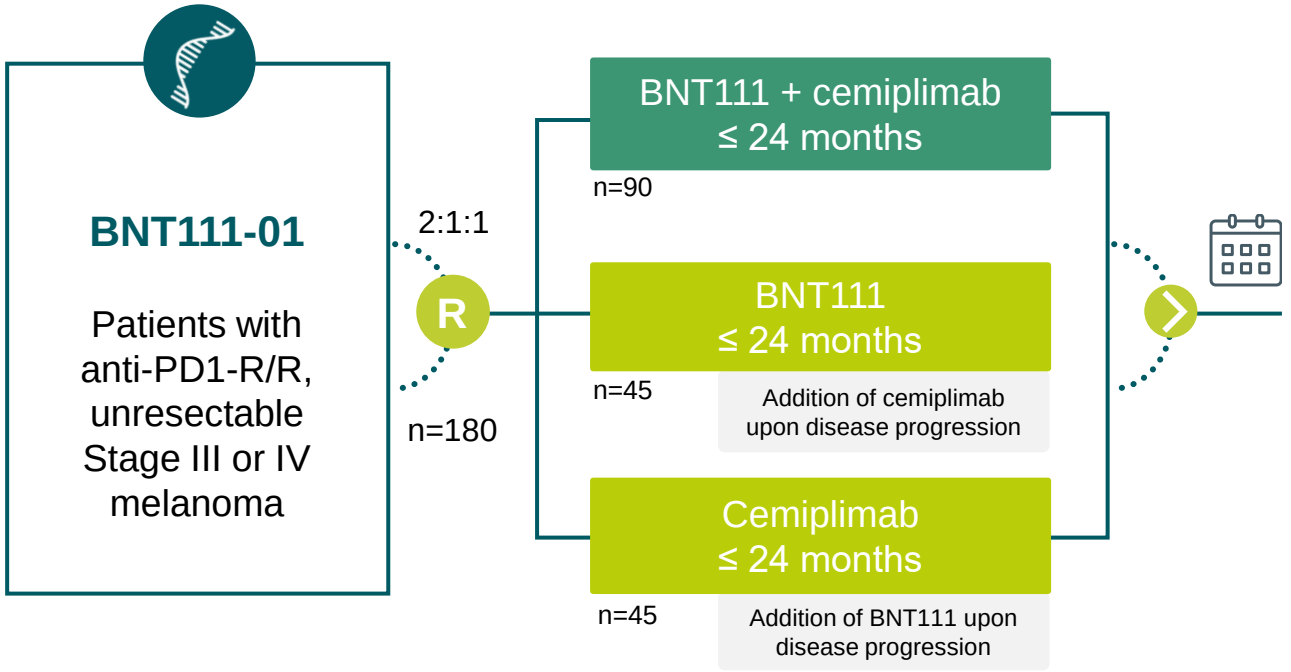
Data cut-off: May 24, 2021

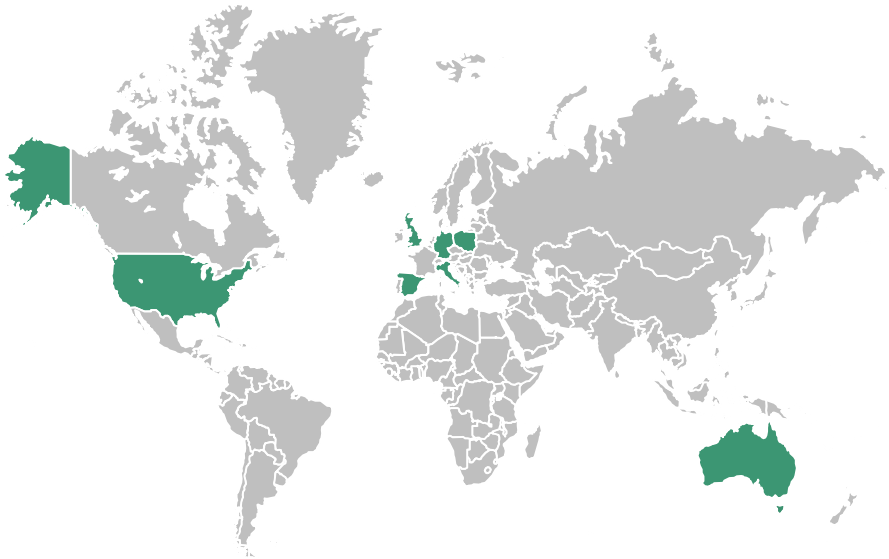
AE; adverse event; TEAE, treatment emergent adverse event; DFS = disease-free survival; CI = confidence interval; ED = evidence of disease; IVS = in vitro stimulation; NED = no evidence of disease; NY-ESO-1 = New York esophageal squamous cell carcinoma-1; MAGE-A3 = melanoma-associated antigen 3; TPTE = transmembrane phosphatase with tensin homology; TAA = tumor-associated antigen.

Loquai C, et al. Oral presentation at the 36th Annual Meeting of the Society for Immunotherapy of Cancer (SITC), November 10–14, 2021, Washington DC.

BIONTECH

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

PD1, Programmed cell death protein 1; R/R, refractory/relapsed; ORR, overall response rate; DoR, Duration of Response; DCR, disease control rate; TTR, time to response; PFS, progression free survival; OS, overall survival; PRO, patient reported outcomes
https://clinicaltrials.gov/ct2/show/record/NCT04526899

BIONTECH

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

Melanoma Remains the Deadliest Skin Cancer[1,2]

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 options[4]

Significant Opportunity to Improve on Standard of Care

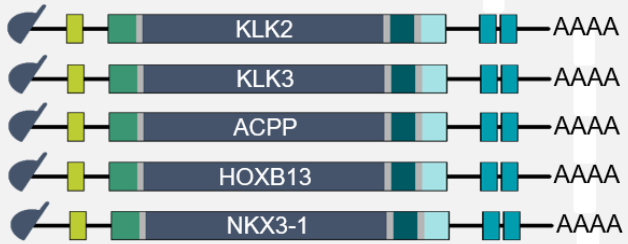
- 5-year survival for metastatic melanoma still only 29.8%[5]
- Frontline immunotherapy with CPI induces durable responses in max. 45-50% of patients but with relatively short PFS[4]
- CPI resistant/refractory patients that fail to respond to CPI or relapse after CPI have an especially poor prognosis 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; [2]Global Cancer Observatory – 2018 data from 'Cancer Today';
[3]Global Cancer Observatory – projected 2025 data from 'Cancer Tomorrow'; [4]Larkin J. et al. NEJM 2019;381(16):1535-1546; [5]https://seer.cancer.gov/statfacts/html/melan.html Accessed August 06, 2021

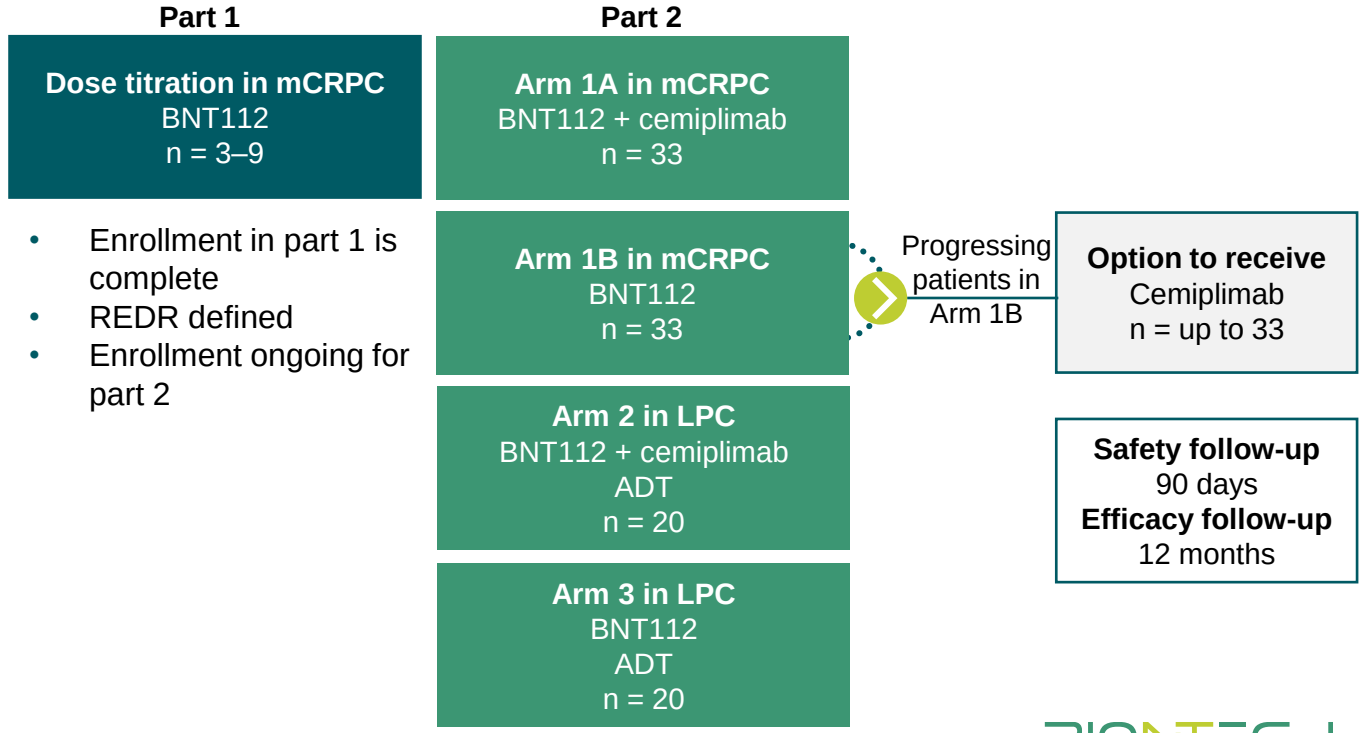
BNT112: Off-the-Shelf Therapeutic Vaccine for Prostate Cancer

FixVac containing 5 related prostate cancer-specific antigens



Phase 1/2 First-in-human Trial in Patients with Metastatic Prostate Cancer

- PRO-MERIT trial – Safety and tolerability of BNT112 with monotherapy and in combination with a PD-1 inhibitor (cemiplimab)
- Targeting
  - Metastatic castration-resistant prostate cancer
  - High-risk localized prostate cancer in neo-adjuvant settings



KLK2 = kallikrein-2; KLK3 = kallikrein-3; ACPP = acid phosphatase prostate; HOXB13 = homeobox B13; NKX3-1 = NK3 homeobox 1; ADT = androgen deprivation therapy; LPC = localized prostate cancer; mCRPC = metastatic castration-resistant prostate cancer; PD-1 = programmed cell death protein 1; REDR = recommended expansion dose range

BIONTECH

SITC 2021 - BNT112 Phase 1/2: Induction of Robust Immune Response and Preliminary Signs of Anti-tumor Activity

14 Patients analyzed

- Median age 68 years
- Most patients Stage 4 at diagnosis and majority had ≥ 2 prior lines of therapy
- Monotherapy: n=9 in Part 1; n=2 in Part 2/1B
- BNT112 + cemiplimab: n=3 in Part 2/1A

No safety signals of concern

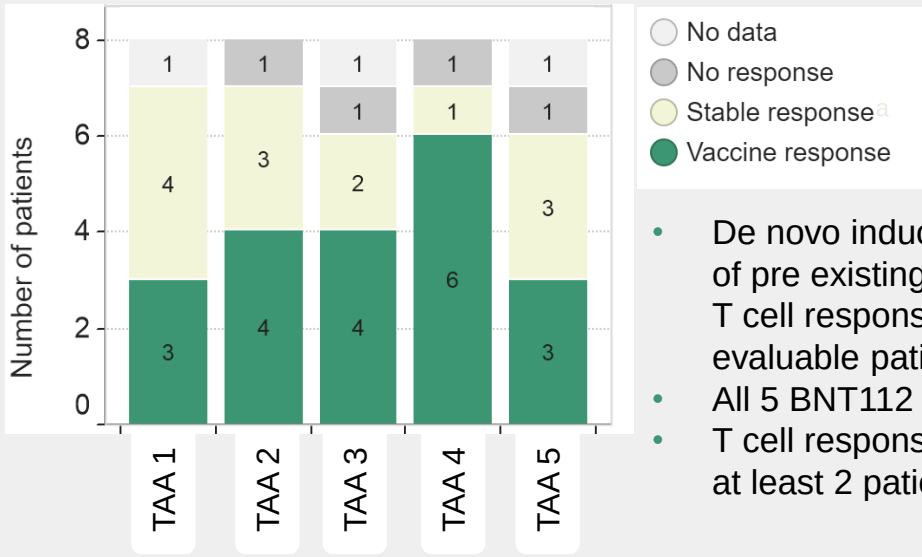
- AEs mostly mild to moderate
- Most common related AEs: pyrexia and hypertension
- Dose reduction due to Grade 3 hypertension in 2 patients
  - Patients recovered within 24 hours
  - Did not meet DLT definition according to Safety Review Committee
- 8 serious AEs in 5 patients unrelated to BNT112

Vaccine induced cytokine release (monotherapy, n=11)

- Increased levels of IFN-α, IFN-γ, and TNF-α following BNT112 administration

Vaccine induced T cell response (Part 1 + 2, n=8),

Post-IVS ELISpot



- De novo induction and expansion of pre existing antigen specific T cell responses in all ELISpot evaluable patients
- All 5 BNT112 TAAs* immunogenic
- T cell responses to each antigen in at least 2 patients

Signs of anti-tumor activity

- PSA level reduced in 2 patients with monotherapy

Data cut-off: May 10, 2021

AE, adverse event; DLT, dose-limiting toxicity; IFN, interferon; TNF, tumor necrosis factor; TAA = tumor-associated antigen; PSA = prostate-specific antigen.

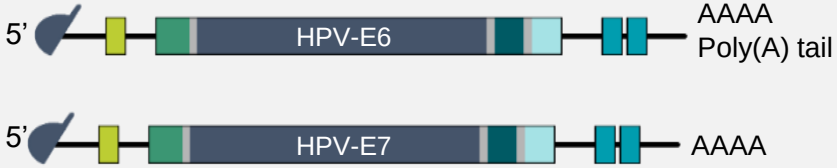
*Linch M, et al. Oral presentation at the 36ht Annual Meeting of the Society for Immunotherapy of Cancer (SITC), November 10–14, 2021, Washington DC.

BIONTECH

BNT113: Off-the-Shelf Therapeutic Vaccine for HPV16+ Head and Neck Cancer

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
- Potential to increase response rate and DoR to CPI by stimulating immune response against HPV16 proteins



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

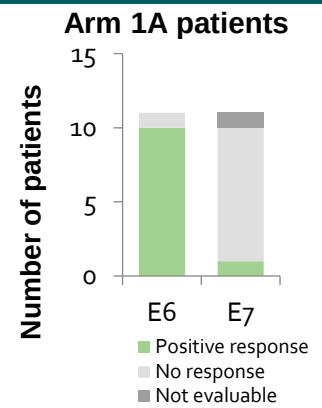
HPV, human papilloma virus; DoR, Duration of Response, CPI, check point inhibitor; PD1, Programmed cell death protein 1.

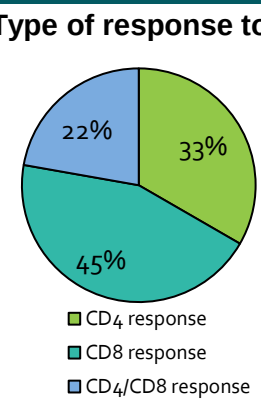
BNT113: Potent Antigen-Specific T Cell Responses in Phase 1 Trial[1,2]

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

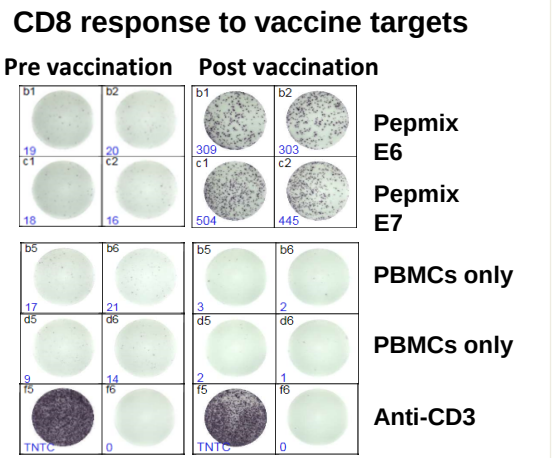
A Overview of T cell responses Arm 1A

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

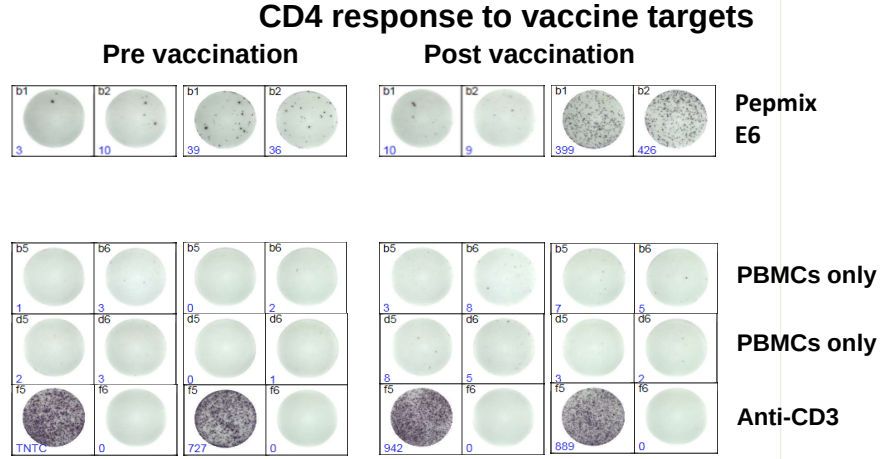




B ELISPOTS[3] Patient 7



ELISPOTS[3] Patient 6



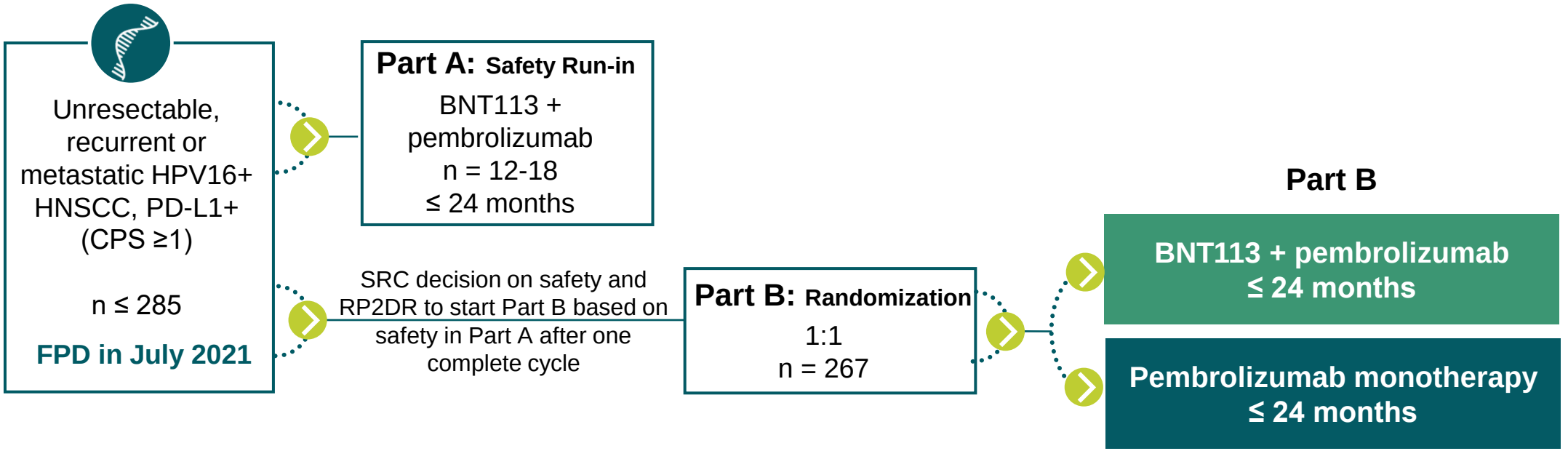
TD, total dose; CD, Cluster of Differentiation; NE, Not Evaluated; NR, Not Reported; PBMC, peripheral blood mononuclear cells

[1]HARE-40 trial

[2]Presented at CIMT 2019

[3]ELISPOT (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: Phase 2 Trial in HPV16+ and PD-L1+ HNSCC



Open-label, controlled, Phase 2 trial

- 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%

HPV, human papilloma virus; PD-L1, programmed death-ligand 1; HNSCC, head and neck squamous cell carcinoma; FPD, first patient dosed; CPS, Combined positive score; SRC, safety review committee; TEAEs, treatment emergent adverse events; OS, overall survival; mOS, median overall survival; ORR, overall response rate; HR, hazard ratio; DOR, duration of response; DCR, disease control rate; PFS, progression free survival

[1]Burtness, et al. Lancet 2019 Nov 23; 394(10212):1915-28
https://www.clinicaltrials.gov/ct2/show/NCT04534205

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 2018[2]
- Oropharyngeal is most common HNSCC, accounting for 70% of cases, and 80-90% are HPV16+[3]

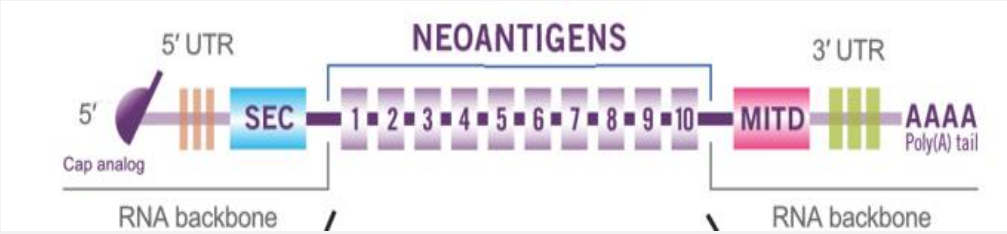
Limited treatment options for patients not responding to or relapse on CPI[1]

- 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 patients[4]:
  - 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

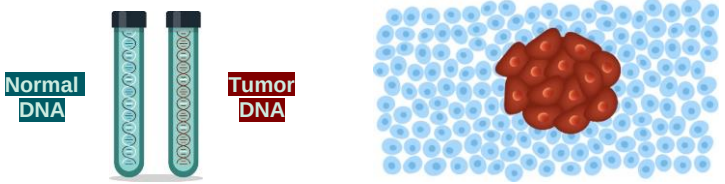
HPV, human papilloma virus; HNSCC, head and neck squamous cell carcinoma, CPI, check point inhibitor; R/R refractory/recurrent
[1]Sabatini ME and Chiocca S. BJC 2020; 122:306-314, [2]Johnson DE, et al., 2020, Nature Reviews Disease Primers 6:92
[3]Saraiya et al. 2015, Vaccines; [4]HNSCC NCCN Guidelines 2020, HNSCC ESMO Guidelines 2020; [5]Burtness, et al. Lancet 2019 Nov 23; 394(10212):1915-28;
[6]https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6563923/pdf/nihms-1024161.pdf

iNeST[1]: Tailored Treatment to Exploit Individual Targets



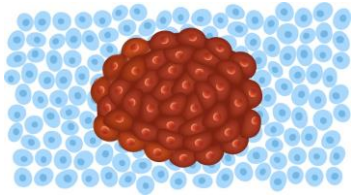
- Fully customized to the individual patient
- Targeting 20 neo-antigens per patient

ADJUVANT



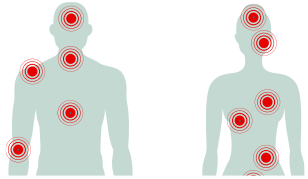
Residual cancer cells may remain – emphasis on recurrence free survival

1L METASTATIC



Rapidly growing but often still in early phase of metastases

LATE-LINE METASTATIC



Bulky tumors with multiple organs involved

iNeST

Product Candidate[3]	Indication (Targets)	Preclinical	Phase 1	Phase 2
autogene cevumeran (BNT122)	1L melanoma			
	adjuvant colorectal cancer			
	solid tumors			

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

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

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

BIONTECH

Autogene Cevumeran (BNT122): Phase 1 Data Update Reported at AACR 2020

Dose escalation: Monotherapy in locally advanced or metastatic solid tumors

- **31 patients**, **doses ranging from 25-100µg**
  - Most common tumor types: 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,
  - **Confirmed CR in 1 patient** with **gastric cancer and metastatic liver lesions** (ongoing for 10 months)
  - **12 SD**

Combination with atezolizumab: clinical activity in heavily pre-treated patients

- **132 patients**, **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 **CR as best response** (0.9%),
  - **8 PR** (7.4%), and
  - **53 SD** (49.1%)

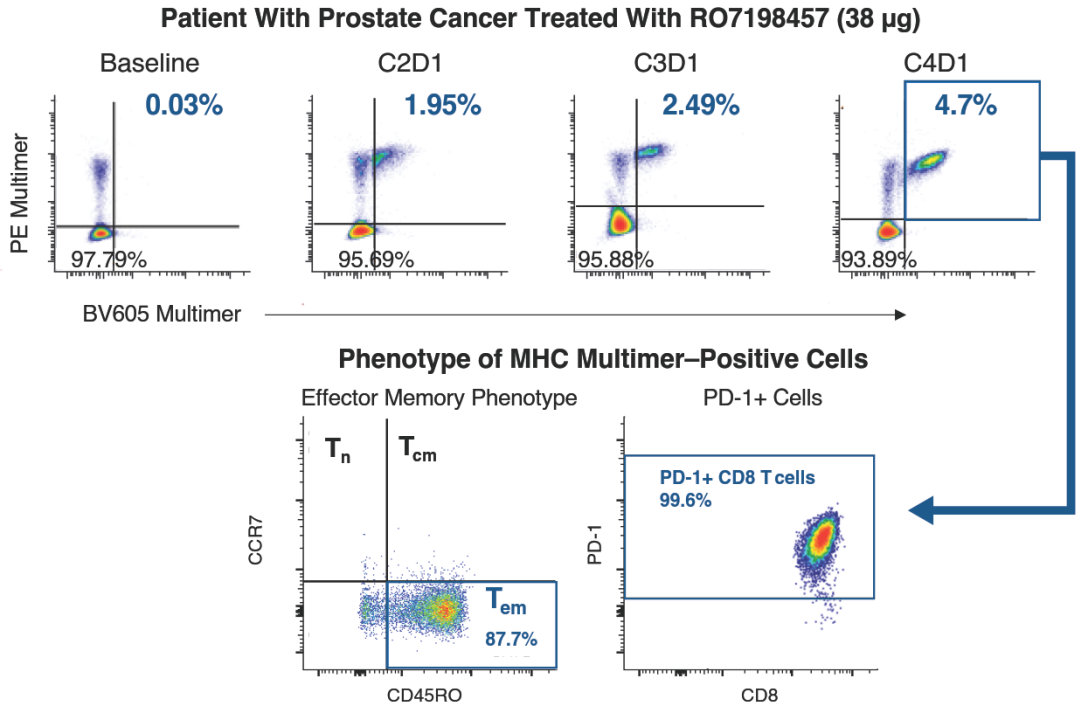
- **Demonstrates ability to elicit significant T cell responses of both effector and memory phenotype as monotherapy and in combination**
- **TEAEs primarily transient systemic reactions, manifesting as low grade CRS, IRR or flu-like symptoms**
- **Early evidence of clinical activity in highly refractory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

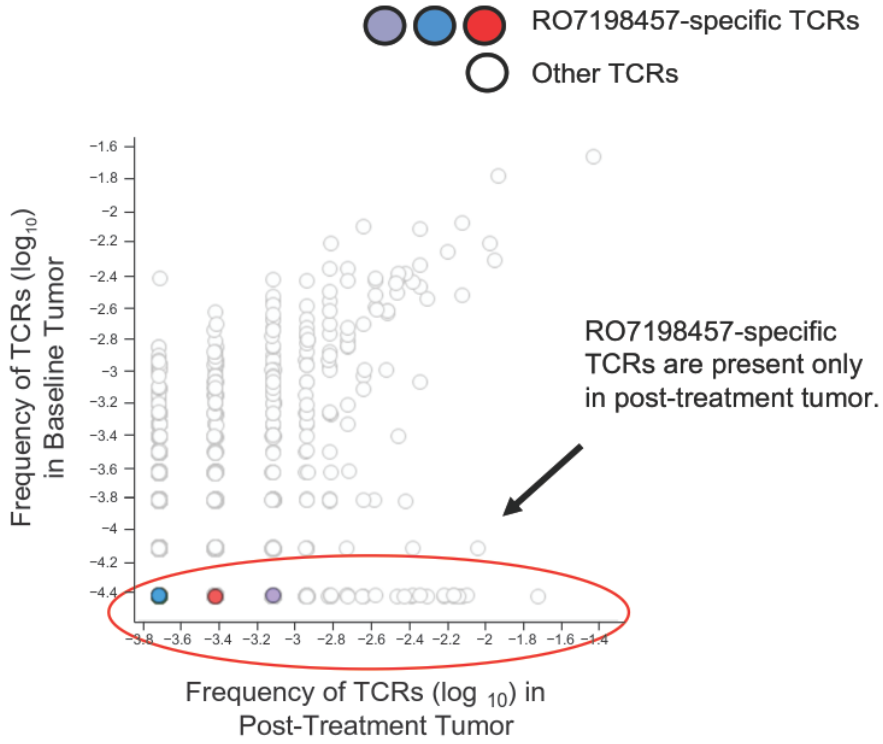
PD-L1, programmed death-ligand 1; CR, complete response; SD, stable disease; CPI, checkpoint inhibitor; PR, partial response; TEAE, treatment emergent adverse event; CRS, cytokine release syndrome; IRR, infusion-related reaction; AE, adverse event.
Note: Patients in both cohorts received personalized product manufactured on per patient basis with **up to 20 patient-specific neoantigens, in both cohorts majority of AEs were Grad 1 or Grade 2**

Autogene Cevumeran (BNT122): Phase 1 Data Update Reported at AACR 2020 (Cont'd)

Autogene Cevumeran (BNT122) induces:

- CD8+ T cells in CPI-sensitive and CPI-insensitive tumor types
- CD8+ T cell infiltrates in tumors





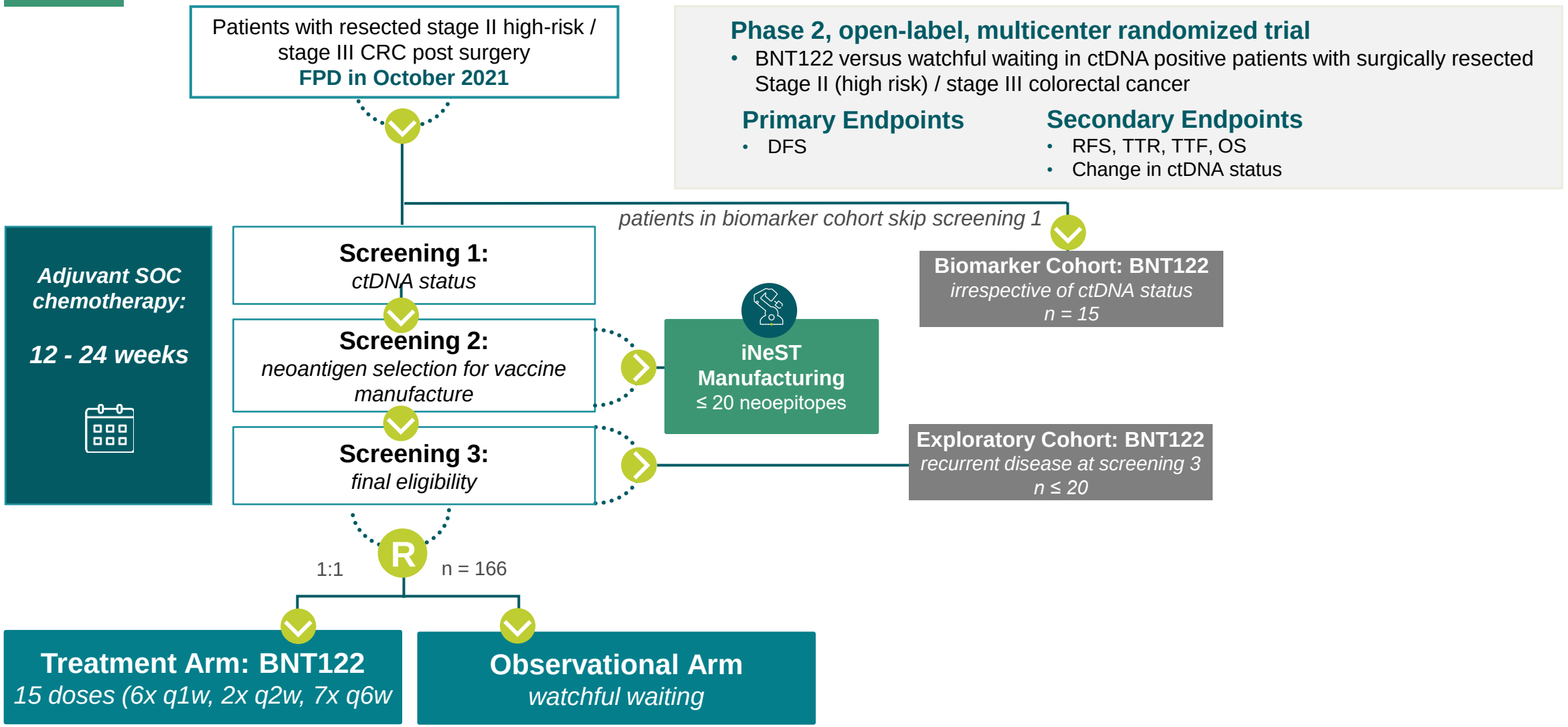
CPI, checkpoint inhibitor; TCR, T-cell receptor

Autogene cevumeran (BNT122): 2 Ongoing Randomized Phase 2 Trials

	First-line advanced melanoma Phase 2	Adjuvant colorectal cancer Phase 2
Study design and patient population	Open-label, multicenter randomized trial of the efficacy and safety of Autogene Cevumeran in combination with pembrolizumab vs. pembrolizumab in patients with previously untreated advanced melanoma	Open-label, multicenter randomized trial to compare the efficacy of Autogene Cevumeran versus watchful waiting in patients with ctDNA positive, surgically resected Stage 2/3 rectal cancer, or Stage 2 high risk/stage 3 colorectal cancer
Rationale	• **Evaluate added benefit of 1L Autogene Cevumeran in an advanced CPI-sensitive tumor (PFS, ORR)** • **Success may unlock 1L use of iNeST in CPI-sensitive advanced cancers for combination therapy**	• **Evaluate added benefit of Autogene Cevumeran in a micrometastatic CPI-insensitive tumor (RFS)** • **Success may unlock adjuvant use of iNeST for CPI-insensitive ctDNA+ cancer types**

1L, first-line; CPI, checkpoint inhibitor; PFS, progression-free survival; ORR, overall response rate; RFS, relapse free survival; ctDNA, circulating tumor DNA.

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



CRC, colorectal cancer; ctDNA, circulating tumor DNA; SOC, standard of care; q1w, once weekly; q2w, every two weeks; q6w, every six weeks; DFS, disease-free survival; RFS, relapse-free survival; TTR, time to response; TTF, time to treatment failure; OS, overall survival; https://www.clinicaltrials.gov/ct2/show/NCT04486378;
BNT122/iNeST is partnered with Genentech/Roche

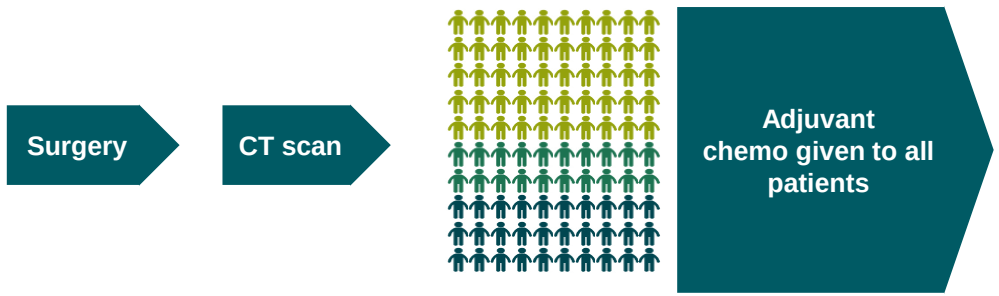
Autogene cevumeran (BNT122): Adjuvant treatment of circulating tumor DNA positive, surgically resected Stage II (high risk)/Stage III colorectal cancer

High medical need in the adjuvant treatment of Stage II (high risk)/Stage III colorectal cancer

- Colorectal cancer is second deadliest cancer worldwide[1], 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 months[5]

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

Stage II (high risk) and Stage III colorectal cancer



No Residual Disease	50%	Cured by surgery alone
Microscopic Residual Disease	20%	Cured by chemo on top of surgery
	30%	Recur despite surgery + chemo

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

[1]WHO factsheet on cancer. 2018; [2]Seer database; [3]Fan et al, PLoS One 2017; [4]Loupakis et al. 2021, JCO Precision Oncology; [5]Reinert et al., JAMA Oncology, 2019

*Autogene cevumeran is partnered with Genentech

BIONTECH

Digitalization and Automation for Neo-antigen Vaccine Manufacturing

Paperless documentation

Semi-automatic manufacturing

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

SIEMENS

BIONTECH

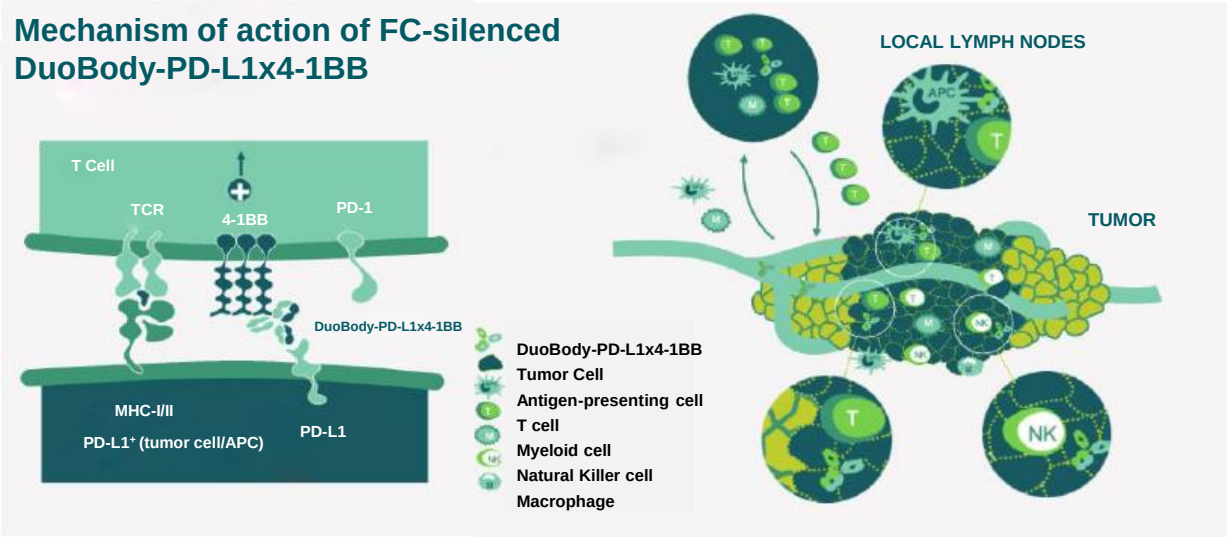
Agenda

- **Overview and business outlook**
  - Pipeline
- **Deeper dive on our key programs**
  - COVID-19 vaccine program (project “Lightspeed”)
  - mRNA vaccines – FixVac and iNeST
  - Antibodies
  - Cell Therapies – CARVac and NEO-STIM T cell therapy
  - Small Molecule Immunomodulators
  - RiboCytokines

BIONTECH

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 1/2 trial presented at SITC 2020

- 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**

Started Phase 2 trial of BNT311 as monotherapy and in combination with pembrolizumab in R/R metastatic NSCLC – FPD in December 2021

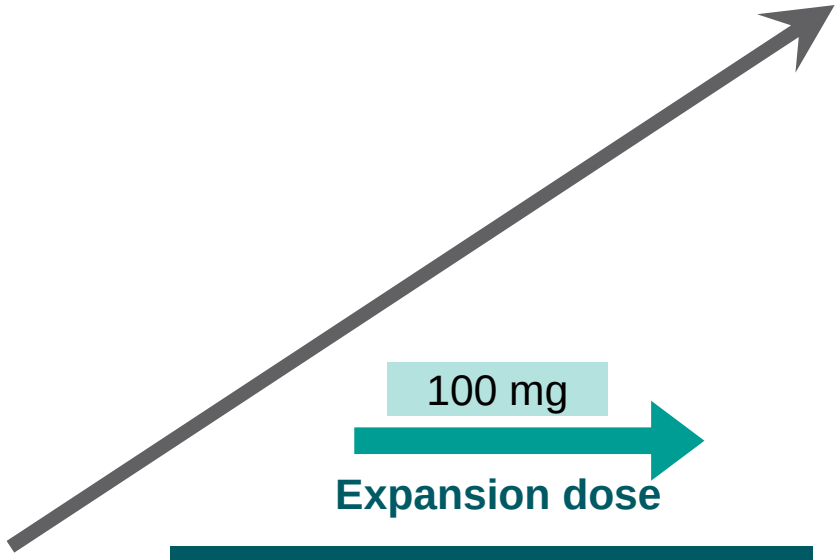
R/R, refractory/relapsed; NSCLC, non-small cell lung cancer.
SITC 2020, Muik et al. and SITC 2020, Garralda et al.
*BNT311 (Gen1046) is partnered with Genmab based on 50/50 sharing of costs and profits

BNT311: Phase 1/2 Safety Trial in Patients with Malignant Solid Tumors

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

Expansion dose

10 expansion cohorts are ongoing

Dose Expansion
N = Up to 40 per cohort

NSCLC, Urothelial cancer, Endometrial cancer, TNBC, SCCHN, Cervical cancer

Study Endpoints

Safety and tolerability
PK/PD
Anti-tumor activity
Biomarkers

PK, pharmacokinetics; PD, Pharmacodynamics; NSCLC, non-small cell lung cancer, TNBC, Triple-negative breast cancer; SCCHN, Squamous cell carcinoma of the head and neck.
*BNT311 (Gen1046) is partnered with Genmab based on 50/50 sharing of costs and profits

BNT311: Interim Results of Ongoing Phase 1/2 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

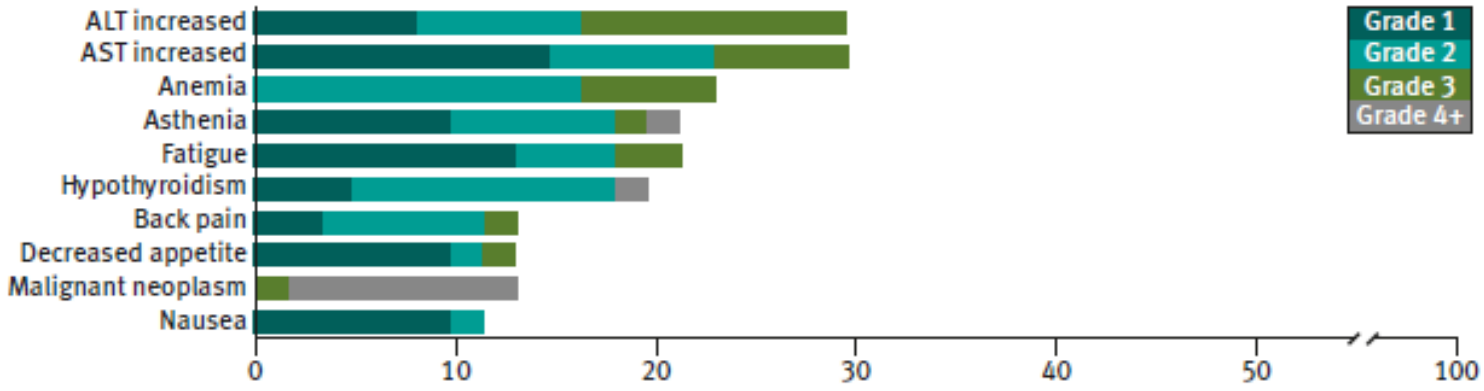
Dose expansion

- **Encouraging preliminary efficacy** in 12 **PD-L1 relapsed/refractory NSCLC** patients
  - **2** confirmed **PR**
  - **1** unconfirmed **PR**
  - **4** patients demonstrated **SD**
- Enrollment ongoing in 8 additional cohorts

FIH, first-in-human; AE, adverse event; DLT, dose-limiting toxicity; MTD, maximum tolerated dose; NSCLC, non-small cell lung cancer, TNBC, Triple-negative breast cancer; CPI, checkpoint inhibitor; IP10, interferon-gamma induced protein 10; PD-L1, programmed death-ligand 1; PR, partial response; SD, stable disease.
SITC 2020, Garralda et al., Poster #412

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

TEAEs occurring in ≥10% of patients



TRAEs occurring in ≥10% of patients

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

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

TEAE, treatment emergent adverse event; TRAE, treatment related adverse event; MTD, maximum tolerated dose.
SITC 2020, Garralda et al., Poster #412

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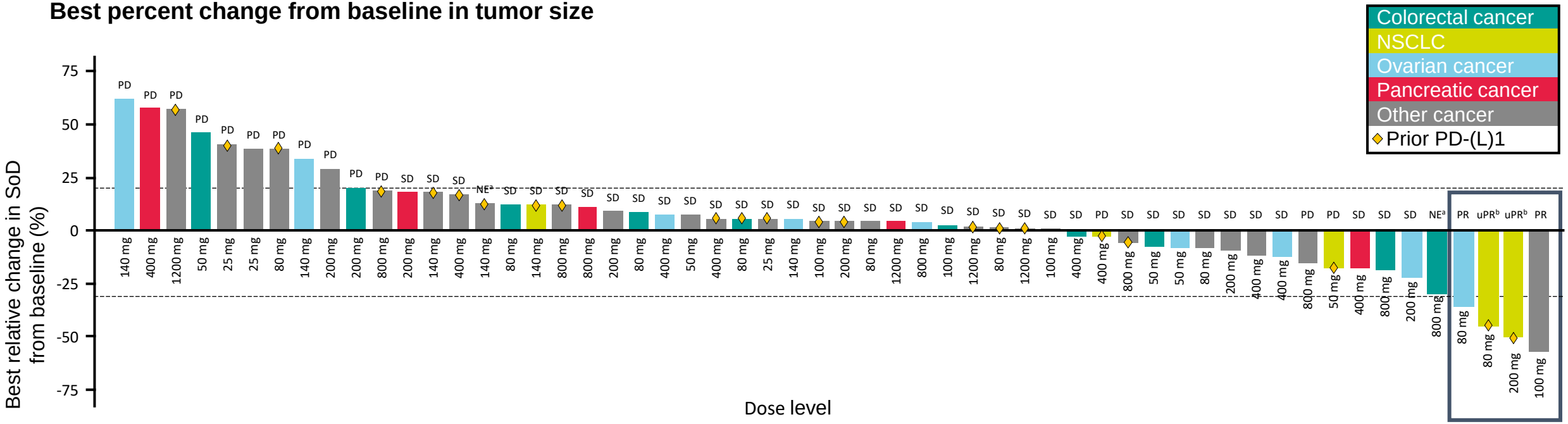
BNT311: Interim Results of Ongoing Phase 1/2- Anti-tumor Activity in Dose Escalation

Best percent change from baseline in tumor size



Disease control achieved in 65.6% of patients; four patients with PR

Includes 4 early partial responses in TNBC (1), ovarian cancer (1), and ICI-pre treated NSCLC (2) patients

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

[a]Minimum duration of response (5 weeks) per RECIST v1.1 not reached.

[b]PR was not confirmed on a subsequent scan.

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

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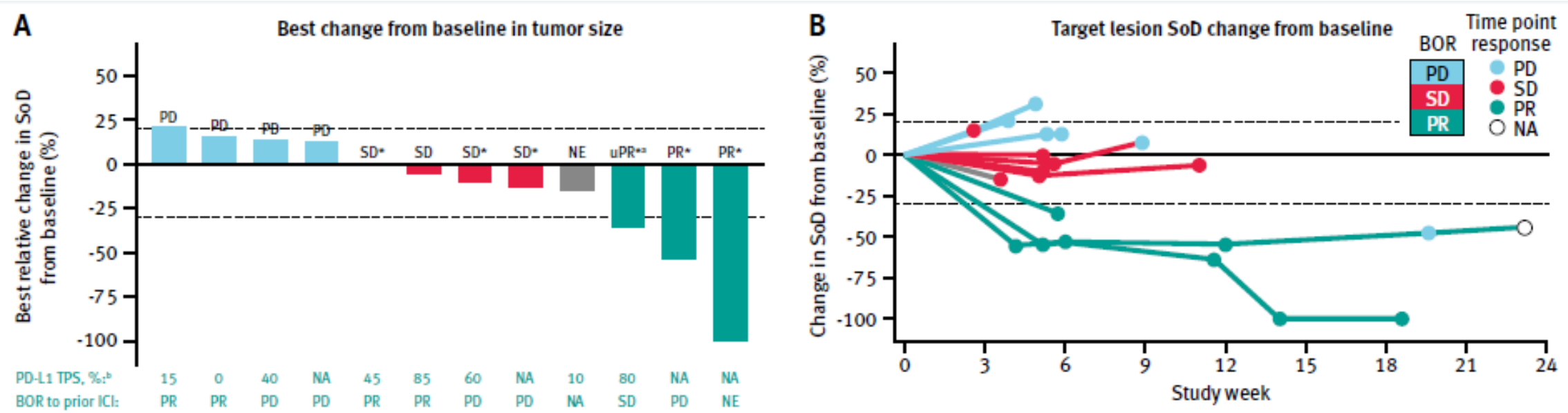
BNT311: Interim Results of Ongoing Phase 1/2 – Anti-tumor Activity in CPI Recurrent/Refractory NSCLC Expansion



As of October 12, 2020, 24 patients enrolled in expansion cohort 1, including 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

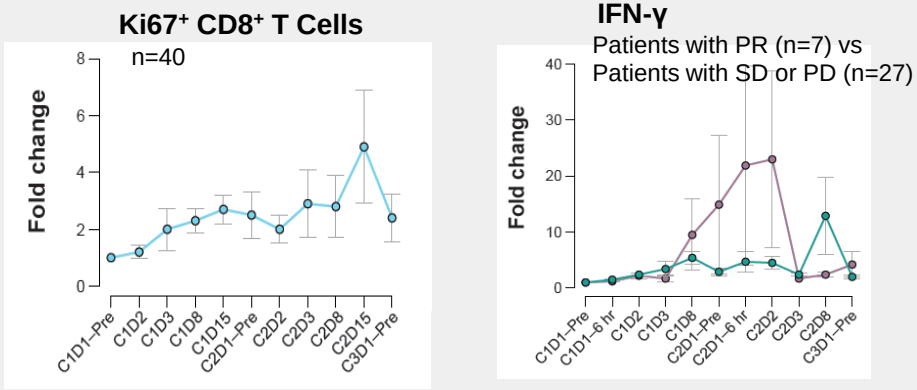
Data cut-off: October 12, 2020

*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.

SITC 2021 - BNT311 Phase 1/2: Peripheral and Tumoral Immunologic Responses Supportive of Proposed Mechanism of Action in CPI-experienced NSCLC Patients

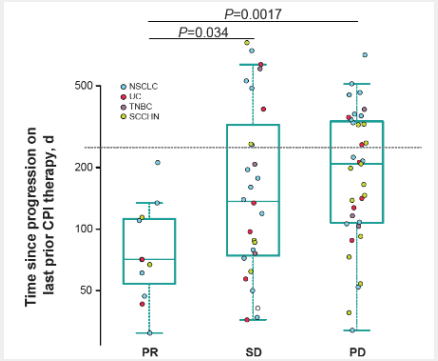
40 patients analyzed : Patients with PD-(L)1Inhibitor–Pretreated NSCLC

Positive pharmacodynamics responses

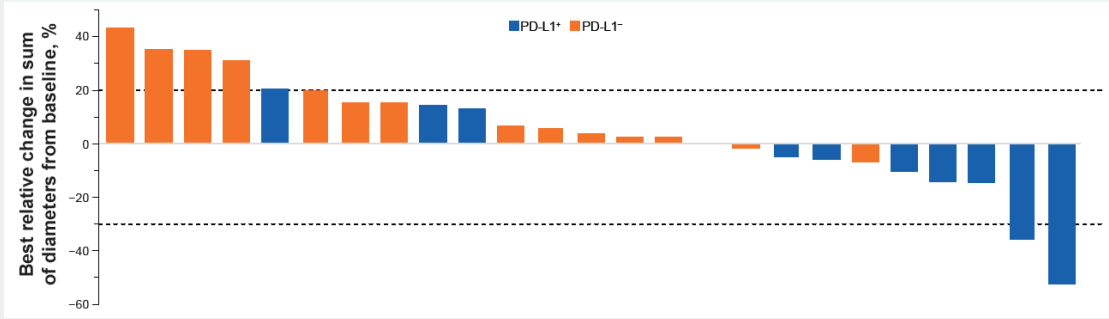


- Induction of IFN-γ and expansion of CD8+ effector memory T cells & activated NK cells
- Greater induction of IFN-γ, CXCL9/10 and activated NK cells in responders vs non-responders

Relationship between disease control and PD-L1 expression, as well as time from last prior anti–PD-1 therapy



- Higher disease control rates in patients with prior anti-PD-1 therapy within 8 months from first dose of study drug



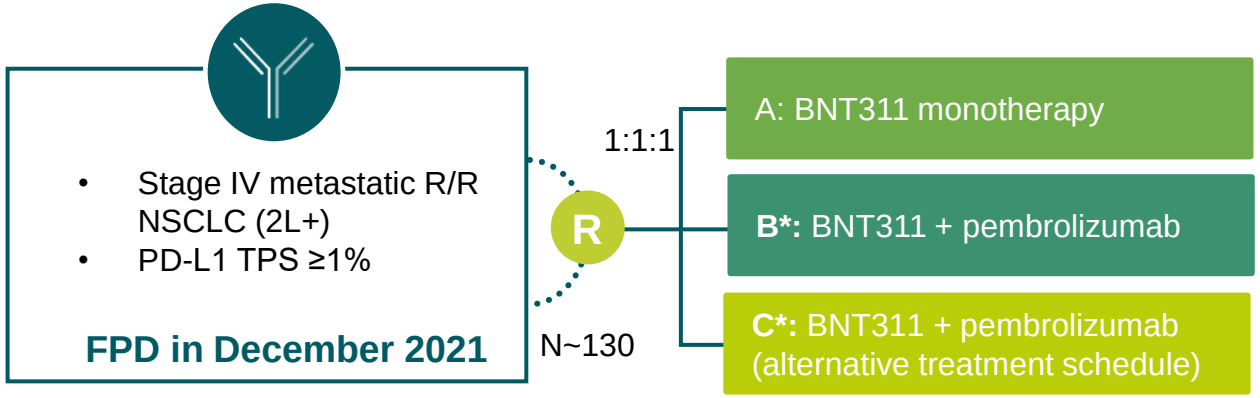
- Patients with tumor reduction mainly PD-L1+ tumors
- Tumor reduction in 7 of 11 patients with PD-L1+ tumors

Data cut-off: September 21, 2021

†PR includes confirmed and unconfirmed responses. *P* values based on Wilcoxon test. Time since last prior CPI was an independent predictor among multiple covariates. CAR = chimeric antigen receptor; CLDN6 = Claudin 6; CPI = checkpoint inhibitor; IFN-γ, interferon-γ; NK = natural killer; PR = Partial Response; SD = Stable Disease; PD = Progressive Disease; NSCLC = non-small cell lung cancer; PD-1 = programmed cell death protein 1; PD-L1 = programmed death-ligand 1; R/R = relapsed/refractory.

Ponce Aix S, et al. Oral presentation at the 36th Annual Meeting of the Society for Immunotherapy of Cancer (SITC), November 10–14, 2021, Washington DC

BNT311: Phase 2 Trial Targeting CPI-experienced PD-L1+ R/R NSCLC



Open-label, randomized Phase 2 trial

BNT311 as monotherapy and in combination with Pembrolizumab after treatment with SOC immune checkpoint inhibitor

Primary Endpoints
- ORR per RECIST 1.1

Standard of Care Benchmark
- Docetaxel, ORR: 4-15%[2]

Secondary Endpoints
- PFS
- DoR

Significant unmet need in R/R NSCLC

- ~1.8 million lung cancer deaths worldwide annually[1]
- NSCLC is most common type (~85%)[2]
- 5-year survival only 4% for advanced or metastatic NSCLC[3]
- CPI therapy fails in majority of NSCLC patients due to evolution of resistance
- Poor prognosis for CPI R/R NSCLC
  - Estimated PFS of < 6 months and OS of <1 year

New strategies needed to overcome resistance and maximize efficacy

Partnered with Genmab; 50:50 profit/loss collaboration
R/R, refractory/relapsed; NSCLC, non-small cell lung cancer; PD-L1, programmed death-ligand 1; SOC, Standard of Care; CPI, check point inhibitor; TPS, tumor proportion score; ORR; objective response rate; PFS, progression free survival; DoR, duration of response; OS, Overall Survival
*Following Safety run-in

[1]Bray et al., 2018; [2]https://www.cancer.net/cancer-types/lung-cancer-non-small-cell/statistics; [3]Cancer statistics, 2018.Siegel et al., CA Cancer J Clin. 2018 Jan; 68(1):7-30
[2]Qu et al., 2022; https://journals.sagepub.com/doi/10.1177/1758835921992968

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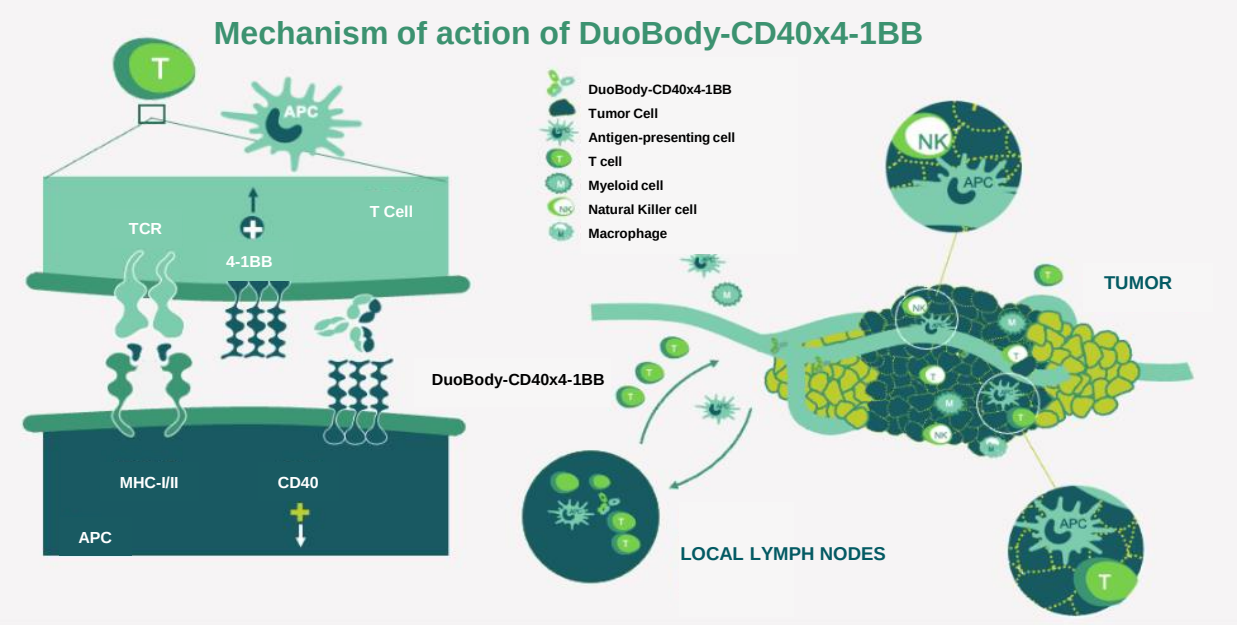
BNT312 Phase 1/2: First-in-Human Study of DuoBody-CD40x4-1BB, A Next-Generation Bispecific Antibody

Next-generation immunomodulator

- Bispecific antibody* combines targeting and conditional activation of CD40 and 4-1BB on immune cells
- Potential to enhance priming and (re-)activation of tumor-specific immunity
- Bispecific antibody is 50:50 profit/loss share partnered with Genmab



Open-label dose-escalation trial with expansion cohorts to evaluate safety and anti-tumor activity

Patients with relapsed or refractory, advanced or metastatic solid tumors who are not candidate for SoC
N~50

Part 1

BNT312 dose escalation

Expansion dose 100 mg

Expansion Cohorts

Combination	Monotherapy
n = up to 40 per cohort	n = up to 22 per cohort
Melanoma, NSCLC, Colorectal Cancer, PDAC, HNSCC	Post-CPI melanoma (MoA)

Combination expansion cohorts are currently recruiting

SoC = Standard of Care; NSCLC = Non-small Cell Lung Cancer; PDAC = Pancreatic ductal adenocarcinoma; HNSCC = Head and neck squamous cell carcinoma
*BNT312 (Gen1042) is partnered with Genmab based on 50/50 sharing of costs and profits

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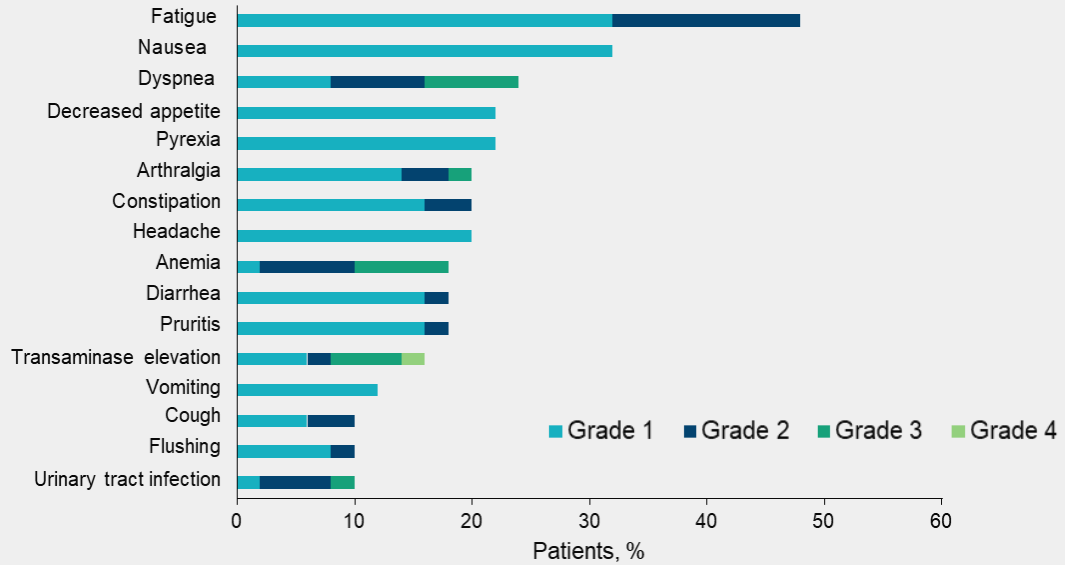
SITC 2021 - BNT312 Phase 1/2: Dose Escalation Showed Favorable Safety Profile Across a Wide Dose Range

50 patients analyzed : Median age 57 years; 60% had ≥3 prior lines of therapy; Cancer types: CRC (22%), Melanoma (20%), NSCLC (8%), Other (50%)

Manageable safety profile

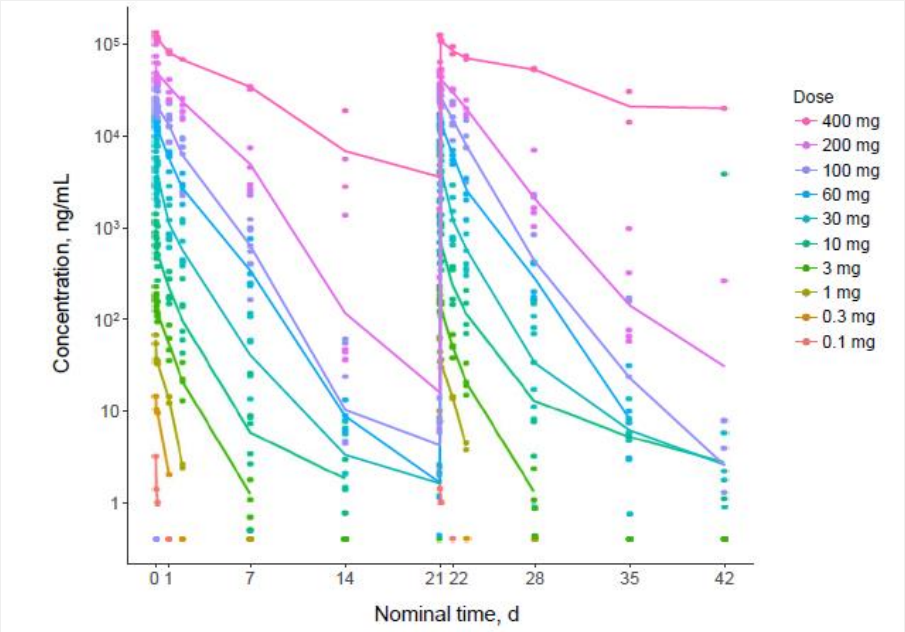
TEAEs:



- MTD not reached
- 1 DLT (grade 4 transaminase elevation at 200 mg)
  - Resolved with corticosteroids
- No drug-related grade ≥3 thrombocytopenia or CRS
- No treatment-related deaths

PK: C_{max} observed shortly after end of infusion

PK of BNT312 evaluated for doses 0.1–400 mg Q3W



- Faster clearance at low doses indicates target-mediated drug disposition

Data cut-off: August 27, 2021

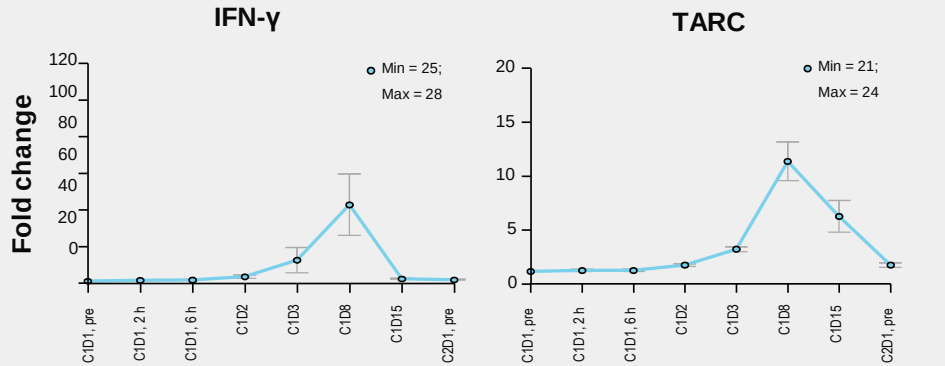
CRS = cytokine release syndrome; DLT = dose-limiting toxicity; MTD = maximum tolerated dose; PK = Pharmacokinetics; C_{max}, peak serum concentration; Q3W = once every 3 weeks.

Johnson M, et al. Oral presentation at the 36th Annual Meeting of the Society for Immunotherapy of Cancer (SITC), November 10–14, 2021, Washington DC.

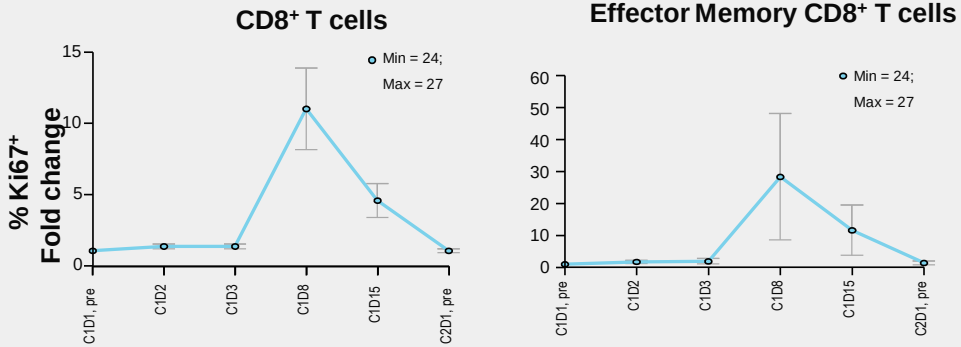
SITC 2021 - BNT312 Phase 1/2: Preliminary Antitumor Activity Across Multiple Dose Levels (at least 3 mg)

50 patients analyzed : Median age 57 years; 60% had ≥3 prior lines of therapy; Cancer types: CRC (22%), Melanoma (20%), NSCLC (8%), Other (50%)

Biological activity consistent with mechanism of action



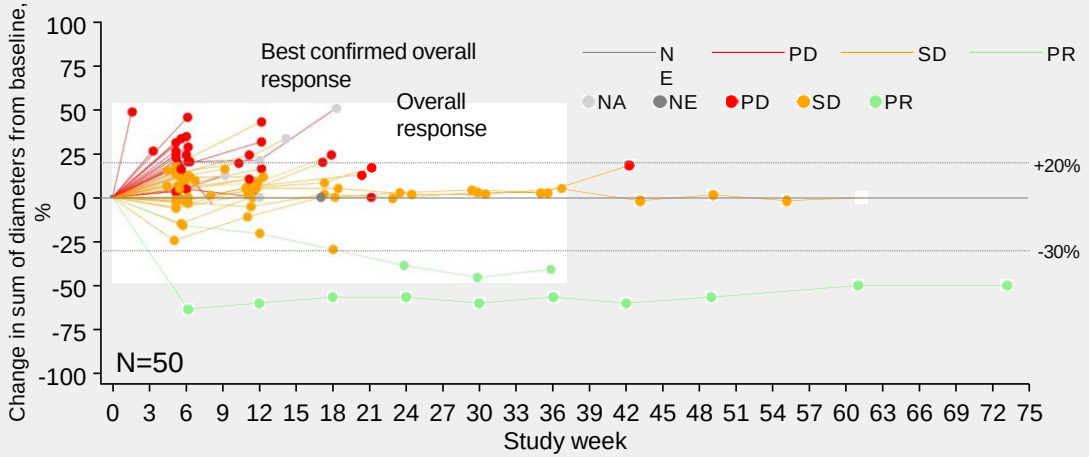
- Doses ≥30 mg effectively induce cytokine release



- T cell proliferation with Doses ≥30 mg

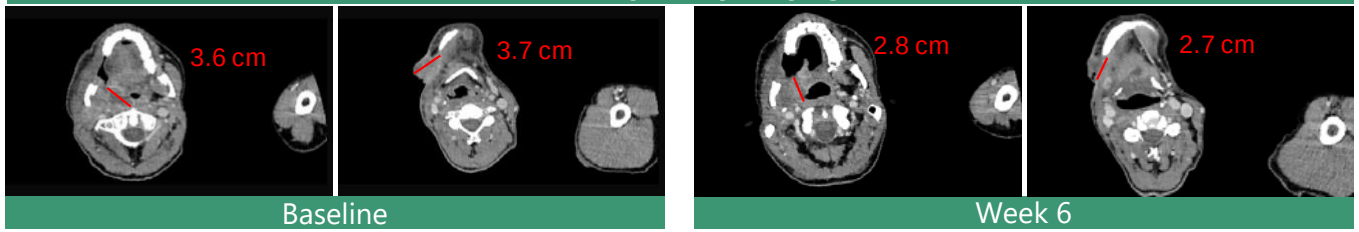
Minimum and maximum numbers of patients with available data (n) at any given point are displayed

Disease control in 50% of patients



- 23 patients had SD, with 6 patients maintaining SD ≥12 weeks
- **2 patients with confirmed PR:**
  - Melanoma (duration ≥15.4 months; 3 mg)
  - Neuroendocrine lung cancer (duration ≥2.8 months; 30 mg)

Clinical case study: oropharyngeal cancer



Data cut-off: August 27, 2021

IFN-γ= interferon-γ; NA = not available; NE = not evaluable; PD = progressive disease; PR = partial response; SD = stable disease; TARC = thymus- and activation-regulated chemokine.

Johnson M, et al. Oral presentation at the 36th Annual Meeting of the Society for Immunotherapy of Cancer (SITC), November 10–14, 2021, Washington DC.

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

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Proprietary Cell Therapy Pipeline and Capabilities

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

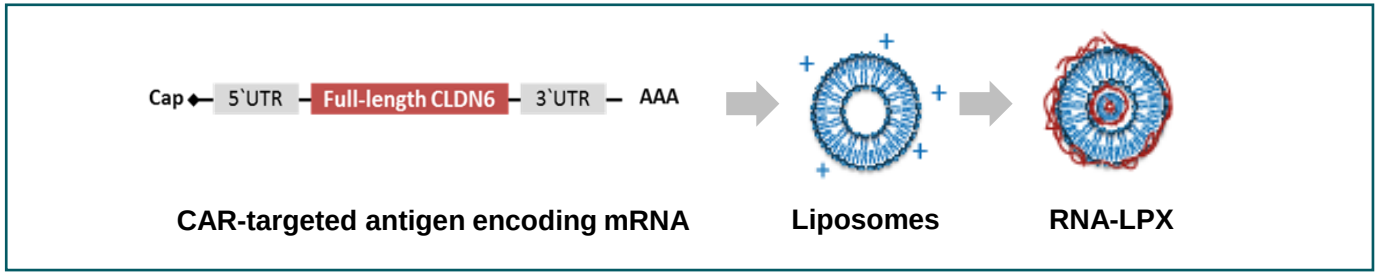
CARVac CAR-T cell amplifying mRNA therapy for solid tumors	**NEOSTIM** individualized neoantigen-T cell therapy	**Personalized TCR-T cell therapy**
Next generation CAR-T targeting CLDN6 with CARVac ***Advanced tumors***	Patient‘s PBMCs used to induce and expand multiple $CD4^+$ and $CD8^+$ neoantigen T cell populations ex-vivo ***CPI nonresponsive tumors***	Ex-vivo engineered neoantigen specific TCR-T cell therapy further strengthened by an acquistion from Kite ***Advanced tumors***

IiO, immuno-oncology; PBMC, peripheral blood mononuclear cell;

BNT211: Next Generation CAR-T Therapy in Solid Tumors

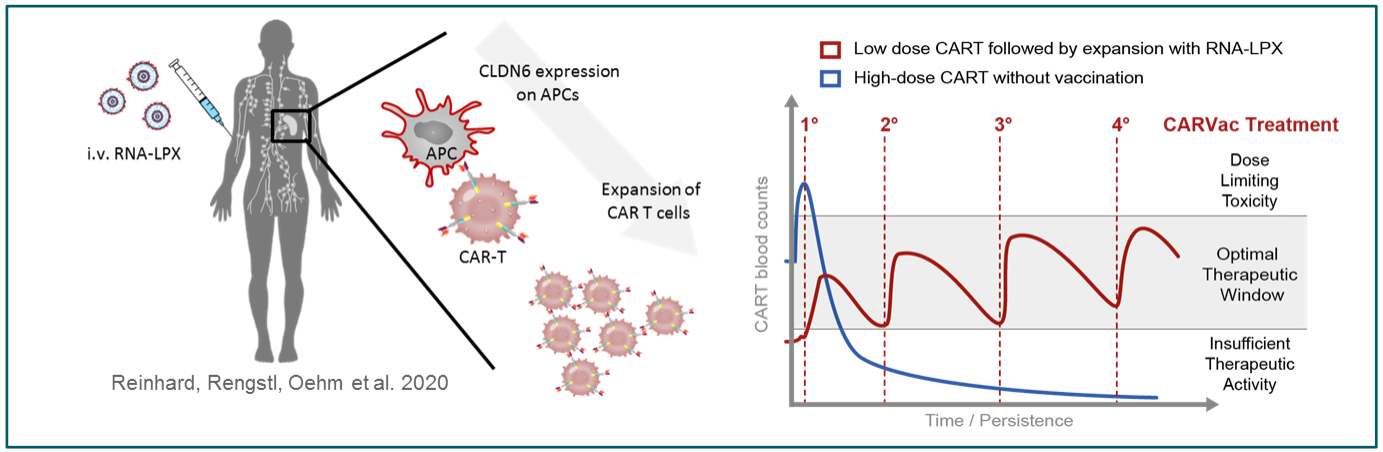
CAR-T cell Amplifying RNA Vaccine (CARVac) drives in vivo expansion and efficacy of CAR-T against solid tumors

CARVac production



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

CARVac based CAR-T expansion



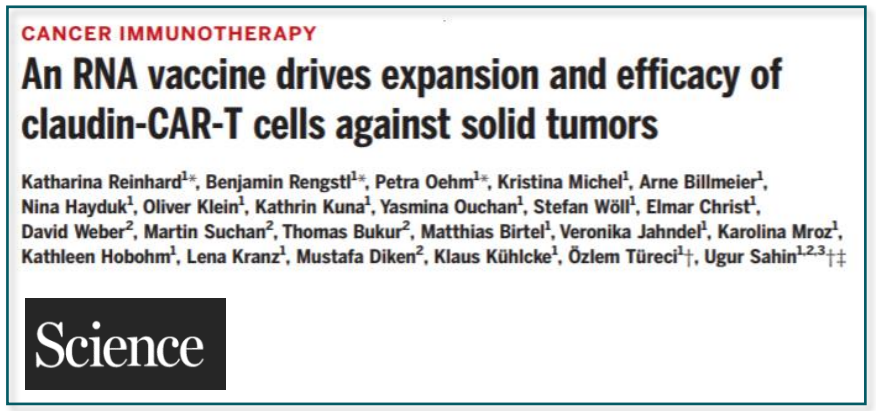
- Repetitive administration of CARVac results in **increased frequency, persistence and activity of CAR-T cells** with a memory phenotype
- Combination of sub-therapeutic CAR-T dose and CARVac demonstrated **eradication of advanced tumors in mice**

CLDN6, Claudin-6; CAR-T cells, chimeric antigen receptor engineered T cells; RNA-LPX, RNA-lipoplex; APCs, antigen presenting cells

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

BIONTECH

BNT211: CLDN6-CAR Demonstrates Potent and Robust Target Recognition

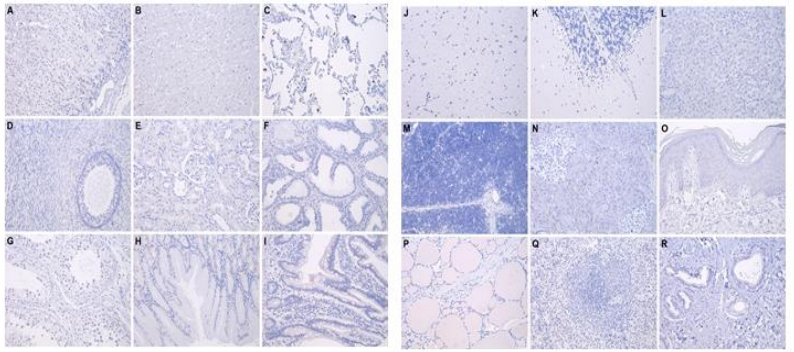

CANCER IMMUNOTHERAPY

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

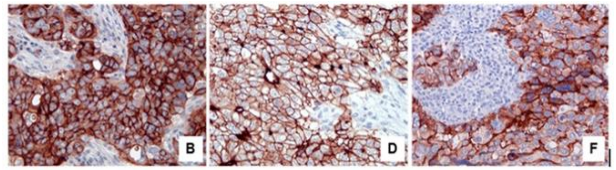
Katharina Reinhard[1]*, Benjamin Rengstl[1]*, Petra Oehm[1]*, Kristina Michel[1], Arne Billmeier[1], Nina Hayduk[1], Oliver Klein[1], Kathrin Kuna[1], Yasmina Ouchan[1], Stefan Wöll[1], Elmar Christ[1], David Weber[2], Martin Suchan[2], Thomas Bukur[2], Matthias Birtel[1], Veronika Jahndel[1], Karolina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

Science

CLDN6 not present in healthy tissues



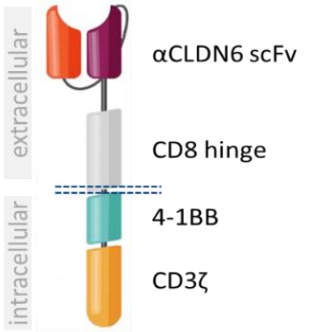
CLDN6 expressed in multiple cancers



Ovarian Testicular Lung

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

BNT211 CAR Structure

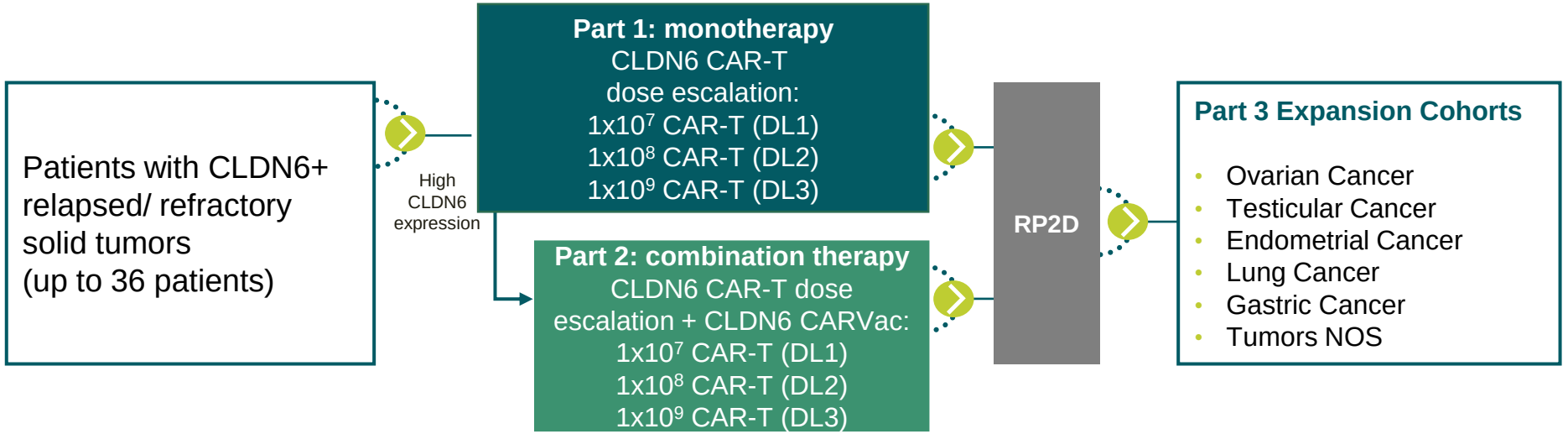


CLDN6, Claudin-6; CAR-T cells, chimeric antigen receptor engineered T cells; scFv, single chain variable fragment

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

BIONTECH

BNT211: First-in-human Phase 1/2 trial in Solid Tumors



Open-label Phase 1/2 trial of BNT211 in patients with advanced solid tumors

- Evaluation of safety and tolerability
- Monotherapy DL 1 (n=3) and 2 (n=6), **completed**
- Combination therapy DL 1 (n=3) and DL 2 (n=4), **DL2 ongoing**
- **Data update presented at AACR 2022**

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

BNT211: CAR-T in Solid Tumors Encouraging Efficacy and Safety Profiles Presented at AACR 2022

Safety

CLDN6 CAR-T cells as monotherapy or combined with CARVac **well tolerated** at dose levels evaluated to date ($1x10^7$ and $1x10^8$ CAR-T)

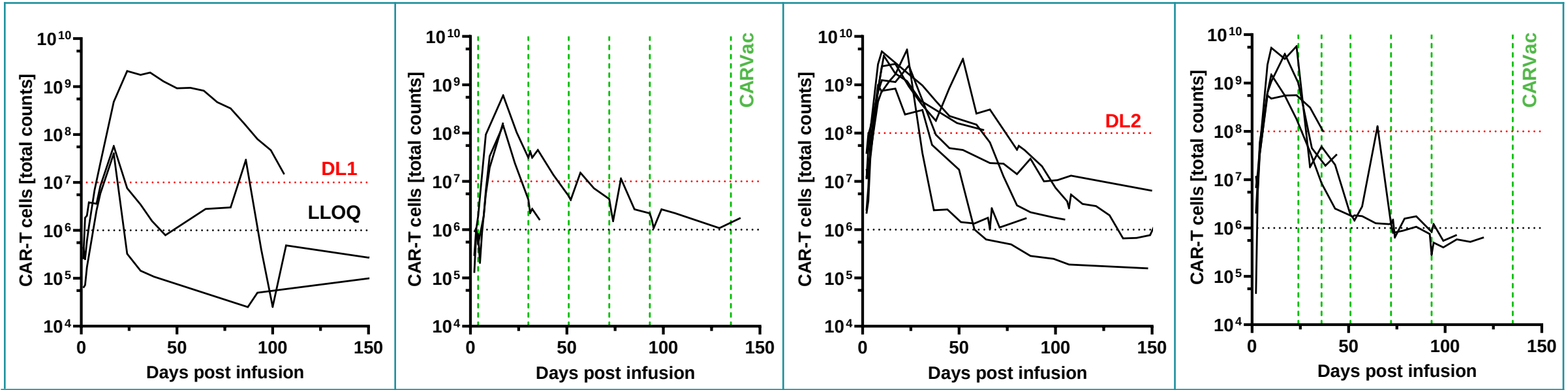
- Grade 1-2 CRS seen in 70% of patients at $1x10^8$ CAR-T dose, manageable by administration of tocilizumab
- 2 DLTs observed, both patients fully recovered and showed clinical benefit
- MTD not reached yet

Efficacy

- Robust CAR-T engraftment achieved in all patients translating into clinical activity: **ORR 43%, DCR of 86%** in evaluable patients (n=14; $1x10^7$ and $1x10^8$ CAR-T)
  - 6 PR, 5 SD+, 1 SD (Testicular, ovarian and other tumors, 6 weeks post-infusion)
  - 5 testicular cancer patients show promising responses at $1x10^8$ CAR-T: ORR 80%, DCR 100%;
    1 CR, 3 PR, 1 SD
- CARVac supports CAR-T engraftment and mediates physiologic expansion plus upregulation of survival pathways
- Some patients show continuing CAR-T persistence (>150 days post infusion)
- Patients with initial PR showed further deepening of responses

Data cut-off: MAR 10, 2022
DL1: $1x10^7$ CAR-T; DL2: $1x10^8$ CAR-T
CLDN6, Claudin-6; DLT, dose-limiting toxicity; MTD, maximum tolerated dose; CRS, cytokine release syndrome; CR, complete response; DCR, disease control rate; DL, dose level; ORR, overall response rate; PR, partial response; SD, stable disease

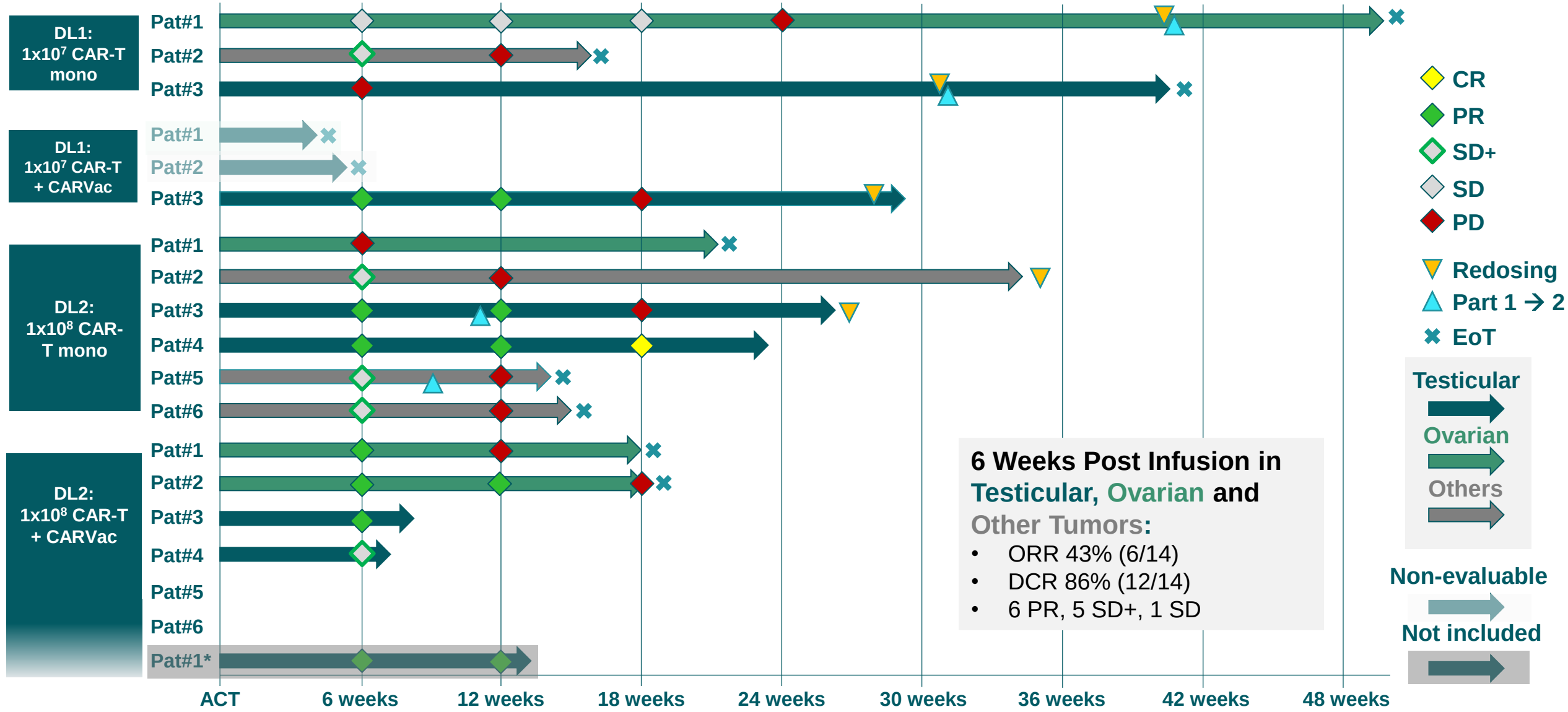
Robust CAR-T Engraftment Seen in all Patients and Persisting CAR-T in Responding Patients



Cohort	DL1: 1x10^7 CAR-T mono (n = 3)	1x10^7 CAR-T + CARVac (n = 3)	DL2: 1x10^8 CAR-T mono (n = 6)	1x10^8 CAR-T + CARVac (n = 4)
CRS, n	0 (0%)	1 (33%)	4 (66%)	3 (75%)
PR, n*	0 (0%)	1 (33%)	2 (33%)	3 (75%)
SD, n*	1 (33%)	0 (0%)	3 (50%)	1 (25%)
ORR*	0%	33%**	33%	75%
DCR*	33%	33%**	83%	100%

Data cut-off: MAR 10, 2022.
DL1: 1x10^7 CAR-T; DL2: 1x10^8 CAR-T
CRS, cytokine release syndrome; DCR, disease control rate; DL, dose level; DLT, dose-limiting toxicity; ORR, overall response rate; PR, partial response; SD, stable disease; *At first tumor assessment (6 weeks post infusion); **2 patients died due to disease progression before first tumor assessment.

Efficacy Observed at 6 Weeks Post Infusion



6 Weeks Post Infusion in Testicular, Ovarian and Other Tumors:

- ORR 43% (6/14)
- DCR 86% (12/14)
- 6 PR, 5 SD+, 1 SD

Data cut-off: MAR 10, 2022.
DL1: 1x10^7 CAR-T; DL2: 1x10^8 CAR-T
DL, dose level; CR, complete response; DCR, disease control rate; EoT, end of trial (due to PD); ORR, overall response rate; PD, progressive disease; PR, partial response; SD, stable disease, SD+, SD with shrinkage of target lesions; *50% lymphodepletion

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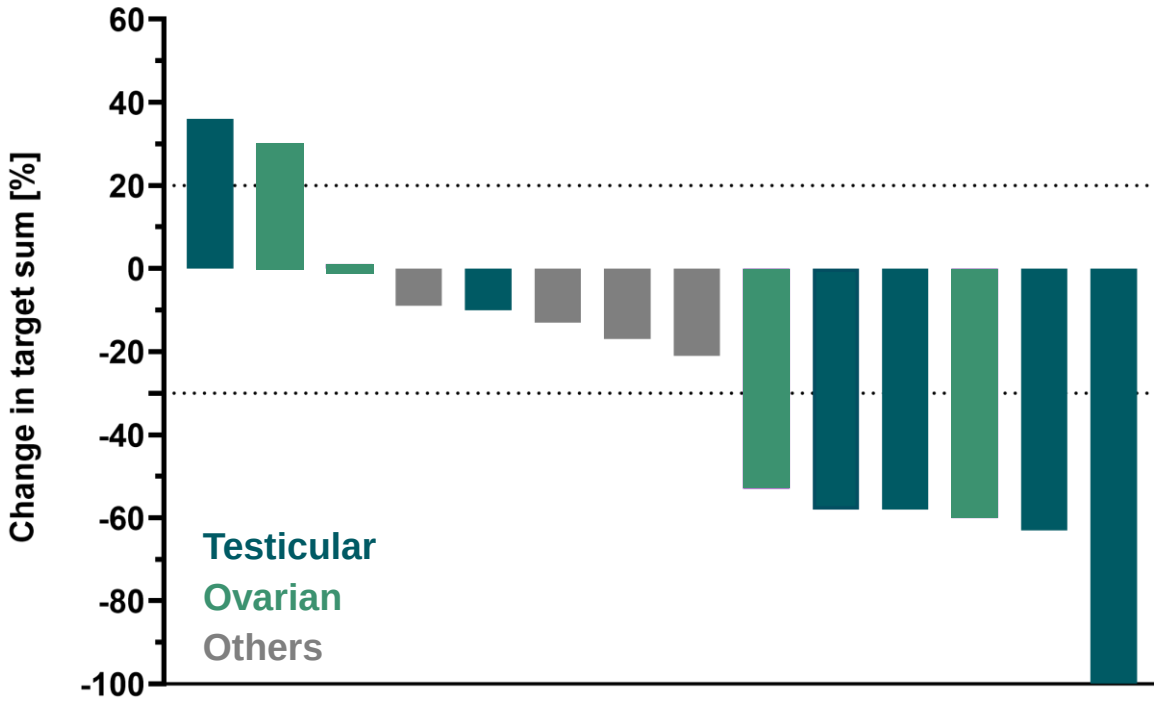
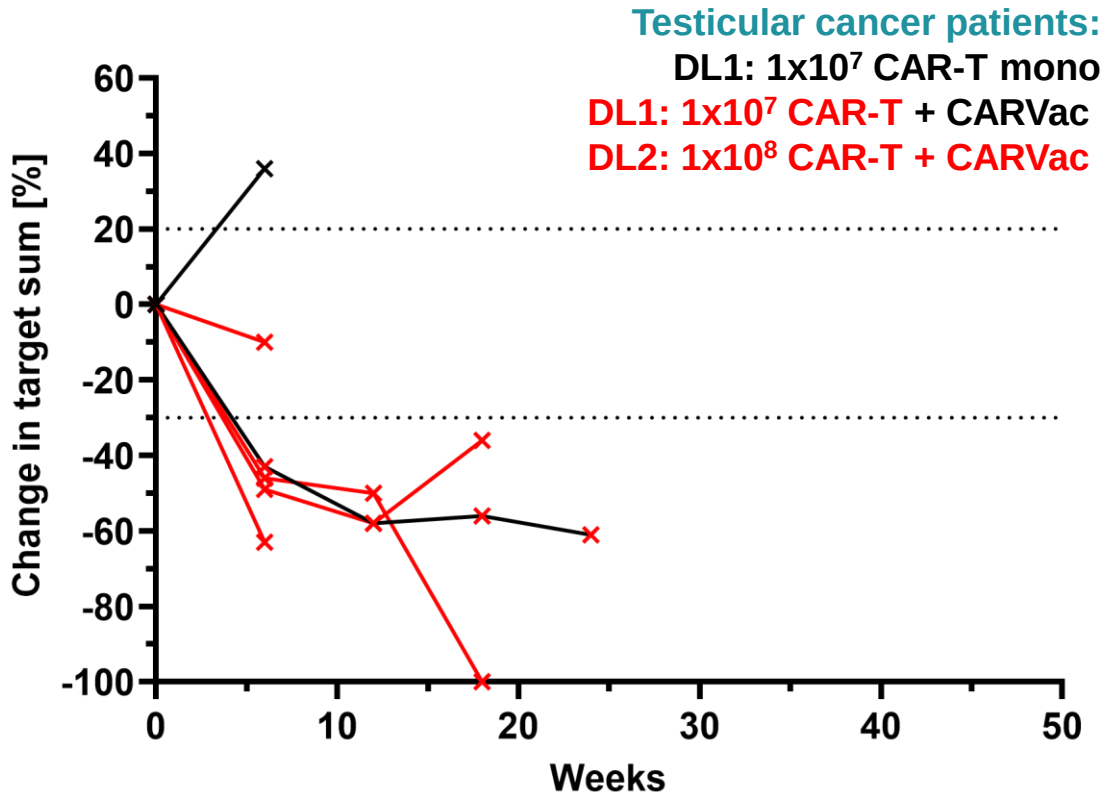
Continuing Responses in Testicular Cancer with One PR Deepening to CR

Best response



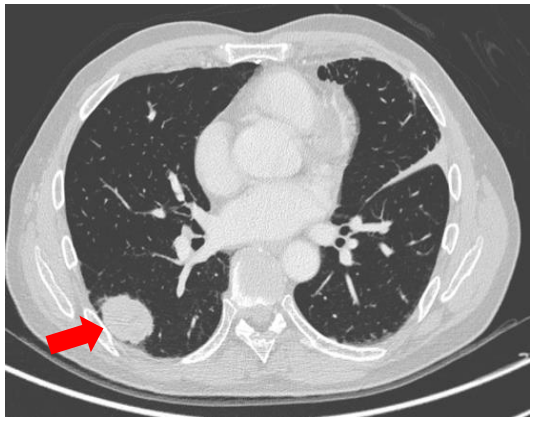
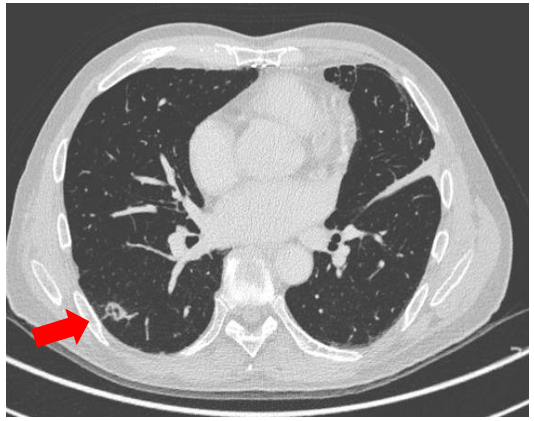
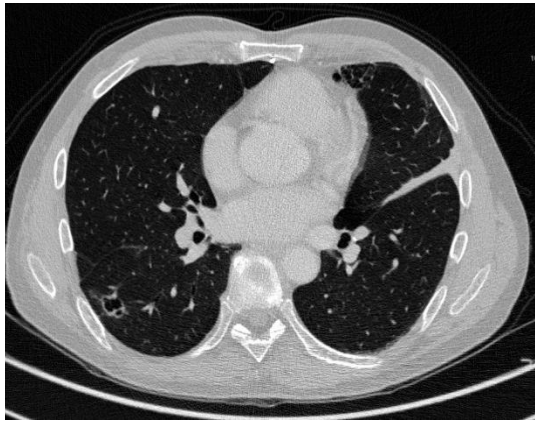
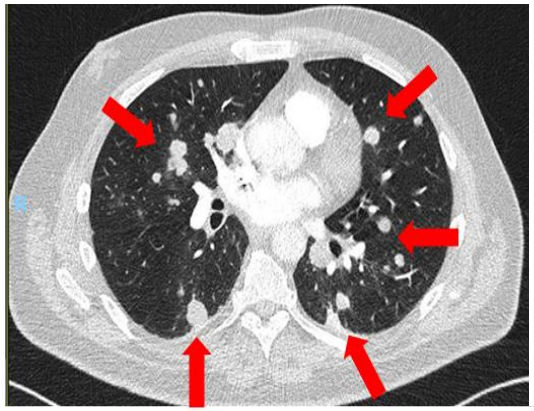
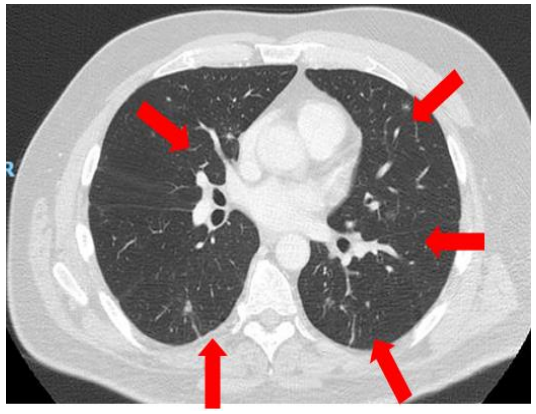
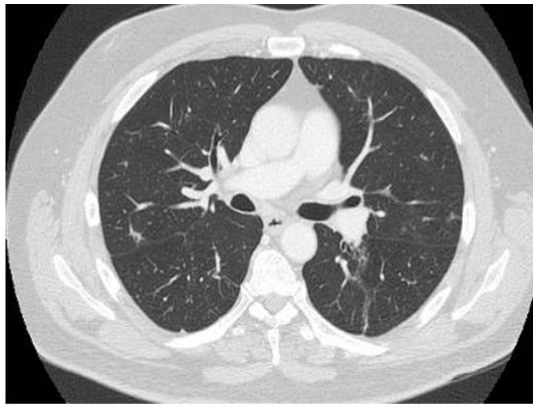
Durability of responses



PR, partial response; CR, complete response; DL, dose level

BIONTECH

Responses in Two Testicular Cancer Patients with Relapse After Prior Treatment

	Baseline	6 weeks post infusion	12 weeks post infusion	Post 12-week scan
Patient 1 61-year-old male patient diagnosed 2008 (DL2: $1x10^8$)				• No new lesions detected • Tumor marker (AFP) at normal level • Patient has ongoing CR
Patient 2 56-year-old male patient diagnosed 2020 (DL1: $1x10^7$ + CARVac)				• After initial response New lesions were detected • On-treatment biopsy showed positivity for CLDN6 • Patient was re-dosed on d197

Data cut-off: MAR 10, 2022

AFP, alpha-fetoprotein; CR, complete response; CLDN6, Claudin-6.

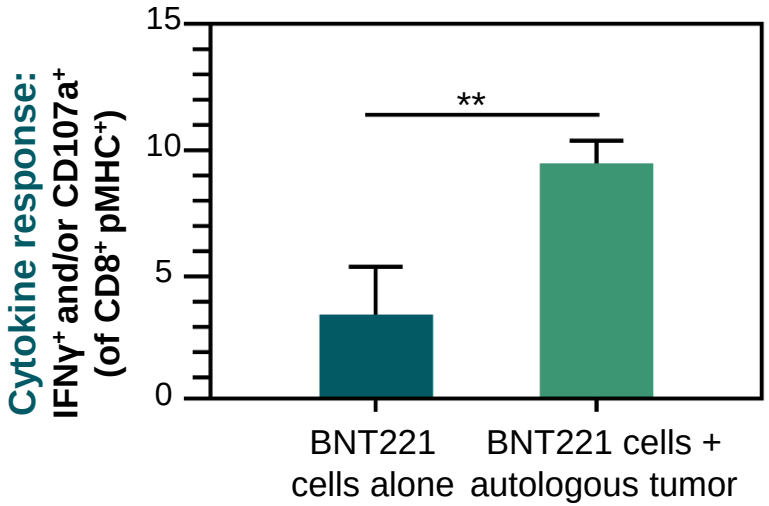
BIONTECH

BNT221: NEO-STIM® Personalized Neoantigen-targeted Adoptive Cell Therapy

Addresses limitations of TIL cell therapy approaches

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

BNT221 cells specifically recognize autologous tumor



TIL, tumor-infiltrating lymphocyte

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

Agenda

Overview and business outlook

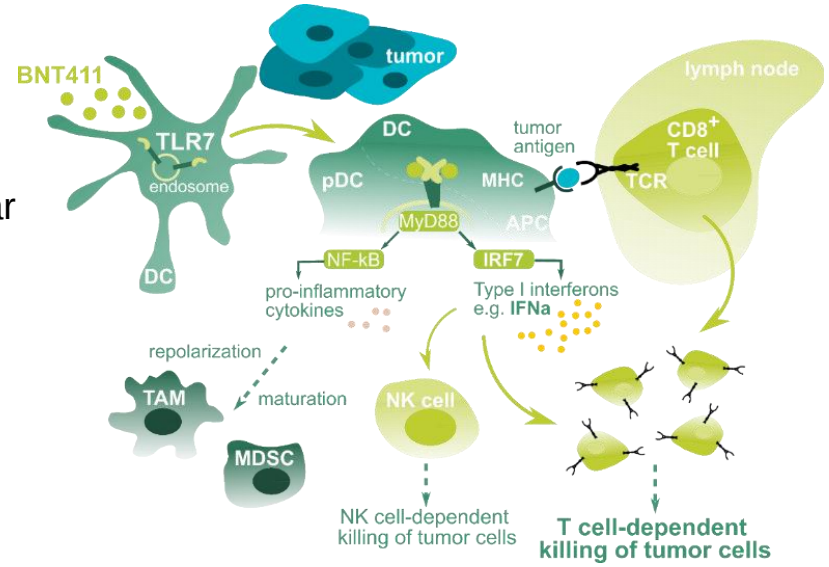
Deeper dive on our key programs

- 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

BIONTECH

BNT411: Small molecule immunomodulator designed to activate both the adaptive and innate immune system through the TLR-7 pathway

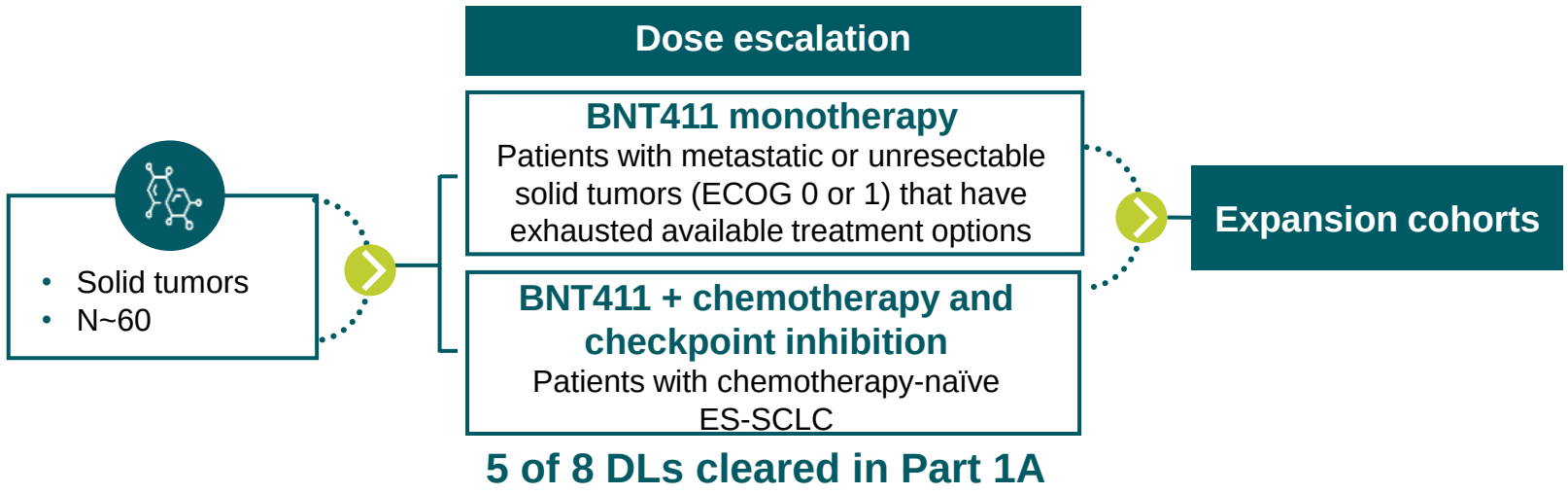
- BNT411 is an intravenously administered small molecule TLR7 agonist
- Engineered for high potency and high TLR7 receptor-selectivity at the therapeutically active dose range
- Activation of both adaptive and innate immune system has been observed, in particular in combination with cytotoxic therapies and CPIs
- Stimulation of tumor antigen-specific CD8+ T cells, B cells, and innate immune cells[1]
- Type 1 interferon-dominated release of cytokines and chemokines
- Expected therapeutic potential across various solid tumor indications
- Phase 1/2 clinical trial as a mono and combination therapy ongoing



TLR-7, Toll-like receptor 7; CPI, Check-point Inhibitor APC, antigen-presenting cell; DC, denditric cell; IFNa, interferon alpha; IRF7, interferon regulatory factor 7; MDSC, myeloid-derived suppressor cells; MHC, major histocompatibility complex; Myd-88, myeloid differentiation primary response 88; NF-κB , nuclear factor kappa-light-chain-enhancer of activated B cells; NK , natural killer; pDCs , plasmacytoid dendritic cells; TAM , tumor-associated macrophages; TCR, T cell receptor.

BNT411: Phase 1/2 First-in-Human Trial in Patients with Solid Tumors

- Phase 1/2, first-in-human, open-label, dose-escalation trial
- Safety, pharmacokinetics, pharmacodynamics, and preliminary efficacy of BNT411
  - As a monotherapy in patients with solid tumors
  - In combination with atezolizumab, carboplatin and etoposide in patients with chemotherapy-naïve extensive-stage small cell lung cancer



BNT411 monotherapy: Presented at SITC 2021	
Patients analyzed	N = 18
Male/Female	10 (56%) / 8 (44%)
Median age, years (range)	58 (32 – 78)
Tumor types	
Cervical cancer Colon cancer Hepatic cancer Malignant melanoma Malignant solitary fibrous tumor NSCLC Ovarian cancer Pancreatic carcinoma Prostate cancer Rectal cancer SCLC Ureteral cancer	
Prior lines of systemic therapy, median (range)	**2 (0-5)**
≤1	6 (33%)
≥2	12 (67%)
Prior anti-PD-1/PD-L1 therapy	**6 (33%)**

Data cut-off: August 26, 2021

ECOG, Eastern Cooperative Oncology Group; DL, dose level; ES-SCLC, extensive-stage small cell lung cancer; SCLC, small cell lung cancer; PD-1, programmed cell death protein 1; PD-L1, programmed death-ligand 1.

1. Vascotto et al., 2019, OncoImmunology; Symeonides S, et al. Oral presentation at the 36th Annual Meeting of the Society for Immunotherapy of Cancer (SITC), November 10–14, 2021, Washington DC.

SITC 2021 - BNT411 Phase 1/2: Acceptable Safety Profile at All Doses Tested and Substantial Type-1 Interferon-dominated Cytokine Response

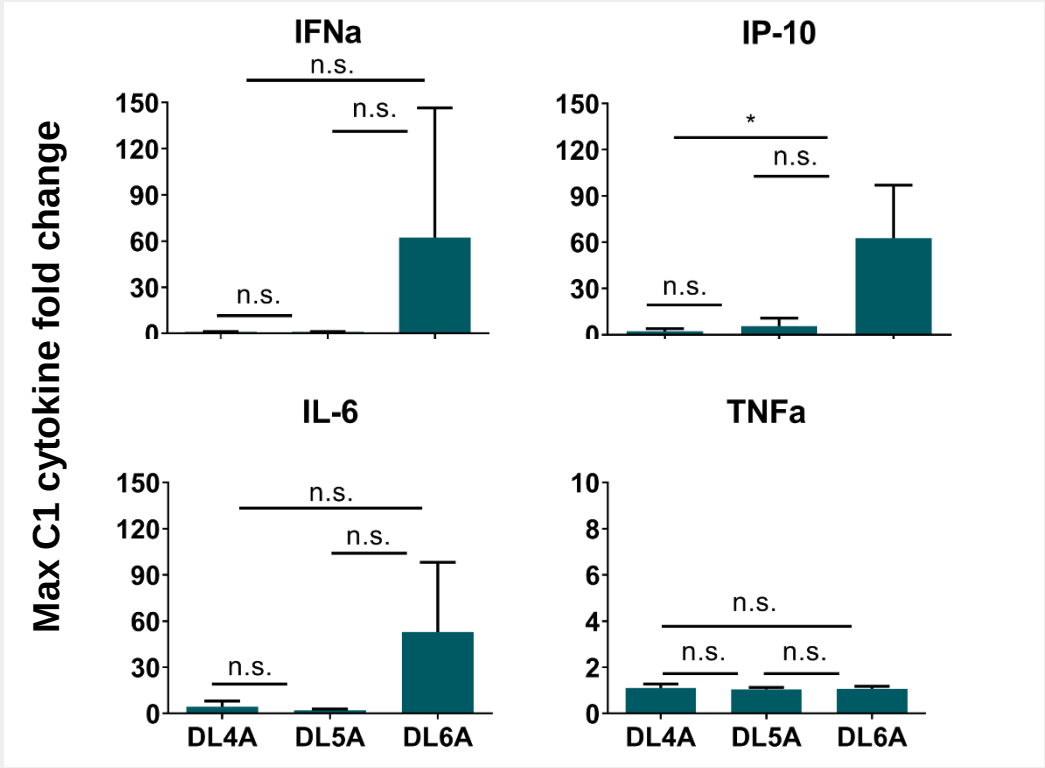
Manageable safety profile at all doses tested (n=15)

Most frequent AEs related to BNT411 monotherapy	n (%)	Grade 3, n	Dose level
Pyrexia	3 (20%)	1	1, 2, and 6
Chills	2 (13%)	0	1 and 6
Anemia	2 (13%)	1	4 and 5
TEAEs related to BNT411 + atezo/EC	**n (%)**	**Grade 3,n**	**Dose level**
Pyrexia	1 (33.3%)	0	
Pneumonia	1 (33.3%)	1	4

- No DLTs or related grade 4-5 AEs with BNT411 monotherapy or combined with atezo/EC

Pharmacodynamics responses warrant further evaluation in various cancer indications, as monotherapy and in combination with atezo/EC and other immunotherapy-based regimens

Dose-dependent cytokine release with monotherapy (n=10): In line with anticipated mode-of-action



Part 1A, n = 10: DL4A, n = 3; DL5A, n=4; DL6A, n = 3

- Substantial type-1 interferon-dominated cytokine response at DL6A while levels of IL-6 and TNFa remain relatively low

Data cut-off: August 26, 2021

AE = adverse event; TEAE = treatment-emergent adverse event; Atezo/EC = atezolizumab/etoposide and carboplatin; DL = dose level; DLT = dose-limiting toxicity; IFN = Interferon; IL = Interleukin; IP = interferon-gamma-inducible protein; TNF = tumor necrosis factor.

Symeonides S, et al. Oral presentation at the 36th Annual Meeting of the Society for Immunotherapy of Cancer (SITC), November 10–14, 2021, Washington DC.

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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

BIONTECH

RiboCytokines: Designed to Overcome Limitations of Recombinant Cytokine Therapy

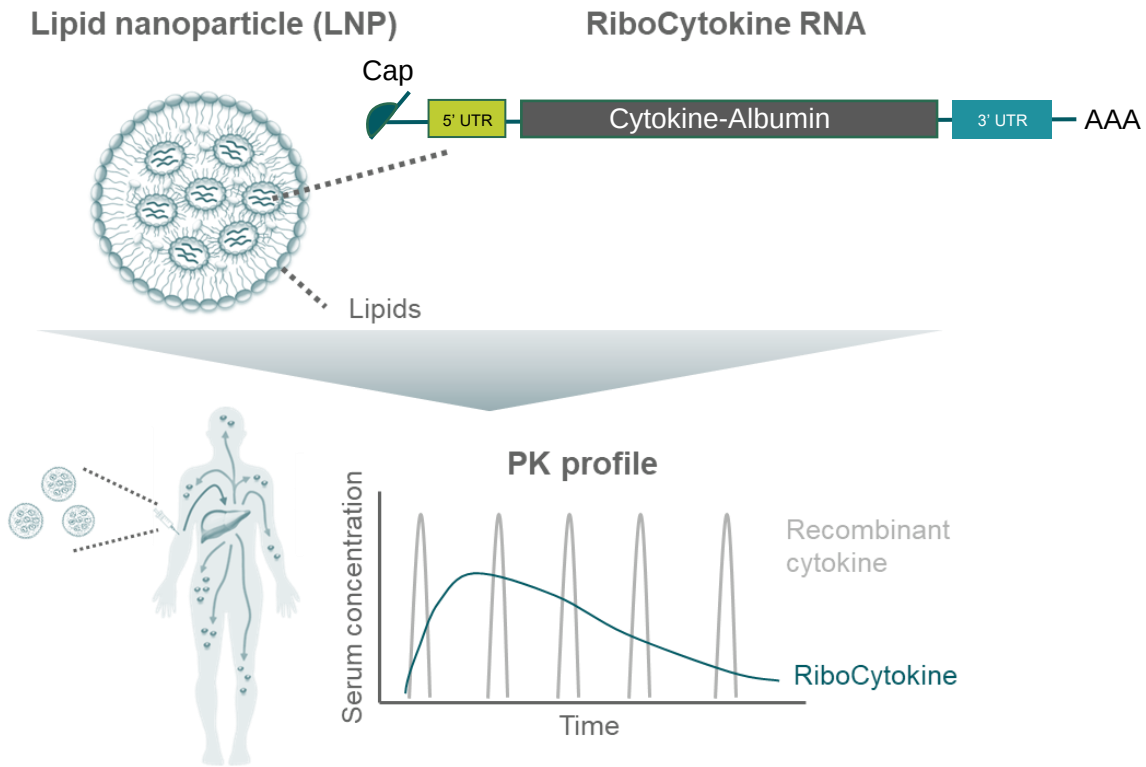
Cytokines encoded by mRNA: A novel therapeutic concept

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

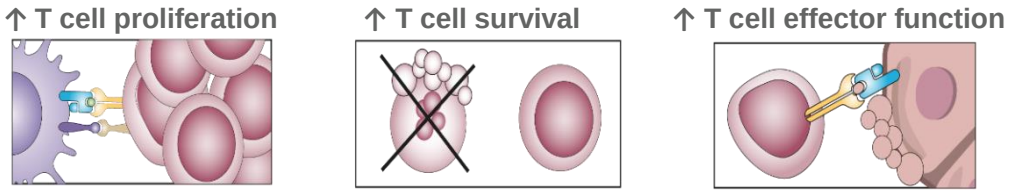


Product Candidate	Indication	Pre-clinical	Phase 1	Phase 2
BNT151 (modified IL-2)	Solid Tumors			
BNT152+153 (IL-7 + IL-2)	Solid Tumors			

LNP, lipid nanoparticle; PK, pharmacokinetic; IL-2, Interleukin-2; IL7, Interleukin-7; UTR, untranslated region

RiboCytokines: A Tailored Approach to T Cell Regulation and Stimulation

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



BNT151

mRNA encoding sequence-modified IL-2 variant

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

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

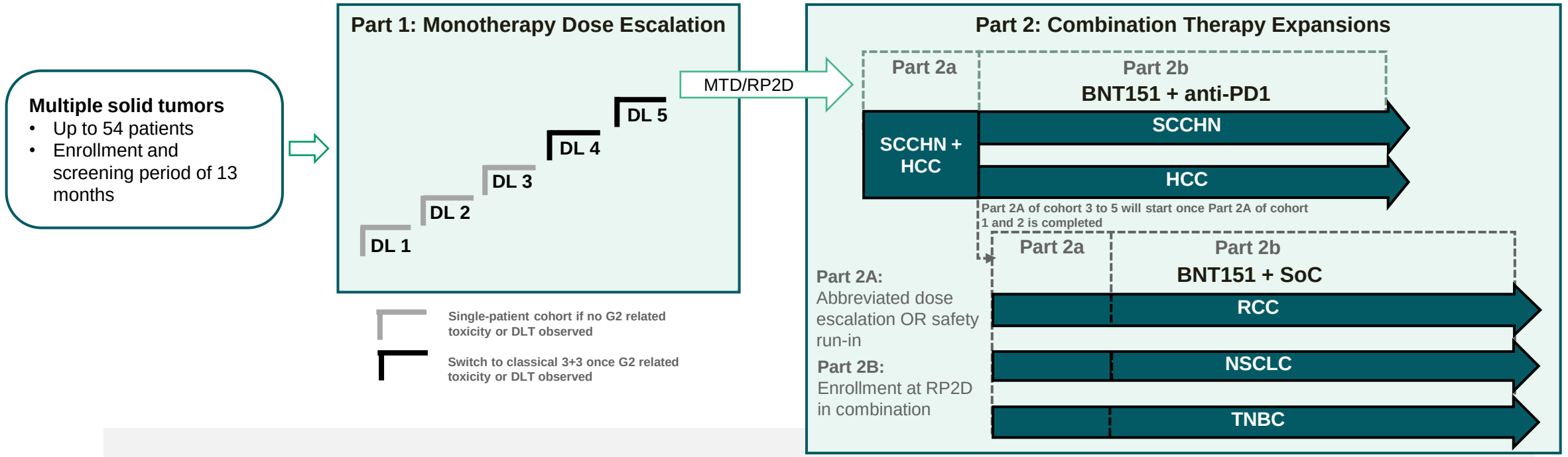
Combination with anti-PD-1/PD-L1 therapy

Combination with RNA vaccine

IL-2, interleukin-2; IL-7, interleukin-7; IL-2Rα, interleukin-2 receptor alpha subunit

BNT151: Phase 1/2 Trial in Patients with Solid Tumors

First-in-Human RiboCytokines Trial Evaluating mRNA-encoded sequence-modified IL-2 variant



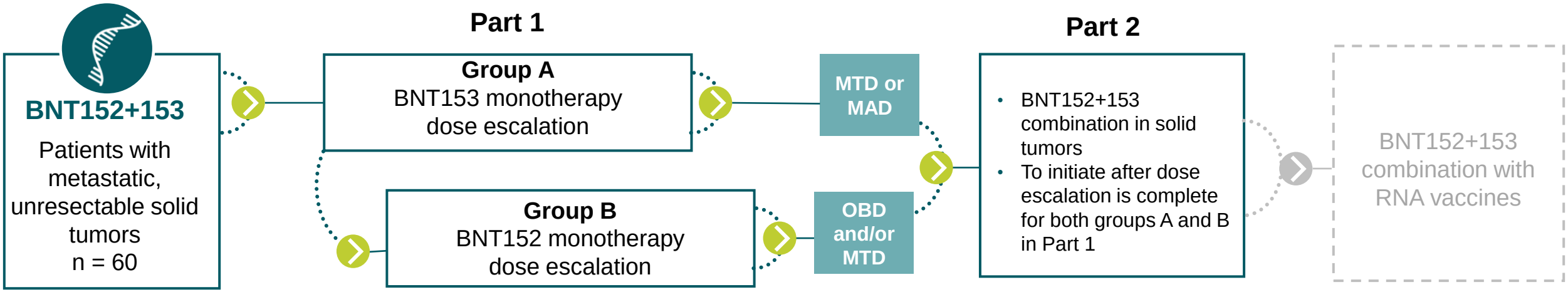
Dose escalation, safety, pharmacokinetics and pharmacodynamics of BNT151 with expansion cohorts in multiple solid tumor indications

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

BIONTECH

BNT152 + BNT152: Phase 1 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

IL-2, Interleukin-2; IL-7, Interleukin-7; MTD, maximum tolerated dose; MAD, maximum administered dose; OBD, optimal biologic dose; PK, pharmacokinetics; PD, pharmacodynamics
TEAE, treatment emergent adverse events, ORR, overall response rate; DCR, disease control rate; DOR, duration of response

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