

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE MONTH OF JANUARY 2021

COMMISSION FILE NUMBER 001-39081

BioNTech SE

(Translation of registrant's name into English)

An der Goldgrube 12

D-55131 Mainz

Germany

+49 6131-9084-0

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F: Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

DOCUMENTS INCLUDED AS PART OF THIS FORM 6-K

On January 11, 2021, BioNTech SE (the “Company”) provided a presentation at the JP Morgan Healthcare Conference 2021. The presentation materials are attached hereto as Exhibit 99.1.

SIGNATURE

Pursuant to the requirements of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BioNTech SE

By: /s/ Dr. Sierk Poetting
Name: Dr. Sierk Poetting
Title: Chief Financial Officer

Date: January 11, 2021

EXHIBIT INDEX

<u>Exhibit</u>	<u>Description of Exhibit</u>
99.1	Next Generation Immunotherapy January 2021.

Next Generation Immunotherapy

Ugur Sahin, M.D.
January 2021



BIONTECH 

This slide presentation includes forward-looking statements

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 product candidates and expectations for data announcements with respect to BioNTech's product candidates; 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 2021 and beyond; the creation of long-term value for BioNTech shareholders; the ability of BioNTech to successfully develop and commercialize a vaccine for COVID-19 in partnership with Pfizer and Fosun Pharma; the timing for any potential emergency use authorizations or approvals for BNT162; and the ability of BioNTech to supply the quantities of BNT162 to support clinical development and, market demand, including its production estimates for 2020 and 2021 and the impact of COVID-19 on our clinical trials and business operations, are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, as amended. 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 and 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 the Company's 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 its 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.

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 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 (<https://www.cdc.gov/vaccines/covid-19/>)**
- 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 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 <https://vaers.hhs.gov/reportevent.html> 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*

Harnessing the immune system's full potential to fight human disease

2020: A TRANSFORMATIONAL YEAR FOR BIONTECH



Globally developed COVID-19 vaccine, COMIRNATY^{®*}, in 10 months



Building a fully integrated biopharma company



Broadened clinical stage pipeline to 11 immuno-oncology product candidates



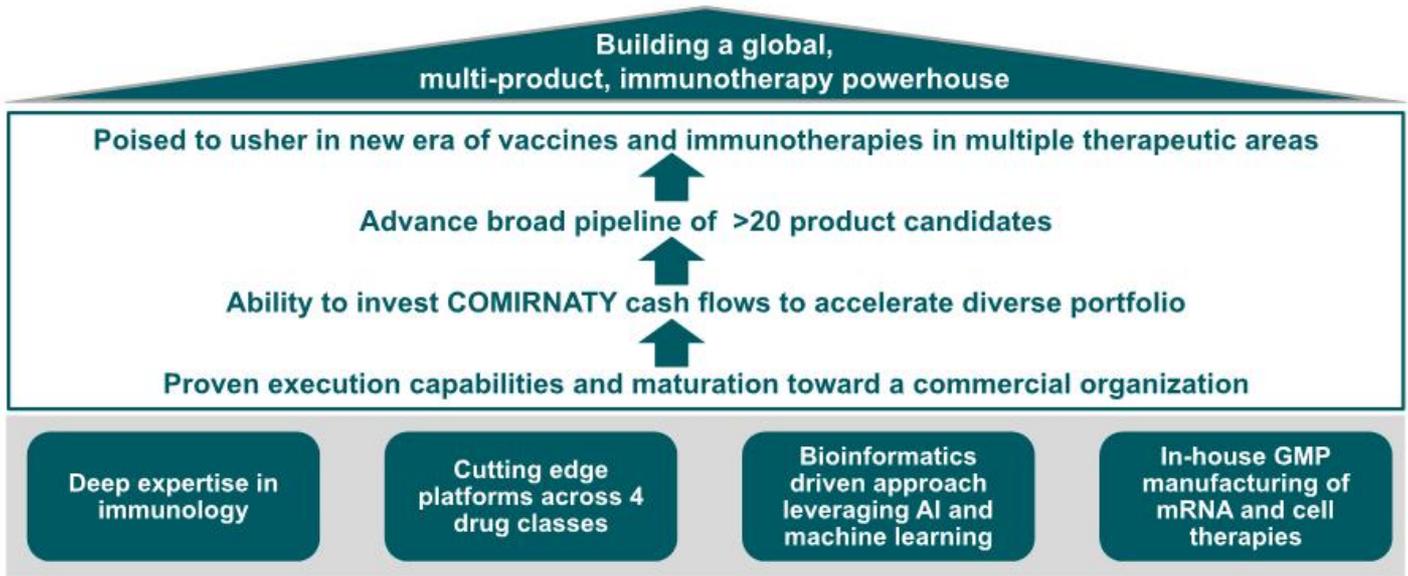
Established R&D hub in the US and established presence in Asia



Matured mRNA manufacturing base from clinical to global commercial scale

5 *COMIRNATY[®] is the brand name for BNT162b2 in the EU and Switzerland, where it has received conditional marketing authorization

OPPORTUNITY IN 2021 AND BEYOND



COMIRNATY: LEADING THE FIGHT AGAINST COVID-19

- **First vaccine authorized for use in the US and the EU**
- **Authorization for Emergency Use / Temporary Use or Conditional Approval in > 45 countries**
- **32.9m million doses shipped¹**
- Global phase 3 trial data indicates vaccine is **highly efficacious** and **generally well tolerated**
 - **95% vaccine efficacy** in 43,000+ participants
 - 94% efficacy in participants older than 65 years
 - Generally well tolerated with most **adverse events being mild to moderate in intensity and transient in effect**
 - Most common adverse events are fatigue, headache, pain at injection sites, chills, muscle and joint pain
- **Broad immunogenicity profile (poly-epitopic, multi-effector),** inducing high titer of neutralizing antibody and T cell responses

COMIRNATY[®]
COVID-19 mRNA Vaccine



**For use in individuals
16 years and older**

¹ As of January 10th, 2021

BIONTECH

SUPPLY UP TO TWO BILLION VACCINE DOSES IN 2021



- FY 2021 manufacturing capacity target: **2.0 billion doses***
- Committed Doses for 2021: **>1 billion doses**
- **50:50** gross profit share with Pfizer (worldwide ex-China); **35-40%** gross profit share with Fosun Pharma in China
- **6 manufacturing sites** in Pfizer and BioNTech alliance
- **Additional external CMO sites** expanding LNP and fill-finish capacity



8 *We now believe that we can potentially deliver approximately 2 billion doses in total by the end of 2021, which incorporates the updated 6-dose label. This is based on continuous process improvements and expansion at our current facilities, and contingent upon adding more suppliers as well as contract manufacturers.

MULTIPLE STRATEGIC LEVERS TO EXPAND COMIRNATY ACCESS



Increase Supply Capacity

- 6-dose vial
- Continuous process improvements
- New sites, suppliers and CMOs

Broaden global distribution

- New country / regional authorizations
- BLA submission in U.S. and other regions
- Order book growth

Expand label

- Pediatric indications
- Pregnant women
- Additional sub-populations

Develop optimized formulations

- Further stability testing update for current formulation
- Improved thermostable formulation
- PEG-free formulation

COVID-19 WILL LIKELY BECOME AN ENDEMIC DISEASE

Unmet Medical Needs

Key Strengths

1	Safety & Efficacy	Compelling efficacy & safety in all tested age groups
2	Emergence of new viral variants	Ability to create re-engineered vaccine in 6 weeks¹
3	Naturally waning immune response	mRNA vaccine well-suited for re-vaccination

INFECTIOUS DISEASES REPRESENT A LONG-TERM GROWTH PILLAR

Unmet Medical Needs

- Increasing number of highly unaddressed indications
- Only **7** infectious disease vaccines approved by the FDA from 2017 to 2020
- Many high incident infections with **no vaccine or therapy approved**
- Efficacy of multiple approved vaccines is suboptimal

BioNTech infectious diseases portfolio

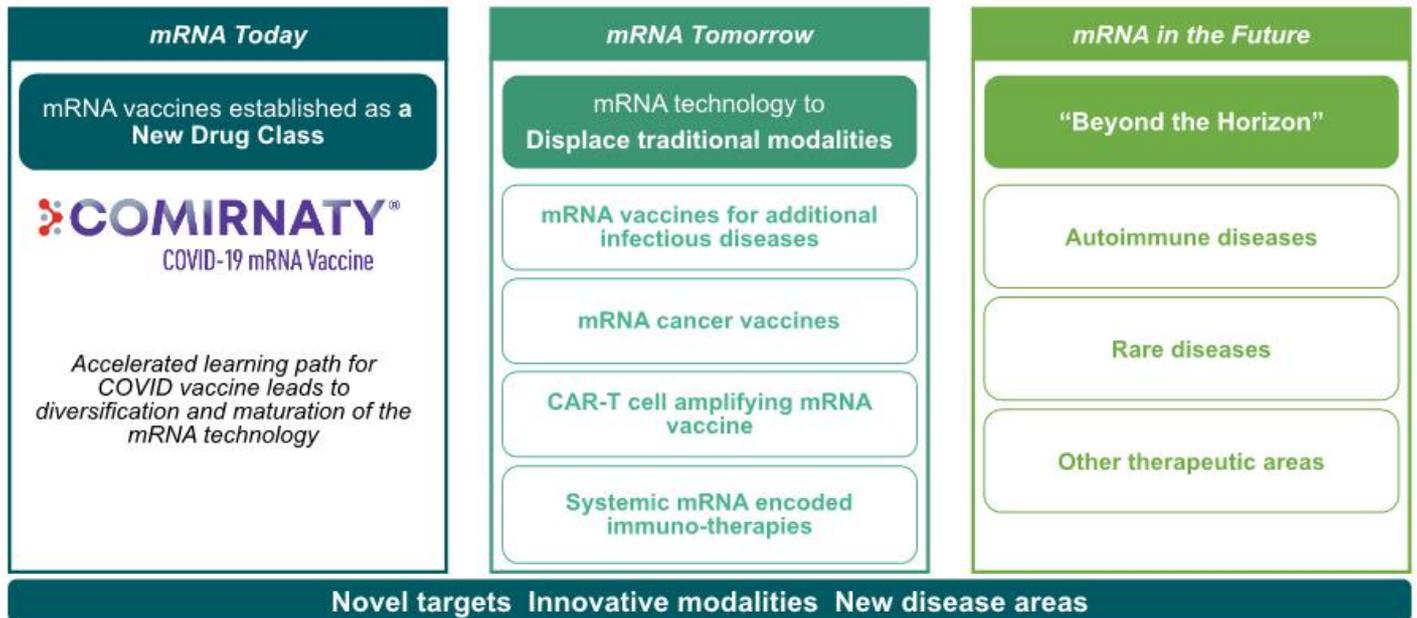
COMIRNATY

Next generation COVID-19 vaccines

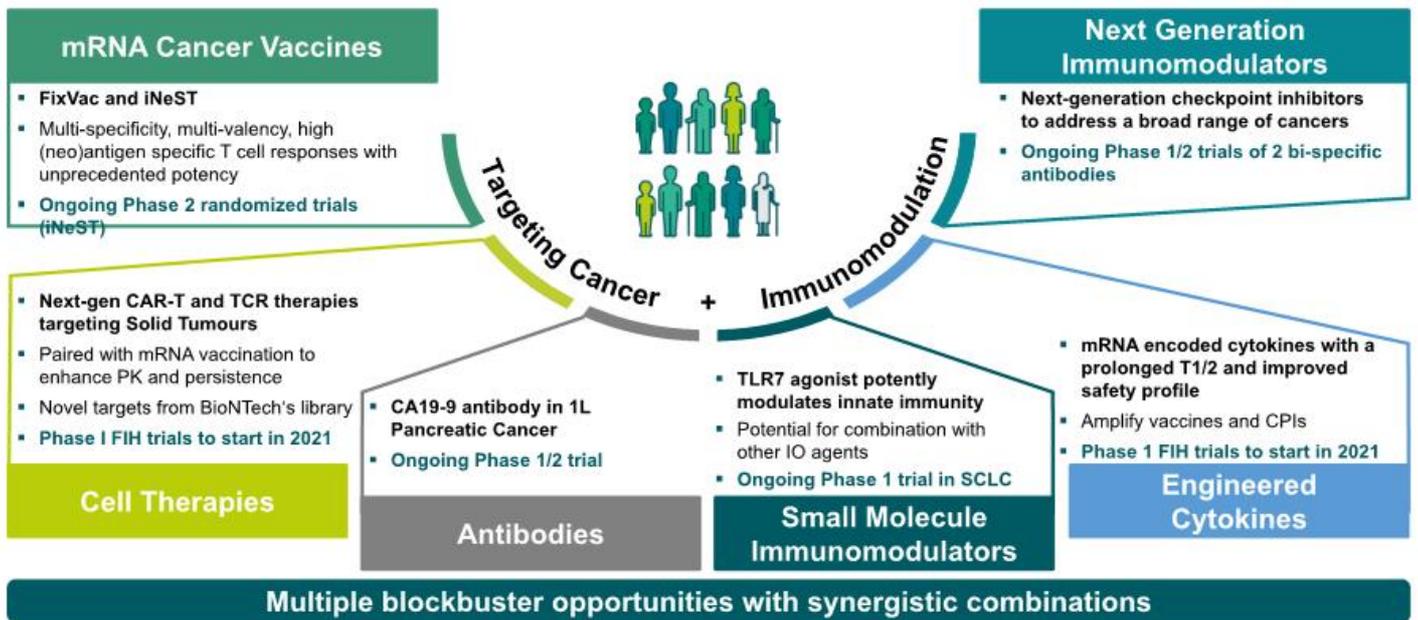
Influenza, HIV and TB vaccines

6 undisclosed programs

mRNA TECHNOLOGY POISED TO REVOLUTIONIZE IMMUNOTHERAPY



RATIONALLY DESIGNED MULTI-PLATFORM IO STRATEGY

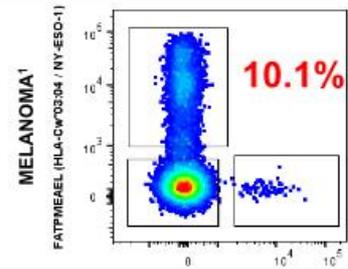
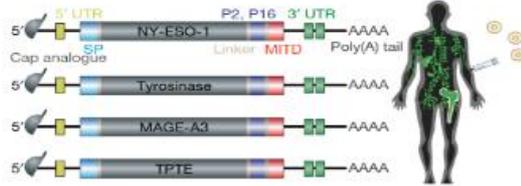


FIXVAC: LEVERAGING SHARED ANTIGENS TO BREAK IMMUNE TOLERANCE

Novel Structure

Fixvac

- Multi-valency + Off-the-shelf
- Applicable for almost all types of tumor antigens



Product candidate ²	Preclinical	Phase 1	Phase 2
BNT111	Advanced melanoma <i>NY-ESO-1, MAGE-A3, Tyrosinase, TPTE</i>		
BNT113	HPV+ head & neck cancer <i>HPV E6 and E7 oncoproteins</i>		
BNT112	Prostate cancer <i>PSA, PAP, 3 addition undisclosed antigens</i>		
BNT116	NSCLC		

¹⁴ Sahin et al, Nature 2020

² Additional exploratory indications: TNBC, Ovarian Cancer

iNeST: TAILORED TREATMENT TO EXPLOIT INDIVIDUAL TARGETS

5' UTR
5' Cap analog
RNA backbone /
SEC
NEOANTIGENS 1 2 3 4 5 6 7 8 9 10
MITD
3' UTR
AAAA Poly(A) tail
RNA backbone \

- Fully customized to the individual Patient
- Targeting 20 neo-antigens per patient

ADJUVANT

Normal DNA Tumor DNA

Residual cancer cells may remain – emphasis on recurrence free survival

1L METASTATIC

Rapidly growing but often still in early phase of metastases

LATE-LINE METASTATIC

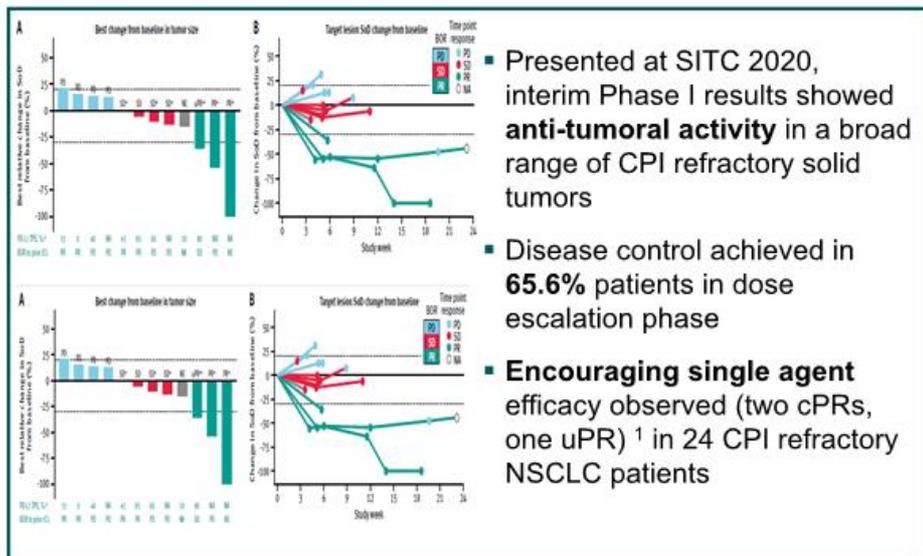
Bulky tumors with multiple organs involved

iNeST

- Phase 2 trial planned
- 8 of 8 stage III/IV melanoma patients with stable disease cancer free for up to 60 months (BNT121)¹
- Ongoing Phase 2 trial in 1L melanoma
- Single agent activity in melanoma¹ and gastric² Cancer
- Encouraging efficacy signal validates iNeST potential in early settings

15 ¹Sahin et. al. Nature 2017
² AACR 2020

BNT311 DEMONSTRATED SINGLE AGENT ANTI-TUMOR ACTIVITY



- Presented at SITC 2020, interim Phase I results showed **anti-tumoral activity** in a broad range of CPI refractory solid tumors
- Disease control achieved in **65.6%** patients in dose escalation phase
- Encouraging single agent efficacy** observed (two cPRs, one uPR)¹ in 24 CPI refractory NSCLC patients

7 expansion cohorts are currently recruiting

N = Up to 40 per cohort

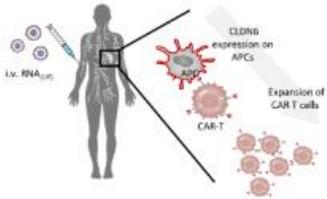
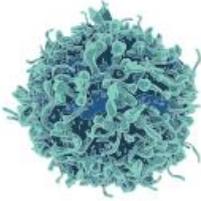
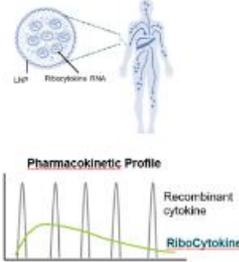
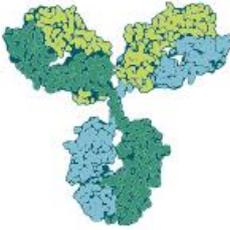
- EC1: NSCLC ≤ 2-4L p. ICI
- EC2: NSCLC ≤ 2-4L ICI n.
- EC3: Urothelial Ca ≤ 2-4L p. ICI
- EC4: Endometrial Ca ≤ 2-4L ICI n.
- EC5: TNBC ≤ 2-4L CPI n./ p. ICI
- EC6: SCCHN ≤ 2-4L CPI n./ p. ICI
- EC7: Cervical Ca ≤ 2-4L ICI n.

p. ICI = post immune checkpoint inhibitor
CPI n. = check point inhibitor naive

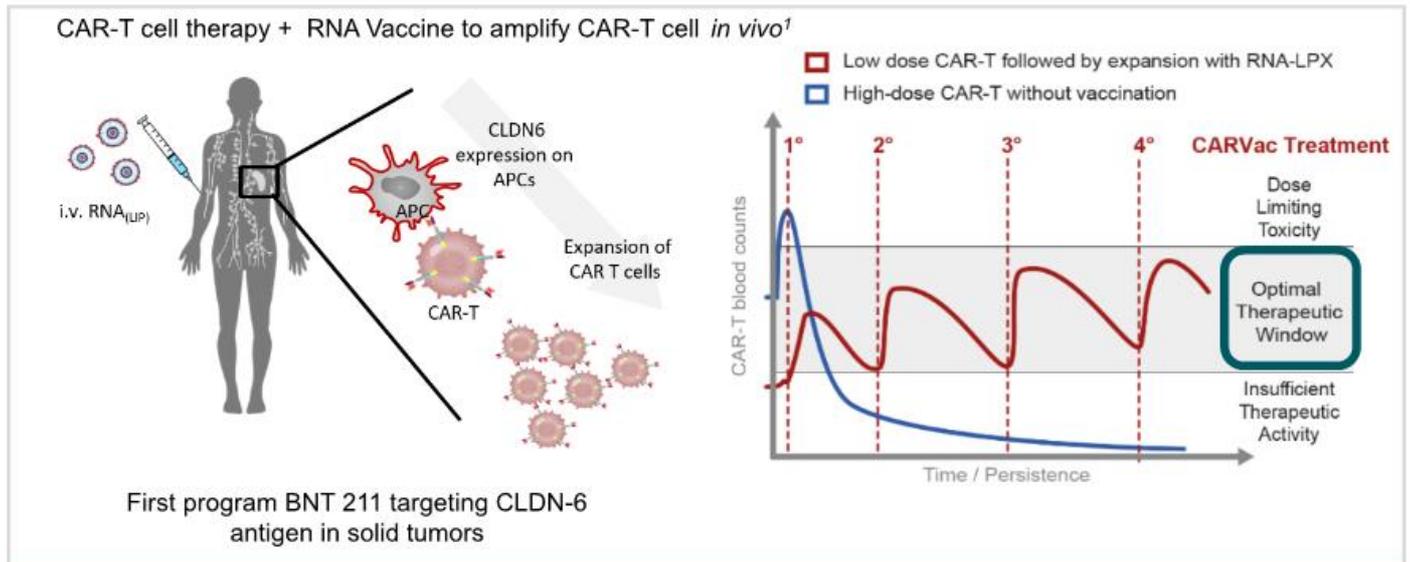
¹ Data cut-off: October 12, 2020.

One PR was not confirmed yet by a subsequent scan. Includes all patients who had at least one post-baseline tumor assessment (schedule is every 6 weeks), and thus could be assessed for clinical benefit; 6 of 12 patients are still on treatment.

ADVANCING INNOVATION BEYOND CURRENT BOUNDARIES

CARVac¹ <i>CAR-T cell amplifying mRNA therapy for solid tumors</i>	NEOSTIM T cell therapy <i>Individualized Neoantigen specific T cell therapy</i>	RiboCytokines <i>mRNA encoded Cytokines</i>	RiboMabs² <i>mRNA encoded Antibodies</i>
 <ul style="list-style-type: none"> ▪ BNT 211 (CLDN 6 CAR) 	 <ul style="list-style-type: none"> ▪ BNT 221 (PBMC derived ex vivo T cell therapy) 	 <ul style="list-style-type: none"> ▪ BNT 151 (modified IL2) ▪ BNT152 & 153 (IL-2/IL-7) 	 <ul style="list-style-type: none"> ▪ BNT 141 (undisclosed) ▪ BNT 142 (CD3xCLDN6)
Wholly owned ✓	✓	✓	✓
FIH start 2021	2021	2021	2021

CARVAC: OPENING UP CAR-T THERAPY FOR SOLID TUMORS



Potential to enhance persistence and safety of CAR-T cell therapy

mRNA VACCINES FOR AUTO IMMUNE DISEASES

Novel non-inflammatory mRNA for treatment of Multiple Sclerosis published in Science¹

- A therapeutic approach to **emulate natural immune tolerance**
- Induced **considerable reduction** in pro-inflammatory effector T cell infiltration in CNS
- Led to **strong autoimmunity suppression without broad immune suppression**
- Correlated with **CNS function restoration and disease regression** in preclinical models

Potential applicability of mRNA vaccine in a plethora of autoimmune diseases

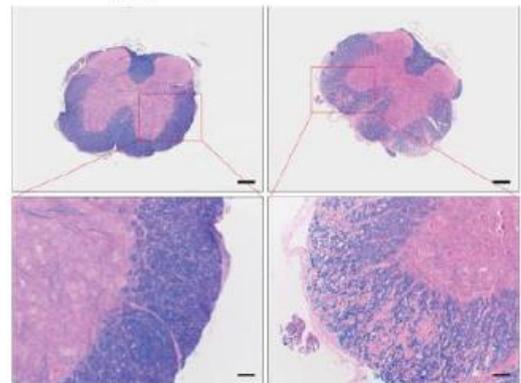
RESEARCH ARTICLE

MULTIPLE SCLEROSIS

A noninflammatory mRNA vaccine for treatment of experimental autoimmune encephalomyelitis

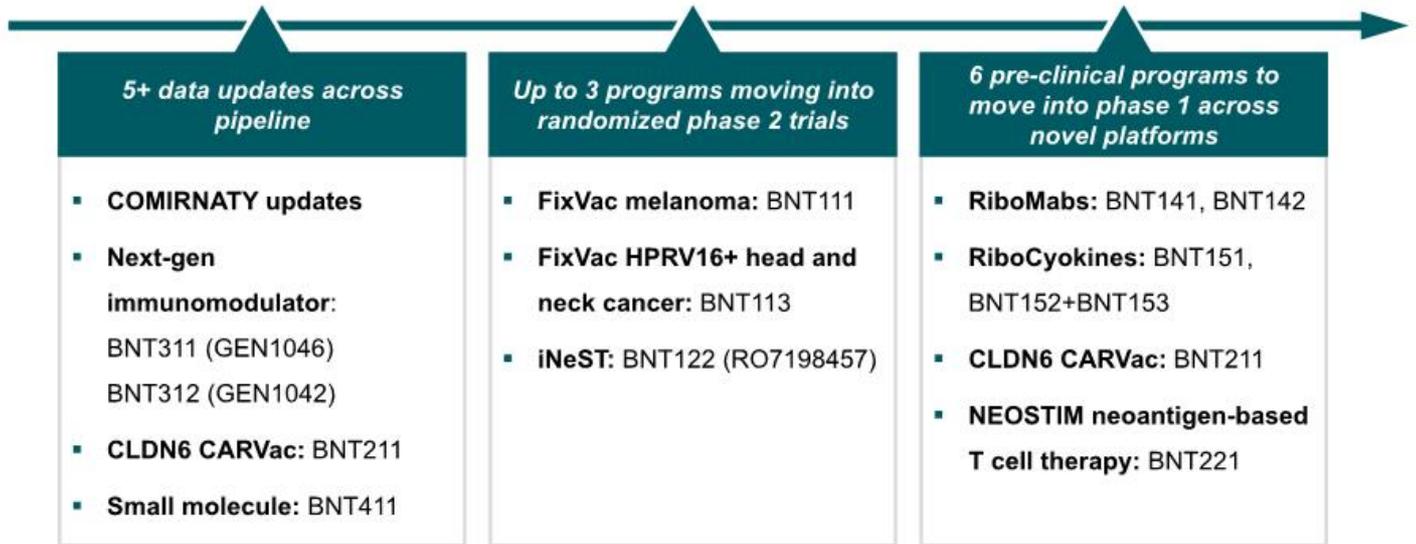
MOG₃₅₋₅₅_m1Ψ

irrelevant_m1Ψ



Luxol fast blue (LFB) staining reveals reduction of demyelination in the spinal cord of mice¹

KEY PIPELINE MILESTONES EXPECTED IN 2021



BETTER PLACED THAN EVER TO BRING INNOVATION TO PATIENTS

2021 Corporate Outlook

- Deliver COMIRNATY to up to 1 billion people globally
- Advance up to 3 oncology programs into randomized Phase 2 trials
- Initiate first trials in oncology with registrational potential
- Extend mRNA technology into new disease areas
- Expand global capabilities and footprint in the U.S., Europe, and Asia
- Continue to hire the best and brightest

Long- term

- Usher in a new era of individualized cancer medicine
- Build a global business and commercialize our own products
- Become a 21st century immunotherapy powerhouse

The Biontech logo is displayed in a light green, sans-serif font. The letters 'B', 'I', 'O', 'N', 'T', 'E', and 'C' are in a standard weight, while the 'H' is significantly bolder. The background of the slide is a dark teal color with a pattern of faint, overlapping white circles and arcs.

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