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 2022

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, 2022, BioNTech SE (the "Company") CEO and co-founder Ugur Sahin presented at the JP Morgan Healthcare Conference 2022. The presentation is 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 Operating Officer

Date: January 11, 2022

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	BioNTech Presents at JP Morgan Healthcare Conference 2022

Exhibit 99.1

BIONTECH

J.P. MORGAN
HEALTHCARE CONFERENCE
January 11th 2022

Ugur Sahin, M.D.
CEO and Co-founder

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: BioNTech's expected revenues and net profit related to sales of BioNTech's COVID-19 vaccine, referred to as COMIRNATY® where approved for use under full or conditional marketing authorization, in territories controlled by BioNTech's collaboration partners, particularly for those figures that are derived from preliminary estimates provided by BioNTech's partners; BioNTech's pricing and coverage negotiations with governmental authorities, private health insurers and other third-party payors after BioNTech's initial sales to national governments; the extent to which initial or booster doses of a COVID-19 vaccine continue 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 rate and degree of market acceptance of BioNTech's COVID-19 vaccine and, if approved, BioNTech's investigational medicines; the collaboration between BioNTech and Pfizer to develop a COVID-19 vaccine (including aa 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; BioNTech's ability to identify research opportunities and discover and develop investigational medicines; 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's COVID-19 vaccine and other products and product candidates developed or manufactured by us; BioNTech's ability to progress BioNTech's Malaria, Tuberculosis and HIV programs, including 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; BioNTech's estimates of research and development revenues, commercial revenues, cost of sales, research and development expenses, sales and marketing expenses, general and administrative expenses, capital expenditures, income taxes, shares outstanding; BioNTech's ability and that of BioNTech's collaborators to commercialize and market BioNTech's product candidates, if approved, including BioNTech's COVID-19 vaccine; BioNTech's ability to manage BioNTech's development and expansion; regulatory developments in the United States and foreign countries; BioNTech's ability to effectively scale BioNTech's production capabilities and manufacture BioNTech's products, including BioNTech's target COVID-19 vaccine production levels, and BioNTech's product candidates; and other factors not known to BioNTech 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 presentation 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 quarterly report for the three and nine months ended September 30, 2021 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 for-ward-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.

BIONTECH

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 5 years of age and older. 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

- Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with a known hypersensitivity to the active substance or to any of the excipients listed
- 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
- There is an increased risk of myocarditis and pericarditis following vaccination with Comirnaty. These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males. Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis
- Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions (e.g., dizziness, palpitations, increases in heart rate, alterations in blood pressure, tingling sensations and sweating) may occur in association with the vaccination process itself. It is important that precautions are in place to avoid injury from fainting
- Vaccination should be postponed in individuals suffering from acute severe febrile illness or acute infection. The presence of a minor infection and/or low-grade fever should not delay vaccination.
- As with other intramuscular injections, the vaccine should be given with caution in individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following an intramuscular administration in these individuals
- 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.
- The duration of protection afforded by the vaccine is unknown as it is still being determined by ongoing clinical trials.
- 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.
- Comirnaty ® has no or negligible influence on the ability to drive and use machines. However, some of side effects mentioned below, may temporarily affect the ability to drive or use machines.
- The overall safety profile of Comirnaty® in participants 5 to 15 years of age was similar to that seen in participants 16 years of age and older.
- The most frequent adverse reactions in children 5 to 11 years of age were injection site pain (>80%), fatigue (>50%), headache (>30%), injection site redness and swelling (>20%), myalgia and chills (>10%).
- The most frequent adverse reactions in adolescents 12 to 15 years of age that received 2 doses were injection site pain (> 90%), fatigue and headache (> 70%), myalgia and chills (> 40%), arthralgia and pyrexia (> 20%).
- In clinical studies, the most frequent adverse reactions in participants 16 years of age and older that received 2 doses were injection site pain (> 80%), fatigue (> 60%), headache (> 50%), myalgia (> 40%), chills (> 30%), arthralgia (> 20%), pyrexia and injection site swelling (> 10%) and were usually mild or moderate in intensity and resolved within a few days after vaccination. A slightly lower frequency of reactogenicity events was associated with greater age.
- In clinical trials, the most frequent adverse reactions in participants 18 to 55 years of age who received a booster were injection site pain (> 80%), fatigue (> 60%), headache (> 40%), myalgia (> 30%), chills and arthralgia (> 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.
- For complete information on the safety of COMIRNATY® always make reference to the approved Summary of Product Characteristics and Package Leaflet available in all the languages of the European Union on the EMA website.

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, telephone +49 6131 9084 0, or our website https://medicalinformation.biontech.de/

Safety Information

AUTHORIZED USE IN THE U.S.

COMIRNATY® (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine 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. It is also authorized under EUA to provide a 2-dose primary series to individuals 5 years of age and older, a third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise, a single booster dose to individuals 16 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY®, a single booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized COVID-19 vaccine. The booster schedule is based on the labeling information of the vaccine used for the primary series.

IMPORTANT SAFETY INFORMATION

Individuals should not get the vaccine if they:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

Individuals should tell the vaccination provider about all of their medical conditions, including if they:

- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects the immune system
- are pregnant, plan to become pregnant, or are breastfeeding
- have received another COVID-19 vaccine
- have ever fainted in association with an injection

The vaccine may not protect everyone. Side effects reported with the vaccine include:

- There is a remote chance that the vaccine could cause a severe allergic reaction
  - A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the vaccine. For this reason, vaccination providers may ask individuals to stay at the place where they received the vaccine for monitoring after vaccination
  - Signs of a severe allergic reaction can include difficulty breathing, swelling of the face and throat, a fast heartbeat, a bad rash all over the body, dizziness, and weakness
  - If an individual experiences a severe allergic reaction, they should call 9-1-1 or go to the nearest hospital
- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of the vaccine. The chance of having this occur is very low. Individuals should seek medical attention right away if they have any of the following symptoms after receiving the vaccine:
  - chest pain
  - shortness of breath
  - feelings of having a fast-beating, fluttering, or pounding heart
- Additional side effects that have been reported with the vaccine include:
  - severe allergic reactions; non-severe allergic reactions such as rash, itching, hives, or swelling of the face; myocarditis (inflammation of the heart muscle); pericarditis (inflammation of the lining outside the heart); injection site pain; tiredness; headache; muscle pain; chills; joint pain; fever; injection site swelling; injection site redness; nausea; feeling unwell; swollen lymph nodes (lymphadenopathy); decreased appetite; diarrhea; vomiting; arm pain; fainting in association with injection of the vaccine
- These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials. Call the vaccination provider or healthcare provider about bothersome side effects or side effects that do not go away

Data on administration of this vaccine at the same time as other vaccines have not yet been submitted to FDA. Individuals considering receiving this vaccine with other vaccines, should discuss their options with their healthcare provider. Patients should always ask their healthcare providers for medical advice about adverse events. Individuals are encouraged to report negative side effects of vaccines to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Visit https://www.vaers.hhs.gov or call 1-800-822-7967. In addition, side effects can be reported to Pfizer Inc. at www.pfizersafetyreporting.com or by calling 1-800-438-1985.

Our Vision

Harnessing the power of the immune system to fight human diseases

BioNTech 2021 Highlights | A Year of Historic Impact

- First ever approved mRNA therapy[1]
- Fastest pharma product development and launch
- ~ 2.6 bn doses shipped[2, 3]
- ~ 1 bn to low- and middle-income countries[2]
- > 1 bn individuals vaccinated[4]
- > 160 countries / regions reached

Millions of cases of severe illness or death likely averted[4]

Trillions of dollars of global economic impact[5]

[1]Approved for emergency use/temporary supply or Conditional Marketing Authorization in more than 90 countries worldwide including the U.S. and EU, December 2021
[2]As of mid December 2021 3. Manufactured approximately 3 bn doses in 2021 4. Efficacy against symptomatic infection, Polack FP, et al. NEJM 2020, 383:2603-2615;
[4]Eric C. Schneider et al., The U.S. COVID-19 Vaccination Program at One Year: How Many Deaths and Hospitalizations Were Averted? (Commonwealth Fund, December 2021); European Centre for Disease Prevention and Control; [5]Statista

Pfizer BIONTECH

BioNTech 2021 Highlights (cont.) | A Year of Historic Impact

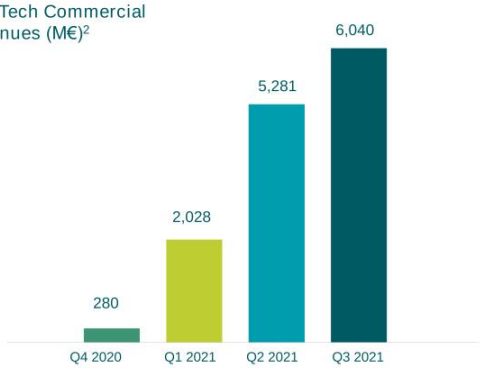
Pipeline expansion	9 oncology clinical trial starts, including 4 Phase 2 trials and 5 FIH studies
R&D expansion	Increased R&D team by >40% to more than 850 professionals
Global presence	Acquired and integrated new site in Gaithersburg, US; Established offices in Singapore, China and Turkey
Production capacity	Commercial scale mRNA production and addition of US cell therapy manufacturing facility
Commercial infrastructure	Deployed commercial team in Germany

FIH, first-in-human

Strong Financial Performance

Historic Chance to Accelerate our Vision Through Reinvestment in the Company

BioNTech Commercial Revenues (M€)[2]



Enabled by early scale up of production capacity:
~3 bn doses manufactured in 2021

Estimated COMIRNATY market share
74% in U.S. and 80% in Europe[1]

Outlook for COVID-19 vaccine revenues booked by BioNTech

FY 2021 guidance: **€16**-17 bn

FY 2022 estimate: **€13**-17 bn

[1]As of December 2021;
[2]Represents an estimated figure based on preliminary data shared between Pfizer and BioNTech. Changes in share of the collaboration partner's gross profit will be recognized prospectively. Graphic is for illustration only

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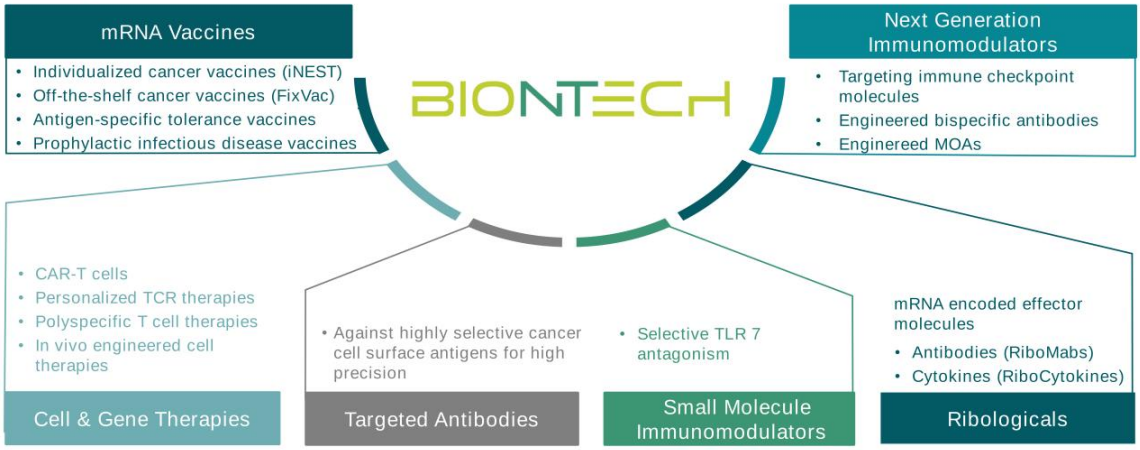
BioNTech Today | A 21st Century Immunotherapy Powerhouse

BIONTECH


MULTI-PLATFORM
STRATEGY
10
BIONTECH

Multi-Platform Strategy | Technology Agnostic Innovation Engine

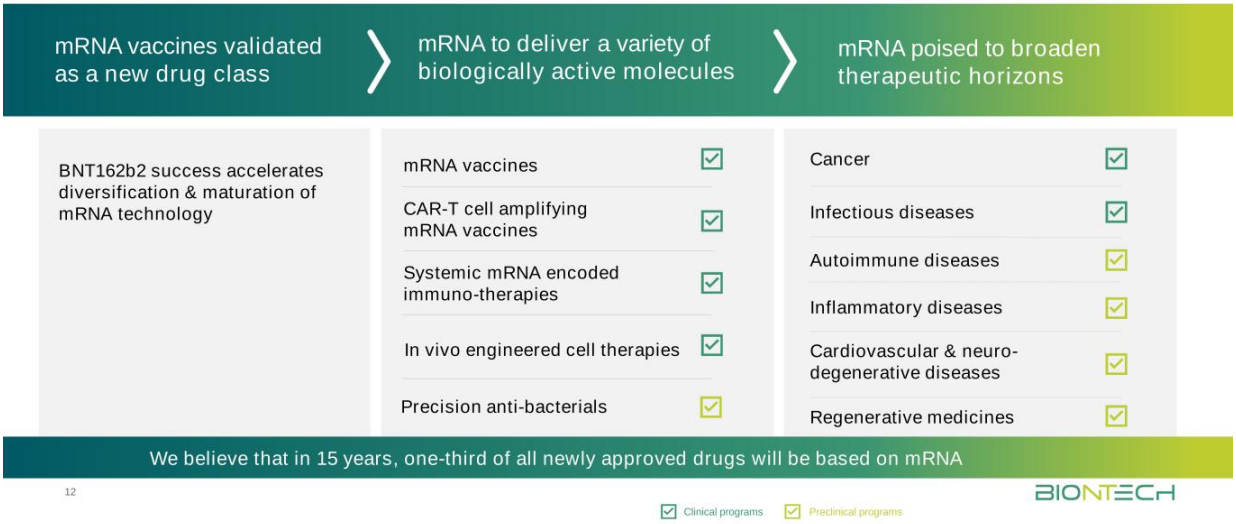


Multiple product classes with unique combination potential

MOA, mechanism of action

Entering a New Era of mRNA Technology & Synthetic Biology

Impact poised to be comparable to introduction of recombinant technology



Clinical programs Preclinical programs

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DIVERSIFIED PRODUCT PIPELINE

Significant Pipeline Expansion and Maturation in 2022

GOALS

Global Leadership → **Near- and Mid-term Growth Drivers** → **Long-term Growth Drivers**

COVID-19 Vaccine[1]	Immuno-Oncology	Infectious Diseases	New Areas
Multiple new product launches	5 randomized phase 2 trials	5 mRNA vaccines in human trials	Multiple programs in lead candidate selection
Label expansions Pediatric dosage forms Variant adaptations	FixVac – 1L Melanoma ☑ FixVac – HPV16+ Cancers ☑ iNeST[2] – 1L Melanoma ☑ iNeST[2] – Adjuvant CRC ☑ Bispecific AB PD-L1x4-1BB[3] ☑	Influenza[1] ☑ Shingles[1] Malaria Tuberculosis[4] HSV 2	Cardiovascular diseases Neurodegenerative diseases Autoimmune diseases

[1]Partnered with Pfizer; [2]Partnered with Genentech; [3]Partnered with Genmab in a 50/50 collaboration; [4] Partnered with BMGF

☑ Phase 1 ongoing ☑ Phase 2 ongoing

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BNT162b2 Poised for Continued Global Impact in 2022

Up to 4B doses manufacturing capacity in 2022

Ensuring equitable access	• 2 bn doses pledged to low- and middle-income countries through end of 2022
Doses for the unvaccinated	• >3 billion people globally not yet vaccinated[1]
Adolescent / pediatric doses	• > 25% of global population ages 0-14[2] • First vaccine to launch for children 6 mths – 5 yrs of age pending marketing authorization
3rd Booster	• > 600 m people already boosted[3] • Booster vaccination vital to mitigate impact of Omicron[4]
Variant-specific vaccine	• Omicron variant-specific vaccine approach could be ready as early as March 2022, subject to regulatory approval • Rapid vaccine adaption process for future variants, if needed

[1]WHO & United Nations; [2]The World Bank; [3]Our World in Data;
[4]BioNTech Press Conference, December 8, 2021, slide 9; https://investors.biontech.de/static-files/47b4131a-0545-4a0b-a353-49b3a1d01789.

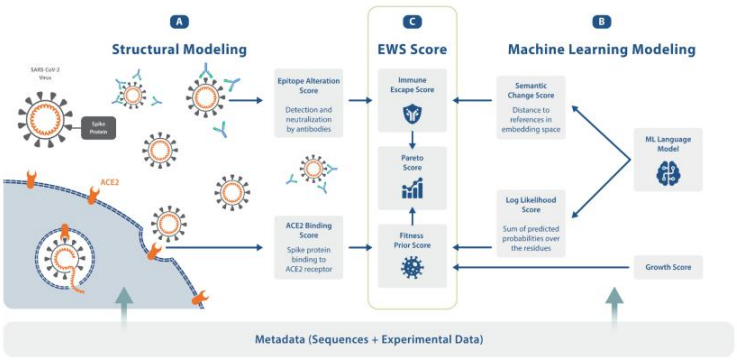
COVID-19: The long road to an endemic disease

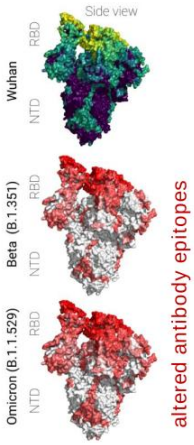
Continued need for regular booster vaccinations and pediatric vaccinations

[1] Canadian Paediatric Society; [2] Destin Groff et al. JAMA Network.2021 https://jamanetwork.com/searchresults?author=Anna+E.+Ssentongo&q=Anna+E.+Ssentongo

Early Computational Detection of High Risk SARS-CoV-2 Variants*

Early Warning System (EWS) combines Spike protein structural modeling with artificial intelligence (AI) to detect and monitor high risk SARS-CoV-2 variants





EWS identifies and scores >90% of new variants on average two months prior to their official designation by WHO

*Artificial intelligence Collaboration of BioNTech and InstaDeep https://www.biorxiv.org/content/10.1101/2021.12.24.474095v1

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Infectious Disease Product Strategy Rooted in Global Social Responsibility

Advancing programs to combat major health burdens

mRNA-based vaccines and therapeutics

Malaria: 229 million cases and 409,000 deaths annually[1]

Tuberculosis*: 10 million people contracted TB in 2019[2]

HIV*: 37.7 million people living with HIV, two-thirds in WHO African region[3]

Democratizing global access to mRNA medicines

Ensuring equitable COVID-19 vaccine access to LMICs[4]

Expanding COVID-19 manufacturing network to Africa and South America

Construction of state-of-the-art mRNA manufacturing sites in Africa and Asia in mid-2022 to establish sustainable local supply

mRNA Vaccines | Ribologicals | Synthetic Lysins

[1] World Health Organization https://www.who.int/news-room/fact-sheets/detail/malaria
[2] World Health Oganization https://www.who.int/news-room/fact-sheets/detail/tuberculosis
[3] World Health Organization https://www.who.int/data/gho/data/themes/hiv-aids
[4] Low- and low-middle income countries

* Collaboration with Bill & Melinda Gates Foundation.

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5 mRNA Vaccines in Human Trials in 2022

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3 mRNA vaccines partnered w/Pfizer

10+ other infectious disease programs

[1] Collaboration with Bill & Melinda Gates Foundation. BioNTech holds worldwide distribution rights except developing countries where BMG holds distribution rights;
[2] University of Pennsylvania collaboration

Expected Phase 1 trial initiation in 2022

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Oncology Pipeline Expected to Significantly Expand

Drug class	Platform	Product candidate	Indication (targets)	Pre-clinical	Phase 1	Phase 2	Phase 3	Partner
mRNA	FixVac* (fixed combination of shared cancer antigens)	BNT111	Advanced melanoma (Adjuvant & Metastatic)					
		BNT112	Prostate cancer					
		BNT113	HPV16+ head and neck cancer					
		BNT115[1]	Ovarian cancer[1]					
		BNT116	NSCLC					
	iNeST (patient specific cancer antigen therapy)	Autogene cevumeran (BNT122)	1L melanoma					Genentech
			Adjuvant colorectal cancer					
			Solid tumors					
	Intratumoral Immunotherapy	SAR441000 (BNT131)	Solid tumors (IL-12sc, IL15-sushi, GM-CSF, IFNα)					Sanofi
	RiboMabs* (mRNA-encoded antibodies)	BNT141	Multiple solid tumors (CLDN18.2)					
		BNT142	Multiple solid tumors (CD3+CLDN6)					
	RiboCytokines* (mRNA-encoded cytokines)	BNT151	Multiple solid tumors (optimized IL-2)					
		BNT152, BNT153	Multiple solid tumors (IL-7, IL-2)					
Cell Therapies	CAR-T Cells*	BNT211	Multiple solid tumors (CLDN6)					
		BNT212	Pancreatic, other cancers (CLDN18.2)					
	Neoantigen-based T cell therapy*	BNT221 (NEO-PTC-01)	Multiple solid tumors					
	TCRs*	To be selected	All tumors					
Antibodies	Next-Gen CP Immunomodulators	GEN1046 (BNT311)	Multiple solid tumors (PD-L1x4-1BB)					Genmab
		GEN1042 (BNT312)	Multiple solid tumors (CD40x4-1BB)					
	Targeted Cancer Antibodies	BNT321 (MVT-5873)	Pancreatic cancer (sLea)					
SMIM	Toll-Like Receptor Binding	BNT411	Solid tumors (TLR7)					

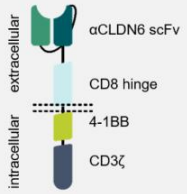
[1] investigator-initiated Phase 1 trial; CP: Checkpoint inhibitor; SMIM, Small molecule immunomodulators;
* Fully-owned rights

BNT211: Phase 1/2 Trial Evaluating Next Generation CAR-T Targeting Claudin-6 with CARVac in Solid Tumors

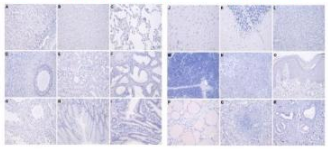
CAR-T cell therapy + RNA Vaccine to amplify CAR-T cell (CARVac) in vivo

- 2nd generation CAR directed against CLDN6, a cancer specific carcino-embryonic antigen
- CLDN6 is expressed in multiple solid cancers with high medical need
- CARVac drives in vivo expansion, persistence and efficacy of CAR-T

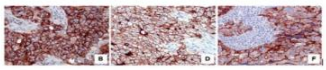
BNT211 CAR Structure



CLDN6 not present in healthy tissues



CLDN6 expressed in multiple cancers

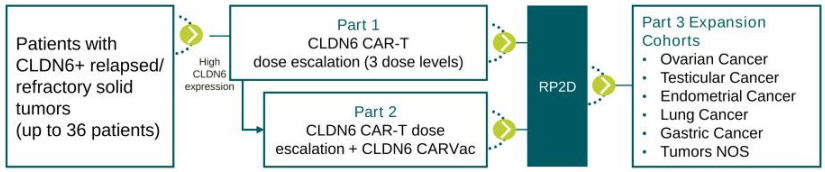


CANCER IMMUNOTHERAPY

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

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

Science



CLDN6, Claudin-6; CAR-T cells, chimeric antigen receptor engineered T cells; scFv, single chain variable fragment; RP2D, recommended Phase 2 dose; NOS, not otherwise specified; Reinhard K, et al. Science 2020; 367:446-453

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ESMO-IO 2021/BNT211 Phase 1/2: CAR-T Engraftment and Tolerable Safety Profile with CLDN6 CAR-T without (Part 1) and with (Part 2) CARVac

Cohort/Patient Characteristics	Part 1 DL1 (n=3)	Part 2 DL1 (n=3)	Part 1 DL2 (n=6)	Part 2 DL2 w/ LD (n=2)	Part 2 DL2 w/o LD (n=1)	All patients (n=15)
Median (range) age, years	33 (25-68)	41 (27-56)	56 (35-66)	53.5 (46-61)	56	54 (25-68)
Cancer type, n						
Testicular	1	3	2	0	1	7
Ovarian	1	0	1	2	0	4
Endometrial	0	0	1	0	0	1
Fallopian tube	0	0	1	0	0	1
Sarcoma	1	0	0	0	0	1
Gastric	0	0	1	0	0	1
Median (range) CLDN6 II/III^{+} cells, %	60 (60-80)	90 (90-95)	82.5 (50-90)	95 (90-100)	85	85 (50-100)
Median (range) of prior treatment lines	4 (3-5)	4 (3-4)	5 (2-11)	6 (5-7)	4	4 (2-11)

Safety

- CLDN6 CAR-T cells alone or combined with CARVac well tolerated at the dose levels evaluated to date with only 1 DLT observed
- CRS was seen in 1 patient at DL1 + CARVac and 6 patients at DL2, and was manageable by administration of tocilizumab

Efficacy

- Robust engraftment of CAR-T cells resulting in a total amount of around 10^9 achieved in most patients and seems predictive for clinical activity
- 9 of 10 patients evaluable for efficacy assessment showed initial disease control including 4 PRs (3 in testicular cancer patients with recent relapse after HDCT/ASCT)

Data cutoff = NOV 18, 2021; CRS, cytokine release syndrome; DL, dose level; DLT, dose-limiting toxicity;
Haanen J., et al. Oral presentation at the ESMO Immuno-Oncology Congress, December 08–14, 2021;
Haanen J. et al. Anals fo Concology (2021) 32 (suppl._7): S1392-S1397

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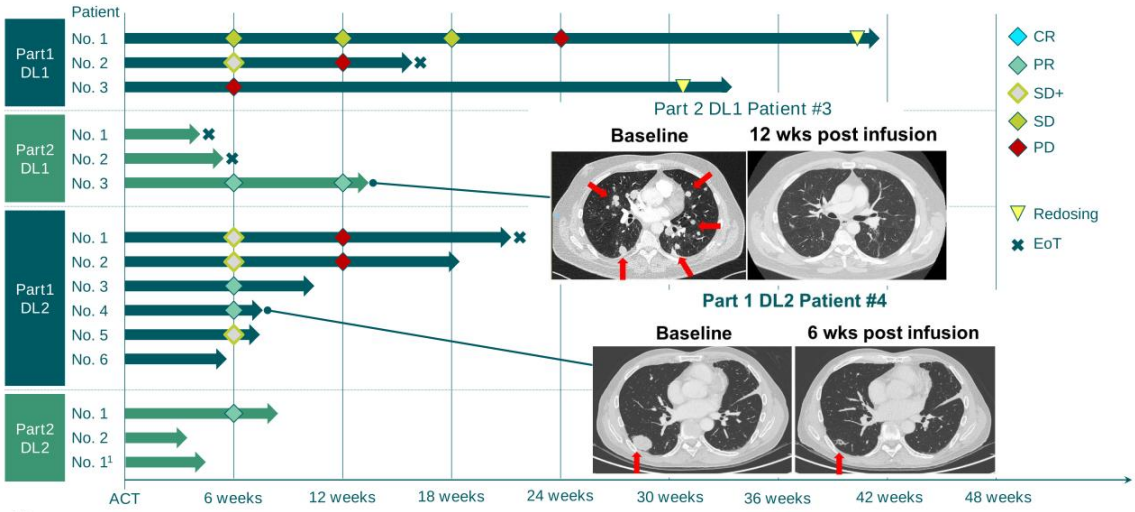
BNT211 Phase 1/2: First Indications of Clinical Activity - 4 PR, 4 SD+, 1 SD at 6 Weeks Post Infusion (ORR 4/10, DCR 9/10)

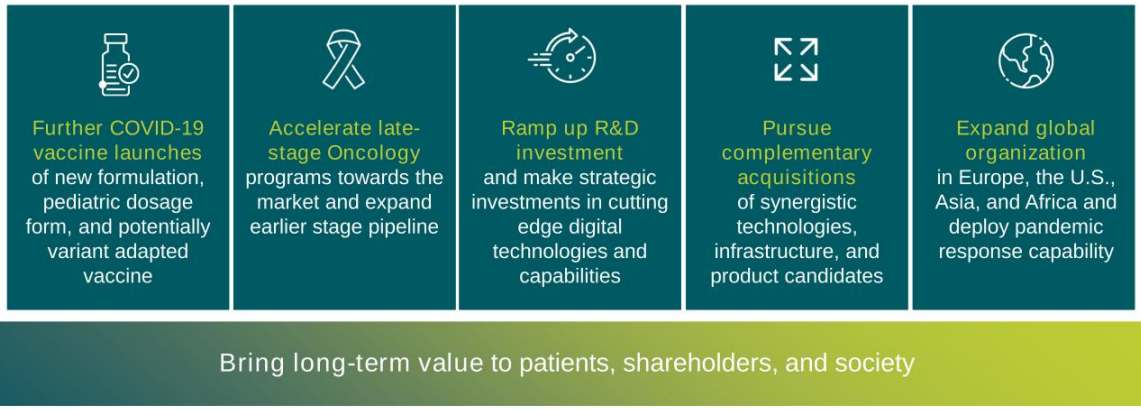


Data cutoff = NOV 18, 2021. Haanen J., et al. Oral presentation at the ESMO Immuno-Oncology Congress, December 08–14, 2021; Haanen J. et al., Anals fo Concology (2021) 32 (suppl._7): S1392-S1397
ASCT, autologous stem cell transplantation; DCR, disease control rate; EoT, end of trial (due to PD); HDCT, high-dose chemotherapy; ORR, overall response rate; PD, progressive disease; PR, partial response; SD, stable disease, SD+, SD with shrinkage of target lesions; wks, weeks; ¹w/o lymphodepletion.

OUTLOOK
2022 AND BEYOND

Outlook 2022 and Beyond

Once in a generation opportunity to transform medicine



Bring long-term value to patients, shareholders, and society

THANK
YOU

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