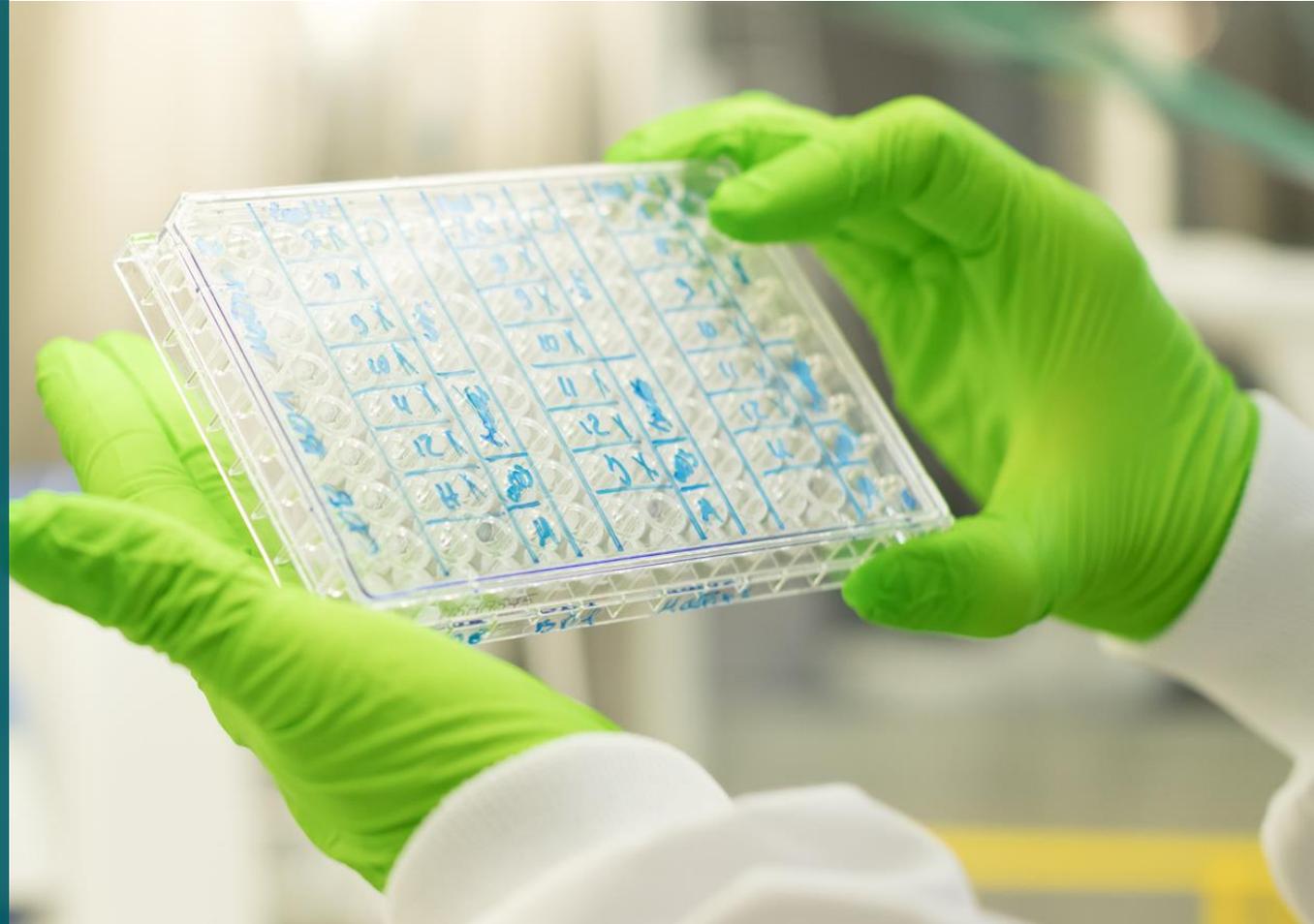


# Second Quarter 2021

Corporate update and  
financial results

.....●.....  
*August 09, 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: our expected revenues and net profit related to sales of our COVID-19 vaccine, referred to as COMIRNATY® in the European Union as authorized for use under conditional marketing approval, in territories controlled by our collaboration partners, particularly for those figures that are derived from preliminary estimates provided by our partners; our pricing and coverage negotiations with governmental authorities, private health insurers and other third-party payors after our initial sales to national governments; the extent to which a COVID-19 vaccine continues to be necessary in the future; competition from other COVID-19 vaccines or related to our other product candidates, including those with different mechanisms of action and different manufacturing and distribution constraints, on the basis of, among other things, efficacy, cost, convenience of storage and distribution, breadth of approved use, side-effect profile and durability of immune response; the rate and degree of market acceptance of our COVID-19 vaccine and our investigational medicines, if approved; the initiation, timing, progress, results, and cost of our research and development programs and our current and future preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs; the timing of and our ability to obtain and maintain regulatory approval for our product candidates; the collaboration between BioNTech and Pfizer to develop a COVID-19 vaccine (including a potential booster dose of BNT162b2 and/or a potential booster dose of a variation of BNT162b2 having a modified mRNA sequence); the ability of BNT162b2 to prevent COVID-19 caused by emerging virus variants; our ability to identify research opportunities and discover and develop investigational medicines; the ability and willingness of our third-party collaborators to continue research and development activities relating to our development candidates and investigational medicines; the impact of the COVID-19 pandemic on our development programs, supply chain, collaborators and financial performance; unforeseen safety issues and claims for personal injury or death arising from the use of our COVID-19 vaccine and other products and product candidates developed or manufactured by us; BioNTech's Malaria, Tuberculosis and HIV programs; timing for selecting clinical candidates for these programs and the commencement of a clinical trial, as well as any data readouts; the nature of the collaboration with the African Union and the Africa CDC; the nature and duration of support from WHO, the European Commission and other organizations with establishing infrastructure; the development of sustainable vaccine production and supply solutions on the African continent and the nature and feasibility of these solutions; our estimates of research and development revenues, commercial revenues, cost of sales, research and development expenses, sales and marketing expenses, general and administrative expenses, other operating income less expenses, finance income less expenses, income taxes, shares outstanding and basic and diluted profit for the period per share and our needs for or ability to obtain additional financing; our ability to identify, recruit and retain key personnel; our and our collaborators' ability to protect and enforce our intellectual property protection for our proprietary and collaborative product candidates, and the scope of such protection; the development of and projections relating to our competitors or our industry; our ability and that of our collaborators to commercialize and market our product candidates, if approved, including our COVID-19 vaccine; the amount of and our ability to use net operating losses and research and development credits to offset future taxable income; our ability to manage our development and expansion; regulatory developments in the United States and foreign countries; our ability to effectively scale our production capabilities and manufacture our products, including our target COVID-19 vaccine production levels, and our product candidates; our ability to implement, maintain and improve effective internal controls; our plans for expansion in southeast Asia and China, including our planned regional headquarters and manufacturing facility in Singapore as well as the joint venture with Fosun Pharma; and other factors not known to us at this time. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. The forward-looking statements in this quarterly report are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond BioNTech's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. You should review the risks and uncertainties described under the heading "Risk Factors" in this quarterly report and in subsequent filings made by BioNTech with the SEC, which are available on the SEC's website at <https://www.sec.gov/>. Except as required by law, BioNTech disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this quarterly report in the event of new information, future developments or otherwise. These forward-looking statements are based on BioNTech's current expectations and speak only as of the date hereof.

# Safety Information

## 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 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%)
- 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 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)
  - 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 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 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).

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

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

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

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

In clinical studies, adverse reactions in participants 16 years of age and older included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.4%), 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%)

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

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

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**Second Quarter  
2021 Highlights**

**COVID-19  
Vaccine Update**

**Oncology  
Pipeline Update**

**Financial  
Results**

**Corporate  
Update &  
Outlook**

.....●.....

2021

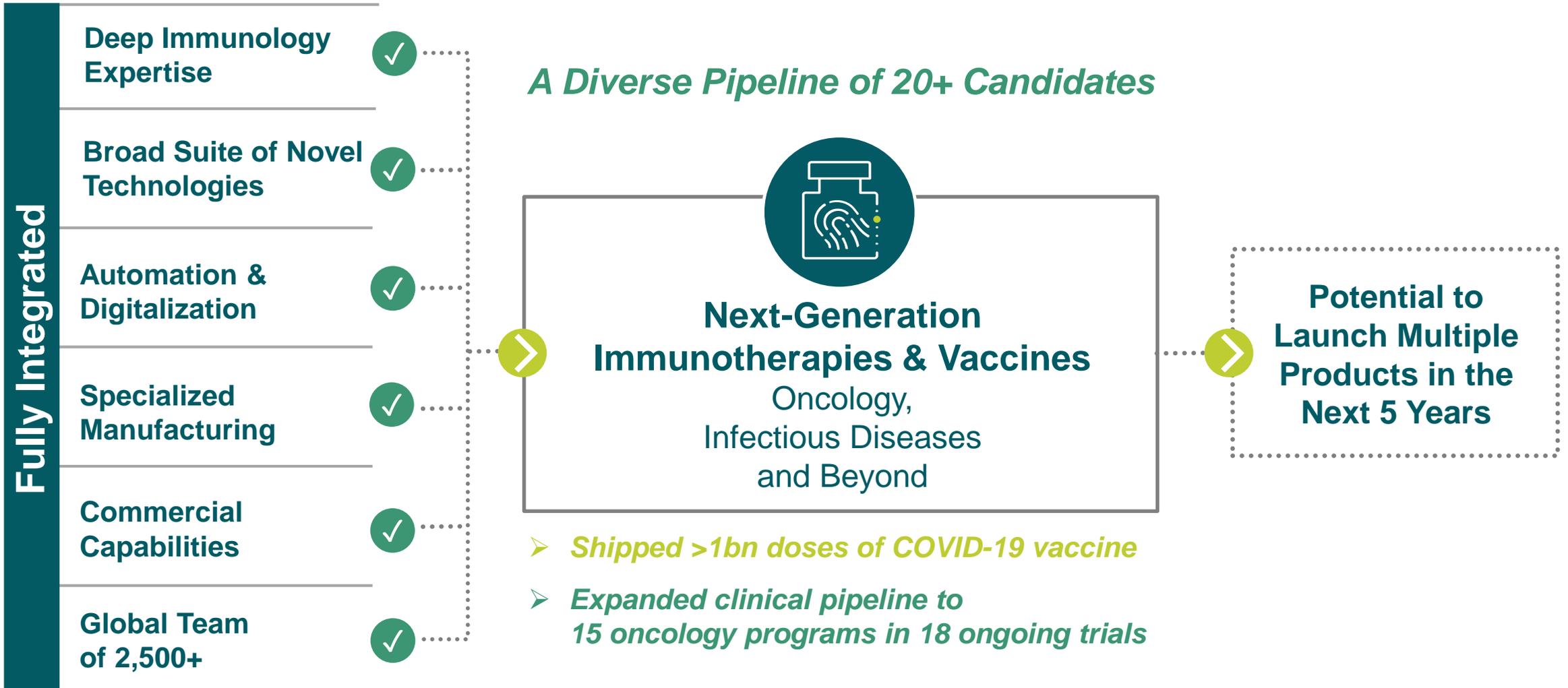
Accelerating our Vision to  
Build a Next Generation  
Immunotherapy Company

.....●.....



BIONTECH

# BioNTech: A Global Immunotherapy Powerhouse



# Strong Performance in the First Half of 2021

## Second Quarter 2021 Highlights

### COVID-19 vaccine\*

- Shipped >1 billion doses to >100 countries & territories worldwide
- Signed supply contracts for ~2.2 billion doses for delivery in 2021
- Committed to deliver >2 billion doses to low- and middle-income nations

### Continued pipeline expansion

#### Randomized Phase 2 trial starts

- **Melanoma FixVac:** BNT111 (CPI-R/R)
- **HPV16 FixVac:** BNT113 (HPV16+ HNSCC)
- **iNeST:** BNT122 (Adjuvant CRC)

#### First-in-Human Phase 1 trial starts

- **CARVac:** BNT211 (Multiple solid tumors)
- **NEOSTIM:** BNT221 (Multiple s.t.)
- **RiboCytokines:** BNT151/2/3 (Multiple s.t.)

### Further corporate updates

- Reported Q2 total revenues of €5.3 billion
- Jens Holstein appointed to Management Board as CFO as of July 1, 2021
- Acquired personalized TCR platform and cGMP manufacturing facility from Kite Pharma

\*As of July 21, 2021: includes doses shipped by collaboration partner Pfizer;  
s.t., solid tumors;

# Infectious Diseases: A Long-term Growth Pillar

## mRNA vaccines to combat major global health burden

### **Malaria<sup>1</sup>:**

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

### **HIV and tuberculosis<sup>2</sup>:**

- Preclinical development of multiple product candidates ongoing

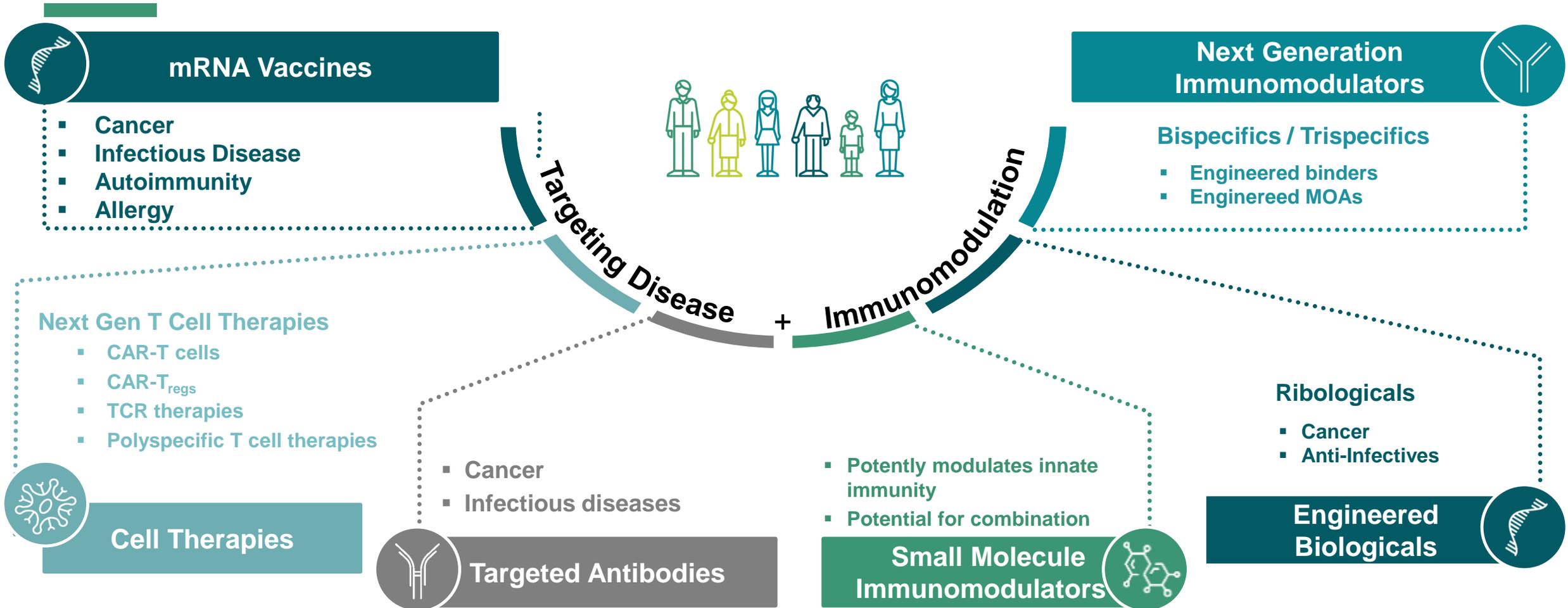
## Opportunity to impact infectious diseases with high unmet need

- Up to 10 mRNA vaccine candidates in preclinical development<sup>3</sup>

## BNT161 influenza vaccine candidate designed to improve traditional vaccines

- FIH trial expected Q3 2021
- Eligible for milestone payments and royalties through Pfizer agreement

# Disease Horizon: Expanding the Application Spectrum of Our Technology



Grow & mature novel technologies across oncology, infectious diseases and beyond

# New Product Paradigms

## Broaden Disease Horizon

- Infectious disease
- Oncology
- Allergy
- Autoimmune and inflammatory disease
- Regenerative medicine

## Expand on Traditional Modalities

- mRNA infectious disease vaccines
- mRNA therapeutic cancer vaccines
- CAR-T cell amplifying mRNA vaccine
- mRNA encoded protein immunotherapies

Immunology Expertise and Validated mRNA Technology Unlocks New Therapeutic Universe

# Agenda

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Second Quarter  
2021 Highlights

**COVID-19  
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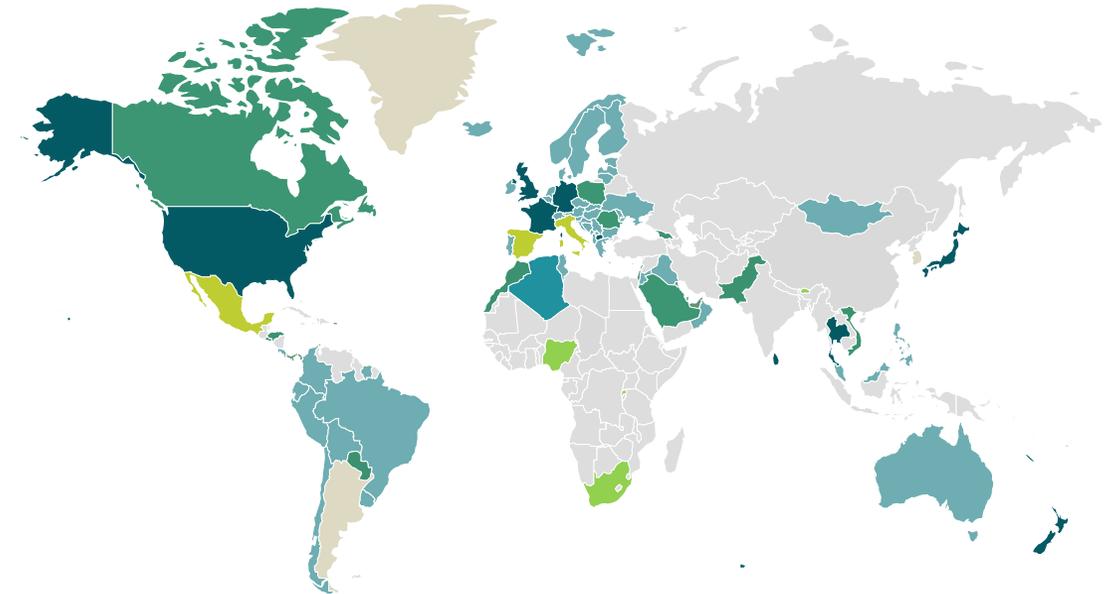
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Corporate  
Update &  
Outlook

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

## Expanding Access to Low & Middle-Income Countries

Selected Regions	2021 Orders	2022 and Beyond
EU	660 m	900 m doses (plus option for additional 900 m)
US	410 m	90 m
Other	~1.150 m	Canada, Israel and others
<b>TOTAL</b>	<b>~2.2 bn</b>	<b>&gt; 1 bn (excl. options)</b>



Ongoing discussions for additional doses in 2021/2022 and beyond

- 2 bn doses pledged over the next 18 months to ensure global equitable vaccine access
- Plans to provide 500 m doses to U.S. government for donation to ~100 countries, including those in African Union via COVAX

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

## Increased Manufacturing Capacity



- South African collaboration with Biovac to expand BNT/Pfizer manufacturing network with fill and finish and distribution
- Continued efforts to establish multi-continent manufacturing capabilities to support global vaccine needs

## Label Expansion to Additional Populations



- Expansion of authorizations for adolescents 12 years of age and older in U.S., EU and other countries
- Ongoing trial in children 2 to 11 years and 6 months to 2 years of age: data expected Q3 and Q4 2021
- Global Phase 2/3 trial in healthy pregnant women: data expected Q3 2021

## Regulatory Advancement Across All Geographies



- U.S. rolling BLA submission finalized; FDA granted priority review; PDUFA date: Jan. 2022
- Converting existing emergency use authorizations into regulatory approvals globally
- Regulatory submission for BLA in China underway

## Optimize Formulations to Further Simplify Access Worldwide



- Storage at 2-8 °C for 31 days approved by multiple regulators, including EMA and FDA
- Phase 3 trial for ready-to-use and lyophilized formulations: data expected Q3 2021

## Addressing Waning Immune Responses



- Expanded trials for third booster dose of BNT162b2 and multiple variant-specific approaches in both vaccine-naive and previously vaccinated individuals 6-12 months post dose 2
- Initial, preliminary booster data: ~6 months after dose 2 of BNT162b2 show overall consistent tolerability profile while eliciting SARS-CoV-2 neutralization titers against wild type, Beta and Delta variant

## Addressing SARS-CoV-2 Variants

# Vaccine Efficacy Remains High up to 6 Months Following 2<sup>nd</sup> Dose<sup>1,2</sup>

Pivotal Phase 3 trial: ~46,000 participants, ~150 clinical sites globally

Efficacy Endpoint	BNT162b2 (30 µg) N=23,040		Placebo N=23,037		Vaccine Efficacy, (95% CI)
	No. of cases	Surveillance time (n) <sup>†</sup>	No. of cases	Surveillance time (n) <sup>†</sup>	
First COVID-19 occurrence ≥7 days after Dose 2	82	6.649 (22,132)	889	6.371 (22,001)	91.2% (88.9-93.0)
First Severe COVID-19 <sup>†</sup> occurrence ≥7 days after Dose 2	1	6.663 (22,142)	23	6.505 (22,048)	95.7% (73.9-99.90)

\*Subjects with and without prior evidence of Infection

<sup>†</sup> Based on FDA definitions



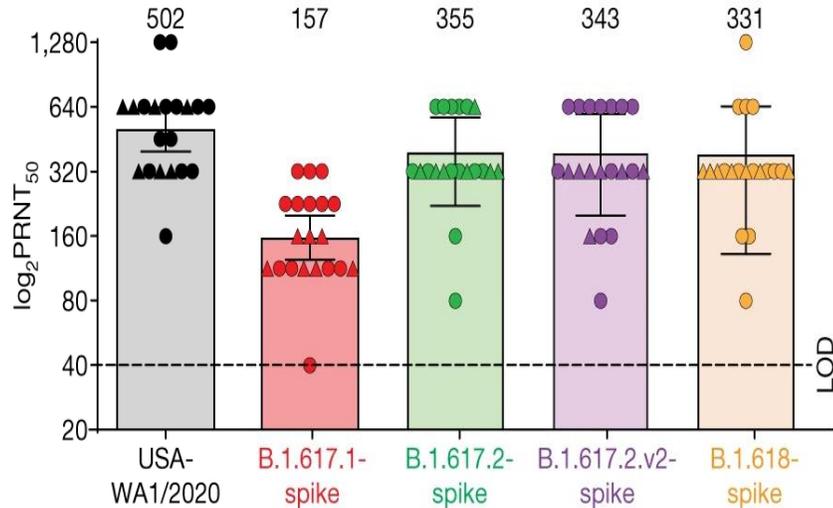
## Phase 3 Clinical data demonstrated clinical protection against the Beta strain<sup>2</sup>

- In 800 South African participants: 9 COVID-19 cases, all in the placebo group, eight of which were the B.1.351 variant

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

## Neutralizing antibody titers

Reduced, yet preserved *in vitro* neutralizing activity of immune sera against several variants of concern, including: Alpha, Gamma, Beta, Eta, Delta<sup>1, 2, 3</sup>



## Poly-specific T cell responses

Vaccinated individuals generate a T cell response targeting epitopes conserved across a number of variants, including the Delta variant<sup>2,4</sup>

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

## Real world data

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

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

1. Liu J et al Nature 2021 <https://www.nature.com/articles/s41586-021-03693-y>. 2. Xie X et al Nature Med <https://doi.org/10.1038/s41591-021-01270-4> 2021. 3. Liu J et al Nature Med 2021 <https://doi.org/10.1038/s41586-021-03693-y>. 4. Sahin U et al Nature 2021 <https://www.nature.com/articles/s41586-021-03653-6> 5. Bernal et al. NEJM 2021 <https://www.nejm.org/doi/pdf/10.1056/NEJMoa2108891?articleTools=true> 6. Stowe et al (preprint) available from [https://media.tghn.org/articles/Effectiveness\\_of\\_COVID-19\\_vaccines\\_against\\_hospital\\_admission\\_with\\_the\\_Delta\\_B\\_G6gngqJ.pdf](https://media.tghn.org/articles/Effectiveness_of_COVID-19_vaccines_against_hospital_admission_with_the_Delta_B_G6gngqJ.pdf) 7. Nasreen et al MedRxiv preprint 10.1101/2021.06.28.21259420 8. Sheikh et al. Lancet 2021 doi: 10.1016/s0140-6736(21)01358-1; 9. Press release Israel MoH [https://www.gov.il/BlobFolder/reports/vaccine-efficacy-safety-follow-up-committee/he/files\\_publications\\_corona\\_two-dose-vaccination-data.pdf](https://www.gov.il/BlobFolder/reports/vaccine-efficacy-safety-follow-up-committee/he/files_publications_corona_two-dose-vaccination-data.pdf)

# Preemptive Strategy to Address SARS-CoV-2 Variants

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

## Prototype Approach substantiated by broad clinical data

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

# BNT162b2 Booster Dose Results in a Broad, Robust Neutralisation Response

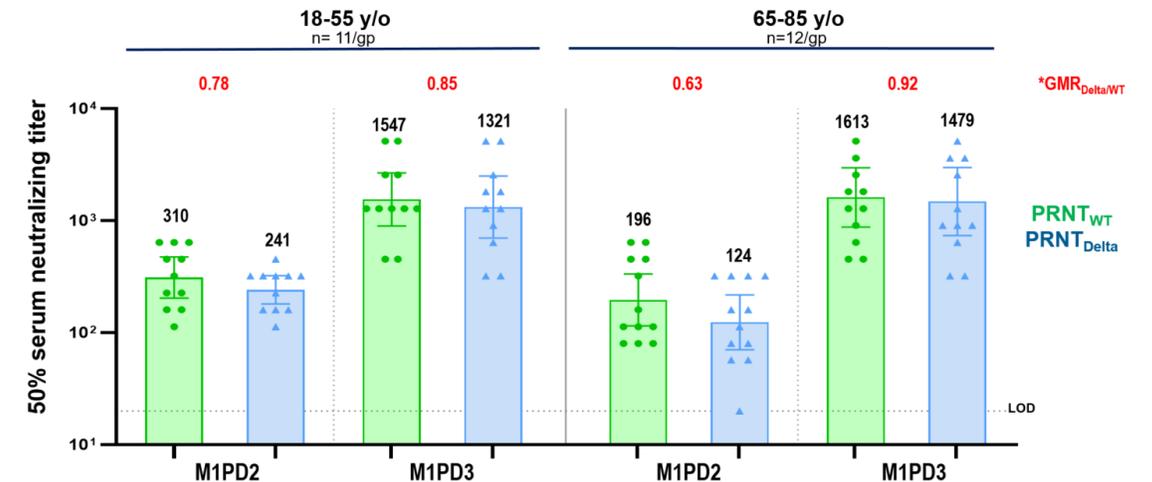
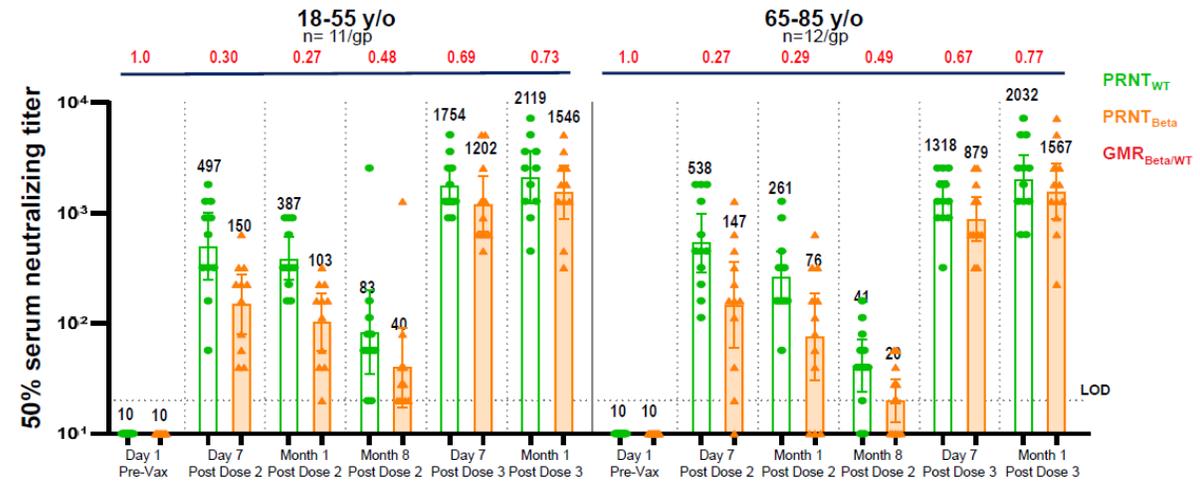
Booster dose could prolong protection and further increase breadth of protection against SARS-CoV-2 variants

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

when comparing month 1 data after dose 2 or dose 3

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

Data being prepared for submission to regulatory authorities globally.



# Agenda

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Second Quarter  
2021 Highlights

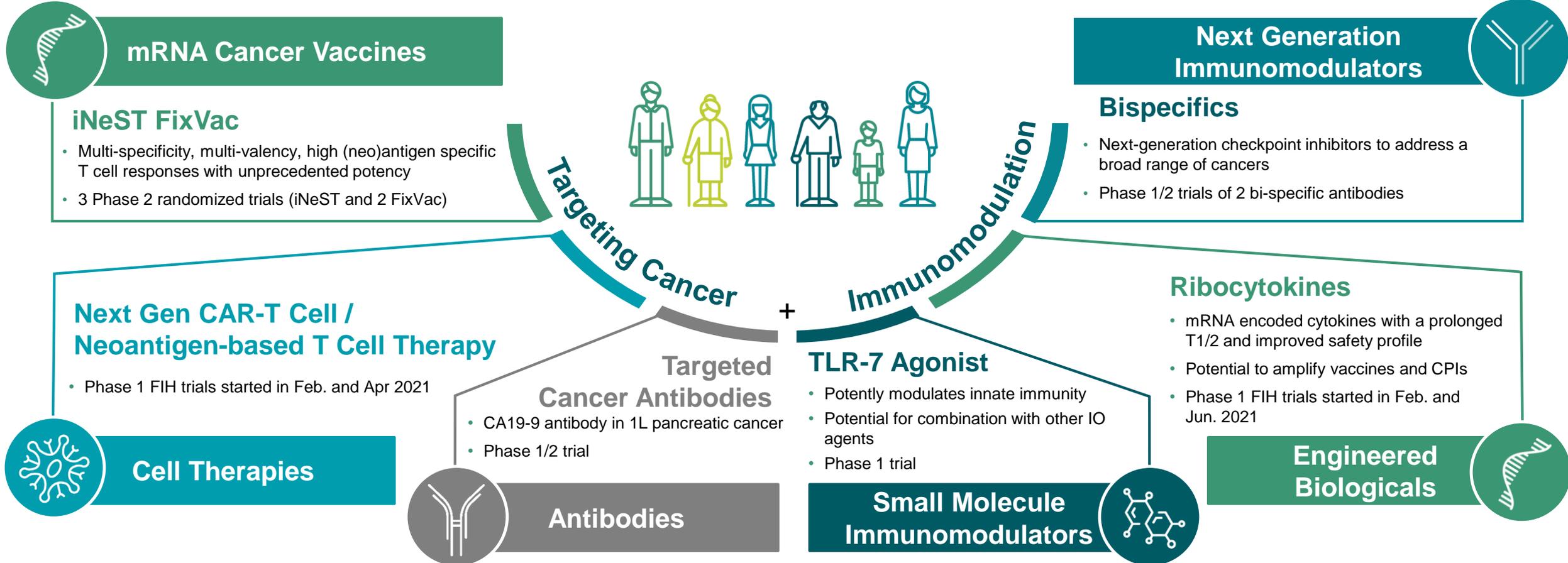
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Update &  
Outlook

# Potential to Tackle Multiple Diseases with Different Therapeutic Modalities



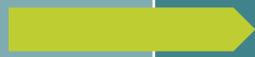
**Oncology: Multiple product opportunities with unique combination potential in clinical testing**

# Oncology: Multiple Phase 2 Trials Starting in 2021

15 product candidates in 18 clinical trials

Three randomized Phase 2 trials

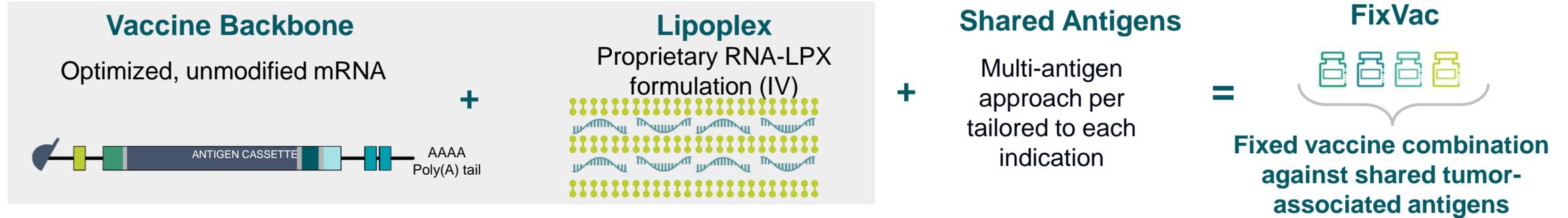
Near-Term Milestones

Drug Class	Platform	Product Candidate	Indication (Targets)	Phase 1	Phase 2	
mRNA	FixVac (fixed combination of shared cancer antigens)	BNT111	CPI-R/R melanoma			FPD in Phase 2 in June 2021 ✓
		BNT112	prostate cancer			
		BNT113	HPV16+ head and neck cancer			FPD in Phase 2 in July 2021 ✓
	iNeST (patient specific cancer antigen therapy)	autogene cevumeran (BNT122)	1L melanoma adjuvant colorectal cancer	 		Phase 2 to start in 2H 2021 (adjuvant CRC)
Antibodies	Next-Gen Checkpoint Immunomodulators	GEN1046 (BNT311)	solid tumors (PD-L1×4-1BB)			Data update in 2H 2021
		GEN1042 (BNT312)	solid tumors (CD40×4-1BB)			Data update in 2H 2021
Cell Therapies	CAR-T Cell Therapy	BNT211	solid tumors (CLDN6)			Data update in 2H 2021
	Neoantigen-based T Cell Therapy	BNT221	advanced or metastatic melanoma			

21 Planned randomized trial start in 2H 2021:   
 CPI, checkpoint inhibitor; R/R, relapsed or refractory; Next-Gen, Next generation; HPV, Human Papilloma Virus; FPD, first patient dosed; 1L, first-line; CRC, colorectal cancer; CAR, chimeric antigen receptor; CLDN6, Claudin-6

# FixVac: Leveraging Shared Antigens to Break Immune Tolerance

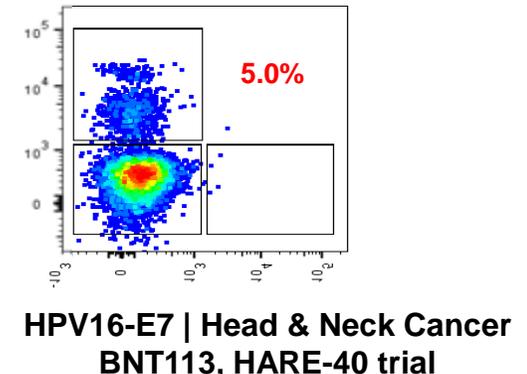
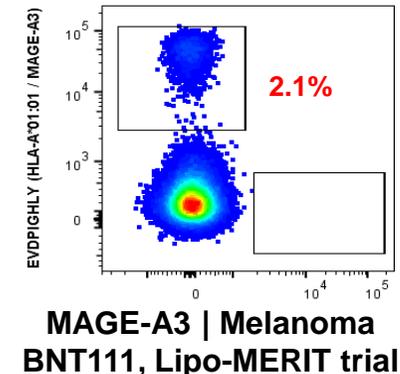
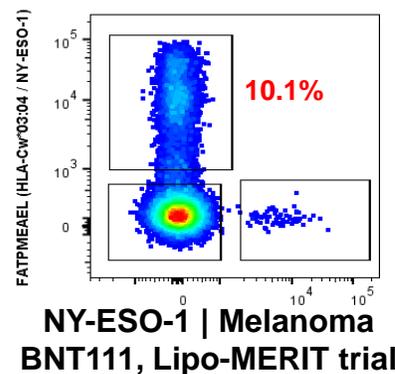
Off-the Shelf Concept: Scalable for multiple indications



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

- Strong immunogenicity observed *in vivo* via TLR-driven adjuvant effect<sup>1</sup>
- Potent induction of strong *ex vivo* CD4<sup>+</sup> and CD8<sup>+</sup> T cell responses<sup>1</sup>

## Antigen-specific CD8<sup>+</sup> T cell responses<sup>2</sup>:



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

## Melanoma Remains the Deadliest Skin Cancer

### Incidence

↑ **50%**

Annual cases have increased by nearly 50% to over 287,000<sup>1,2</sup>

### Deaths

↑ **20%**

WHO predicts by 2025, number of deaths will increase by 20%<sup>3</sup>

### CPI R/R patients

~ **55%**

patients refractory to or relapse on CPI treatment, leaving them with limited treatment options<sup>4</sup>

## Significant Opportunity to Improve on Standard of Care

- 5-year survival for metastatic melanoma still only 29.8%<sup>5</sup>
- Frontline immunotherapy with CPI induces durable responses in max. 45-50% of patients but with relatively short PFS<sup>4</sup>
- 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

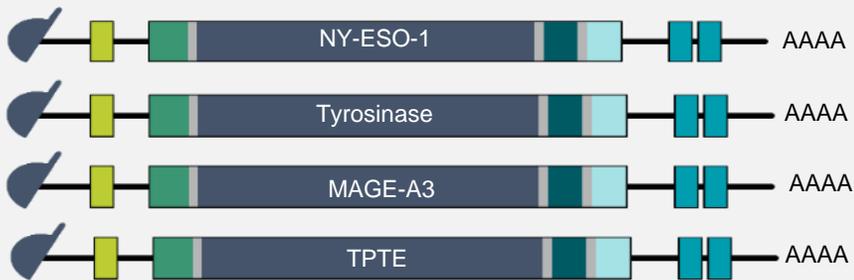
<sup>1</sup><https://www.melanomauk.org.uk/2020-melanoma-skin-cancer-report>; <sup>2</sup>Global Cancer Observatory – 2018 data from 'Cancer Today';

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

# BNT111: Off-the Shelf Therapeutic Vaccine for Melanoma

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

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



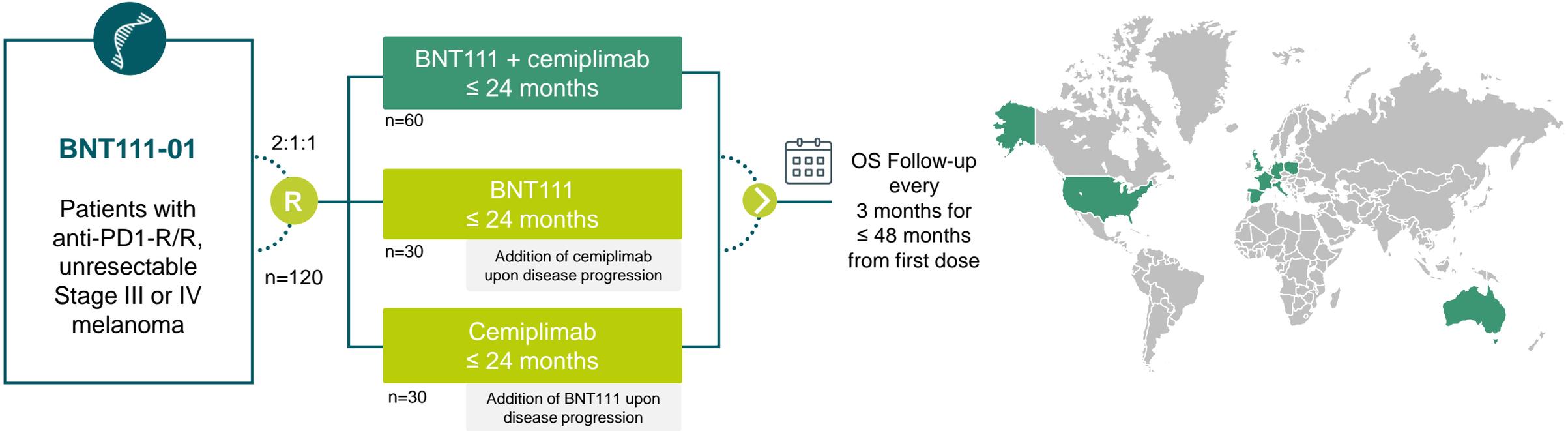
nature<sup>2</sup>

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

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



## Open-label, randomized Phase 2 trial

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

## Success Measures for BNT111 Trial

ORR 30%

## Primary Endpoints

- Arm 1: ORR by RECIST 1.1

## Secondary Endpoints

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

# BNT113: 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<sup>2</sup>
- Oropharyngeal is most common HNSCC, accounting for 70% of cases, and 80-90% are HPV16+<sup>3</sup>

## Limited treatment options for patients not responding to or relapse on CPI<sup>1</sup>

- 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<sup>4</sup>:
  - Chemotherapy, surgery, radiation
  - CPI

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

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

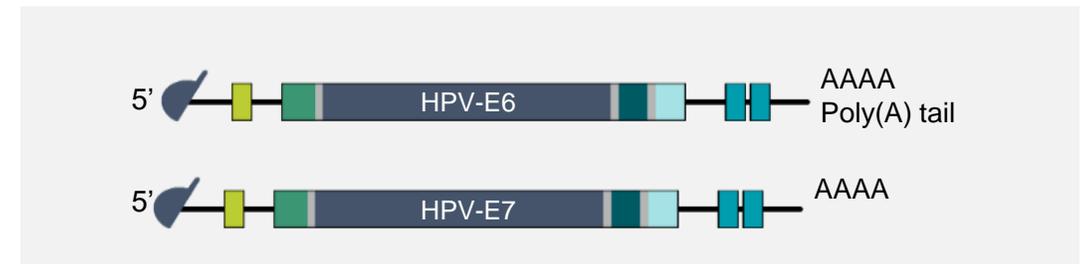
<sup>3</sup>Saraiya et al. 2015, Vaccines; <sup>4</sup>HNSCC NCCN Guidelines 2020, HNSCC ESMO Guidelines 2020; <sup>5</sup>Burtress, et al. Lancet 2019 Nov 23; 394(10212):1915-28;

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

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

## BNT113 encodes HPV16 oncoproteins E6 & E7

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



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

# BNT113: Potent Antigen-Specific T Cell Responses in Phase 1 Trial<sup>1,2</sup>

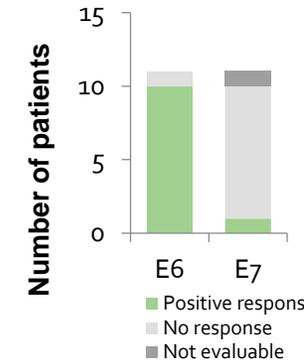
- CD4<sup>+</sup> and CD8<sup>+</sup> T cell responses
- Responses detectable ex vivo, implying high numbers of T cells
- Responses against multiple E6 or E7 epitopes

A

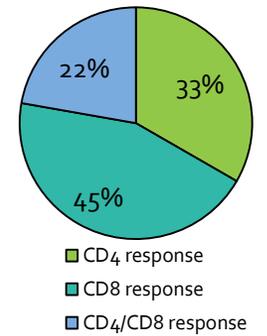
## Overview of T cell responses Arm 1A

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

Arm 1A patients



Type of response to E6

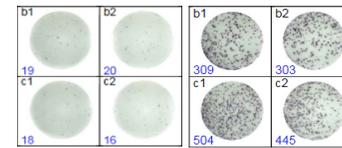


B

## ELISPOTS<sup>3</sup> Patient 7

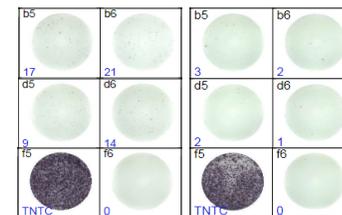
CD8 response to vaccine targets

Pre vaccination Post vaccination



Pepmix  
E6

Pepmix  
E7



PBMCs only

PBMCs only

Anti-CD3

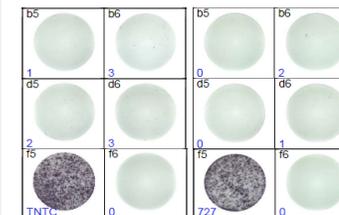
## ELISPOTS<sup>3</sup> Patient 6

CD4 response to vaccine targets

Pre vaccination Post vaccination



Pepmix  
E6



PBMCs only

PBMCs only

Anti-CD3

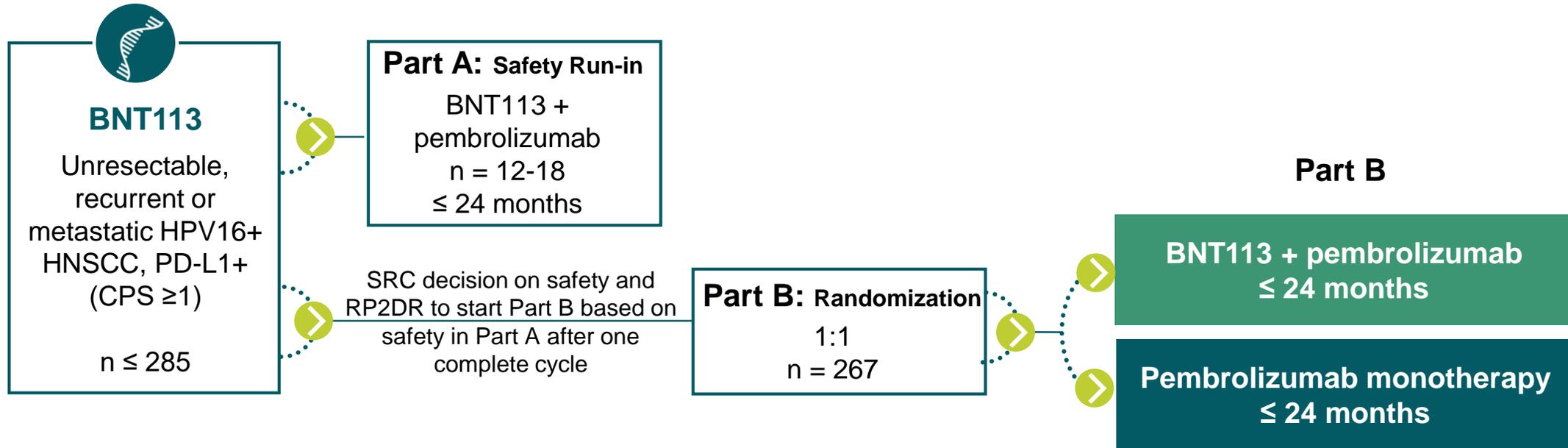
TD, total dose; CD, Cluster of Differentiation; NE, Not Evaluated; NR, Not Reported; PBMC, peripheral blood mononuclear cells

<sup>1</sup>HARE-40 trial

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

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

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



## Open-label, controlled, Phase 2 study

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

### Primary Endpoints

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

### Secondary Endpoints

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

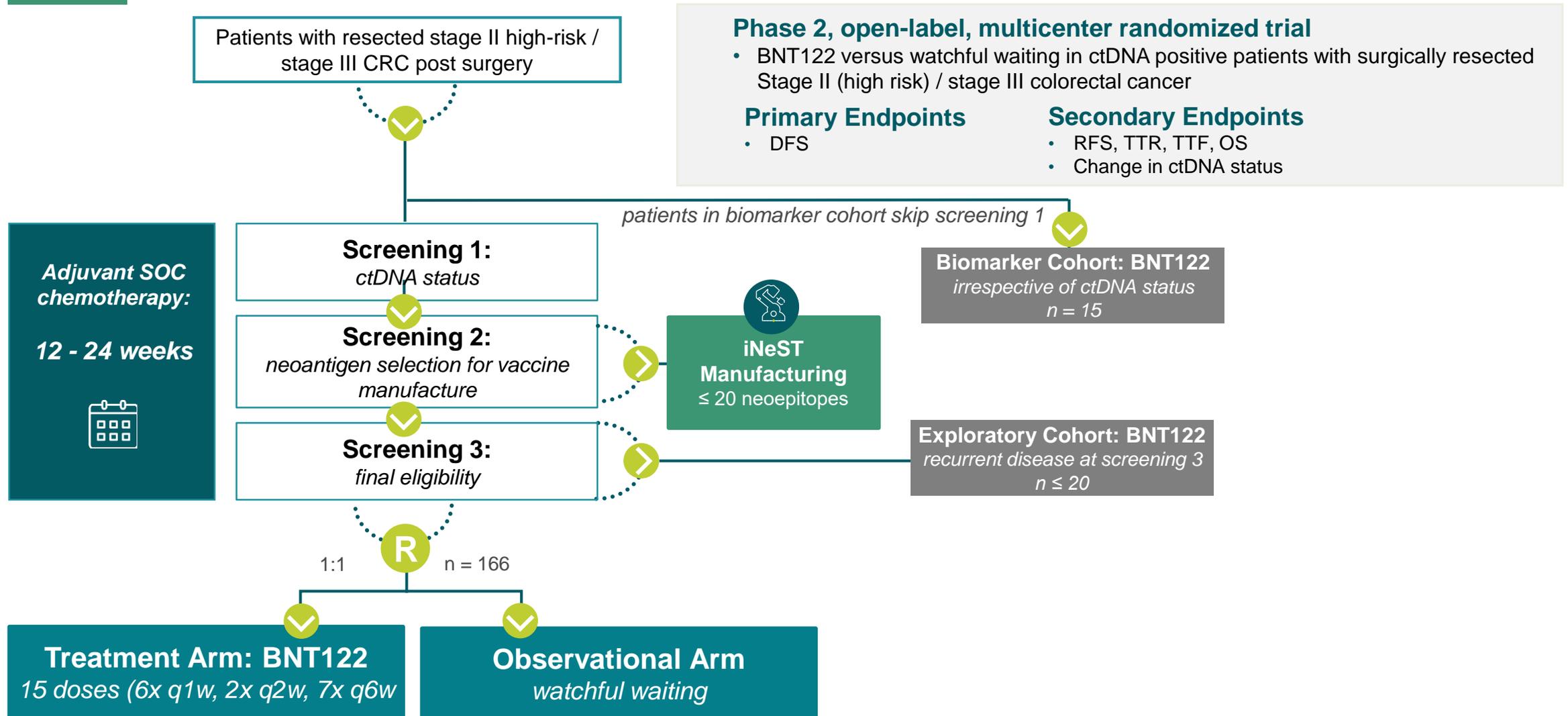
### Success Measures for BNT113 Trial

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

HPV, human papilloma virus; PD-L1, programmed death-ligand 1; CPS, Combined positive score; HNSCC, head and neck squamous cell carcinoma; 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

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

# BNT122: Randomized Phase 2 Trial in Adjuvant Colorectal Cancer



# RiboCytokines: Designed to Overcome Limitations of Recombinant Cytokine Therapy

## Cytokines encoded by mRNA: A novel therapeutic concept

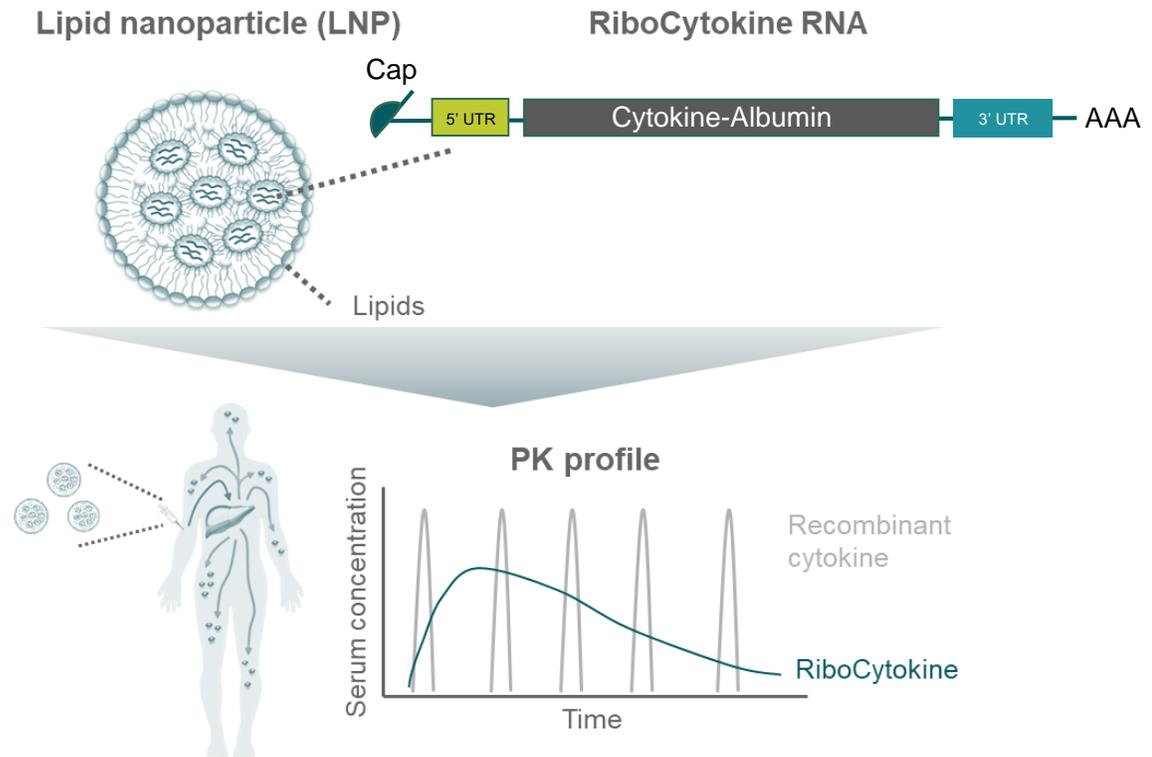
### Systemic delivery with minimal immunogenicity

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

### Designed for optimized safety, tolerability and dosing

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

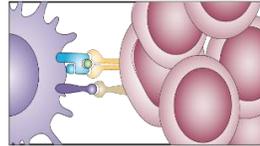
Product Candidate	Indication	Pre-clinical	Phase 1	Phase 2
BNT151 (modified IL-2)	Solid Tumors	▶		
BNT152+153 (IL-7 + IL-2)	Solid Tumors	▶		



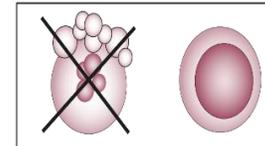
# RiboCytokines: A Tailored Approach to T Cell Regulation and Stimulation

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

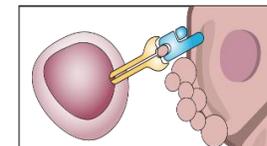
↑ T cell proliferation



↑ T cell survival



↑ T cell effector function



## BNT151

**mRNA encoding sequence-modified IL-2 variant**

- Sequence modification that weakens binding to IL-2R $\alpha$  (CD25)
- Designed to stimulate naïve and effector T cells with low to no expression of IL-2R $\alpha$  (CD25<sup>low/neg</sup>)
- Stimulates anti-tumor effector cells without extensively triggering immunosuppressive regulatory T cells

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

## BNT152 + 153

**mRNAs encoding IL-2 and IL-7**

**BNT153 (IL-2)**

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

**BNT152 (IL-7)**

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

**Combination with RNA vaccine**

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

## Six Clinical Trial Initiations in 1H 2021, Including Two Randomized Phase 2



### 5+ Trial Updates

- ✓ **BNT162b2:** Multiple updates
- **BNT311:** Bi-specific CPI: PD-L1 x 4-1BB in solid tumors
- **BNT312:** Bi-specific CPI: CD40 x 4-1BB in solid tumors
- **BNT211:** CLDN-6 CAR-T + CARVac in solid tumors
- **BNT411:** TLR-7 agonist +/- CPI in solid tumors



### 3 Randomized Phase 2 Trial Starts

- ✓ **BNT111:** FixVac + CPI in CPI-R/R melanoma
- ✓ **BNT113:** FixVac HPV16+ + CPI in 1L HNSCC
- **BNT122:** iNeST (autogene cevumeran) in adjuvant mCRC



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

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

# Agenda

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Second Quarter  
2021 Highlights

COVID-19  
Vaccine Update

Oncology  
Pipeline Update

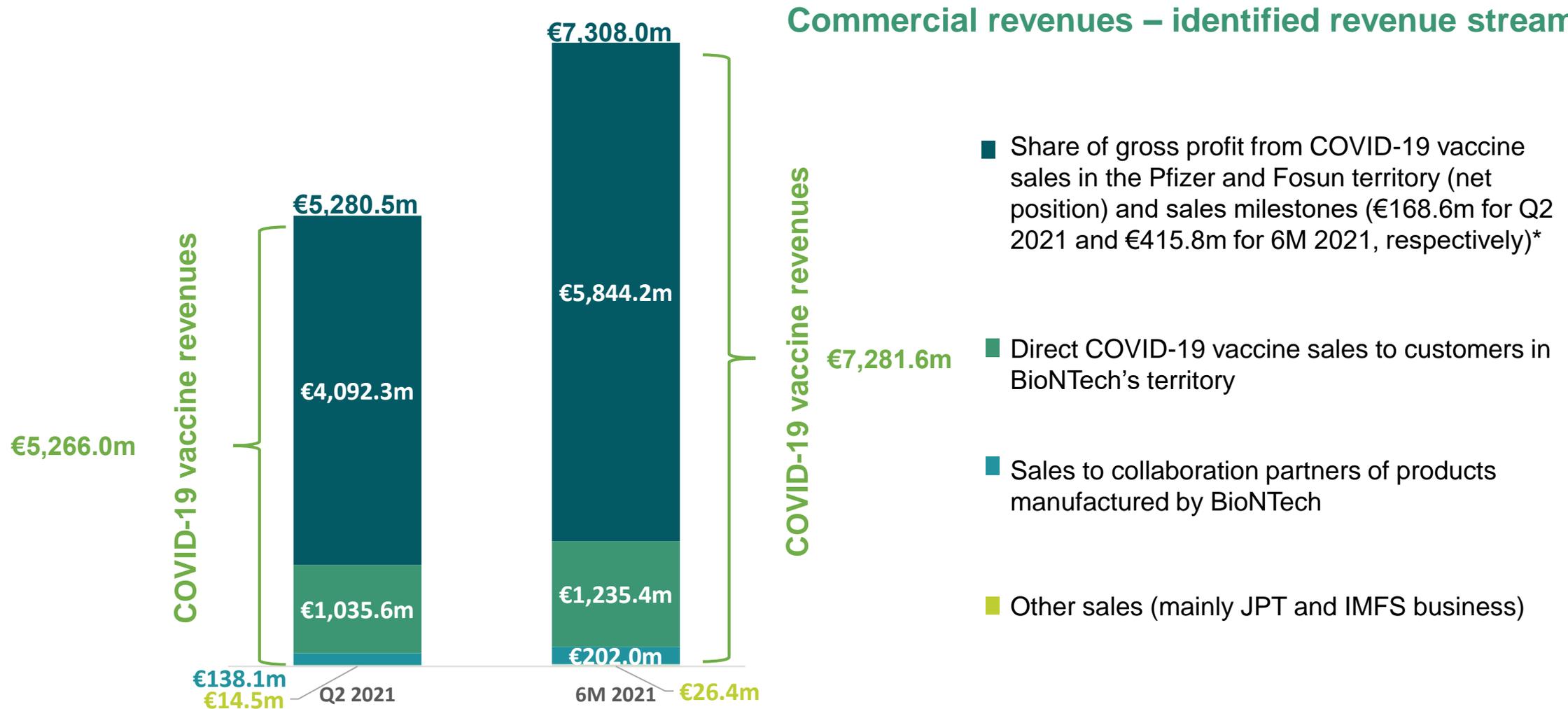
**Financial  
Results**

Corporate  
Update &  
Outlook

## Q2 2021 and 6M 2021 Financial Results (unaudited) – Profit or Loss

<i>(in millions, except per share data)*</i>	Three months ended June 30		Six months ended June 30	
	2021	2020	2021	2020
• Research & development revenues	€28.0	€32.5	€48.9	€53.7
• Commercial revenues	5,280.5	9.2	7,308.0	15.7
<b>Total revenues</b>	<b>€5,308.5</b>	<b>€41.7</b>	<b>€7,356.9</b>	<b>€69.4</b>
• Cost of sales	(883.8)	(5.6)	(1,116.9)	(11.5)
• Research and development expenses	(201.1)	(95.2)	(417.3)	(160.3)
• Sales and marketing expenses	(13.3)	(3.0)	(22.0)	(3.5)
• General and administrative expenses	(47.8)	(18.8)	(86.7)	(34.6)
• Other operating income less expenses	35.9	0.0	146.6	0.3
<b>Operating profit / (loss)</b>	<b>€4,198.4</b>	<b>€(80.9)</b>	<b>€5,860.6</b>	<b>€(140.2)</b>
• Finance income less expenses	(175.6)	(9.6)	(195.5)	(3.7)
• Income taxes	(1,235.6)	2.2	(1,749.8)	2.2
<b>Profit / (loss) for the period</b>	<b>€2,787.2</b>	<b>€(88.3)</b>	<b>€3,915.3</b>	<b>€(141.7)</b>
<b>Earnings per share</b>				
• Basic profit / (loss) for the period per share	€11.42	€(0.38)	€16.07	€(0.62)
• Diluted profit / (loss) for the period per share	€10.77	€(0.38)	€15.14	€(0.62)

# Q2 2021 and 6M 2021 COVID-19 Vaccine Deliveries Drove Revenue Growth



# Update of Previously Stated Financial Outlook for the 2021 Financial Year

## Update on Current Signed COVID-19 Vaccine Order Book for the 2021 Financial Year

- Estimated COVID-19 vaccine revenues to BioNTech for the 2021 financial year upon delivery of currently signed supply contracts (~2.2 billion doses as of July 21, 2021): ~€15.9 billion\*

## Planned 2021 Financial Year Expenses and Capex\*

- R&D expenses: **€950 million – €1,050 million**
- SG&A expenses: **€250 million – €300 million**
- Capital expenditures: **€175 million – €225 million**
- *Ranges reflect current base case projections*
- *Ramp-up of R&D investment in 2H 2021 planned to expand and accelerate the pipeline development*

## Estimated 2021 Financial Year Tax Assumptions

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

# Agenda

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Second Quarter  
2021 Highlights

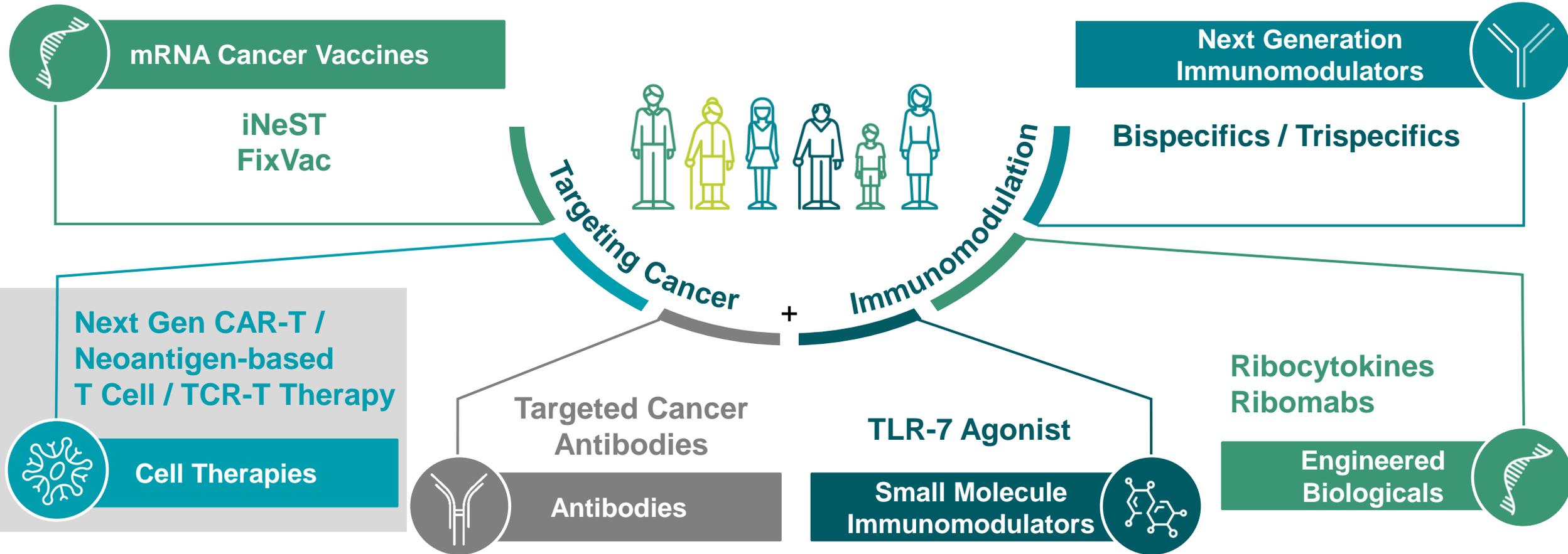
COVID-19  
Vaccine Update

Oncology  
Pipeline Update

Financial  
Results

Corporate  
Development &  
Outlook

# We intend to expand and accelerate our IO pipeline development through a mix of targeted in-licensing, strategic collaborations, and M&A



Recently announced Kite transaction strengthens our Cell Therapy pipeline and capabilities

# Acquisition of Kite's Solid Tumor TCR-T cell platform and related assets

## Transaction overview:

- On July 19, BioNTech announced an asset purchase agreement with Kite to acquire its Neoantigen TCR Cell Therapy R&D Platform and cGMP manufacturing facility in the U.S.
- Transaction closed on August 4, 2021

## What we gain:

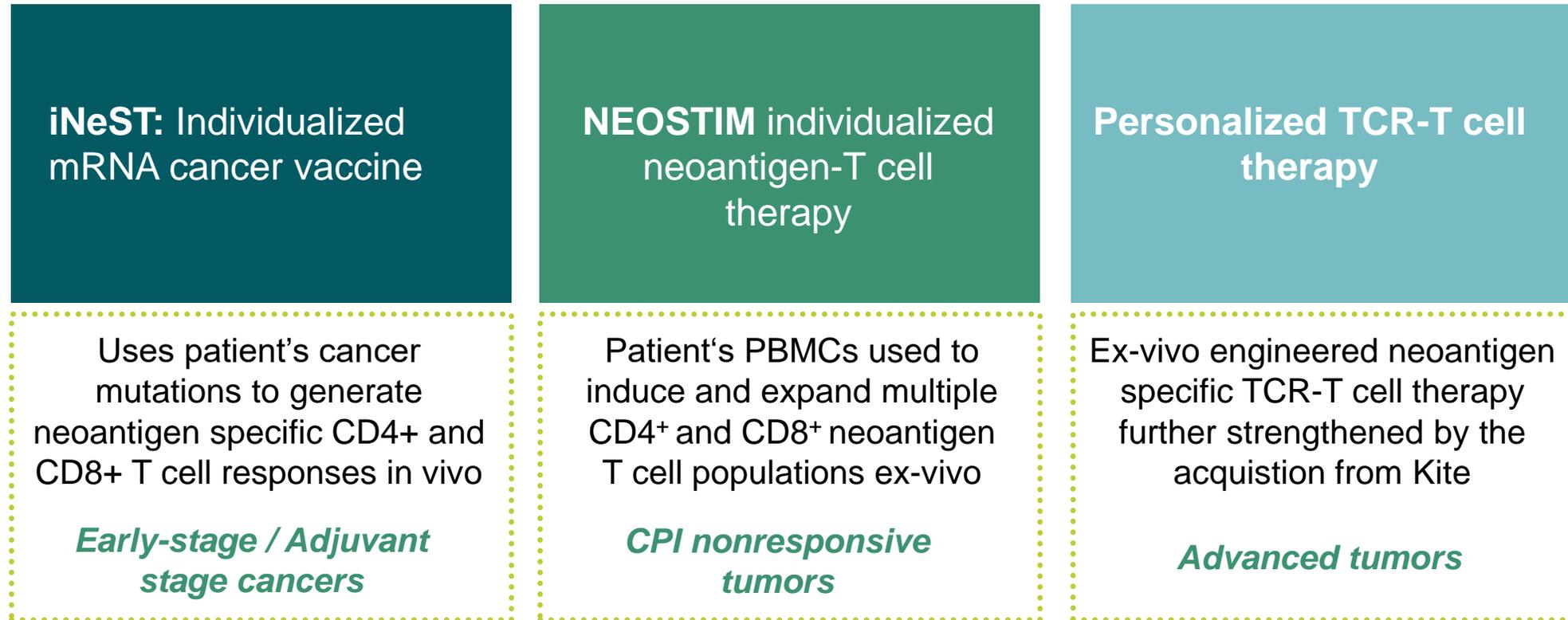
- Leased U.S. clinical-stage cell therapy manufacturing facility in Gaithersburg, Maryland
- Brings more than 50 highly trained cell & gene therapy scientists and production experts
- Personalized Neo-antigen TCR program
- Library of other preclinical TCR assets

## Strategic rationale:

- ✓ Add turn-key U.S. cell therapy facility to complement existing facility in Idar-Oberstein, Germany
- ✓ Enable expansion of U.S. clinical supply of CARVac and other BioNTech cell therapies
- ✓ Strengthen U.S. team with highly skilled TCR scientists and manufacturing workforce
- ✓ Expand BioNTech's proprietary cell therapy pipeline and capabilities

# Acquisition strengthens individualized IO pipeline

- Multiple individualized therapy approaches to address wide range of Solid Tumors indications



# Strong momentum moving into 2H 2021

**Our Vision: Harnessing the immune system's full potential to fight human disease.**



**Robust pipeline with growing number of late and early stage programs**



**Diverse range of platform technologies with broad applications across diseases**



**Global team with deep expertise**



**World-class collaborators**



**Strong financial position to support organic innovation and continued corporate development**

**Building long-term value for patients, shareholders and society**

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

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