

# Third Quarter 2021

Corporate update  
and financial results

.....●.....  
*November 9, 2021*



**BIONTECH**

# This Slide Presentation Includes Forward-looking Statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements concerning: BioNTech's expected revenues and net profit related to sales of BioNTech's COVID-19 vaccine, referred to as COMIRNATY® where approved for use under full or conditional marketing authorization, in territories controlled by BioNTech's collaboration partners, particularly for those figures that are derived from preliminary estimates provided by BioNTech's partners; BioNTech's pricing and coverage negotiations with governmental authorities, private health insurers and other third-party payors after BioNTech's initial sales to national governments; the extent to which initial or booster doses of a COVID-19 vaccine continue to be necessary in the future; competition from other COVID-19 vaccines or related to BioNTech's other product candidates, including those with different mechanisms of action and different manufacturing and distribution constraints, on the basis of, among other things, efficacy, cost, convenience of storage and distribution, breadth of approved use, side-effect profile and durability of immune response; the rate and degree of market acceptance of BioNTech's COVID-19 vaccine and, if approved, BioNTech's investigational medicines; the initiation, timing, progress, results, and cost of BioNTech's research and development programs and BioNTech's current and future preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and BioNTech's research and development programs; the timing of and BioNTech's ability to obtain and maintain regulatory approval for BioNTech's product candidates; the collaboration between BioNTech and Pfizer to develop a COVID-19 vaccine (including a potential booster dose of BNT162b2 and/or a potential booster dose of a variation of BNT162b2 having a modified mRNA sequence); the ability of BNT162b2 to prevent COVID-19 caused by emerging virus variants; BioNTech's ability to identify research opportunities and discover and develop investigational medicines; the ability and willingness of BioNTech's third-party collaborators to continue research and development activities relating to BioNTech's development candidates and investigational medicines; the impact of the COVID-19 pandemic on BioNTech's development programs, supply chain, collaborators and financial performance; unforeseen safety issues and claims for personal injury or death arising from the use of BioNTech's COVID-19 vaccine and other products and product candidates developed or manufactured by us; BioNTech's ability to progress BioNTech's Malaria, Tuberculosis and HIV programs, including timing for selecting clinical candidates for these programs and the commencement of a clinical trial, as well as any data readouts; the nature of the collaboration with the African Union and the Africa CDC; the nature and duration of support from WHO, the European Commission and other organizations with establishing infrastructure; the development of sustainable vaccine production and supply solutions on the African continent and the nature and feasibility of these solutions; BioNTech's estimates of research and development revenues, commercial revenues, cost of sales, research and development expenses, sales and marketing expenses, general and administrative expenses, capital expenditures, income taxes, shares outstanding; BioNTech's ability and that of BioNTech's collaborators to commercialize and market BioNTech's product candidates, if approved, including BioNTech's COVID-19 vaccine; BioNTech's ability to manage BioNTech's development and expansion; regulatory developments in the United States and foreign countries; BioNTech's ability to effectively scale BioNTech's production capabilities and manufacture BioNTech's products, including BioNTech's target COVID-19 vaccine production levels, and oBioNTech'sur product candidates; and other factors not known to BioNTech at this time. In some cases, forward-looking statements can be identified by terminology such as “will,” “may,” “should,” “expects,” “intends,” “plans,” “aims,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue,” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. The forward-looking statements in this quarterly report are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond BioNTech's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. You should review the risks and uncertainties described under the heading “Risk Factors” in BioNTech's quarterly report for the three and nine months ended September 30, 2021 and in subsequent filings made by BioNTech with the SEC, which are available on the SEC's website at <https://www.sec.gov/>. Except as required by law, BioNTech disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this quarterly report in the event of new information, future developments or otherwise. These forward-looking statements are based on BioNTech's current expectations and speak only as of the date hereof.

# Safety Information

## AUTHORIZED USE IN THE U.S.:

The Pfizer-BioNTech COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older.

## IMPORTANT SAFETY INFORMATION FROM U.S. FDA EMERGENCY USE AUTHORIZATION PRESCRIBING INFORMATION:

- Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (eg, anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine
- Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine
- Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>)
- Reports of adverse events following use of the Pfizer-BioNTech COVID-19 Vaccine under EUA suggest increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The decision to administer the Pfizer-BioNTech COVID-19 Vaccine to an individual with a history of myocarditis or pericarditis should take into account the individual's clinical circumstances
- Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting
- Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine
- The Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients
- In clinical studies, adverse reactions in participants 16 years of age and older included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%), following administration of the primary series
- In a clinical study, adverse reactions in adolescents 12 through 15 years of age included pain at the injection site (90.5%), fatigue (77.5%), headache (75.5%), chills (49.2%), muscle pain (42.2%), fever (24.3%), joint pain (20.2%), injection site swelling (9.2%), injection site redness (8.6%), lymphadenopathy (0.8%), and nausea (0.4%), following administration of primary series
- In a clinical study, adverse reactions in adults 18 through 55 years of age following administration of a booster dose were pain at the injection site (83.0%), fatigue (63.7%), headache (48.4%), muscle pain (39.1%), chills (29.1%), joint pain (25.3%), lymphadenopathy (5.2%), nausea (0.7%), decreased appetite (0.3%), rash (0.3%), and pain in extremity (0.3%)
- Following administration of the Pfizer-BioNTech COVID-19 Vaccine, the following have been reported outside of clinical trials:
  - severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions, diarrhea, vomiting, and pain in extremity (arm) and syncope
  - myocarditis and pericarditis
- Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine
- Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy
- Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion
- There is no information on the co-administration of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.
- An overall review of adverse reactions reported in the study following the Pfizer-BioNTech COVID-19 Vaccine heterologous booster dose did not identify any new safety concerns, as compared with adverse reactions reported following a Pfizer-BioNTech COVID-19 Vaccine primary series doses or homologous booster dose
- Vaccination providers must report Adverse Events in accordance with the Fact Sheet to VAERS online at <https://vaers.hhs.gov/reportevent.html>. For further assistance with reporting to VAERS call 1-800-822-7967. The reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report
- Vaccination providers should review the Fact Sheet for Information to Provide to Vaccine Recipients/Caregivers and Mandatory Requirements for Pfizer-BioNTech COVID-19 Vaccine Administration Under Emergency Use Authorization
- Before administration of Pfizer-BioNTech COVID-19 Vaccine, please see Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including Full EUA Prescribing Information available at [www.cvdvaccine-us.com](http://www.cvdvaccine-us.com)

# Safety Information

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

## Important safety information

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

# Agenda

**Third Quarter  
2021 Highlights**

Ugur Sahin

**COVID-19  
Vaccine Update**

Sean Marett  
Özlem Türeci

**Oncology  
Pipeline Update**

Özlem Türeci

**Financial  
Results**

Jens Holstein

**Corporate  
Update &  
Outlook**

Ryan Richardson

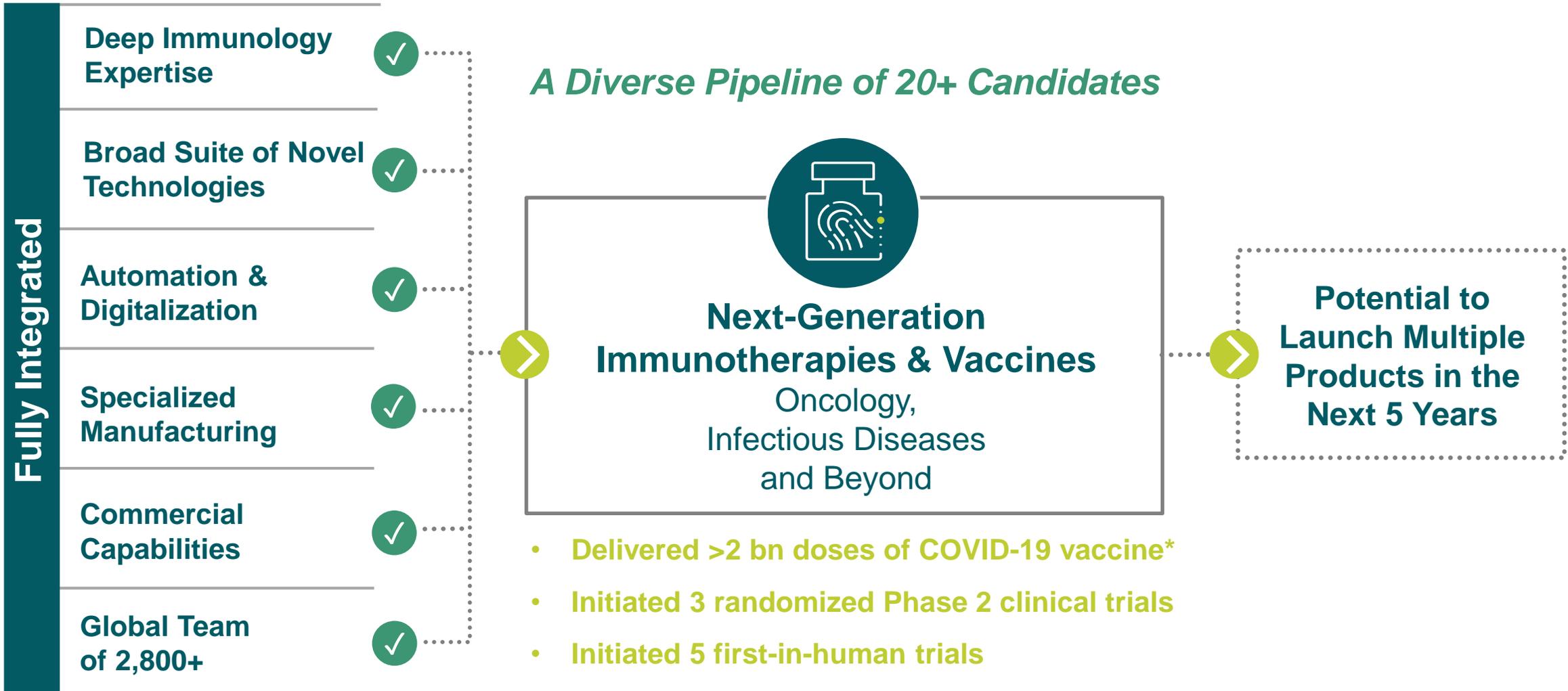
2021

Strong Commercial  
Performance and  
Continued Pipeline  
Expansion



BIONTECH

# BioNTech: A Global Immunotherapy Powerhouse



# Harnessing the Power of the Immune System to Address Serious Diseases



## Infectious Disease

1 MARKETED  
VACCINE

1 PHASE 1  
PROGRAM

9 PRECLINICAL  
PROGRAMS

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

**Focus on significant global health needs, including COVID-19<sup>1</sup>, malaria<sup>2</sup>, HIV<sup>3</sup>, TB<sup>3</sup>, influenza<sup>1</sup>**



## Oncology

15 PROGRAMS IN  
19 CLINICAL TRIALS

4 RANDOMIZED  
PHASE 2 PROGRAMS

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

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



**Broaden Disease Horizon:**

**Autoimmune and inflammatory diseases, regenerative medicine**

# Strong Performance in the Third Quarter of 2021

## Third Quarter 2021 Highlights

### Corporate Updates

- Reported Q3 total revenues of €6.1 bn
- Acquisition of PhagoMed: Expansion into new class of precision antibacterials

### Continued Pipeline Advancement

#### RANDOMIZED PHASE 2 TRIAL STARTS

- **iNeST:** autogene cevumeran (BNT122 / RO7198457; adjuvant treatment of ctDNA+, resected Stage II/III colorectal cancer)

#### FIRST-IN-HUMAN PHASE 1 TRIAL STARTS

- **mRNA vaccine:** BNT161 (influenza)

#### SITC PRESENTATIONS

- Safety and preliminary efficacy signals for 6 oncology programs across 3 therapeutic platforms

#### BNT111 GRANTED FDA ORPHAN DESIGNATION IN CPI R/R MELANOMA

### COVID-19 Vaccine\*

- Delivered >2 bn doses to more than 152 countries and territories worldwide, including low- and middle-income countries\*
- Expect to deliver up to 2.5 bn doses in 2021
- U.S. government purchased an additional 50 m pediatric doses (5 to <12 years of age)

#### BLA APPROVAL IN U.S.

#### BOOSTER DOSE

- Approved in EU for individuals  $\geq 18$  years of age
- Authorized for  $\geq 65$  and high-risk populations in U.S.

#### LABEL EXTENSION

- Clinical data for children aged 5 to <12 submitted to regulators globally
- EUA approval in the U.S. for children 5 to <12

# Agenda

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Third Quarter  
2021 Highlights

**COVID-19  
Vaccine Update**

Oncology  
Pipeline Update

Financial  
Results

Corporate  
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# A Leading Provider of COVID-19 Vaccines Globally

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

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

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

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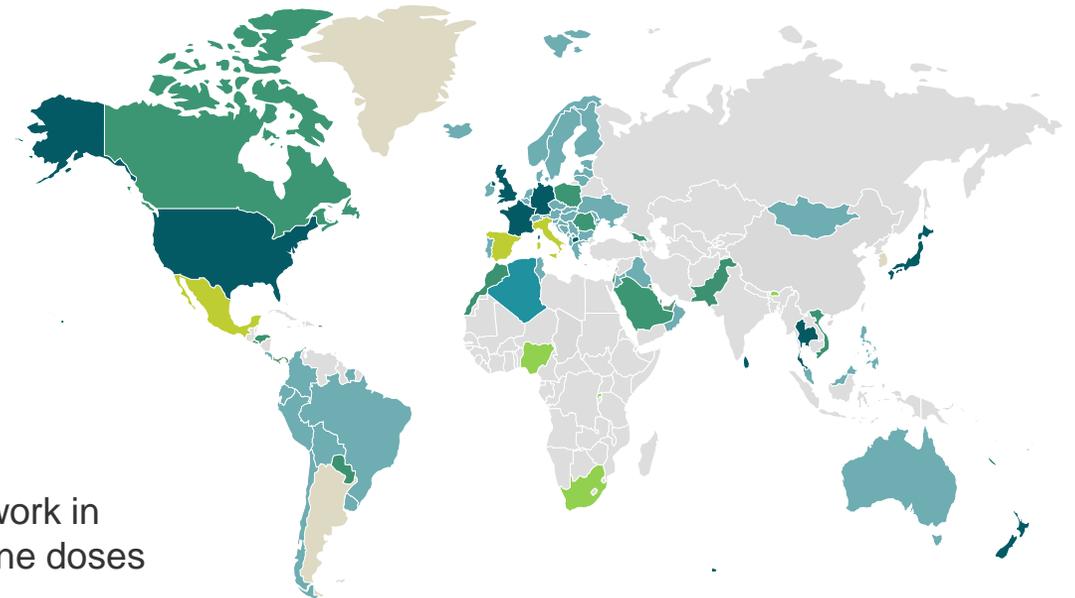
### 2 bn doses pledged through end of 2022 to ensure global equitable vaccine access\*

- Agreement with U.S. government to provide 1 bn doses for donation via COVAX to ~100 countries, including those in African Union
- Expanding manufacturing network to Africa and South America

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### Plan to initiate construction of state-of-the-art mRNA vaccine manufacturing site in Africa in mid-2022

- Development and implementation of scalable regional manufacturing network in Africa to enable an annual manufacturing capacity of several 100 m vaccine doses



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

## Increased Manufacturing Capacity



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

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



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

## Regulatory Advancement Across All Geographies



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

### Booster dose

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

### Label extension

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

## Optimize Formulations to Further Simplify Access Worldwide



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

## Addressing Waning Immune Responses



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

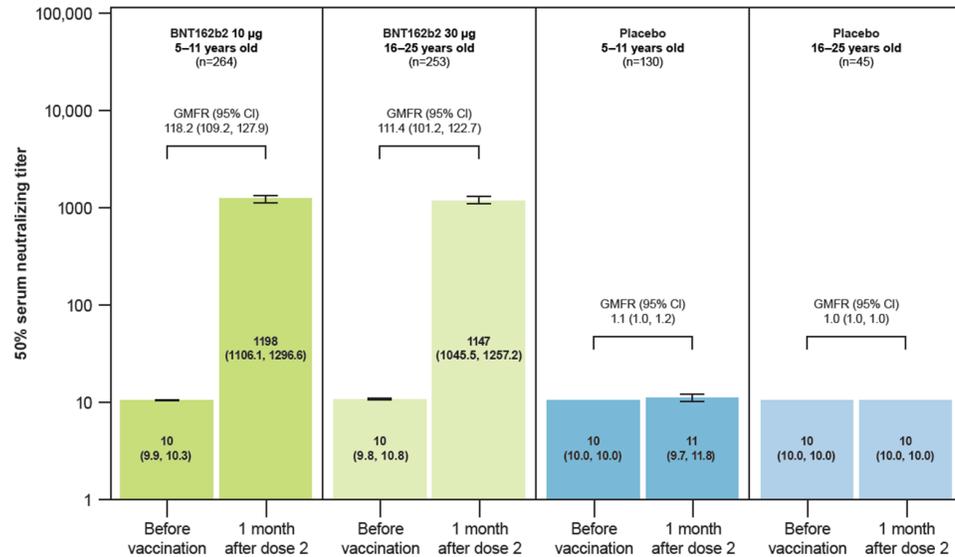
## Preemptive Prototype Approach to Addressing SARS-CoV-2 Variants



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

# Clinical Data Support Label Extension of BNT162b2 to Children 5 to 11 Years of Age<sup>1</sup>

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



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

## BNT162B2 efficacy across age groups

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

## Further pediatric expansion

- Pediatric cohorts: 2-5 years and 6 months to 2 years of age
- Data expected in late Q4 2021 or early Q1 2022

13 <sup>1</sup> These data are currently under review by the regulatory authorities and have been submitted for publication. The vaccine has received U.S. EUA for 5 to <12 year olds. A decision has not yet been issued in the E.U.

# Clinical Strategy Supports Boosters and Platform Approach to Variants

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

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

1

BNT162b2:  
3<sup>rd</sup> dose

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

First data published<sup>1</sup>

2

BNT162b2:  
3<sup>rd</sup> Dose

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

Data in Q4 2021

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

3

Beta Variant-Encoding Vaccine:  
3<sup>rd</sup> dose or naïve

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

Data in Q1 2022

4

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

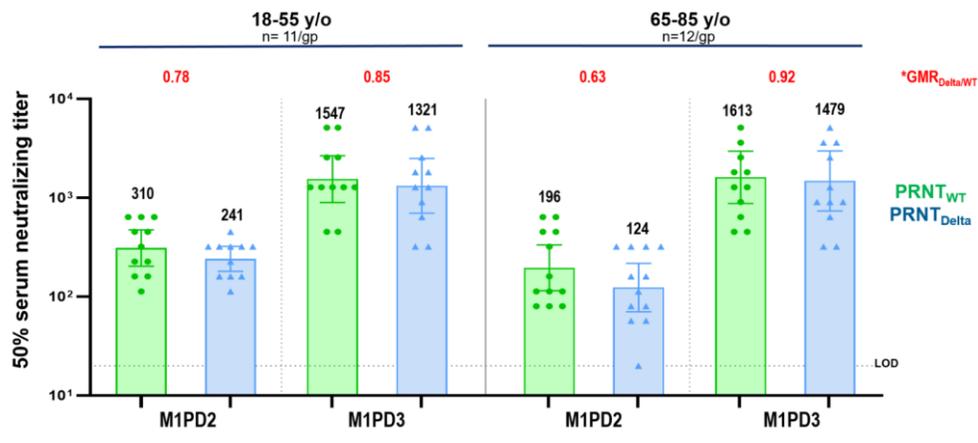
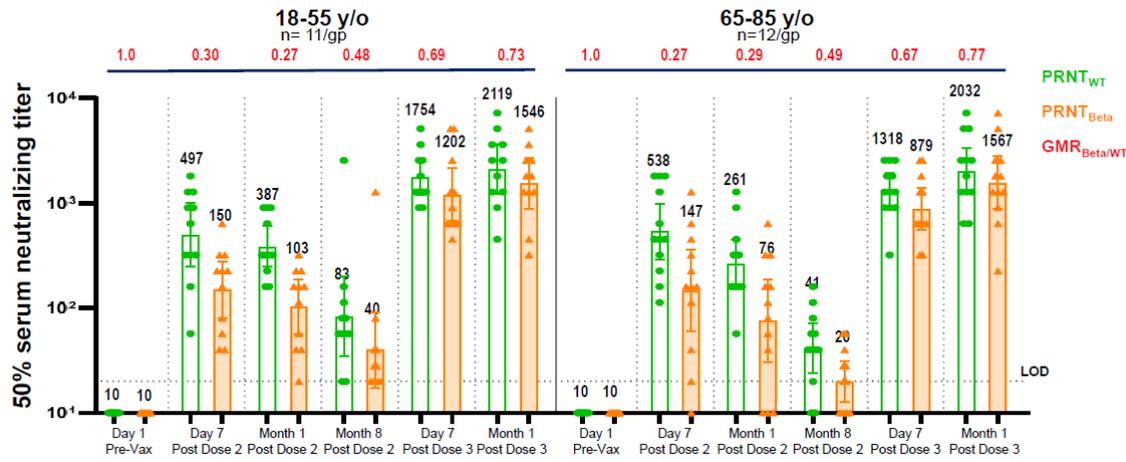
Safety & immunogenicity trial  
N=~600; N=~300 (naïve)

Data in Q4 2021

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

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

## Greater, Broader SARS-CoV-2 Neutralization with BNT162b2 Vaccine Dose 3<sup>1</sup>



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

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

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

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

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

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

## Real world vaccine effectiveness post primary dose schedule

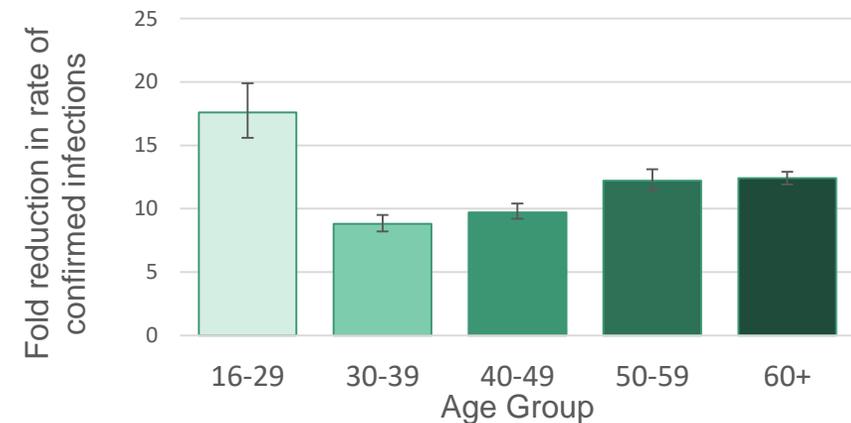
Global data reflecting high vaccine effectiveness post primary regimen.

Population analysis from the Israeli Ministry of Health data found BNT162b2 had a high level of VE across a range of outcomes<sup>1</sup>:

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

## Real world evidence that a booster dose restores high levels of vaccine effectiveness for confirmed infections and severe disease<sup>3</sup>

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

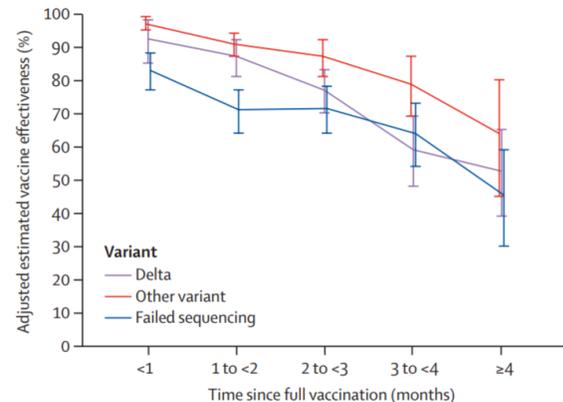


At ≥12 days post booster dose vs non-booster cohort:

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

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

Analysis of more than three million US healthcare records<sup>2</sup> demonstrated that BNT162b2 was **90% (95%CI 89-92) effective** against hospitalization



# Agenda

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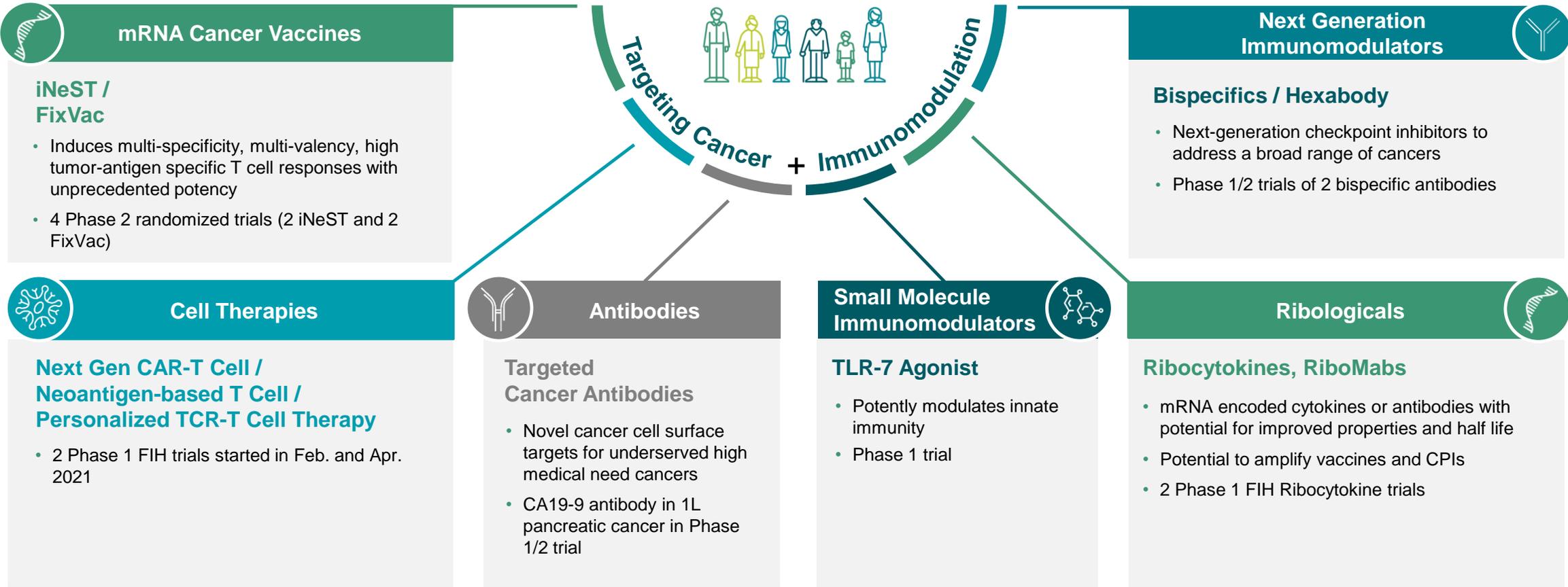
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# Potential To Tackle Multiple Diseases With Different Therapeutic Modalities



Clinical progress across all platforms

# Strong Clinical Execution: On Track To Achieve 2021 Corporate Milestones

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

## 5+ Trial Updates



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

## 4 Randomized Phase 2 Trial Starts



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

## 6 First-in-human Phase 1 Trial Starts



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

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

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

- Colorectal cancer is second deadliest cancer worldwide<sup>1</sup>, 5 year OS in regional disease is 71%<sup>2</sup>
- 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<sup>3,4</sup>
- In ctDNA-positive, Stage 2 (high risk) and Stage 3 CRC post AdCTx, duration of disease free survival is 6 months<sup>5</sup>

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



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

# Clinical Data Showing at SITC 2021 Provides Further Proof-of-Concept Of Therapeutic Platforms & Support Continued Advancement

## 6 PROGRAM

Clinical Data Presentations across  
**4 THERAPEUTIC**  
Platforms

- ✓ mRNA Cancer Vaccines
- ✓ Engineered Cell Therapies
- ✓ Next Generation Checkpoint Immunomodulators
- ✓ Small Molecule Immunomodulator

## 1 LATE Breaker

CAR-T therapy:  
CARVac (BNT211)

## 2 ORAL

Presentations

Next Gen Immunomodulator (BNT312)  
CLDN-6 CARVAC (BNT211)

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## 5 POSTERS

FixVac (BNT111)    TLR-7 agonist (BNT411)  
FixVac (BNT112)    Bispecific antibody (BNT311)  
iNeST (BNT122)



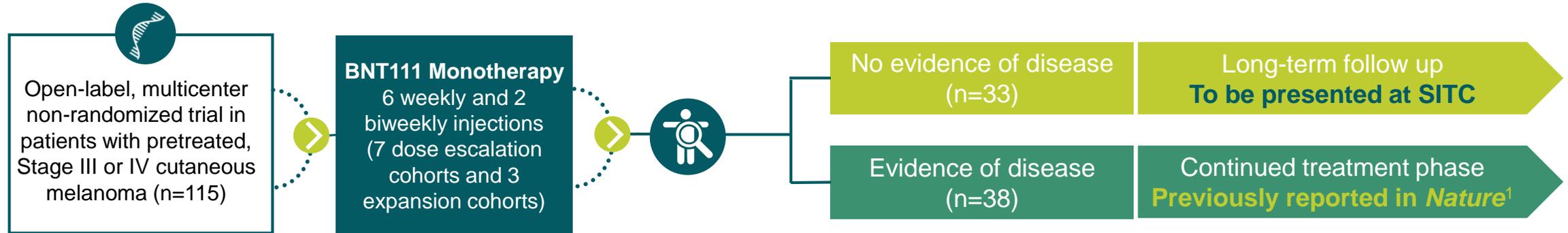
**6** Clinical Programs Showed  
Promising Signs of  
Clinical Activity and Favorable Safety Profiles



**Additional Data to be  
Presented at SITC**

# SITC 2021 - BNT111 Phase 1: Strong Immunogenicity and Promising Clinical Activity in Cutaneous Melanoma Patients with Evidence of Disease and No Evidence of Disease

FixVac off-the-shelf mRNA vaccine targeting 4 tumor-associated shared antigens



## Favorable Safety profile

- Most common treatment-related AEs: 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  $\geq 3$

**nature**<sup>1</sup>

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

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

## CD4+ and CD8+ T cell responses

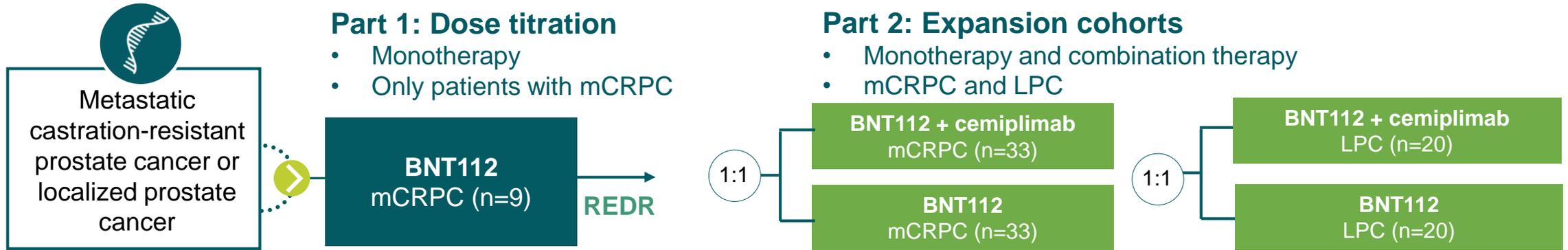
- Frequent high magnitude T cell responses; comparable between *evidence of disease* & *no evidence of disease* populations
- **Ex vivo** ELISpot response against  $\geq 1$  tumor-associated antigen in:
  - 14/22 (63.6%) *evidence of disease* patients
  - 19/28 (67.7%) *no evidence of disease* patients
- Substantial fraction of **de novo** induced responses

## Median disease-free survival 34.8 months

- In *no evidence of disease* patients
- 95% CI: 7.0-not reached

# BNT112 Phase 1/2: FixVac Off-the-Shelf mRNA Vaccine as Monotherapy and in Combination with PD-1 Inhibitor in Patients with Prostate Cancer

BNT112 targets 5 prostate cancer tumor-associated shared antigens



## Patients

- All patients Stage 4 at diagnosis
- Median age 68 years
- 11 patients treated with monotherapy
- 3 with BNT112 + cemiplimab

## 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

**No safety signals of concern**

## Vaccine induced immune responses

- All ELISpot-evaluable patients (n=7) showed vaccine-induced immune response
- All 5 BNT112 tumor-associated antigens are immunogenic
- T cell responses to each antigen in at least 2 of 7 evaluable patients

## Signs of anti-tumor activity

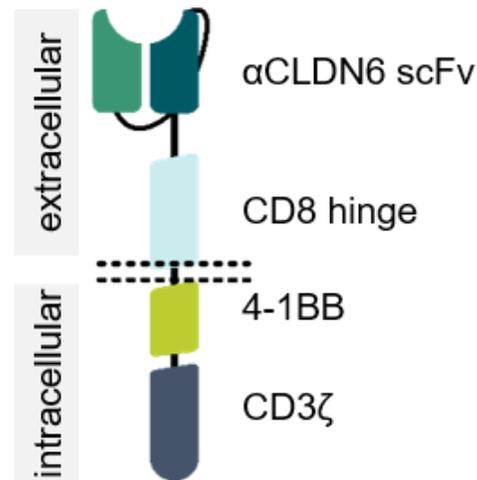
- Decreased prostate-specific antigen (PSA) levels in 2 patients with monotherapy

# BNT211: Phase 1/2 trial evaluating next Generation CAR-T Targeting Claudin-6 with CARVac in Solid Tumors

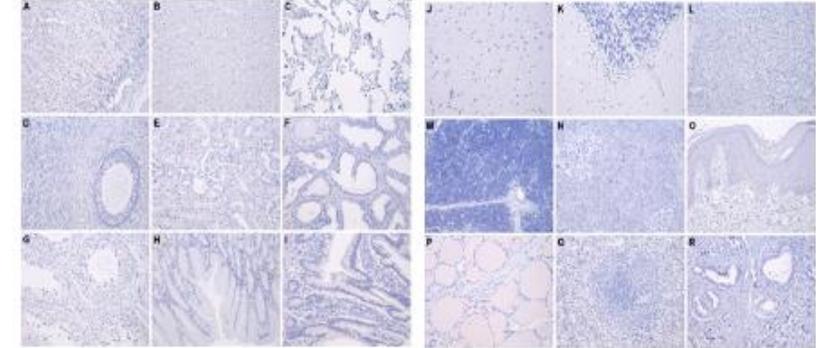
## CAR-T cell therapy + CARVac RNA Vaccine to amplify CAR-T cell *in vivo*

- New 2<sup>nd</sup> generation CAR directed against CLDN6, a new highly cancer cell specific carcino-embryonic antigen
- CLDN6 is expressed in multiple solid cancers with high medical need tumor types
- CARVac drives *in vivo* expansion, persistence and efficacy of CAR-T

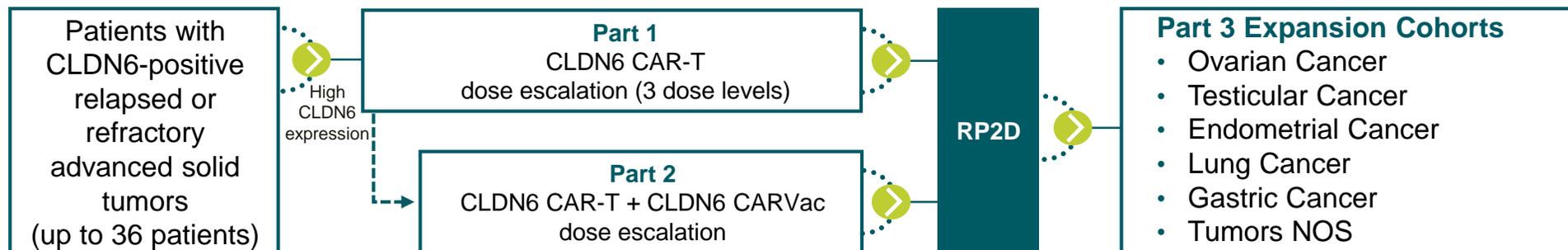
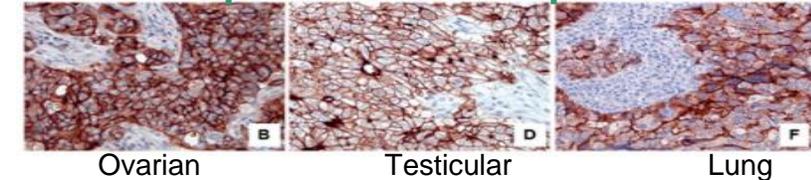
### BNT211 CAR Structure



### CLDN6 not present in healthy tissues



### CLDN6 expressed in multiple cancers



# SITC 2021 - BNT211 Phase 1/2 trial: Favorable Safety Profile and Encouraging Signs of Efficacy for CLDN6 CAR-T Cells +/- CARVac

## Heavily pretreated patients

- Testicular, ovarian, endometrial cancer, CUP & soft-tissue sarcoma
- 8 patients treated
  - CLDN6 CAR-T cells monotherapy: 3 patients treated with DL1 and 2 with DL2
  - CLDN6 CAR-T + CARVac: 3 patients treated with DL1

## No DLTs or serious drug-related AEs with monotherapy

- Manageable cytokine release syndrome
- No signs of neurotoxicity with monotherapy
- Transient and moderate elevations of IL-6 and CRP in patients without clinical CRS symptoms
- Transient flu-like symptoms in patient with CLDN6 CAR-T + CARVac, resolving within 24 hours

## Robust CAR-T cell engraftment

- Enhanced expansion of CAR-T cells in 2 patients with liver metastases
  - Elevated ALT, AST and AP levels
  - Total bilirubin unaffected

## Signs of clinical activity

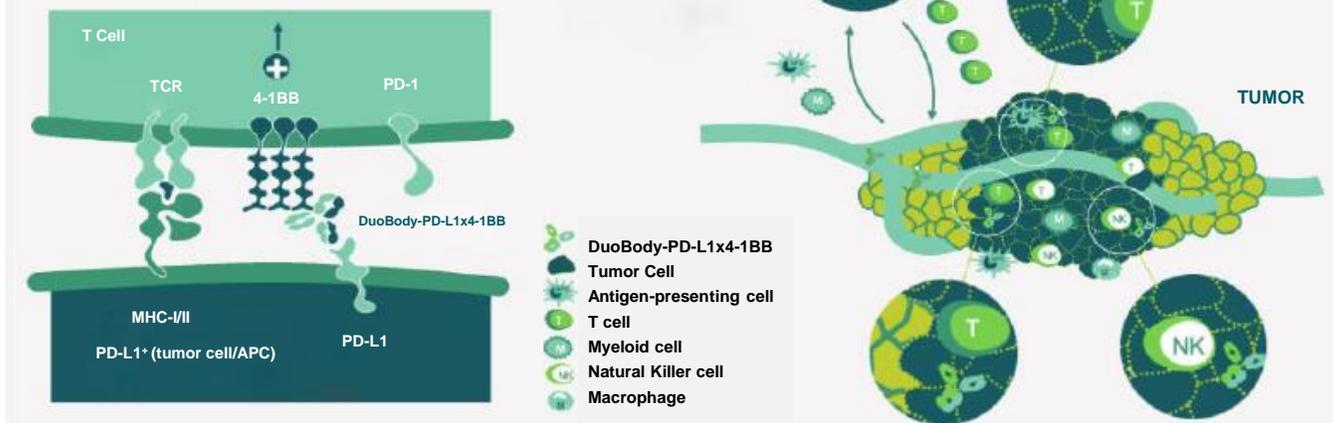
- 6-week tumor assessment available for 5 of 8 patients
  - 4 SD (3 transitioned into PD after an additional 6-18 weeks) and 1 PD
  - 3 patients showed initial tumor shrinkage according to RECIST1.1 (reduction of target sum: -18%, -21% and -27%)

# BNT311 Phase 1/2: First-in-Human Study of DuoBody-PD-L1x4-1BB, A Next-Generation Bispecific Antibody

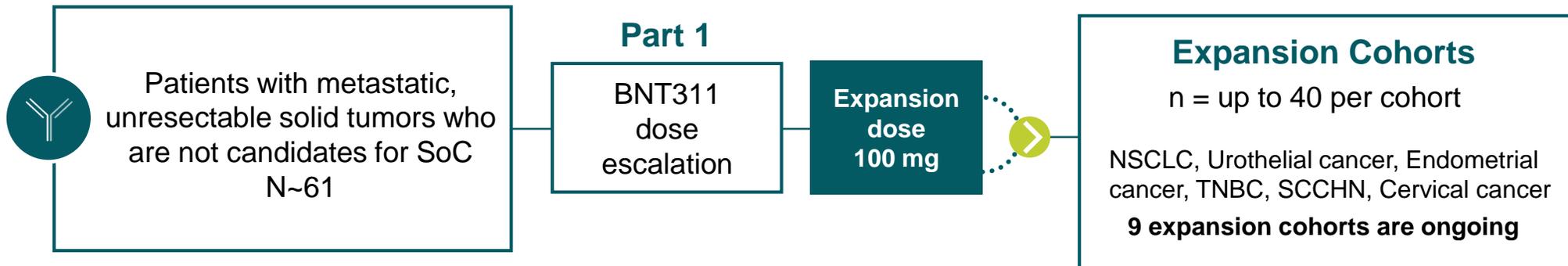
## Next Generation Immunomodulator

- Bispecific antibody\* designed to induce an antitumor immune response by simultaneous and complementary PD-L1 blockade and conditional 4-1BB stimulation

## Mechanism of action of FC-silenced DuoBody-PD-L1x4-1BB



## Open-label, dose-escalation trial with expansion cohorts to evaluate safety



# SITC 2021 - BNT311 Phase 1/2: Pharmacodynamic Effects Consistent with Proposed Mechanism of Action in Patients with NSCLC who Progressed on PD-L1 Therapy

## Peripheral and tumoral immune activity in expansion cohort of patients with PD-L1-R/R NSCLC

### Positive pharmacodynamics responses

- Induction of cytokines (IFN- $\gamma$  & CXCL9/10)
- Expansion of CD8+ effector memory T cells & activated NK cells
- 5 patients with confirmed partial response
- Greater induction of IFN- $\gamma$ , 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

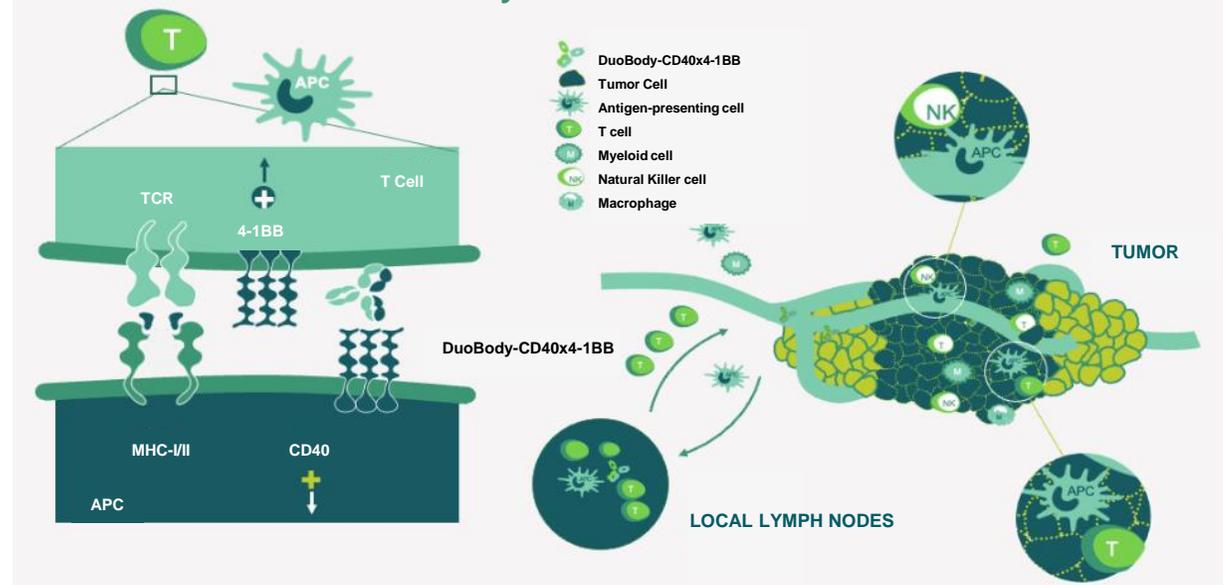
**Phase 2 trial of BNT311 as monotherapy and in combination with pembrolizumab in R/R metastatic NSCLC expected to start in Q4 2021**

# 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

## Mechanism of action of DuoBody-CD40x4-1BB



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



# SITC 2021 - BNT312 Phase 1/2: Favorable Safety Profile, Biologic Activity and Early Antitumor Activity Observed with Monotherapy

## BNT312 monotherapy in dose escalation cohort: 50 patients

- Median 57 years old
- Most common cancer types
  - Colorectal (22%)
  - Melanoma (20%)
  - NSCLC (8%)
- Median of 2.5 treatment cycles
- C<sub>max</sub> observed shortly after end of infusion

## Maximum tolerated dose not reached

- Treatment-related AEs occurring in ≥10% of patients

	All grades	Grade ≥3
Fatigue	22%	-
Pyrexia	16%	-
Nausea	10%	-
Transaminase elevation	10%	6%

- One DLT of elevated transaminases (grade 4)
  - Occurred at 200 mg dose
  - Resolved upon corticosteroid administration
- No drug-related grade ≥3 thrombocytopenia

## Biological activity consistent with mechanism of action

### Increased levels of:

- Peripheral monocyte and DC cytokines (IFN-γ, TARC)
- CD8<sup>+</sup> total and effector memory T cells

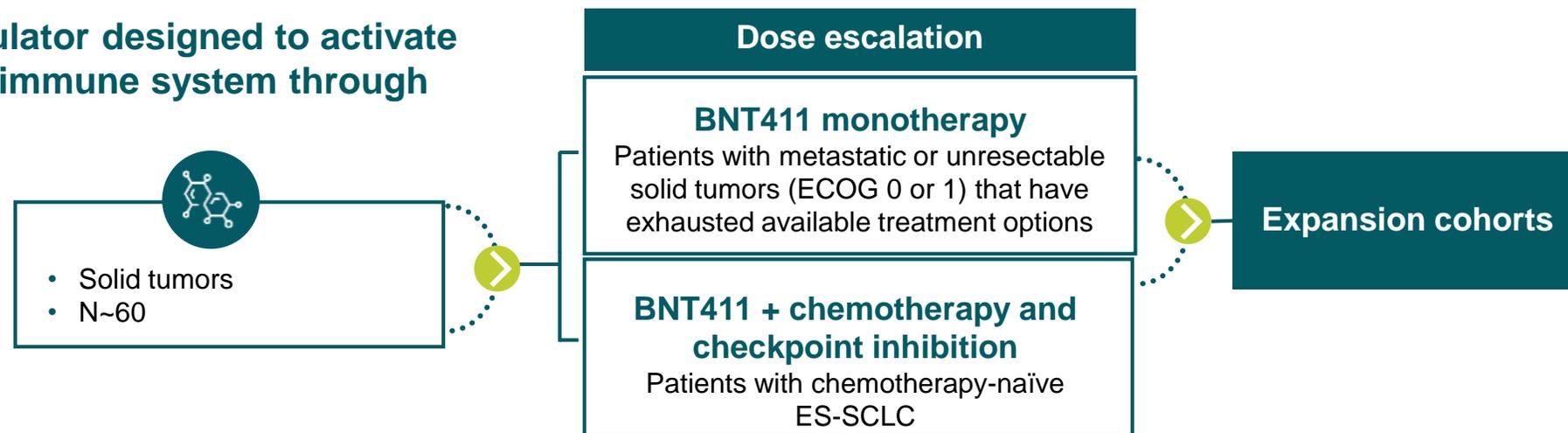
## 51% of patients (n=25/49) achieved disease control

- Defined as best overall response of complete/partial response and stable disease
- 2 confirmed partial responses (melanoma and neuroendocrine lung cancer)

Further Evaluation: **100 mg every 3 weeks was identified as the expansion dose**

# SITC 2021 - BNT411 Phase 1/2: Tolerable Safety Profile and Encouraging Pharmacodynamic Signals with Monotherapy at All Doses

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



## BNT411 monotherapy: 11 patients

- Median age 62 years
- Previously received 2–5 systemic cancer therapies

**5 of 8 DLs cleared in Part 1A**

## Tolerable safety profile and no DLTs tested to-date

- Only drug-related AEs:
- Pyrexia (n=2), grades 1 & 3 (non-serious)
  - Anemia (n=2), grades 1 & 2

## Preliminary biological activity consistent with mechanism of action

- Plasma cytokine levels were highest at DL5 (2.4 µg/kg) in 3/4 of patients
- Interferon-γ induced protein (IP10) increased 2.7– 9.2-fold

# Agenda

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Third Quarter  
2021 Highlights

COVID-19  
Vaccine Update

Oncology  
Pipeline Update

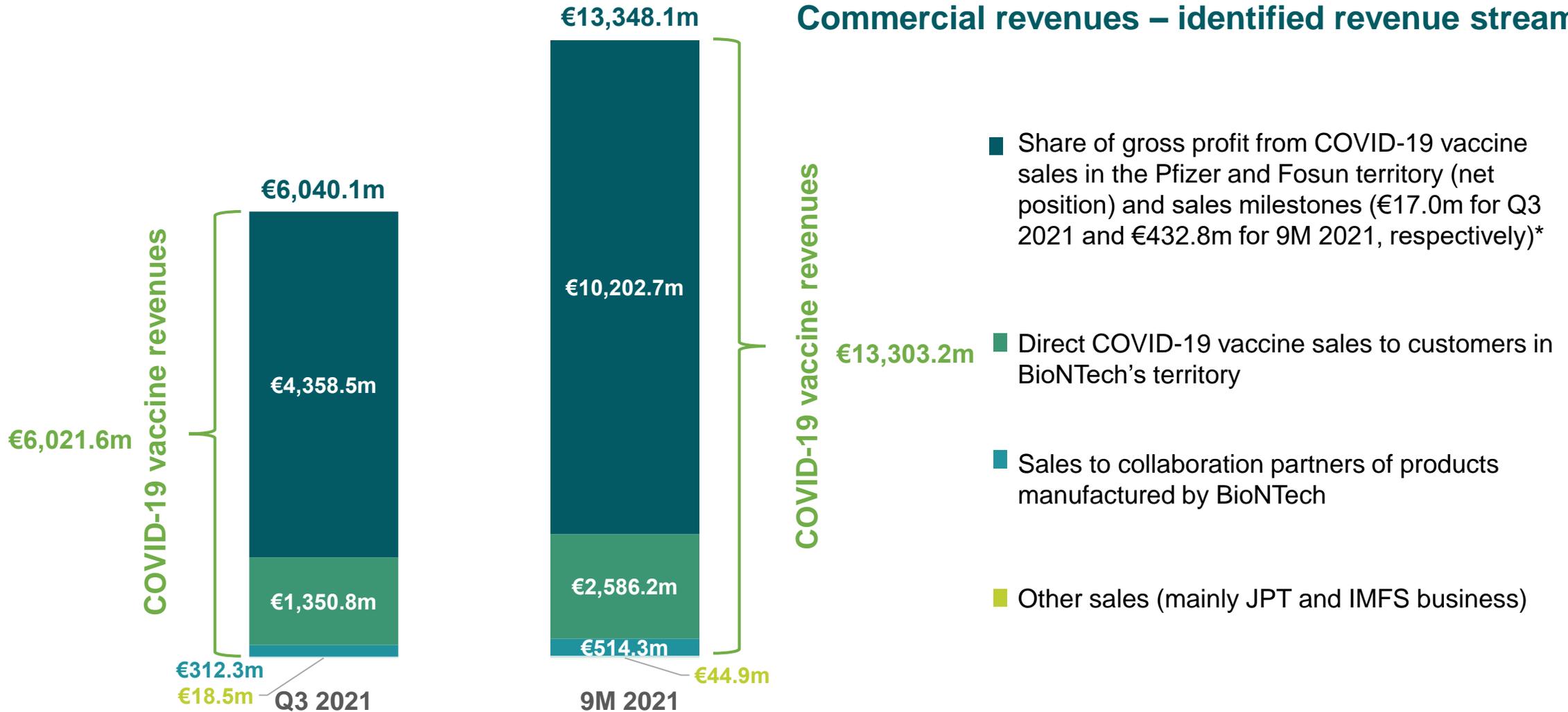
Financial  
Results

Corporate  
Update &  
Outlook

## Q3 2021 and 9M 2021 Financial Results (unaudited) – Profit or Loss

<i>(in millions, except per share data)*</i>	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Research & development revenues	€47.2	€59.7	€96.1	€113.4
Commercial revenues	6,040.1	7.8	13,348.1	23.5
<b>Total revenues</b>	<b>€6,087.3</b>	<b>€67.5</b>	<b>€13,444.2</b>	<b>€136.9</b>
Cost of sales	(1,211.4)	(6.8)	(2,328.3)	(18.3)
Research and development expenses	(260.4)	(227.7)	(677.7)	(388.0)
Sales and marketing expenses	(10.5)	(4.3)	(32.5)	(7.8)
General and administrative expenses	(68.2)	(23.5)	(154.9)	(58.1)
Other operating income less expenses	186.7	8.4	333.3	8.7
<b>Operating income / (loss)</b>	<b>€4,723.5</b>	<b>€(186.4)</b>	<b>€10,584.1</b>	<b>€(326.6)</b>
Finance income less expenses	(56.1)	(21.1)	(251.6)	(24.8)
Income taxes	(1,456.4)	(2.5)	(3,206.2)	(0.3)
<b>Profit / (loss) for the period</b>	<b>€3,211.0</b>	<b>€(210.0)</b>	<b>€7,126.3</b>	<b>€(351.7)</b>
<b>Earnings per share</b>				
Basic profit / (loss) for the period per share	€13.14	€(0.88)	€29.22	€(1.51)
Diluted profit / (loss) for the period per share	€12.35	€(0.88)	€27.46	€(1.51)

# Q3 2021 and 9M 2021 COVID-19 Vaccine Deliveries Drove Revenue Growth



\*Represents an estimated figure based on preliminary data shared between Pfizer and BioNTech. Changes in share of the collaboration partner's gross profit will be recognized prospectively. Graphic is for illustration only.

# Updated Outlook for the 2021 Financial Year

## Update on COVID-19 Vaccine Planned Deliveries for the 2021 Financial Year

- Estimated BioNTech COMIRNATY/COVID-19 vaccine revenues for the full 2021 financial year based on up to 2.5 billion doses: **~€16 billion to €17 billion\***

## Planned 2021 Financial Year Expenses and Capex\*

- Previous cost guidance maintained for the full 2021 financial year
  - R&D expenses **€950 million – €1,050 million**
  - SG&A expenses **€250 million – €300 million**
  - Capital expenditure **€175 million – €225 million**
- Further ramp-up of R&D investment in Q4 2021 planned to expand and accelerate the pipeline development
- Ranges reflect current base case projections

## Estimated 2021 Financial Year Tax Assumptions

- BioNTech Group estimated annual effective income tax rate **~31%**

# Agenda

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Third Quarter  
2021 Highlights

COVID-19  
Vaccine Update

Oncology  
Pipeline Update

Financial  
Results

Corporate  
Development &  
Outlook

# Expansion into New Class of Precision Antibacterials with PhagoMed Acquisition



- PhagoMed: based in Vienna, Austria
- Pioneering new class of precision antibacterials called synthetic lysins



- Lysins are highly bactericidal phage-derived enzymes that cleave the bacterial cell wall
- Potential to address difficult to target pathogens & global challenge of antimicrobial resistance



- LysinBuilder in silico technology platform based on proprietary algorithms
- Designed to rapidly produce recombinant natural lysins against a wide range of pathogens
- Optimization for potency, stability and manufacturing yield



- Total consideration can reach up to ~€150.0 m consisting of upfront consideration of ~€50.0 m (less acquired debt) with the possibility of the selling shareholders earning up to an additional ~€100.0 m
- Transaction closed in Q3
- Forms BioNTech's new R&D hub for precision antibacterials operating as BioNTech R&D Austria

## Acquisition expands Infectious Disease Toolkit:

mRNA Vaccines

| mRNA Encoded Antibodies

| Precision Anti-bacterials

# Expanding our Capabilities and Pipeline in Infectious Diseases

## Addressing Infectious Diseases with Significant Global Impact



### COVID-19

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



### Influenza

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



### Malaria

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



### Tuberculosis

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



### HIV

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



### 5 Additional Non-disclosed Programs

- Multiple product candidates in preclinical development
- Vaccines and Ribologicals



### Bacterial Infections

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

# Oncology Pipeline: 15 Product Candidates in 19 Ongoing Clinical Trials

Drug class	Platform	Product Candidate	Indication (Targets)	Preclinical	Phase 1	Phase 2	Phase 3	Rights Collaborator
mRNA	FixVac (fixed combination of shared cancer antigens)	BNT111	advanced melanoma	▶				fully-owned
		BNT112	prostate cancer	▶				fully-owned
		BNT113	HPV16+ head and neck cancer <sup>1</sup>	▶				fully-owned
		BNT115	ovarian cancer <sup>1</sup>	▶				fully-owned
	iNeST (patient specific cancer antigen therapy)	autogene cevumeran (BNT122)	1L melanoma	▶				Genentech (global 50:50 profit/loss)
			adjuvant colorectal cancer	▶				
			solid tumors	▶				
	Intratumoral Immunotherapy	SAR441000 (BNT131)	solid tumors ( <i>IL-12sc</i> , <i>IL-15sushi</i> , <i>GM-CSF</i> , <i>IFNα</i> )	▶				Sanofi (global profit/loss share)
	RiboCytokines (mRNA-encoded Cytokines)	BNT151	solid tumors (optimized IL-2)	▶				fully-owned
		BNT152 + BNT153	solid tumors ( <i>IL-7</i> , <i>IL-2</i> )	▶				fully-owned
Antibodies	Next-Gen CP <sup>2</sup> Immunomodulators	GEN1046 (BNT311)	solid tumors ( <i>PD-L1</i> × <i>4-1BB</i> )	▶				Genmab (global 50:50 profit/loss)
		GEN1042 (BNT312)	solid tumors ( <i>CD40</i> × <i>4-1BB</i> )	▶				
	Targeted Cancer Antibodies	BNT321 (MVT-5873)	pancreatic cancer (sLea)	▶				fully-owned
SMIM <sup>3</sup>	Toll-Like Receptor Binding	BNT411	solid tumors ( <i>TLR7</i> )	▶				fully-owned
Cell Therapies	CAR-T Cells	BNT211	solid tumors ( <i>CLDN6</i> )	▶				fully-owned
	Neoantigen-based T cell therapy	BNT221 (NEO-PTC-01)	solid tumors	▶				fully-owned

# Poised to Accelerate Our Transformation



## Rapidly advance pipeline

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



## Expand integrated infrastructure

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



## Increase global footprint

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

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

The Biontech logo is displayed in a bold, sans-serif font. The letters 'B', 'I', 'O', 'N', 'T', 'E', and 'C' are in a light blue color, while the letters 'H' and 'H' are in a yellow color. The logo is positioned in the upper left quadrant of the page.

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