

# Next Generation Immunotherapy

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**BIONTECH** 

# This slide presentation includes forward-looking statements

## Forward-looking statements

Various statements in this slide presentation concerning the future expectations of BioNTech, its plans and prospects, including the Company's views with respect to the potential for mRNA therapeutics; the planned next steps in BioNTech's pipeline programs and specifically including, but not limited to, statements regarding plans to initiate clinical trials of BioNTech's product candidates and expectations for data announcements with respect to BioNTech's product candidates; the development of commercial capabilities and the transition of BioNTech to a fully integrated biopharmaceutical company; its expectations with respect to interactions with regulatory authorities such as FDA and EMA, including the potential approval of BioNTech's or its collaborators' current or future drug candidates; expected royalty and milestone payments in connection with BioNTech's collaborations; BioNTech's anticipated cash usage for fiscal year 2021 and beyond; the creation of long-term value for BioNTech shareholders; the ability of BioNTech to successfully develop and commercialize a vaccine for COVID-19 in partnership with Pfizer and Fosun Pharma; the timing for any potential emergency use authorizations or approvals for BNT162; and the ability of BioNTech to supply the quantities of BNT162 to support clinical development and, market demand, including its production estimates for 2021 and the impact of COVID-19 on our clinical trials and business operations, are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, as amended. Words such as "expects," "plans," "potential," "target," "continue" and variations of these words or similar expressions are intended to identify forward-looking statements. Such statements are based on the current beliefs and assumptions of the management team of BioNTech and on the information currently available to the management team of BioNTech, and are subject to change. The Company will not necessarily inform you of such changes. These forward looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors that could cause the Company's actual results, performance or achievements to be materially different than any future results, performance or achievements expressed or implied by the forward-looking statements. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including the Company's ability to discover and develop its novel product candidates and successfully demonstrate the efficacy and safety of its product candidates; the pre-clinical and clinical results for its product candidates, which may not support further development of product candidates; actions of the Company's collaborators regarding continued product development and product commercialization; actions of regulatory authorities, which may affect the initiation, timing and progress of clinical trials or the ability of the Company to obtain marketing authorization for its product candidates; the Company's ability to obtain, maintain and protect its intellectual property; the Company's ability to enforce its patents against infringers and defend its patent portfolio against challenges from third parties; competition from others using technology similar to the Company's and others developing products for similar uses; the Company's ability to manage operating expenses; the Company's ability to obtain additional funding to support its business activities and establish and maintain its existing and future collaborations and new business initiatives; the Company's dependence on collaborators and other third parties for development, manufacture, marketing, sales and distribution of products; the outcome of litigation; and unexpected expenditures. Any forward-looking statements represent the Company's views only as of today and should not be relied upon as representing its views as of any subsequent date. The Company explicitly disclaims any obligation to update any forward-looking statements. The mRNA vaccines and other product candidates discussed in this slide presentation are investigational products being developed by BioNTech and its collaborators and are not currently approved by the FDA, EMA or any other regulatory authority.

# Safety Information

## Authorized use in the U.S.:

- The Pfizer-BioNTech COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

## Important safety information from U.S. FDA emergency use authorization prescribing information:

- Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any [component](#) of the Pfizer-BioNTech COVID-19 Vaccine
- Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine
- **Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (<https://www.cdc.gov/vaccines/covid-19/>)**
- Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine
- The Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients
- In clinical studies, adverse reactions in participants 16 years of age and older included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%)
- Severe allergic reactions have been reported following the Pfizer-BioNTech COVID-19 Vaccine during mass vaccination outside of clinical trials. Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine
- Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy
- Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion
- There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series
- Vaccination providers must report Adverse Events in accordance with the Fact Sheet to VAERS at <https://vaers.hhs.gov/reportevent.html> or by calling [1-800-822-7967](tel:1-800-822-7967). The reports should include the words “Pfizer-BioNTech COVID-19 Vaccine EUA” in the description section of the report
- Vaccination providers should review the Fact Sheet for *Information to Provide to Vaccine Recipients/Caregivers and Mandatory Requirements for Pfizer-BioNTech COVID-19 Vaccine Administration Under Emergency Use Authorization*

# **Harnessing the immune system's full potential to fight human disease**

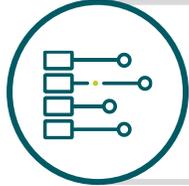
# 2020: A TRANSFORMATIONAL YEAR FOR BIONTECH



**Globally developed COVID-19 vaccine, COMIRNATY<sup>®\*</sup>, in 10 months**



**Building a fully integrated biopharma company**



**Broadened clinical stage pipeline to 11 immuno-oncology product candidates**



**Established R&D hub in the US and established presence in Asia**



**Matured mRNA manufacturing base from clinical to global commercial scale**

# OPPORTUNITY IN 2021 AND BEYOND

**Building a global,  
multi-product, immunotherapy powerhouse**

**Poised to usher in new era of vaccines and immunotherapies in multiple therapeutic areas**

**Advance broad pipeline of >20 product candidates**

**Ability to invest COMIRNATY cash flows to accelerate diverse portfolio**

**Proven execution capabilities and maturation toward a commercial organization**

**Deep expertise in  
immunology**

**Cutting edge  
platforms across 4  
drug classes**

**Bioinformatics  
driven approach  
leveraging AI and  
machine learning**

**In-house GMP  
manufacturing of  
mRNA and cell  
therapies**

# COMIRNATY: LEADING THE FIGHT AGAINST COVID-19

- **First vaccine authorized for use in the US and the EU**
- **Authorization for Emergency Use / Temporary Use or Conditional Approval in > 45 countries**
- **32.9m million doses shipped<sup>1</sup>**
- Global phase 3 trial data indicates vaccine is **highly efficacious** and **generally well tolerated**
  - **95% vaccine efficacy** in 43,000+ participants
  - 94% efficacy in participants older than 65 years
  - Generally well tolerated with most **adverse events being mild to moderate in intensity and transient in effect**
  - Most common adverse events are fatigue, headache, pain at injection sites, chills, muscle and joint pain
- **Broad immunogenicity profile (poly-epitopic, multi-effector),** inducing high titer of neutralizing antibody and T cell responses

 **COMIRNATY**<sup>®</sup>  
COVID-19 mRNA Vaccine

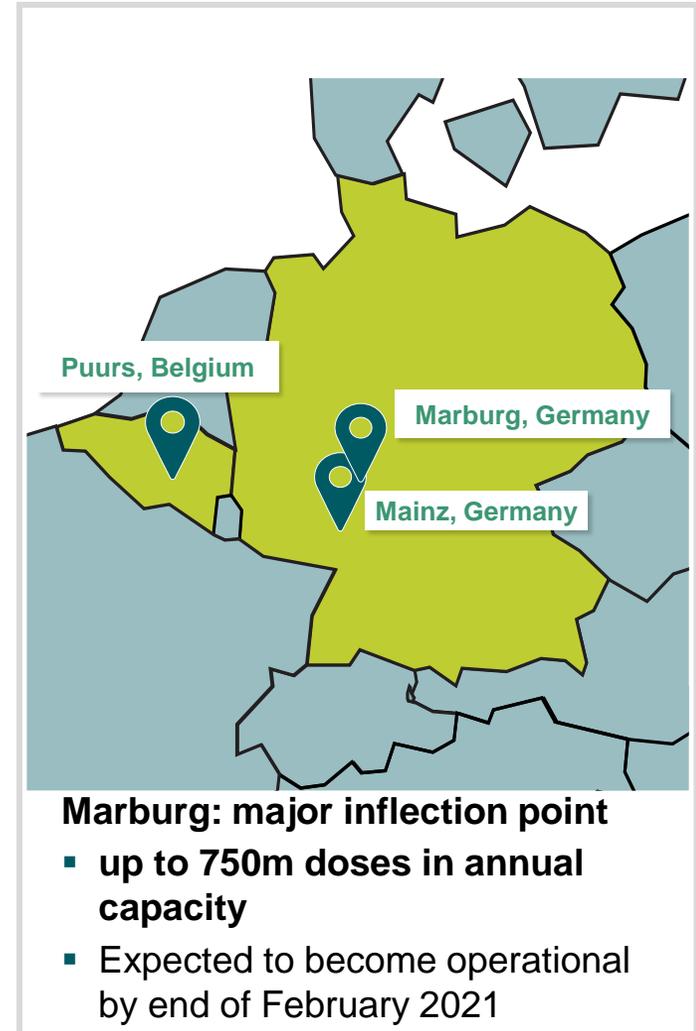


**For use in individuals  
16 years and older**

# SUPPLY UP TO TWO BILLION VACCINE DOSES IN 2021



- FY 2021 manufacturing capacity target: **2.0 billion doses\***
- Committed Doses for 2021: **>1 billion doses**
- **50:50** gross profit share with Pfizer (worldwide ex-China); **35-40%** gross profit share with Fosun Pharma in China
- **6 manufacturing sites** in Pfizer and BioNTech alliance
- **Additional external CMO sites** expanding LNP and fill-finish capacity



# MULTIPLE STRATEGIC LEVERS TO EXPAND COMIRNATY ACCESS



## Increase Supply Capacity

- 6-dose vial
- Continuous process improvements
- New sites, suppliers and CMOs

## Broaden global distribution

- New country / regional authorizations
- BLA submission in U.S. and other regions
- Order book growth

## Expand label

- Pediatric indications
- Pregnant women
- Additional sub-populations

## Develop optimized formulations

- Further stability testing update for current formulation
- Improved thermostable formulation
- PEG-free formulation

# COVID-19 WILL LIKELY BECOME AN ENDEMIC DISEASE

## *Unmet Medical Needs*

## *Key Strengths*

**1 Safety & Efficacy**

**Compelling efficacy & safety in all tested age groups**

**2 Emergence of new viral variants**

**Ability to create re-engineered vaccine in 6 weeks<sup>1</sup>**

**3 Naturally waning immune response**

**mRNA vaccine well-suited for re-vaccination**

# INFECTIOUS DISEASES REPRESENT A LONG-TERM GROWTH PILLAR

## Unmet Medical Needs

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

## BioNTech infectious diseases portfolio

COMIRNATY

Next generation COVID-19 vaccines

Influenza, HIV and TB vaccines

6 undisclosed programs

# mRNA TECHNOLOGY POISED TO REVOLUTIONIZE IMMUNOTHERAPY

## *mRNA Today*

mRNA vaccines established as a  
**New Drug Class**

 **COMIRNATY**<sup>®</sup>  
COVID-19 mRNA Vaccine

*Accelerated learning path for  
COVID vaccine leads to  
diversification and maturation of the  
mRNA technology*

## *mRNA Tomorrow*

mRNA technology to  
**Displace traditional modalities**

mRNA vaccines for additional  
infectious diseases

mRNA cancer vaccines

**CAR-T cell amplifying mRNA  
vaccine**

Systemic mRNA encoded  
immuno-therapies

## *mRNA in the Future*

**“Beyond the Horizon”**

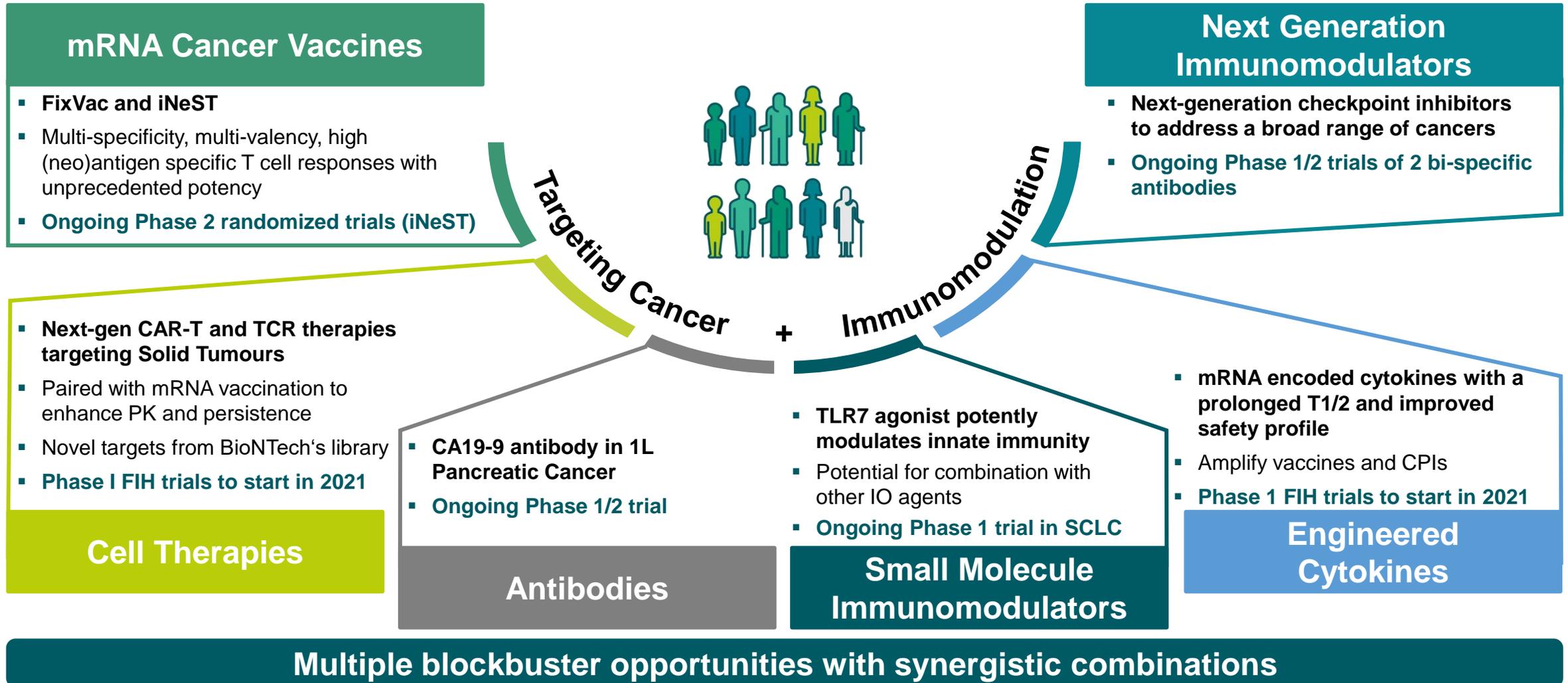
Autoimmune diseases

Rare diseases

Other therapeutic areas

**Novel targets Innovative modalities New disease areas**

# RATIONALLY DESIGNED MULTI-PLATFORM IO STRATEGY

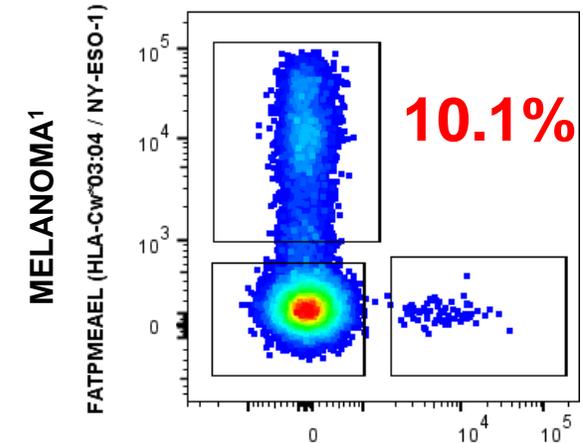
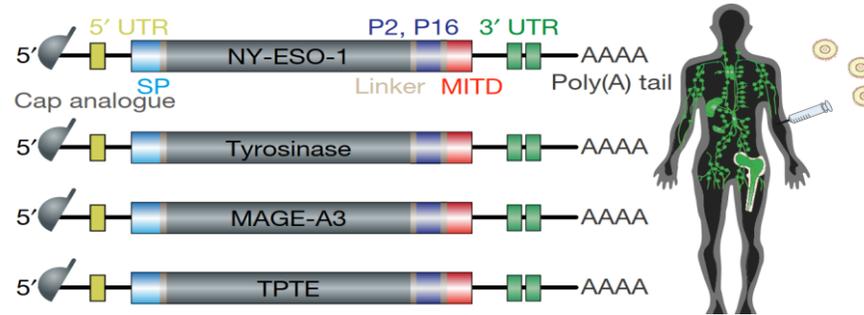


# FIXVAC: LEVERAGING SHARED ANTIGENS TO BREAK IMMUNE TOLERANCE

## Novel Structure

Fixvac

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



Product candidate<sup>2</sup>

BNT111

BNT113

BNT112

BNT116

Preclinical

**Advanced melanoma** *NY-ESO-1, MAGE-A3, Tyrosinase, TPTE*

**HPV+ head & neck cancer** *HPV E6 and E7 oncoproteins*

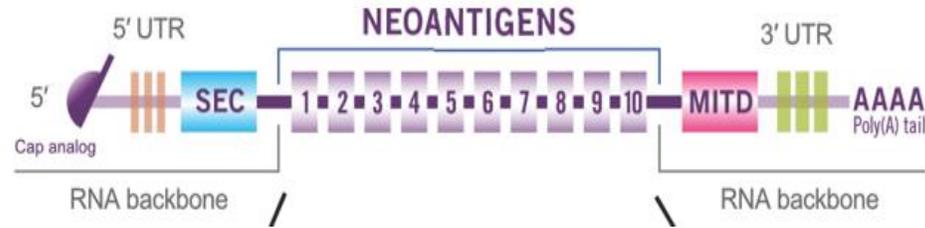
**Prostate cancer** *PSA, PAP, 3 addition undisclosed antigens*

**NSCLC**

Phase 1

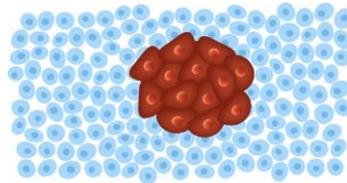
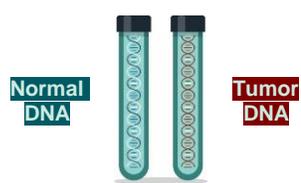
Phase 2

# iNeST: TAILORED TREATMENT TO EXPLOIT INDIVIDUAL TARGETS



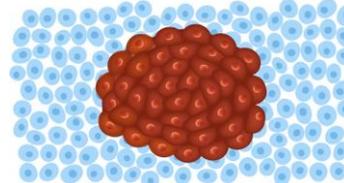
- Fully customized to the individual Patient
- Targeting 20 neo-antigens per patient

## ADJUVANT



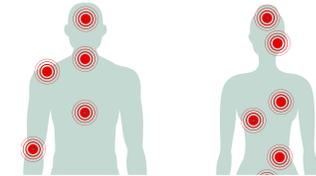
Residual cancer cells may remain – emphasis on recurrence free survival

## 1L METASTATIC



Rapidly growing but often still in early phase of metastases

## LATE-LINE METASTATIC



Bulky tumors with multiple organs involved

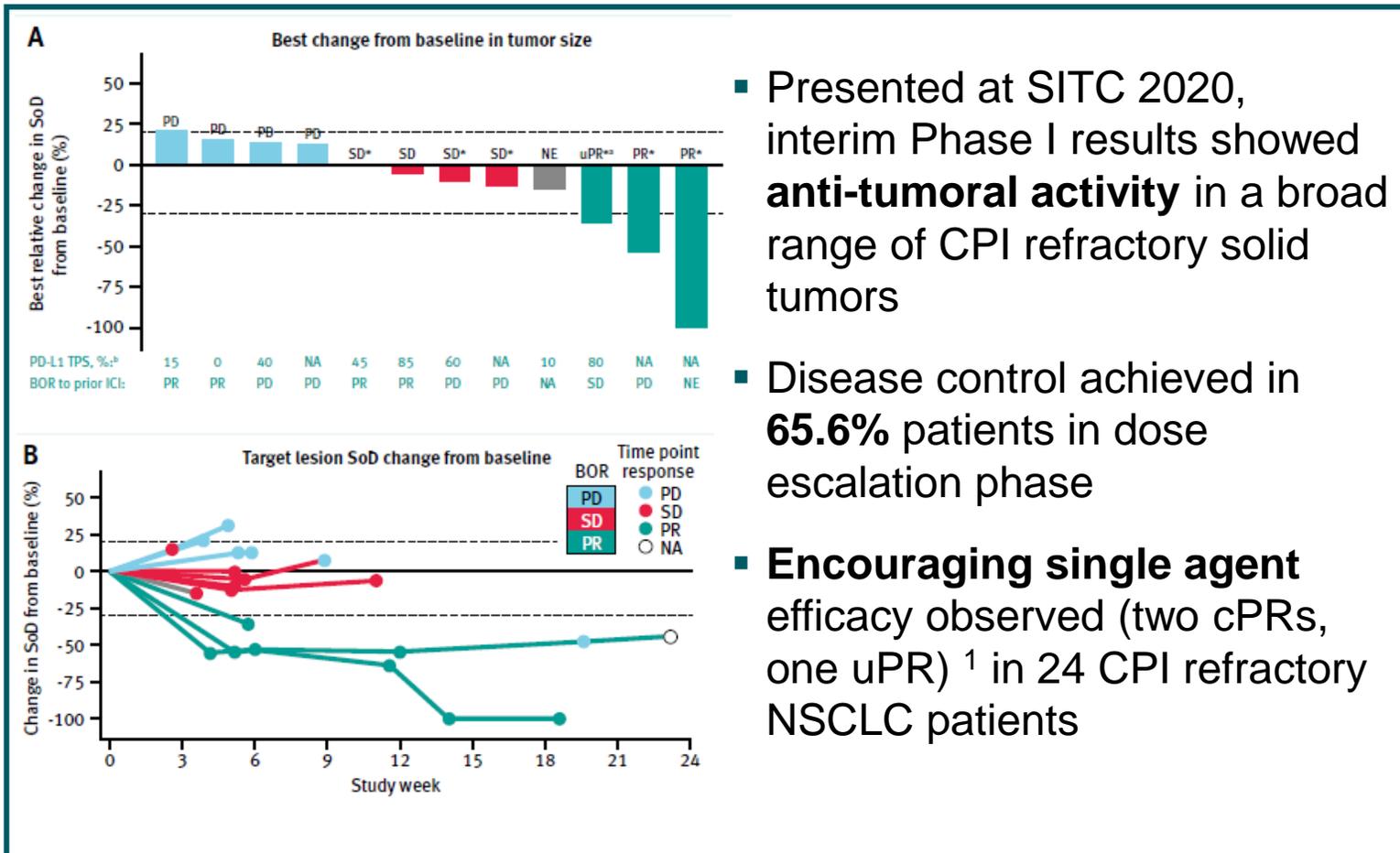
iNeST

- Phase 2 trial planned
- 8 of 8 stage III/IV melanoma patients with stable disease cancer free for **up to 60 months** (BNT121)<sup>1</sup>

- Ongoing Phase 2 trial in 1L melanoma

- **Single agent activity** in melanoma<sup>1</sup> and gastric<sup>2</sup> Cancer
- **Encouraging efficacy signal** validates iNeST potential in early settings

# BNT311 DEMONSTRATED SINGLE AGENT ANTI-TUMOR ACTIVITY



- Presented at SITC 2020, interim Phase I results showed **anti-tumoral activity** in a broad range of CPI refractory solid tumors
- Disease control achieved in **65.6%** patients in dose escalation phase
- Encouraging single agent efficacy** observed (two cPRs, one uPR) <sup>1</sup> in 24 CPI refractory NSCLC patients

**7 expansion cohorts are currently recruiting**

N = Up to 40 per cohort

EC1: NSCLC ≤ 2-4L p. ICI

EC2: NSCLC ≤ 2-4L ICI n.

EC3: Urothelial Ca ≤ 2-4L p. ICI

EC4: Endometrial Ca ≤ 2-4L ICI n.

EC5: TNBC ≤ 2-4L CPI n./ p. ICI

EC6: SCCHN ≤ 2-4L CPI n./ p. ICI

EC7: Cervical Ca ≤ 2-4L ICI n.

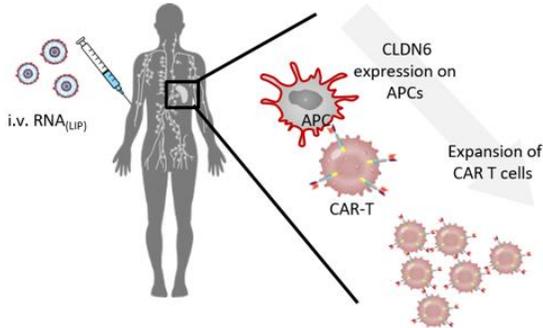
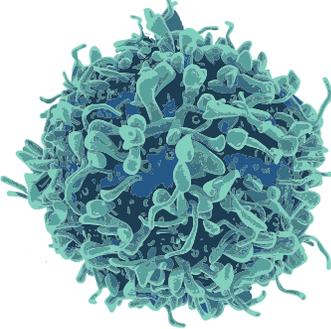
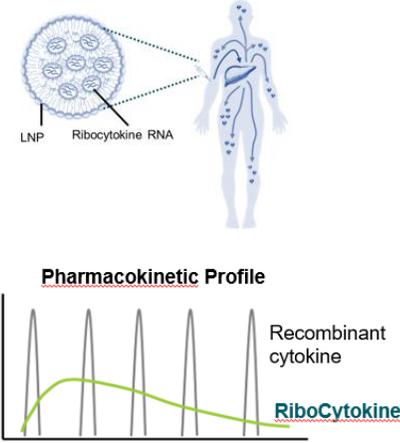
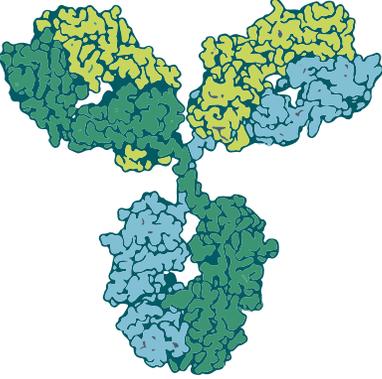
p. ICI = post immune checkpoint inhibitor  
CPI n. = check point inhibitor naive

**BNT311 (GEN1046): Bispecific immunomodulator PD-L1x4-1BB partnered with Genmab (50:50 profit/loss share)**

<sup>1</sup> Data cut-off: October 12, 2020.

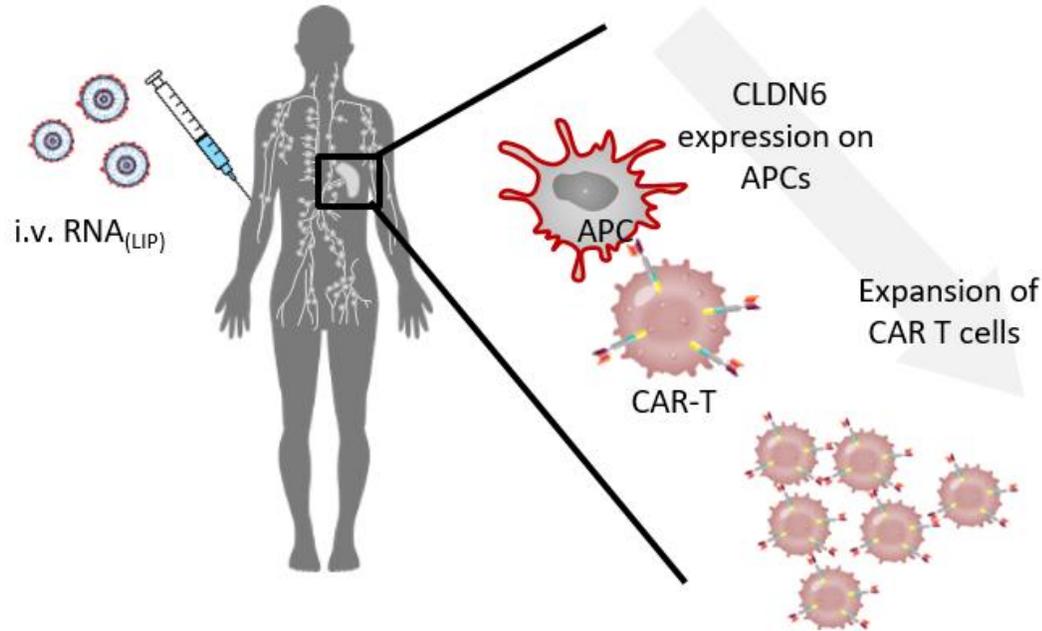
One PR was not confirmed yet by a subsequent scan. Includes all patients who had at least one post-baseline tumor assessment (schedule is every 6 weeks), and thus could be assessed for clinical benefit; 6 of 12 patients are still on treatment.

# ADVANCING INNOVATION BEYOND CURRENT BOUNDARIES

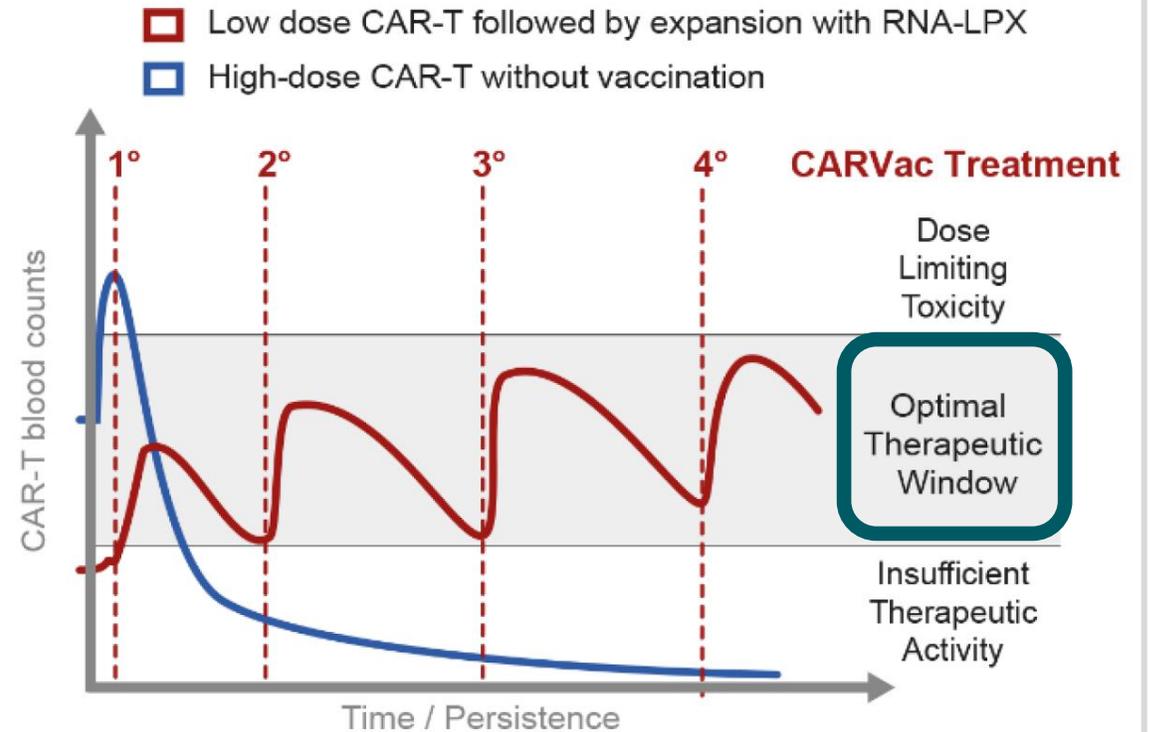
<b>CARVac<sup>1</sup></b> <i>CAR-T cell amplifying mRNA therapy for solid tumors</i>	<b>NEOSTIM T cell therapy</b> <i>Individualized Neoantigen specific T cell therapy</i>	<b>RiboCytokines</b> <i>mRNA encoded Cytokines</i>	<b>RiboMabs<sup>2</sup></b> <i>mRNA encoded Antibodies</i>
 <ul style="list-style-type: none"> <li>▪ BNT 211 (CLDN 6 CAR)</li> </ul>	 <ul style="list-style-type: none"> <li>▪ BNT 221 (PBMC derived ex vivo T cell therapy)</li> </ul>	 <ul style="list-style-type: none"> <li>▪ BNT 151 (modified IL2)</li> <li>▪ BNT152 &amp; 153 (IL-2/IL-7)</li> </ul>	 <ul style="list-style-type: none"> <li>▪ BNT 141 (undisclosed)</li> <li>▪ BNT 142 (CD3xCLDN6)</li> </ul>
<b>Wholly owned</b> ✓	✓	✓	✓
<b>FIH start</b> <b>2021</b>	<b>2021</b>	<b>2021</b>	<b>2021</b>

# CARVAC: OPENING UP CAR-T THERAPY FOR SOLID TUMORS

CAR-T cell therapy + RNA Vaccine to amplify CAR-T cell *in vivo*<sup>1</sup>



First program BNT 211 targeting CLDN-6 antigen in solid tumors



Potential to enhance persistence and safety of CAR-T cell therapy

# mRNA VACCINES FOR AUTO IMMUNE DISEASES

## Novel non-inflammatory mRNA for treatment of Multiple Sclerosis published in Science<sup>1</sup>

- A therapeutic approach to **emulate natural immune tolerance**
- Induced **considerable reduction** in pro-inflammatory effector T cell infiltration in CNS
- Led to **strong autoimmunity suppression** without **broad immune suppression**
- Correlated with **CNS function restoration and disease regression** in preclinical models

*Potential applicability of mRNA vaccine in a plethora of autoimmune diseases*

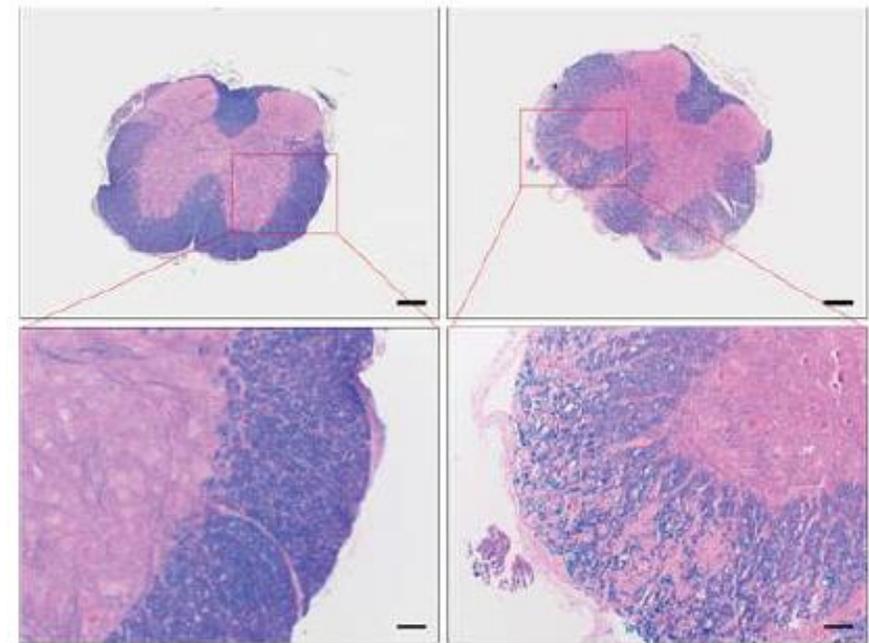
### RESEARCH ARTICLE

#### MULTIPLE SCLEROSIS

**A noninflammatory mRNA vaccine for treatment of experimental autoimmune encephalomyelitis**

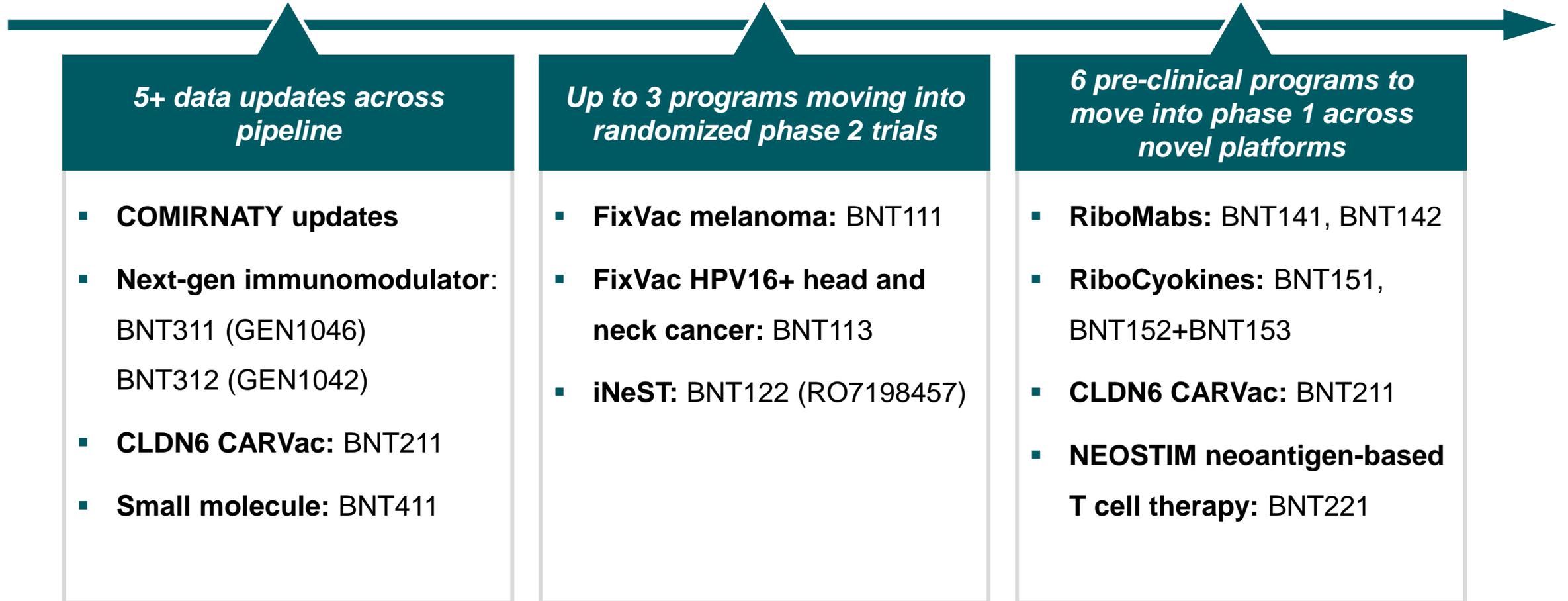
MOG<sub>35-55</sub>\_m1Ψ

irrelevant\_m1Ψ



Luxol fast blue (LFB) staining reveals reduction of demyelination in the spinal cord of mice<sup>1</sup>

# KEY PIPELINE MILESTONES EXPECTED IN 2021



# BETTER PLACED THAN EVER TO BRING INNOVATION TO PATIENTS

## 2021 Corporate Outlook

- Deliver COMIRNATY to up to 1 billion people globally
- Advance up to 3 oncology programs into randomized Phase 2 trials
- Initiate first trials in oncology with registrational potential
- Extend mRNA technology into new disease areas
- Expand global capabilities and footprint in the U.S., Europe, and Asia
- Continue to hire the best and brightest

## Long- term

- Usher in a new era of individualized cancer medicine
- Build a global business and commercialize our own products
- Become a 21st century immunotherapy powerhouse

The logo for BionTech, featuring the word "BIONTECH" in a bold, sans-serif font. The letters "B", "I", "O", "N", "T", "E", and "C" are in a light blue color, while the letters "H" and "H" are in a yellow color. The background of the slide is a dark teal color with several large, overlapping, curved lines in a lighter teal color, creating a grid-like pattern.

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