# Harnessing the full potential of the immune system to solve global health problems



# BIONTECH

## Fourth Quarter and Full Year 2020

Corporate update and financial results

March 30, 2021

### This slide presentation includes forward-looking statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including BioNTech's expected revenues and net profit related to sales of BioNTech and Pfizer's COVID-19 vaccine, referred to as COMIRNATY® in the European Union as authorized for use under conditional marketing approval, in territories controlled by BioNTech's collaboration partners, particularly those such figures that are derived from preliminary estimates provided by BioNTech's partners; the extent to which a COVID-19 vaccine continues 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 pricing and reimbursement of BioNTech and Pfizer's COVID-19 vaccine and BioNTech's investigational medicines, if approved; the rate and degree of market acceptance of BioNTech and Pfizer's COVID-19 vaccine and BioNTech's investigational medicines, if approved; 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 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 and Pfizer's COVID-19 vaccine, and other products and product candidates developed or manufactured by BioNTech; BioNTech's estimates of its expenses, ongoing losses, future revenue and capital requirements and BioNTech's needs for or ability to obtain additional financing; the development of and projections relating to BioNTech's competitors or its industry; BioNTech's ability to effectively scale its production capabilities and manufacture its products, including BioNTech and Pfizer's COVID-19 vaccine, and BioNTech's product candidates; BioNTech's projected net sales for the COVID-19 vaccine in 2021; BioNTech's projected gross margins, expenses and expenditures and tax rate for 2021; BioNTech's target vaccine production for 2021; and BioNTech's COVID-19 vaccine revenues and net sales, which are subject to numerous estimates as more fully described in our Annual Report on Form 20-F. 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 press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond BioNTech's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. You should review the risks and uncertainties described under the heading "Risk Factors" in BioNTech's Annual Report on Form 20-F filed with the US Securities and Exchange Commission (SEC) on March 31, 2020 and in subsequent filings made by BioNTech with the SEC, including the third quarter report, which are available on the SEC's website at 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 press release 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 COVID19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

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

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

Please see Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including Full EUA Prescribing Information available at <u>www.cvdvaccine-us.com</u>.





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### 2020: A momentous year for BioNTech

# First commercial product



### **BioNTech's capabilities were transformed in 2020**



### What 2020 has demonstrated to us

# Our mRNA technology has the potential to address major global health challenges:

The success of "first-generation" mRNA vaccines against COVID-19 highlights their future promise – we expect rapid iterations to further improve this new class of products. We have established a broad toolbox of mRNA technologies that underpin a diverse range of mRNA platforms.

# **BioNTech is well-placed to lead at the intersection of mRNA and immunology:**

We own a vast IP portfolio and have more than a decade of accumulated know-how in the field. We plan to increase investment in our technology platforms to accelerate our platform and pipeline and stay at the forefront of the field.

#### Drug development can be faster:

While COVID-19 was an extraordinary case, we intend to apply the capabilities we have developed during "Project Lightspeed" to rapidly advance other innovative medicines to the market.

#### Our model is powerful:

Our deep focus on innovation, coupled with powerful blue chip collaborators, gives us the ability to establish marketleading positions while building our own capabilities alongside our partners over the long-term.



### **The Opportunity Ahead**

Accelerate and expand our innovative pipeline

Launch multiple new products in the next 5 years

2

Build a 21st century global immunotherapy powerhouse

3



### We aim to fully exploit and industrialize the potential of our mRNA technology





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### **Strong clinical results**



#### **Clinical profile**

- 95% effective against symptomatic COVID-19 infections<sup>1</sup>
- 94% efficacy in participants >65 years
- Well tolerated safety profile
- High titers of neutralizing antibodies
- Robust and poly-epitopic CD8+ and Th1 CD4+ T-cell responses<sup>2</sup>





### **Compelling real-world evidence**



Real-world data from observational study conducted by Israel Ministry of Health

Two weeks post-dose 2

- About 97% effective in preventing
  - symptomatic COVID-19
  - severe/critical COVID 19
  - Hospitalizations
  - Deaths

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- 94% effective against asymptomatic infection
- Protective against B.1.1.7 variant





### **COVID-19 will likely become endemic. Re-vaccination may also be required.**

	Observation	Implication					
1	Waning immune responses	Re-boostings may be required					
2	Variants are driving new infections	Variant-specific vaccines may be needed					
3	New mRNA vaccines can be rapidly designed and produced at scale	mRNA vaccines are well suited for long-term challenge					



### Focused on six key levers to expand COVID-19 vaccine reach

Increased manufacturing capacity	<ul> <li>Up to 2.5 billion doses by end of 2021</li> <li>Continuous process improvements, expansion of supplier and CMO network</li> </ul>
Additional populations	<ul> <li>Global Phase 2/3 trial in healthy pregnant women ≥ 18 years of age ongoing</li> <li>Data in children 12-15 years of age to regulatory authorities in Q2</li> <li>Study in children 6 months to 11 years of age started</li> </ul>
Additional geographies	<ul> <li>Approved in more than 65 countries</li> <li>Japan's Health Ministry approved BNT162b2</li> <li>Submission to regulatory authorities in Mainland China in process</li> </ul>
Broadened & decentralized vaccine access	<ul> <li>U.S. FDA and EMA updated label with 2-week storage and transport at -25°C to -15°C</li> <li>Stability optimized, ready-to-use and lyophilized formulations expected in 2021</li> <li>BLA submission expected in United States in Q2</li> </ul>
Addressing SARS-CoV-2 variants	<ul> <li>Initiated variant-specific registration-enabling trial</li> <li>Additional variant-specific trials expected to be initiated in Q2</li> </ul>
Addressing waning immune	<ul> <li>Initiated trial to evaluate effect of third dose of BNT162b2 at 6 to 12 months post-dose 2</li> </ul>



### Flexible manufacturing allows rapid adaptation to variants



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### Scaling up manufacturing capacity to address pandemic demand

**1.4 billion doses contracted to date** for 2021

Selected Regions	Current Orders				
EU	500M confirmed 100M option				
US	300M				
Japan	144M				
UK	30M				
Other	~450M				
Ongoing discussions for additional doses in 2021/2022					





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#### Marburg facility

- Up to **1 billion doses** in annual run-rate capacity
- First vaccines scheduled for distribution in April

<sup>\*</sup>We along with Pfizer are targeting total supply capacity of approximately 2.5 billion doses by the end of 2021, which incorporates the updated 6-dose label. This assumes continuous process improvements and expansion at our current facilities and contingent upon adding more suppliers and contract manufacturers.



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### Rationally designed multi-platform immuno-oncology strategy



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### Multiple oncology trials with registrational potential starting in 2021

#### Plan to initiate randomized Phase 2 trials for 3 programs

Most Advanced Oncology Pipeline Programs				Near-Term Milestones				
Drug class	Platform	Product Candidate	Indication (Targets)	Preclinical	Phase 1	Phase 2		
	FixVac	BNT111	advanced melanoma				BNT111: Phase 2 to start in 1H 2021	
NA	(fixed combination of shared cancer antigens)	BNT113	HPV16+ head and neck cancer				BNT113: Phase 2 to start in 1H 2021	
mR	<b>iNeST</b> (patient specific cancer antigen therapy)	autogene	1L melanoma				BNT122: Phase 2 to start in 1H 2021	
		(BNT122)	adjuvant colorectal cancer				(adjuvant CRC)	
odies	Next-Gen Checkpoint Immunomodulators	GEN1046 (BNT311)	solid tumors (PD-L1×4-1BB)				BNT311: Data update in 2H 2021	
Antib		GEN1042 (BNT312)	solid tumors <i>(CD40×4-1BB)</i>				BNT312: Data update in 2H 2021	



### Next wave oncology advancing innovation beyond current boundaries



FPD, First patient dosed; CLDN6, Claudin-6, CAR-T cells, Chimeric antigen receptor T cells; IL-2, interleukin 2; IL-7, Interleukin 7 20 <sup>1</sup> Reinhard K, et al. Cancer Immunotherapy 2020; 367:446-453; <sup>2</sup> Stadler et al, Oncoimmunology 2018

### **BNT211: CLDN6-CAR demonstrates potent and robust target recognition**

#### CANCER IMMUNOTHERAPY

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

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

### Science



CLDN6 not present in healthy tissues

#### **CLDN6** expressed in multiple cancers



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

#### **BNT211 CAR Structure**





### BNT211: Repeated CARVac dosing enables tunable expansion of CAR-T cells

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





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

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## BNT211: First-in-human CARVac trial with first data expected this year



Phase 1/2a: Evaluation of safety and tolerability of CLDN6 CAR-T +/- CLDN6 RNA-LPX in patients with CLDN6-positive relapsed or refractory advanced solid tumors

3+3 dose escalation with bifurcated trial design

 NSCLC, Non-Small Cell Lung Cancer; CLDN6, Claudin-6; CAR-T cells, Chimeric Antigen Receptor engineered T cells; RNA-LPX, RNA-lipoplex;
 MTD, maximum tolerated dose; RP2D, recommended Phase 2 dose; NOS, not otherwise specified (e.g. rare tumors) https://clinicaltrials.gov/ct2/show/NCT04503278?term=nct04503278&draw=2&rank=1



### BNT151: Designed to overcome limitations of recombinant cytokine therapy

#### **RiboCytokines: A novel therapeutic concept**

- Cytokines encoded by mRNA and produced in patient
- Major improvements over recombinant cytokine therapies
  - Prolonged serum half-life
  - High bioavailability
  - Lower and less frequent dosing
  - Lower Toxicity
  - Sequence modifications easy to introduce



#### BNT151: Optimized mRNA-encoded IL-2



- BNT151 is nucleoside-modified mRNA encoding human
   IL-2 variant fused to human albumin
- IL-2 is a key cytokine in T cell immunity, supporting differentiation, proliferation, survival and effector functions of T cells
- BNT151 stimulates anti-tumoral T cells without extensively triggering immunosuppressive T<sub>regs</sub>
- First patient dosed in first-in-human Phase 1/2a Trial



### BNT151-01 Open-label, multicenter Phase 1/2a, first-in-human trial



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

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

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### **2020 Full Year Financial Results – Statement of Operations**

(in millions)*	Three months ended December 31,		Years ended December 31,		
	2020	2019	2020	2019	
Research & development revenues	€ 65.4	€ 20.2	€ 178.8	€ 84.4	
Commercial revenues	€ 280.0	€7.8	€ 303.5	€24.2	
Total revenues	€ 345.4	€ 28.0	€ 482.3	€ 108.6	
Cost of sales	(41.0)	(4.4)	(59.3)	(17.4)	
Research and development expenses	(257.0)	(65.4)	(645.0)	(226.5)	
Sales and marketing expenses	(6.7)	(0.8)	(14.5)	(2.7)	
General and administrative expenses	(36.1)	(11.1)	(94.0)	(45.5)	
Other operating income less expenses	239.6	0.8	248.1	2.0	
Operating profit / (loss)	€ 244.2	€ (52.9)	€ (82.4)	€ (181.5)	
Finance income less expenses	(38.6)	(5.6)	(63.4)	2.0	
Income taxes	161.3	0.3	161.0	0.3	
Profit / (loss) for the period	€ 366.9	€ (58.2)	€ 15.2	€ (179.2)	

27 \*Numbers have been rounded, numbers presented may not add up precisely to the totals and may have been adjusted in the table context. Presentation of the statement of operations is condensed.

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### 2020 COVID-19 vaccine deliveries drove revenue growth

#### **Commercial revenues – newly identified revenue streams**



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

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### **2021 Financial Outlook**

#### Update on Current Signed COVID-19 Vaccine Order Book

- Estimated COVID-19 vaccine revenues to BioNTech upon delivery of currently signed orders (~1.4 billion doses):
   ~€9.8 billion
  - Estimate reflects:
    - Expected revenues from direct COVID-19 vaccine sales to customers in our territories
    - Expected revenues from sales to our collaboration partners
    - Expected sales milestone payments from our collaboration partners
    - Expected revenues related to our share of gross profit from COVID-19 vaccine sales in the collaboration partners' territories
- Additional revenues related to further supply contracts for deliveries in 2021 expected
- Full year 2021 manufacturing capacity target raised from 2.0 to 2.5 billion doses to be able to address increased demand



### **2021 Financial Outlook**

#### Planned Full Year 2021 Expenses and Capex

- R&D expenses:
- SG&A expenses:
- Capital expenditures:

€750 million – €850 million Up to €200 million €175 million – €225 million

- Ranges reflect current base case projections
- Ramp-up of R&D investment in 2H 2021 and beyond planned to broaden and accelerate pipeline development

#### Estimated Full Year 2021 Tax Assumptions

- German corporate tax rate: ~31%
- Accumulated tax loss carryforwards as of December 31, 2020: ~€450 million\*





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### **Our strategic priorities for 2021**

Accelerate and expand innovative pipeline

Launch multiple new products in the next 5 years

Build a 21st century global immunotherapy powerhouse

#### Continue to execute while driving iterative innovation against COVID-19

- Execute against our goal to deliver our COVID-19 vaccine to more than 1 billion people in 2021
- Continue to innovate to build sustained global market leadership position

#### Broaden and diversify early- and late-stage pipeline of next generation immunotherapies

- Accelerate pipeline in core therapeutic areas:
  - Infectious Disease: Advance mRNA vaccines to address many infectious diseases
  - Immuno-oncology: Usher in new era of individualized cancer medicine and cell therapy
  - Further optimize platforms and initiate early product development in emerging areas:
    - Autoimmunity and Inflammatory Diseases
    - Regenerative Medicine



### **Expected pipeline milestones in 2021**

#### 5+ trial updates

- Multiple BNT162b2 updates
- BNT311: Bi-specific CPI: PD-L1 x 4-1bb in solid tumors
- BNT312: Bi-specific checkpoint Immunomodulator 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 melanoma + CPI in refractory melanoma
- BNT113: FixVac HPV16<sup>+</sup> + CPI in 1L HNSCC and cervical cancers
- BNT122: iNeST (autogene cevumeran)
   + CPI in adjuvant mCRC

6 First-in-human Phase 1 trial starts

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

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# **COMING SOON**

## **BioNTech Capital Markets Day**

# SECOND HALF 2021

### Better positioned than ever to bring innovation to patients

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Accelerate and expand our innovative pipeline

Launch multiple new products in the next 5 years

Build a 21st century global immunotherapy powerhouse

3

#### Re-invest BNT162b2 proceeds to build long-term value for Patients, Shareholders, and Society

#### Expand global footprint in the U.S., Europe, and Asia

Establish new offices in strategic locations globally

#### Expand clinical, commercial and manufacturing infrastructure to support future product launches

Invest in digital infrastructure and capabilities

#### Ramp up our investment in innovation

Complement internal R&D with external innovation





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