First Quarter 2020

Corporate update and
financial results

May 12, 2020

BioNTech-Pfizer Exhibit 1251
BioNTech SE and Pfizer Inc. v. ModernaTX, Inc. IPR2023-01358

Forward-looking statements

Various statements in this slide presentation concerning the future expectations of BioNTech, its plans and prospects, including the Company's views with respect to the potential for mRNA therapeutics; the planned next steps in BioNTech's pipeline programs and specifically including, but not limited to, statements regarding plans to initiate clinical trials of BioNTech's BNT111, BNT113, iNeST (BNT122), BNT141, BNT142, BNT151, BNT152/153, BNT161, BNT162, BNT211 and BNT411; expectations for data announcements with respect to BioNTech's BNT111, BNT114, iNeST (BNT122), BNT131, BNT 162 and BNT311 clinical trials; the development of commercial capabilities and the transition of BioNTech to a fully integrated biopharmaceutical company; its expectations with respect to interactions with regulatory authorities such as FDA and EMA, including the potential approval of BioNTech's or its collaborators' current or future drug candidates; expected royalty and milestone payments in connection with BioNTech's collaborations; BioNTech's anticipated cash usage for fiscal year 2020; the creation of long-term value for BioNTech shareholders; and the ability of BioNTech to successfully develop and commercialize a vaccine for COVID-19 in partnership with Pfizer and Fosun Pharma, constitute forward-looking statements, and the impact of COVID-19 on our clinical trials and business operations. 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 forward-looking statements. The mRNA vaccines and other product candidates discussed in this slide presentation are investigational products being developed by BioNTech and its collaborators and are not currently approved by the FDA, EMA or any other regulatory authority.

Next generation immunotherapy

Harnessing the full potential of the immune system

Broad suite of novel technology platforms

Immunotherapies for cancer and infectious diseases

Fully integrated with in-house GMP manufacturing

Industry-leading global collaborations

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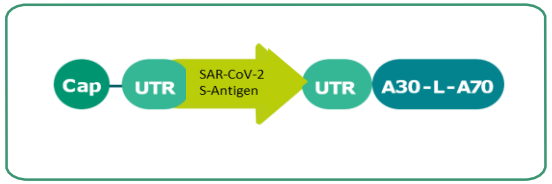
Update on COVID-19 program - BNT162

- Global development program established with new collaboartions with Pfizer and Fosun Pharma
- Four vaccine candidates selected for clinical trials following preclinical testing
- Ongoing Phase 1/2 clinical trials in US and Germany – first cohorts dosed
- Clinical trial supply from BioNTech‘s GMP-certified mRNA manufacturing facilities in Europe – Scale-up of BioNTech manufacturing network underway
- First clinical data expected in June/July 2020

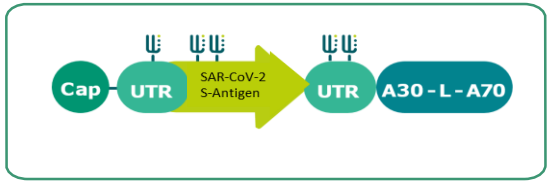
BNT162 mRNA vaccine program

Three mRNA formats

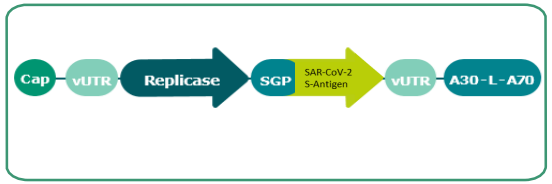
Uridine mRNA (uRNA)



Nucleoside-modified mRNA (modRNA)

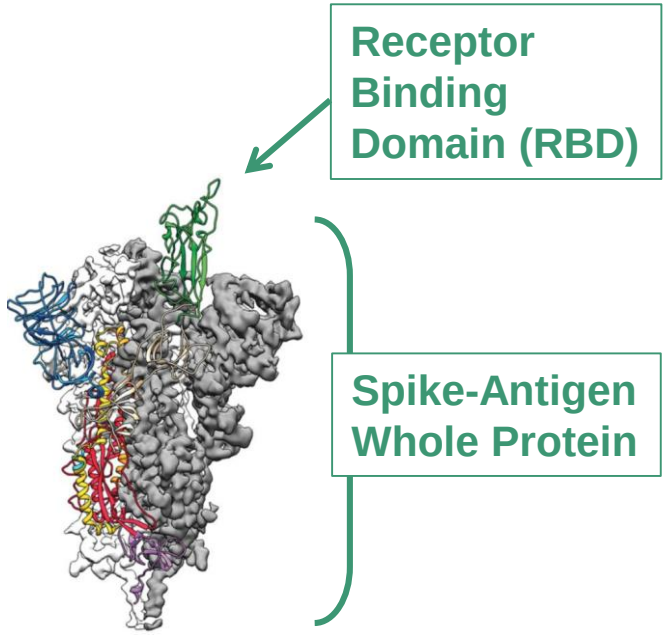


Self-amplifying mRNA (saRNA)



Lipid nanoparticle formulation

Two different antigens



SARS-COV-2 Spike Protein 3D Structure
(Wrapp et al., 2020, Science)

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Global BNT162 clinical development program ongoing

Phase 1/2 trials ongoing in Europe and US

- Testing of 4 vaccine candidates across different countries
- Evaluating safety, efficacy and optimal dose
- Evaluating effects of repeated immunization for 3 candidates using uRNA or modRNA and one prime-only using saRNA
- Potentially accelerated approval pathways being discussed with global regulators

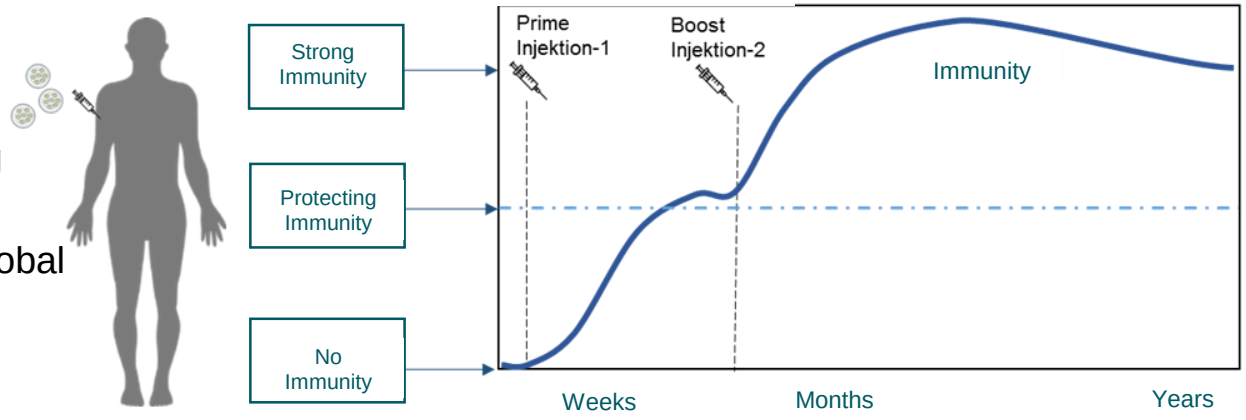
Designs

- Europe: dose escalation part up to 200 healthy subjects aged 18 to 55
- US: seamless study design with several thousand subjects; Initial dose-finding part up to 360 healthy subjects aged 18-85
- Dose range 1 µg to 100 µg
- Single-dose and 2-dose regimens to be tested in initial trial

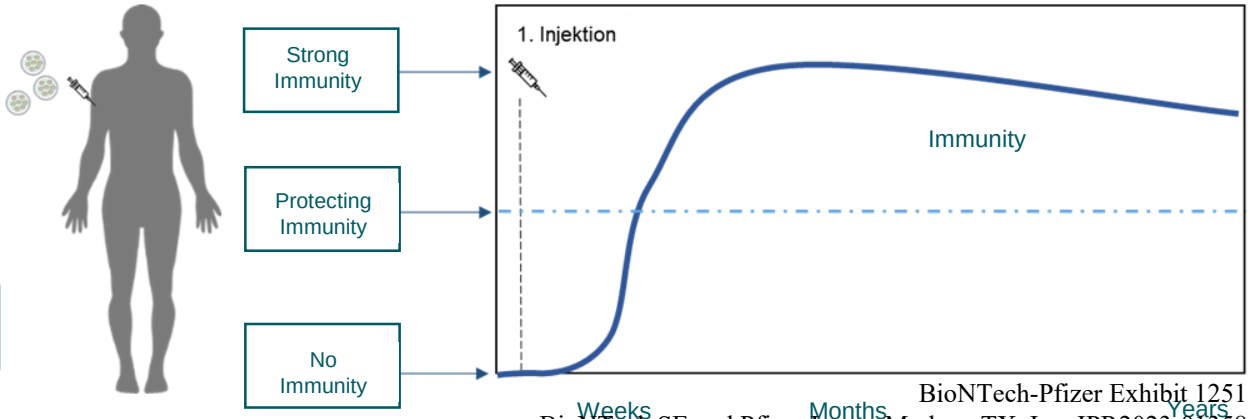
First cohorts dosed in each geography

First clinical data expected June/July 2020

Prime / boost vaccine



Prime-only vaccine



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Expected data readout / update

Significant newsflow expected over next 12-18 months

	Platform	Candidate	Indication *(Target)*	Next milestones [3]
mRNA	FixVac	BNT111	Advanced Melanoma	Start Phase 2 with registrational potential in 2H 2020 Report Phase 1: publication upcoming
		BNT112	Prostate Cancer	
		BNT113	HPV16+ H&N Cancer	Start Phase 2 with registrational potential in 2H 2020
		BNT114	Triple Negative Breast Cancer	Data update Phase 1 in 2H 2020 [4]
	iNeST	RO7198457 (BNT122)	1L Melanoma with CPI	Enrollment update in 2H 2020 [1]
			Multiple ST (basket trial)	Data update Phase 1/2 at AACR Virtual II in June
			NSCLC (adjuvant)	Start Phase 2 in 2H 2020
			undisclosed (adjuvant)	Start Phase 2 in 2H 2020
	Intratumoral Immunotherapy	SAR441000 (BNT131)	Solid tumors *(IL-12sc, IL-15sushi, GM-CSF, IFNα)*	Data update Phase 1/2 in 2H 2020 [2]
	RiboMabs	BNT141	Multiple ST	Start Phase 1 in 1H 2021
		BNT142	Multiple ST *(CD3+CLDN6)*	Start Phase 1 in 1H 2021
	RiboCytokines	BNT151	Multiple ST *(Optimized IL-2)*	Start Phase 1 in 1H 2021
		BNT152/153	Multiple Solid Tumors *(IL-7, IL-2)*	Start Phase 1 in 1H 2021
Others	CAR-T Cells	BNT211	Multiple ST *(CLDN6)*	Start Phase 1/2 in 2H 2020
	Next-Gen CP Immunomodulators	BNT311	Multiple ST *(PD-L1x4-1BB)*	Data update Phase 1/2 in 2H 2020
	TLR7 Ligand	BNT411	Multiple ST *(TLR7)*	Start Phase 1 in 2H 2020
	Infectious and Rare Diseases	BNT161	Influenza	Start first study in 1H 2021
		BNT162	COVID-19	Data update in June/July 2020
			Up to 10 Infectious Disease Indications	Start phase 1 in 1H 2021
			5 Rare Disease Indications	Start first Phase 1 in 1H 2021

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[1]We expect this update to include an update on the ongoing study, including patient enrollment numbers, with full efficacy and safety data for an interim update expected in the second half of 2021; [2]As the trial is sponsored and conducted by Sanofi, the timing of data updates is not under our control, and is subject to change by Sanofi. [3]Our expectations for timing of milestones beyond 2020 are premised on and subject to the achievement of earlier milestones on their expected timelines. Press releases will be issued once first patient has been dosed.
[4]BNT122 (iNeST) is also being investigated in arm 2 (N=15) of the 3 arm TNBC-MERIT trial, with BNT114 as an optional treatment; BNT114 is investigated in arm 1 (N=12) and arm 3 (N=15) of the TNBC-MERIT trial (total patients in study: N=42);

ST: solid tumors

BNT162 Manufacturing Update

Clinical supply

- BioNTech to manufacture all drug substance for clinical supply at its GMP manufacturing facilities in Idar-Oberstein and Mainz (both in Germany, partially 24/7 manufacturing)
- Drug product supply initially supported by BioNTech‘s formulation partner Polymun, with Pfizer and BioNTech ramping up own capacity

Global pandemic and commercial supply capacities

- Joint establishment of pandemic supply capacities at many network sites
  - BioNTech: At Idar-Oberstein and Mainz facilities in Germany
  - Pfizer: At least at three U.S. sites (Massachusetts, Michigan, Missouri) and at Puurs facility (Belgium)
- BioNTech and Pfizer working closely together (joint teams) on scale-up, supply chain and network planning

First Quarter 2020 Financial Results (unaudited) – Profit and Loss

- Cash and cash equivalents of EUR 452m (USD 495m) as of March 31, 2020
- Additional EUR 217m (USD 236m) due in 2Q 2020 from Pfizer and Fosun Pharma (equity investments and non-dilutive deal upfront payments, partially received already)
- Net cash used in operating activities and investments into property, plant and equipment on track with previous guidance of EUR 300m (USD 329m[1]) for base business plan (prior to impact of Neon Therapeutics acquisition and BNT162 program)
- Majority of BioNTech development costs for BNT162 program in 2020 will be funded via Pfizer and Fosun Pharma cost sharing, equity investments and upfront payments.

(in million)	Three months ended March 31, 2020	2019
Revenues resulting from collaboration and license agreements	€ 21.2	€ 21.9
Revenues from other sales transactions	6.5	4.3
Total revenues	**€ 27.7**	**€ 26.2**
Cost of sales	(5.9)	(3.3)
Gross profit	**€ 21.8**	**€ 22.9**
Research and development expenses	(65.1)	(57.2)
Sales and marketing expenses	(0.5)	(0.5)
General and administrative expenses	(15.8)	(9.3)
Other operating income less expenses	0.3	0.3
Finance income less expenses	5.9	3.0
Income taxes	-	-
Loss for the period	**€ (53.4)**	**€ (40.8)**

[1] Rate German Central Bank as of March 31, 2020

Building a next generation immunotherapy company

- Rapid progress in key pipeline programs in both oncology and infectious diseases
- Multiple data read-outs & late-stage trial starts anticipated in 2H 2020
- Expanded transatlantic operations with newly established R&D hub in Cambridge, U.S.
- Strong momentum toward our vision of building a global immunotherapy company

Q&A

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