

# Third Quarter 2019

Highlights operational progress and financial results

November 14, 2019

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#### **Forward-looking statements**

Various statements in this slide presentation concerning the future expectations of BioNTech, its plans and prospects, including the Company's views with respect to the potential for mRNA therapeutics, its expectations with respect to the timing and results of clinical trials and release of clinical data (both in respect of its proprietary product candidates and of product candidates of its collaborators), the development of commercial capabilities and the transition of BioNTech to a fully integrated biopharmaceutical company, its expectations with respect to interactions with regulatory authorities such as FDA and EMA, including the potential approval of BioNTech's or its collaborators' current or future drug candidates, and expected royalty and milestone payments in connection with BioNTech's collaborations, constitute forward-looking statements. Words such as "expects," "plans," "potential," "target," "continue" and variations of these words or similar expressions are intended to identify forward-looking statements. Such statements are based on the current beliefs and assumptions of the management team of BioNTech and on the information currently available to the management team of BioNTech, and are subject to change. The Company will not necessarily inform you of such changes. These forward looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors that could cause the Company's actual results, performance or achievements to be materially different than any future results, performance or achievements expressed or implied by the forward-looking statements. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including the Company's ability to discover and develop its novel product candidates, successfully demonstrate the efficacy and safety of its product candidates, the pre-clinical and clinical results for its product candidates, which may not support further development of product candidates; actions of collaborators regarding continued product development and product commercialization; actions of regulatory authorities, which may affect the initiation, timing and progress of clinical trials or the ability of the Company to obtain marketing authorization for its product candidates; the Company's ability to obtain, maintain and protect intellectual property, the Company's ability to enforce its patents against infringers and defend its patent portfolio against challenges from third parties; competition from others using technology similar to the Company's and others developing products for similar uses; the Company's ability to manage operating expenses; the Company's ability to obtain additional funding to support its business activities and establish and maintain its existing and future collaborations and new business initiatives; the Company's dependence on collaborators and other third parties for development, manufacture, marketing, sales and distribution of products; the outcome of litigation, and unexpected expenditures. Any forward-looking statements represent the Company's views only as of today and should not be relied upon as representing its views as of any subsequent date. The Company explicitly disclaims any obligation to update any forwardlooking statements. The mRNA vaccines and other product candidates discussed in this slide presentation are investigational products being developed by BioNTech and its collaborators and are not currently approved by the FDA, EMA or any other regulatory authority.



### **Our speakers**



Prof. Ugur Sahin, MD Co-founder and CEO



Sean Marett CBO / CCO



Dr. Sierk Poetting CFO / COO



Dr. Özlem Türeci Co-founder and CMO



# Agenda

**#1** Overview of BioNTech



**#3** Financials update

**#4** Outlook

**#5** Closing remarks | Q&A



# Our strategy to individualize cancer medicine and beyond



Rapidly advance our potential first-in-class product candidates in oncology toward market approvals.

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Leverage our multiple drug classes and the synergies between them to expand our pipeline.



Build a fully integrated global biotechnology company

to produce and deliver our products.



#### Our unique approach



# Harnessing the full potential of the immune system

#### Broadening the universe of patients

Improving the treatment success rate

Focusing on curative approaches



## Our clinical pipeline includes 8 product candidates in 9 clinical trials

	Platform	Candidate	Indication (Target)		
mRNA	FixVac	BNT111 BNT112 BNT113 <sup>1</sup>	Advanced Melanoma Prostate Cancer HPV+ H&N Cancer		
		BNT114	Triple Negative Breast Cancer		
	iNeST	RO7198457 (BNT122)	1L Melanoma with CPI Multiple ST <sup>2</sup> (basket trial)		
	Intratumoral Immunotherapy	SAR441000 (BNT131)	ST (IL-12sc, IL-15sushi, GM-CSF, IFNα)		
	RiboMabs	BNT141	Multiple ST		
		BNT142	Multiple ST (CD3+CLDN6)		
	RiboCytokines	BNT151 BNT152	Multiple ST <i>(Optimized IL-2)</i> Multiple Solid Tumors <i>(IL-7)</i>		
	CAR-T Cells	BNT211	Multiple ST (CLDN6)		
SIG	Next-Gen CP <sup>3</sup>	GEN1046 (BNT311)	Multiple ST (PD-L1x4-1BB)		
Othe	Immunomodulators	GEN1042 (BNT312)	Multiple ST (CD40x4-1BB)		
	Antibodies	BNT321 (MVT-5873)	Pancreatic Cancer (CA19-9)		
	TLR7 Ligand	BNT411	Multiple ST (TLR7)		





#### Our pipeline includes updates of several product candidates

	Platform	Candidate	Indication (Target)		
Others mRNA	FixVac	BNT111 BNT112 BNT113 BNT114	Advanced Melanoma Prostate Cancer HPV+ H&N Cancer Triple Negative Breast Cancer		
	iNeST	RO7198457 (BNT122)	1L Melanoma with CPI Multiple ST (basket trial)		
	Intratumoral Immunotherapy	SAR441000 (BNT131)	ST¹ (IL-12sc, IL-15sushi, GM-CSF, IFNa		
	RiboMabs	BNT141 BNT142	Multiple ST Multiple ST <i>(CD3+CLDN6)</i>		
	RiboCytokines	BNT151 BNT152	Multiple ST <i>(Optimized IL-2)</i> Multiple Solid Tumors <i>(IL-7)</i>		
	CAR-T Cells	BNT211	Multiple ST (CLDN6)		
	Next-Gen CP Immunomodulators	GEN1046 (BNT311) GEN1042 (BNT312)	Multiple ST <i>(PD-L1x4-1BB)</i> Multiple ST <i>(CD40x4-1BB)</i>		
	Antibodies	BNT321 (MVT-5873)	Pancreatic Cancer (CA19-9)		
	TLR7 Ligand	BNT411	Multiple ST <i>(TLR7)</i>		

#### **BNT112**

- Fully-owned cancer vaccine
- CTAs for Ph1/2 FIH trial approved in various European countries

#### GEN1042 (BNT312)

- Next generation checkpoint immunomodulator (bispecific)
- Collaboration is a 50:50 cost-profit-share with Genmab
- First patient dosed in Phase 1/2a

#### BNT321 (MVT-5873)

- Fully-owned asset acquired from MabVax Therapeutics
- Targeted cancer antibody against CA19-9 in pancreatic and other GI cancers
- IND transfer to BNT achieved July, 2019



- Fully-owned TLR7 agonist
- IND filed on Nov 5, 2019



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#### Highlights of Q3 and subsequent

## **BNT112: FixVac Prostate Cancer**



#### Ph1/2

- Multipronged vaccine: 5 prostate cancer associated antigens (PAP, PSA and 3 undisclosed antigens)
- RNA-LPX vaccine format validated by our FixVac Melanoma program
- Eligible are patients with
  - mCRPC symptomatic patient population after two lines of systemic chemotherapy for treatment with BNT112 alone or in combination with cemiplimab (aPD1, Regeneron)
  - Newly diagnosed high risk localized prostate cancer for treatment with BNT112 in combination with goserelin acetate & cemiplimab (aPD1, Regeneron) followed by surgery



### **Clinical supply agreement with Regeneron signed in November**

- Regeneron to supply their PD-1 checkpoint inhibitor Libtayo<sup>®</sup> (cemiplimab) at no cost to BioNTech
- Combination with BNT112 (FixVac Prostate Cancer) in first-in-human phase 1/2 trial in advanced prostate cancer
- Targeted antigens of BNT112 are five prostate cancer specific antigens, including PAP and PSA as well as three internally identified antigens
- BioNTech and Regeneron to mutually agree on the clinical development plan for this combination study in prostate cancer
- BioNTech and Regeneron will each retain full commercial rights to BNT112 and Libtayo, respectively
- BioNTech to be sponsor of the trial: clinical trial application in Europe accepted on Nov 5, 2019
- Libtayo is being jointly developed by Regeneron and Sanofi
- We expect this single-agent dose escalation part of the Phase 1/2 trial in Q4-2019, as planned



# **BNT321: Cancer antibody targeting cancer associated carbohydrate sLe<sup>a</sup>**

#### Characteristics

- Clinical stage<sup>1</sup> product (MVT-5873, 5B1) acquired from MabVax Therapeutics Holdings Inc. in 2019
- Fully human IgG1 mAb with subnanomolar affinity, potent cell killing by ADCC &CDC activity
- Targets sialyl Lewis A epitope (sLe<sup>a</sup>) epitope present in a range of glyco-proteins collectively known as CA19-9.
- CA19-9 is specifically expressed in pancreatic and various other cancers. Shedded CA19-9 is a prognostic marker in these cancers.
- CA19-9 is functionally associated with carcinogenesis<sup>2</sup>.
- Six patients evaluated; four of them met the criteria for partial response and two patients met the criteria for stable disease. BNT321 was generally well tolerated by all six patients.
- This MVT-5873 phase 1 trial is currently paused; we intend to resume the trial as a phase 1/2 trial this year.

#### sLe<sup>a</sup> expression in human cancers



- A. Pancreatic ductal adenocarcinoma
- B. Colon carcinoma
- C. Lung adenocarcinoma
- D. Urinary bladder, mucinous adenocarcinoma
- E. Colon metastatic to ovary
- F. Breast carcinoma, lymph node





# Specificity and high affinity make BNT321 a promising product candidate



PET/CT image after injection of 47 mg BNT321 and 3 mg MVT-2163 (PET conjugated Ab 5B1)

 The specificity and high affinity of BNT321 to CA19-9-positive cancer cells make it a promising high-precision drug candidate against pancreatic cancer and other CA19-9 positive tumors.

 We will shortly restart BNT321 trials against pancreatic cancer, as planned.



# First-in-human Ph1 study also supports theranostic potential



- Robust accumulation in tumors lesions; tumor uptake increasing over time.
- Validates the target and the antibody and indicates utility of BNT321 also for detection by radio-imaging and for radiotherapy.



### BNT411: TLR7 agonist has entered the clinical stage

- Intravenously administered small molecule TLR7 (toll-like receptor 7) agonist
- Engineered for high potency and high selectivity for TLR7 receptor at the therapeutically active dose range
- Activates both adaptive and innate immune system
- Type 1 interferon-dominated release of cytokines and chemokines and potent stimulation of antigen-specific CD8+ T cells, B cells and innate immune cells such as NK cells and macrophages
- To be used in combination with chemotherapy and checkpoint inhibitors. Qualifies for various solid tumor indications and small cell lung cancer
- IND was filed on November 5, 2019
- We expect to initiate a Phase 1/2a clinical trial as a mono and combination therapy in solid tumors in H1/2020

#### Planned study design for FIH trial:

Phase 1/2a, first-in-human, open-label, dose-escalation trial with expansion cohorts to evaluate safety, pharmacokinetics, pharmacodynamics, and preliminary efficacy of BNT411 as a monotherapy in patients with solid tumors and in combination with atezolizumab, carboplatin and etoposide in patients with chemotherapy-naïve extensive-stage small cell lung cancer (ES-SCLC)

H1 2020



# BNT411: TLR7 agonist pre-clinical data supporting the IND



Syngeneic subcutaneous colorectal cancer mouse model

#### **Characteristics**

- Activity of BioNTech's TLR7 agonists shown in various mouse tumor models
- Activity on primary tumor growth and metastasis
- Activates tumor antigen specific T-cells as well as NK cells

1 TLR7 agonist (SC1), structurally very similar prototype of BNT411, causes strong tumor growth retardation in s.c. CT-26 model\*



Treatment with TLR7 agonist (SC1) results in complete tumor clearance in 4 of 12 animals



Pharmacodynamic results from mouse tumor models performed with SC1 support BNT411 IND registration



# Third Quarter 2019 Financial Results (unaudited) – Cash Balance

#### **Total Business**

In EURm	<u>September 30,</u>	December 31,	
	<u>2019</u>	<u>2018</u>	
Cash and cash equivalents	463	411	
Net proceeds from IPO incl. overallotment	135 <sup>1</sup>	-	
Pro forma cash and cash equivalents	598	411	



## Third Quarter 2019 Financial Results (unaudited) – Profit and Loss

Total Business <sup>1</sup>	Three mont	ths ended	Nine months ended		
In EURm	Septe	ember 30,	September 30,		
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>	
Collaboration revenue	22.2	16.2	64.3	45.5	
Revenue from other sales transactions	6.4	4.2	16.3	18.3	
Total Revenue	28.7	20.4	80.6	63.8	
Cost of sales	(4.2)	(2.8)	(12.9)	(9.2)	
Gross profit	24.4	17.6	67.7	54.6	
Research and development expenses	(50.4)	(32.8)	(161.0)	(91.2)	
Sales and marketing expenses	(0.7)	(0.8)	(1.9)	(2.0)	
General and administrative expenses	(10.6)	(6.6)	(34.5)	(16.2)	
Other operating / financial income less expenses	7.1	(0.4)	8.8	8.7	
Income taxes	0	(0.6)	0	(0.6)	
Loss for the period	(30.1)	(23.5)	(120.9)	(46.8)	



#### Our expected trial news flow

	Platform	Candidate	Indication (Target)	2H-2019	1H-2020	2H-2020	2021-2022 <sup>3</sup>
mRNA	FixVac	BNT111	Advanced Melanoma		Report Phase 1 Start Phase 2	Start Phase 3	Phase 2/3
		BNT112	Prostate Cancer	Start Phase 1/2			Phase 1/2
		BNT113	HPV+ H&N Cancer			Start Phase 2	
		BNT114	Triple Negative Breast Cancer		Data Update Phase 1		
	iNeST	RO7198457 (BNT122)	1L Melanoma with CPI			Top line Phase 2 <sup>1</sup>	Phase 2
			Multiple ST (basket trial)		Data updat	e Phase 1/2	
	Intratumoral Immunotherapy	SAR441000 (BNT131)	Solid tumors (IL-12sc, IL-15sushi, GM-CSF, IFNa)			Report Phase 1/2 <sup>2</sup>	
		BNT141	Multiple ST			Start Phase 1	
	RiboMabs	BNT142	Multiple ST (CD3+CLDN6)			Start Phase 1	
	PiboCytokinos	BNT151	Multiple ST (Optimized IL-2)		Start Phase 1		Phase 1
Others	The optimities	BNT152	Multiple Solid Tumors (IL-7)			Start Phase 1	
	CAR-T Cells	BNT211	Multiple ST (CLDN6)		Start Phase 1/2		Phase 1/2
	Next-Gen CP Immunomodulators	GEN1046 (BNT311)	Multiple ST (PD-L1x4-1BB)				Report Phase 1/2
		GEN1042 (BNT312)	Multiple ST (CD40x4-1BB)				
	Antibodies	BNT321 (MVT-5873)	Pancreatic Cancer (CA19-9)	Resume Phase 1/2			
	TLR7 Ligand	BNT411	Multiple ST (TLR7)		Start Phase 1		Phase 1/2
18	Legend Expected beg	gin of trial	pected data readout / update	e expect this topline data update to inc cacy and safety data for an interim up	clude an update on the ongoing study, date expected in the second half of 20	including patient enrollment numbers, w 21; <sup>2</sup> As the trial is sponsored and condu	

by Sanofi, the timing of data updates is not under our control, and is subject to change by Sanofi. <sup>3</sup>Our expectations for timing of milestones beyond 2020 are premised on and subject to the achievement of earlier milestones on their expected timelines.