

**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 2023

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 10, 2023, BioNTech SE (the "Company") CEO and co-founder Ugur Sahin presented at the JP Morgan Healthcare Conference 2023. 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 10, 2023

EXHIBIT INDEX

Exhibit

Description of Exhibit

99.1

[BioNTech Presents at JP Morgan Healthcare Conference 2023](#)

A microscopic image of a cell cluster, likely a tumor or a large cell aggregate, rendered in a light green color against a dark teal background. The cell cluster is composed of numerous individual cells with visible nuclei and cytoplasm, some showing long, thin processes extending outwards.

BIONTECH

**J.P. Morgan
Healthcare Conference**

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

January 10, 2023

Forward-Looking Statements and Disclaimer

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 future commercial demand and medical need for initial or booster doses of a COVID-19 vaccine; 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 initiation, timing, progress, results, and cost of BioNTech's research and development programs, including those relating to additional formulations of BioNTech's COVID-19 vaccine, 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 of BioNTech's COVID-19 vaccine to prevent COVID-19 caused by emerging virus variants; BioNTech's and its counterparties' ability to manage and source necessary energy resources; BioNTech's ability to identify research opportunities and discover and develop investigational medicines; 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 potential personal injury or death arising from the use of BioNTech's COVID-19 vaccine and other products and product candidates developed or manufactured by BioNTech; 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 development of sustainable vaccine production and supply solutions on the African continent, including its BioNTainers, 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, and 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. Furthermore, certain statements contained in this presentation relate to or are based on studies, publications, surveys and other data obtained from third-party sources and BioNTech's own internal estimates and research. While BioNTech believes these third-party sources to be reliable as of the date of this presentation, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, any market data included in this presentation involves assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. While BioNTech believes its own internal research is reliable, such research has not been verified by any independent source. In addition, BioNTech is the owner of various trademarks, trade names and service marks that may appear in this presentation. Certain other trademarks, trade names and service marks appearing in this presentation are the property of third parties. Solely for convenience, the trademarks and trade names in this presentation may be referred to without the ® and TM symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. 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 on Form 6-K for the three and nine months ended September 30, 2022 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 forward-looking statements contained in this presentation 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

COMIRNATY® (the Pfizer-BioNTech COVID-19 vaccine) has been granted standard marketing authorization (MA) by the European Commission to prevent coronavirus disease 2019 (COVID-19) in people aged 6 months and older. The vaccine is administered as a 2-dose series 3 weeks apart, in people aged 5 years and older, or as a 3-dose series 3 and 8 weeks apart in children aged 6 months to 4 years. Adults and adolescents from the age of 12 are given 30 micrograms per dose; children aged 5 to 11 years are given 10 micrograms per dose; infants and children aged 6 months to 4 years are given 3 micrograms per dose. In addition, the MA has been expanded to include a booster dose (third dose) at least 3 months after the second dose in individuals 5 years of age and older. A third primary course dose may be administered at least 28 days after the second dose to people aged 5 years and older with a severely weakened immune system. The European Medicines Agency's (EMA's) Committee for Medicinal Products for Human Use (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.

In addition, COMIRNATY has also been granted standard MA for two adapted vaccines: COMIRNATY Original/Omicron BA.1, which contains mRNA encoding for the spike protein of the wild-type and of the Omicron BA.1 subvariant of SARS-CoV-2; and COMIRNATY Original/Omicron BA.4-5, which contains mRNA encoding for the spike protein of the wild-type and of the Omicron BA.4/BA.5 subvariant of SARS-CoV-2. COMIRNATY Original/Omicron BA.1 may be administered as a booster in people aged 12 years and older and COMIRNATY Original/Omicron BA.4-5 may be administered as a booster in people aged 5 years and older who have received at least a primary vaccination course against COVID-19. There should be an interval of at least 3 months between administration of COMIRNATY Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 and the last prior dose of a COVID-19 vaccine.

IMPORTANT SAFETY INFORMATION:

• 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. Close observation for at least 15 minutes is recommended following vaccination. No further dose of the vaccine should be given to those who have experienced anaphylaxis after a prior dose of Comirnaty.

• There is an increased, but very rare risk (<1/100,000 cases) 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. Available data suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis or pericarditis in general.

• Rare cases of acute peripheral facial paralysis, uncommon incidence of insomnia, hyperhidrosis and night sweats, and unknown incidence of paresthesia, hypoaesthesia and erythema multiforme have been identified in post-marketing experience.

• 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. Stress-related reactions are temporary and resolve on their own. Individuals should be advised to bring symptoms to the attention of the vaccination provider for evaluation. 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, COMIRNATY Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 may be lower in immunosuppressed individuals.

• As with any vaccine, vaccination with COMIRNATY, COMIRNATY Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 may not protect all vaccine recipients. Individuals may not be fully protected until 7 days after their second dose of the vaccine.

• Adverse reactions observed during clinical studies are listed below according to the following frequency categories: Very common (≥ 1/10), Common (≥ 1/100 to < 1/10), Uncommon (≥ 1/1,000 to < 1/100), Rare (≥ 1/10,000 to < 1/1,000), Very rare (< 1/10,000), Not known.

• Very common side effects: injection site pain, injection site swelling, tiredness, headache, muscle pain, chills, joint pain, diarrhea, fever

• Common side effects: injection site redness, nausea, vomiting

• Uncommon side effects: enlarged lymph nodes (more frequently observed after the booster dose), feeling unwell, arm pain, insomnia, injection site itching, allergic reactions such as rash or itching, feeling weak or lack of energy/sleepy, decreased appetite, excessive sweating, night sweats

• Rare side effects: temporary one-sided facial drooping, allergic reactions such as hives or swelling of the face

• Very rare side effects: inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis), which can result in breathlessness, palpitations or chest pain.

• Not known side effects (cannot be estimated): anaphylaxis, extensive swelling of vaccinated limbs, facial swelling, pins and needles/tingling, reduced sense of touch or sensation, a skin reaction that causes red spots or patches on the skin, heavy menstrual bleeding.

• A large amount of observational data from pregnant women vaccinated with the initially approved COMIRNATY vaccine during the second and third trimester have not shown an increase in adverse pregnancy outcomes. While data on pregnancy outcomes following vaccination during the first trimester are presently limited, no increased risk for miscarriage has been seen. COMIRNATY can be used during pregnancy. No effects on the breast-fed newborn/infant are anticipated since the systemic exposure of breast-feeding women to the initially approved COMIRNATY vaccine is negligible. Observational data from women who were breast-feeding after vaccination have not shown a risk for adverse effects in breast-fed newborn/infants. COMIRNATY can be used during breast-feeding.

• No data are available yet regarding the use of COMIRNATY Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 during pregnancy. Since differences between products are confined to the spike protein sequence, and there are no clinically meaningful differences in reactivity between those COMIRNATY variant adapted vaccines that have been clinically evaluated, COMIRNATY Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 can be used during pregnancy.

• No data are available yet regarding the use of COMIRNATY Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 during breast-feeding. Observational data from women who were breast-feeding after vaccination with the initially approved COMIRNATY vaccine have not shown a risk for adverse effects in breast-fed newborn/infants. COMIRNATY Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 can be used during breast-feeding.

• Interactions with other medicinal products or concurrent administration of COMIRNATY, COMIRNATY Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 with other vaccines has not been studied.

• Animal studies with COMIRNATY Original do not indicate direct or indirect harmful effects with respect to reproductive toxicity.

• The safety of a COMIRNATY Original/Omicron BA.1 booster dose in individuals from 18 to 55 years of age is extrapolated from safety data from a subset of 315 adults 18 to 55 years of age who received a booster (fourth dose) of Omicron BA.1 30 µg (monovalent) after completing 3 doses of COMIRNATY. The most frequent adverse reactions in these participants 18 to 55 years of age were injection site pain (> 70%), fatigue (> 60%), headache (> 40%), myalgia (> 30%), chills (> 30%) and arthralgia (> 20%).

• In a subset from the Phase 3 study, 305 adults > 55 years of age who had completed 3 doses of COMIRNATY, received a booster of COMIRNATY Original/Omicron BA.1 after receiving Dose 3. The overall safety profile for the COMIRNATY Original/Omicron BA.1 booster (fourth dose) was similar to that seen after the COMIRNATY booster (third dose). The most frequent adverse reactions in participants greater than 55 years of age were injection site pain (> 50%), fatigue (> 40%), headache (> 30%), myalgia (> 20%), chills and arthralgia (> 10%). No new adverse reactions were identified for COMIRNATY Original/Omicron BA.1.

• The safety of a booster dose of COMIRNATY Original/Omicron BA.4-5 is inferred from safety data for a booster dose of COMIRNATY Original/Omicron BA.1, as well as for a booster dose of COMIRNATY Original in individuals 18 years of age and older, as well as for a booster dose of the initially approved Comirnaty vaccine in individuals 5 years of age and older. The safety and efficacy of Comirnaty Original/Omicron BA.1 and Comirnaty Original/Omicron BA.4-5 in children aged less than 12 years of age have not yet been established. No data are available.

• 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 Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 may not protect all vaccine recipients.

• The safety and efficacy of Comirnaty in infants aged less than 6 months have not yet been established.

• For complete information on the safety of COMIRNATY, COMIRNATY Original/Omicron BA.1 and COMIRNATY Original/Omicron BA.4-5, 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. Individuals can help by reporting any side effects they may get. Side effects can be reported to EUra@vaccine.eu or directly to BioNTech using ema.medinfo@biotech.eu, telephone +49 6131 9084 0, or via the website www.biotech.de.

Safety Information

AUTHORIZED USE IN THE U.S.

Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)

- Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) is FDA-authorized under Emergency Use Authorization (EUA) for use in individuals 5 years of age and older as a single booster dose administered at least 2 months after either:
 - completion of primary vaccination with any authorized or approved monovalent COVID-19 vaccine; or
 - receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.
- *Monovalent refers to any authorized and approved COVID-19 vaccine that contains or encodes the spike protein of only the Original SARS-CoV-2 virus.

COMIRNATY® (COVID-19 Vaccine, mRNA)

- 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 12 yrs of age and older. It is also authorized as a third primary series dose to individuals 12 years of age and older who have certain kinds of immunocompromise
- The COVID-19 vaccine is FDA authorized under Emergency Use Authorization (EUA) for use in individuals 6 months and older to provide:
 - a 3-dose primary series to individuals 6 months through 4 years of age
 - a 2-dose primary series to individuals 5 years and older
 - a third primary series dose to individuals 5 years and older with certain kinds of immunocompromise

EMERGENCY USE AUTHORIZATION

Emergency uses of the vaccines have not been approved or licensed by FDA but have been authorized by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) in individuals aged 6 months and older for the Pfizer-BioNTech COVID-19 Vaccine and 5 years and older for the Pfizer-BioNTech COVID-19 Vaccine, Bivalent. The emergency uses are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 364(b)(1) of the FDCA Act unless the declaration is terminated or authorization is revoked sooner.

IMPORTANT SAFETY INFORMATION

Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), COMIRNATY® (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 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

- Individuals should not get COMIRNATY® (COVID-19 Vaccine, mRNA), the Pfizer-BioNTech COVID-19 Vaccine, or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent if they have had a severe allergic reaction after a previous dose of COMIRNATY® or the Pfizer-BioNTech COVID-19 Vaccine or any ingredient in these vaccines

There is a remote chance that these vaccines could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to 1 hour after getting a dose of the vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received the vaccine for monitoring after vaccination. If you experience a severe allergic reaction, call 9-1-1 or go to the nearest hospital.

The vaccine may not protect everyone. Side effects 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; Unusual and persistent irritability; Unusual and persistent poor feeding; Unusual and persistent fatigue or lack of energy; Unusual and persistent cool, pale skin
- Individuals should seek medical attention right away if they have any of the following symptoms: difficulty breathing, swelling of the face and throat, a fast heartbeat, a bad rash all over the body, dizziness, and weakness
- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received COMIRNATY® (COVID-19 Vaccine, mRNA) or Pfizer-BioNTech COVID-19 Vaccine. The observed risk is higher among adolescent males and adult males under 40 years of age than among females and older males, and the observed risk is highest in males 12 through 17 years of age. In most of these people, symptoms began within a few days following receipt of the second dose of vaccine. The chance of having this occur is very low
- These may not be all the possible side effects of the vaccine. Call the vaccination provider or healthcare provider about bothersome side effects or side effects that do not go away.

Individuals should always ask their healthcare providers for medical advice about adverse events. Report vaccine side effects to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-622-7967 or report online to www.vaers.hhs.gov/reportevent.html. In addition, individuals can report side effects to Pfizer Inc. at www.pfizerusa11reporting.com or by calling 1-800-438-1985



Our Vision

Harnessing the power of the immune
system to fight human diseases

BIONTECH

2022 Translating Vision
Highlights into Strong Performance

Commercial & Market Leadership
with COVID-19 Franchise¹

Scientific & Clinical Execution

Corporate Execution

¹ Partnered with Pfizer



2022 Highlights

Translating Vision into Strong Performance

Commercial & Market Leadership with COVID-19 Franchise¹



¹ Partnered with Pfizer
² As of Dec. 16, 2022
³ Pfizer/BioNTech cumulative global COVID-19 market share across reporting countries; CDC, ECDC, OIWD data as of Nov 2022.

~550 million doses
of variant-adapted vaccine²
shipped

~2 billion doses
invoiced in 2022

>60%
market share³

Broadest label
amongst COVID-19
vaccines

2022 Highlights

Translating Vision into Strong Performance

Scientific & Clinical Execution



¹ Partnered with Genmab
² Partnered with Pfizer

³ Partnered with University of Pennsylvania

Clinical POC across multiple modalities:

BNT211 **first cell therapy** for solid tumors

BNT312¹ next-gen **checkpoint immunomodulator**

4 new programs first in human:

BNT116 FixVac in NSCLC

BNT141 Ribomab CLDN18.2

BNT313 Hexabody CD27¹

BNT142 Ribomab CD3xCLDN6

Initiated

3 COVID-19 vaccine trials

3 Phase 1 trials for mRNA vaccines, including new pathogen antigens first-in-human:

Flu+COVID-19²

HSV2³

Malaria

Immuno-oncology

Infectious Disease

2022 Highlights

Translating Vision into Strong Performance

Corporate Execution



¹ As of Oct. 15, 2022

Rapid deployment
~2 months
from regulator
recommendations to
vaccine delivery

Expanded
partnerships
4 new collaborations
accessing a variety
of technologies

Broadened pipeline
22 programs in
26 ongoing trials

Grew team
>1,500
new employees

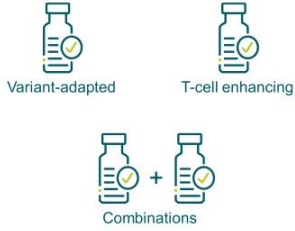
Strong financials
€16.6 bn cash +
€4.1 bn trade receivables¹

BIONTECH ⁹

2023 Strategic Priorities

COVID-19 franchise¹

Sustain leadership in COVID-19
Advance next-gen vaccines



COMIRNATY
COVID-19 mRNA Vaccine

¹ Partnered with Pfizer

² Partnered with Genentech

³ Partnered with Genmab

⁴ Out-licensed to Pfizer

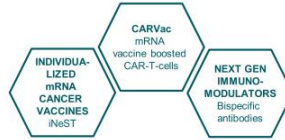
⁵ Partnered with University of Pennsylvania

⁶ Collaboration with BMGF

Immuno-oncology

Advance disruptive platforms
for solid tumors

Initiate multiple potentially
registrational trials



Most advanced programs:

BNT122²
1L Melanoma
& adj. CRC

BNT211
CLDN6+
tumors

BNT311³
BNT312³
Solid tumors

Infectious diseases

Initiate and accelerate clinical programs
for high need indications

Ongoing clinical trials:



Programs advancing to clinic:



Global Powerhouse Built on People, Presence and Strategic Collaborations

>4,500 professionals globally¹

>1,500 new hires in 2022

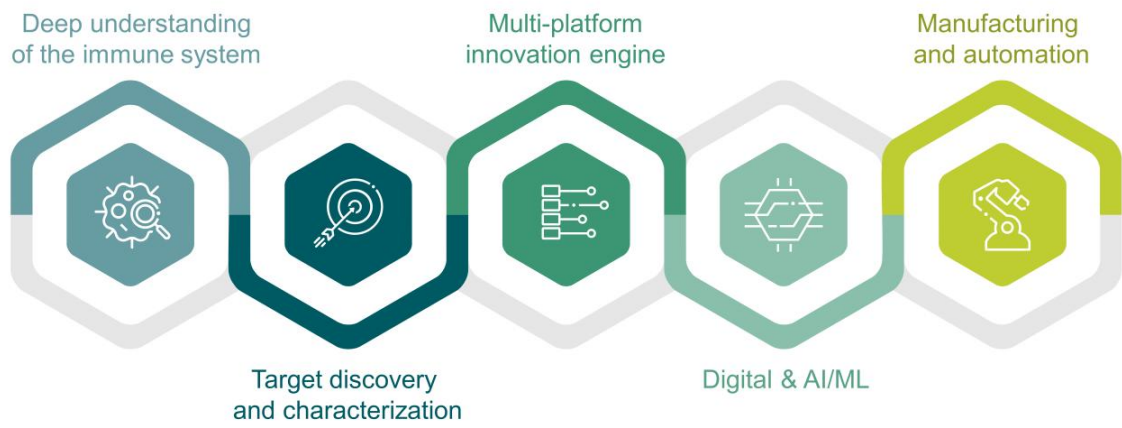
>80 different nationalities

36 average age

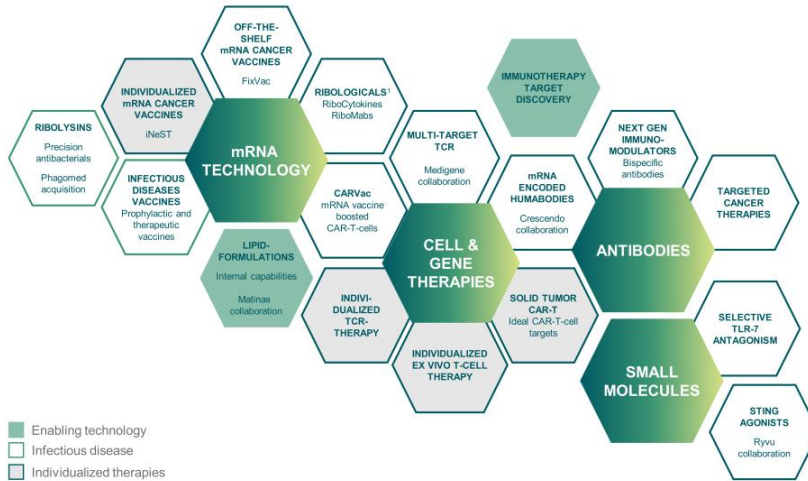
>50 % are female



Focused on Five Innovation Pillars



Our Disruptive Technology Toolkit to Fight Human Diseases



¹ mRNA encoded cancer-targeting antibodies and cytokines

Core principles of our technology strategy

Technology agnostic approach rooted in deep fundamental understanding of biology

Build novel platforms with the ability to produce multiple product candidates

Open up new combination opportunities which leverage synergistic mechanisms of action

Enable individualization of treatment

BIONTECH 13

Uniquely Positioned to Individualize Cancer Medicine

Integrated model for immuno-oncology to transform R&D and patient care at scale



AI & Digitally-integrated target & drug discovery and development



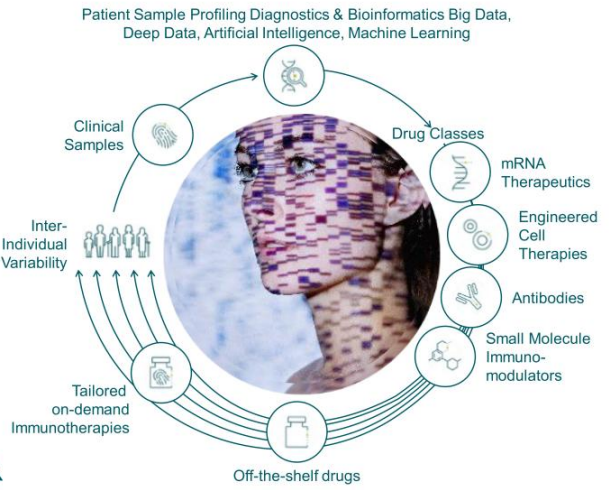
Individualized treatment platforms to address inter-individual variability



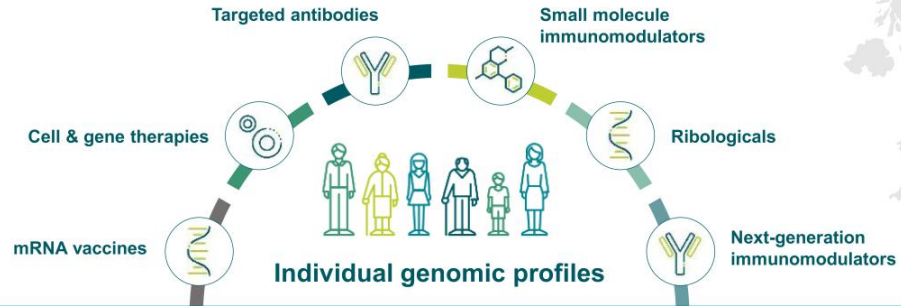
Deep genomics & immunology expertise to leverage patient data



Automated manufacturing to serve patients on time and globally



Landmark UK Collaboration to Implement Personalized Medicine: Moving Immune Therapy Development Closer to the Point of Care



Individualized immunotherapy is poised to disrupt cancer care and requires integrated, health-system-wide collaboration

Multi-agency collaboration is a new model for personalized treatment implementation

Patient genomic data informs personalized treatments

Goal for accelerated clinical and regulatory pathways

Goal: 10,000 personalized therapies to reach patients by 2030

BioNTech Innovation is Data and AI Driven



Deep understanding of the immune system: Understanding and exploiting immunological mechanisms through Data Science and ML since early days, including TRON collaboration since 2010

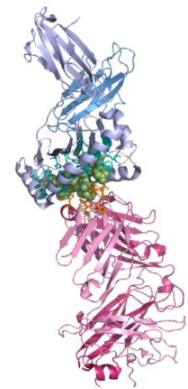
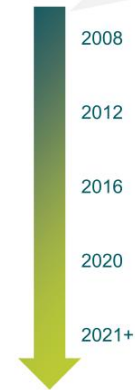
Target discovery and characterization: Exploiting the mutanome for personalized mRNA vaccines. ML drives neoantigen selection and IG prediction algorithms since 2017. Neon Therapeutics acquisition with high quality MS data

Multi-platform innovation engine: Applying AI to support the design of RiboCytokines and RiboMabs. TCR modeling for cell & gene therapies

Digital & AI/ML: Strategic collaboration with InstaDeep since 2020. COVID-19 Early Warning System, AI Immune response detection (ELISPOT) and gene synthesis

Manufacturing and automation: Towards a vertically integrated, AI-driven Automated Lab combined with InstaDeep's DeepChain™ protein design platform

Pre-BioNTech: Large scale in silico target discovery programs set up by co-founders.



BioNTech uses AI and ML in all its pillars since its creation in 2008

InstaDeep, Leader in Artificial Intelligence

Founded in 2014 with **London HQ** and **offices in Cambridge (U.S.), Paris, Tunis, Lagos, Dubai, and Cape Town**

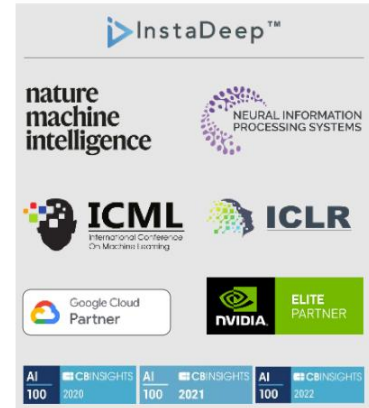
Approx. **240** engineers and tech professionals, including world-class AI & ML researchers. Published in all major ML conferences (**NeurIPS, ICLR, ICML**)

Successful research collaborations with **DeepMind, Google Research, Google Cloud** and **NVIDIA**, plus EMEA ecosystem initiatives

Demonstrated capacity to develop and deploy AI systems at scale in multiple SaaS products (including **DeepChain™**)

Fully owned **Nvidia DGX** supercomputing infrastructure and distributed ML workload management system. **Google Cloud TPU** expertise

On CB Insights' **100 most Innovative AI startups** list for **3 years running**



InstaDeep is focused on productizing disruptive AI innovation

InstaDeep's Planned Acquisition to Accelerate BioNTech's AI-First Strategy

A fruitful, 3 year collaboration with InstaDeep

Improved neoantigen prediction over current BioNTech model

AI-based computer vision system **improved Immune Response evaluation accuracy and speed**

Improved success rate for AI-driven platform DNA/RNA synthesis together with **40x increase in monthly throughput**

DeepChain™ designed **RiboLogicals** validated *in vitro*

DeepChain™ designed **infectious disease vaccine targets**

COVID-19 Early and Future Warning Systems evaluate immune escape from SARS-CoV-2 sequences for improved VOC detection

Transaction Highlights

Upfront cash and BioNTech stock payment of GBP £362 million

Performance-based cash earn-out of up to GBP £200 million within 3 years of transaction close

InstaDeep to become a wholly-owned, London-based BioNTech subsidiary

Closing expected Q1 2023¹

BIONTECH

X

InstaDeep™

Our goal is to integrate AI seamlessly into all aspects of our work

¹ Subject to regulatory approvals and other customary closing conditions.

COVID-19

Long-term leadership
for our COVID-19 vaccine franchise

BIONTECH

First-to-Market BA.4/5-Adapted Bivalent Vaccine Launch: Scientific and Manufacturing Preparation Leads to Rapid Execution

Omicron-adapted vaccine in ~2 months from regulator recommendation to market

FDA Recommended

Omicron-adapted bivalent vaccine encoding BA.4/5 sublineages

June 30

~2 months

First shipments

COMIRNATY BA.4/5-adapted bivalent vaccine

September 1



Approved in **60+** countries and regions¹

Broad label covering ages **6 months+** in U.S.² and **5 years+** in EU³

~550 million doses shipped globally⁴ of BA.4/5-adapted bivalent vaccine



Comprehensive research program and rapid response strategy



Safety database with more than 1.5 billion people treated



Capability to rapidly roll out new vaccines at commercial scale within months



Growing set of commercial relationships and partners around the world



Expanding innovation capabilities in the field of infectious diseases

¹ Including conditional approvals as of December 15, 2022

² Pfizer-BioNTech COVID-19 Vaccine is FDA authorized under 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 aged 6 months and older.

³COMIRNATY has been granted standard marketing authorization (MA) by the European Commission to prevent coronavirus disease 2019 (COVID-19) in people aged 5 years and older

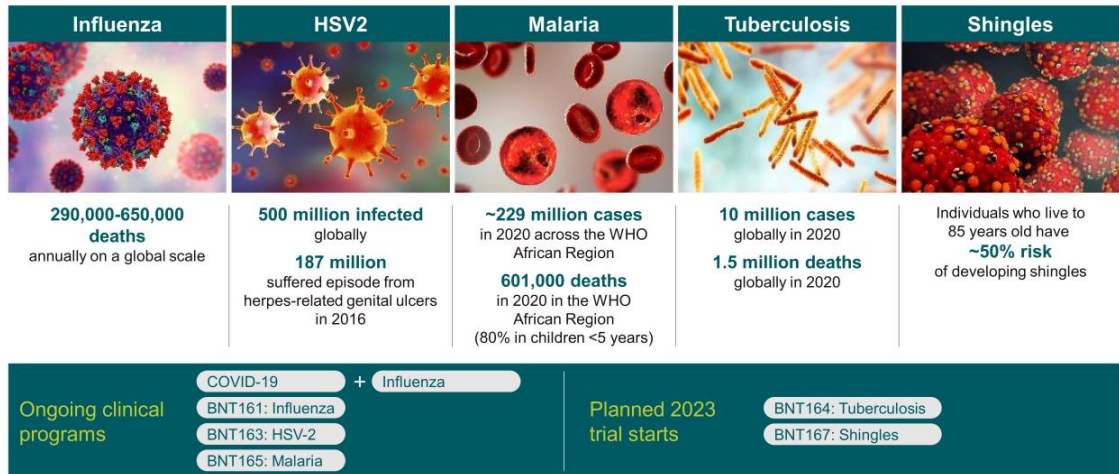
⁴ As of December 16, 2022

Infectious Disease

Expanding and accelerating our pipeline

BIONTECH

Infectious Diseases: Important Growth Area Addressing High Medical and Global Health Need



All figures from World Health Organization fact sheets. <https://www.who.int/news-room/fact-sheets> (accessed June 09, 2022).

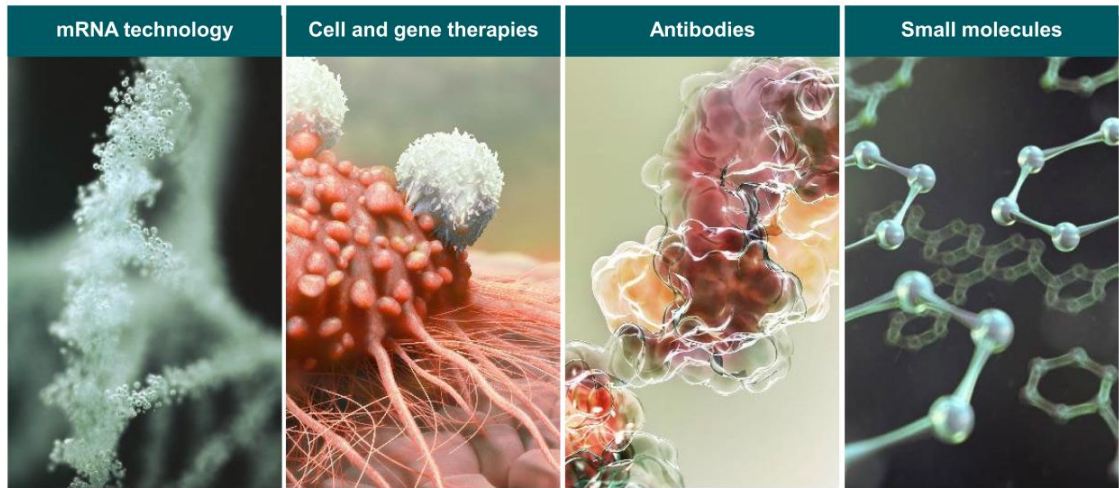
A microscopic image of cells, likely cancer cells, is visible in the background of the slide. The cells are dark and have a complex, interconnected structure. The overall color of the slide is a dark teal or green.

Oncology

Accelerating high-priority programs into potentially
registrational trials across multiple modalities

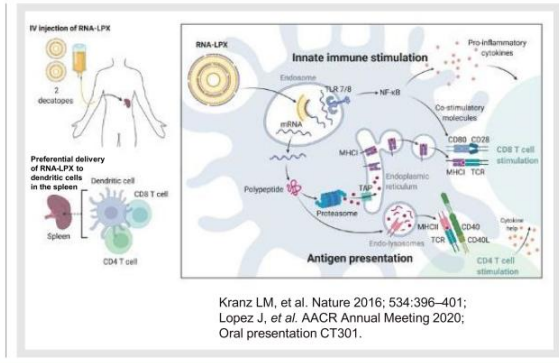
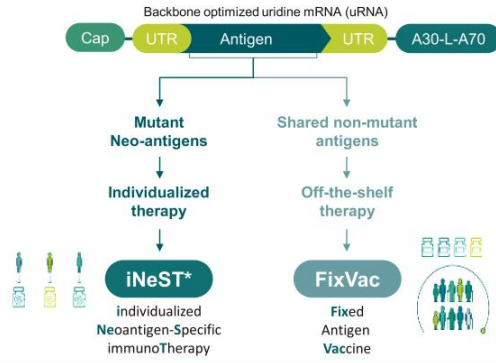
BIONTECH

The Tools we Have Developed to Treat Cancer



19 Clinical Programs in 22 ongoing Clinical Trials

Planned Advancement of mRNA Cancer Vaccines in 2023 Paves the Way to Potentially Registrational Trials



Individualized Vaccine

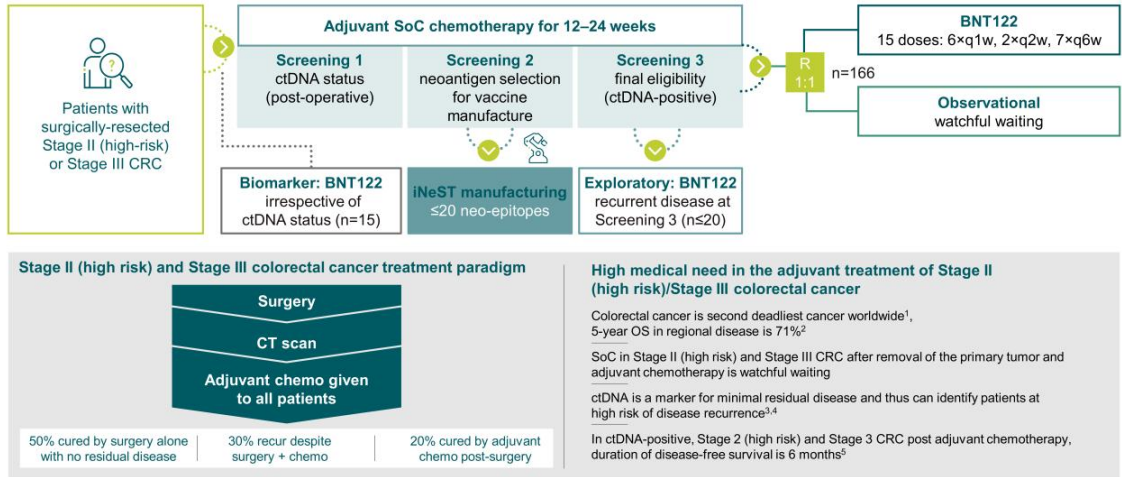
BNT122¹ randomized Phase 2 trials ongoing in 1L melanoma & adjuvant colorectal cancer
 BNT122¹ randomized Phase 2 planned in pancreatic cancer based on encouraging Ph 1 data²
 BNT122¹ Phase 1/2 in multiple tumor types completed
 IVAC Phase 1 in adjuvant TNBC completed

FixVac

BNT111 randomized Phase 2 ongoing in r/r melanoma
 BNT113 randomized Phase 2 ongoing in HPV16+ PD-L1+ 1L HSCC
 BNT112 Phase 1 ongoing in localized and metastatic prostate cancer
 BNT116 Phase 1 ongoing in 1L and 2L+ NSCLC

¹ Collaboration with Genentech.
² Balachandran VP, et al. ASCO Annual Meeting 2022; Poster presentation 2516.

iNeST | Autogene Cevumeran (BNT122): Phase 2 Randomized Trial vs Watchful Waiting in Adjuvant Colorectal Cancer



¹ WHO factsheet on cancer, 2018

² Gler database

³ Fan G, et al. PLoS One 2017; 12: e0171991

⁴ Loupakis F, et al. JCO Precis Oncol 2021; 5:PO.21.00101

⁵ Rainert T, et al. JAMA Oncology, 2019; 5:1124-1131.

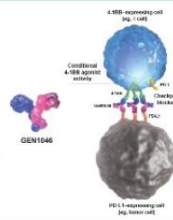
Intercepting Immune-Immune & Immune-Tumor Interactions: Next Generation Checkpoint Immuno-modulators with Pan-Tumor Potential

GEN1046/BNT311¹

Conditional 4-1BB co-stimulation while blocking PD-(L)1 axis

2 ongoing clinical trials:
Phase 2: BNT311 + Pembro in r/r, 2L+, PD-L1+ NSCLC

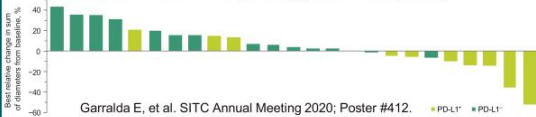
Phase 1/2: BNT311 mono / + PD-(L)1 combination in advanced solid tumors



Expansion cohorts in aPD-(L)1 r/r solid tumors

Cervical HNSCC	TNBC Endometrial	NSCLC Urothelial
----------------	------------------	------------------

Initial signs of clinical activity in PD-(L)1 r/r NSCLC (n=25)



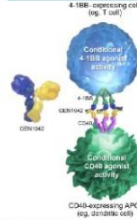
Garraida E, et al. SITC Annual Meeting 2020; Poster #412.

GEN1042/BNT312¹

Conditional activation of CD40 and 4-1BB on immune cells

Potential to treat solid tumors in 1L combination with standard-of-care aPD-(L)1 or chemo treatment

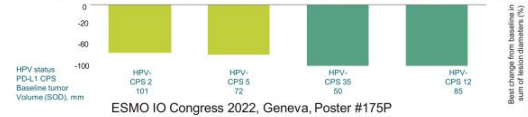
Ongoing Phase 1/2 clinical trial in advanced solid tumors



Expansion cohorts in 1L solid tumors

HNSCC Melanoma	NSCLC PDAC
----------------	------------

PRs and CRs observed in HNSCC patients in combo with pembro + chemo



ESMO IO Congress 2022, Geneva, Poster #175P

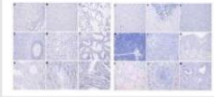
Multiple data updates from ongoing expansion cohorts expected in 2023

¹ Collaboration with Genmab based on 50/50 sharing of costs and profits

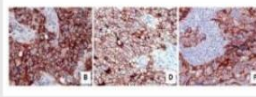
Bringing Cell Therapy to Solid Tumors: Combining the Potential of a Novel Highly Selective Target and a CAR T Cell Amplifying Vaccine

BNT211: Autologous CAR-T +/- CARVac targeting CLDN6+ solid tumors

CLDN6 not present in healthy tissues



CLDN6 expressed in multiple cancers



Science

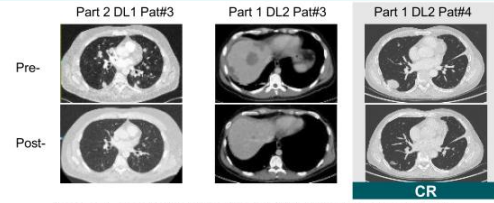
An RNA vaccine drives expansion and efficacy of claudin-CAR-T cells against solid tumors

Reinhard K, et al. *Science* 2020; 367:446-453.

Manageable safety profile and observed clinical activity

- 1x10⁷ and 1x10⁸ CAR-T dose levels well tolerated
- MTD not reached
- Efficacy signal in testicular cancer patients (n=7)
 - ORR 57%, DCR 85% (1 CR, 3 PR, 2 SD)
 - One CR confirmed at 18 and 52 weeks
- EMA PRIME designation in testicular cancer

Selected scans of responses in various patients



Haanen J, et al. AACR Annual Meeting 2022; Oral presentation CT002.

Additional data readout and Phase 2 trial planned for 2023

Outlook

2023 and beyond

BIONTECH

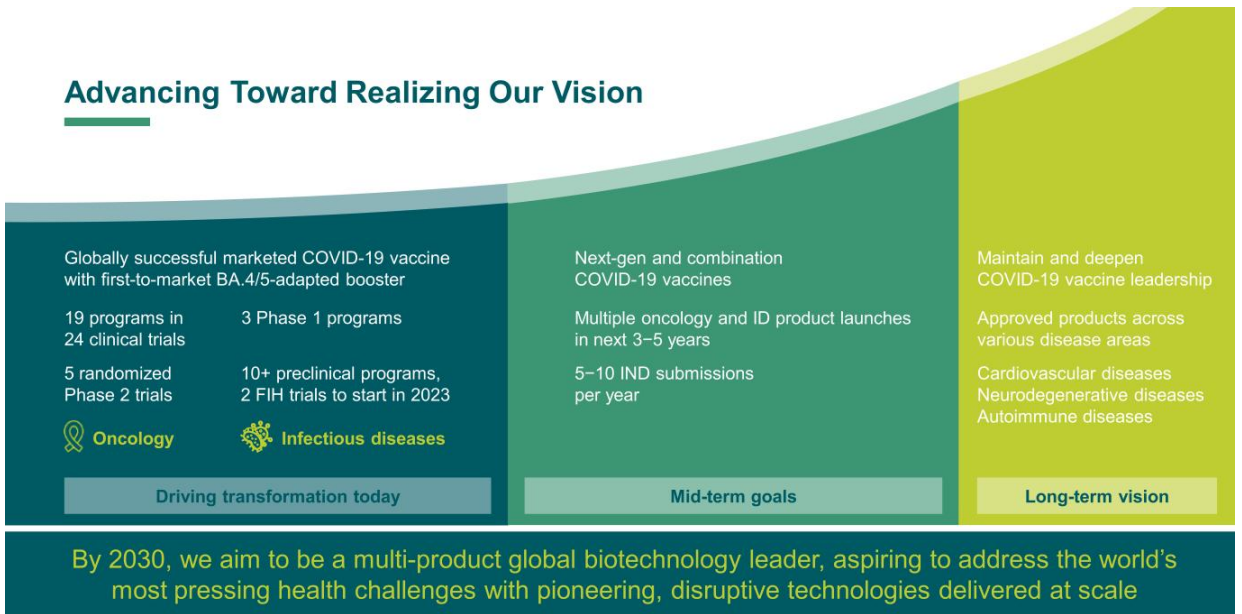
Multiple Late- and Early-stage Pipeline Milestones Expected in 2023

Modality	Indication	Program	Select milestones	Anticipated timing
mRNA vaccines for infectious disease	COVID-19 ¹	BA.4/5-adapted bivalent	Pediatric label expansion	2H 2023
	COVID-19 – influenza combination ¹	BA.4/5-adapted bivalent+ BNT161	Phase 1 data update	1H 2023
	Malaria	BNT163	Phase 1 data update	2H 2023
	HSV2 ²	BNT165	Phase 1 data update	2H 2023
	Shingles ¹	BNT167	Phase 1 FPD	1H 2023
	Tuberculosis ³	BNT164	Phase 1 FPD	Early 2023
iNeST individualized mRNA vaccines	1L melanoma ⁴	Autogene Cevumeran (BNT122)	Phase 2 data update	2023
	Adjuvant CRC ⁴	Autogene Cevumeran (BNT122)	Phase 2 data update	-
	Adjuvant PDAC ⁴	Autogene Cevumeran (BNT122)	Phase 2 FPD	2023
Next-gen immune checkpoint modulators	Multiple solid tumors ⁵	BNT311 (PD-L1x4-1BB)	Expansion cohort data update	2023
	Multiple solid tumors ⁵	BNT312 (CD40x4-1BB)	Expansion cohort data update	2023
Cell therapies	CLDN6+ solid tumors	BNT211	Phase 1 data update	2023
	2L+ testicular cancer	BNT211	Phase 2 FPD	Late 2023

¹ Partnered with Pfizer
² Partnered with University of Pennsylvania
³ Collaboration with BMGF
⁴ Partnered with Genentech

⁵ Collaboration with Genmab based on 50/50 sharing of costs and profits
 FPD = First Patient Dosed

Advancing Toward Realizing Our Vision



THANK YOU
BIONTECH

Appendix

BIONTECH

Infectious Disease Pipeline: Multiple Opportunities Built on Proven Platform

	Indication	Product candidate	Pre-clinical	Phase 1	Phase 2	Phase 3	Commercial	2022 and 2023 Milestones
mRNA vaccines partnered w/Pfizer		COMIRNATY®						
		BNT162b2(Original/Omicron BA.4/5-adapted bivalent)						Pediatric label expansion exp. 2H23
	COVID-19 ¹	BNT162b2 (Original/Omicron BA.1-adapted bivalent)						Launch + Data updates
		BNT162b4 (T-cell enhancing)						Phase 1 initiated in December 2022
		BNT162b5 (Enhanced spike antigen)						Phase 2 started in July 2022
	Covid-19 – Influenza combination ¹	BNT162b2+BNT161 (qFlu + BA.4/5-adapted bivalent)						Phase 1 initiated in October 2022
	Influenza ¹	BNT161						Data update in July 2022 Phase 3 started in September 2022
	Shingles ¹	Un-named program						Start Phase 1: 1H23
10+ other infectious disease programs	HSV 2 ²	BNT163						Phase 1 data update exp. 2H23
	Tuberculosis ³	BNT164						Start Phase 1: early 2023
	Malaria	BNT165						Phase 1 data update exp. 2H23
	HIV ³	Un-named program						
	Additional mRNA vaccine programs ³	Un-named programs						
	Precision antibacterials	Un-named programs						

¹ Partnered with Pfizer

² Partnered with University of Pennsylvania

³ Collaboration with BMGF. BioNTech holds worldwide distribution rights except developing countries where BMGF holds distribution rights.

Oncology Pipeline: Significant Progress and Expansion in 2022

Drug class	Platform	Product candidate	Indication (targets)	Pre-clinical	Phase 1	Phase 2	Phase 3	2022 and 2023 Milestones	
mRNA	FixVac	BNT111	Advanced and R/R melanoma						
		BNT112	Prostate cancer						
		BNT113	HPV16+ head and neck cancer						
		BNT116	NSCLC 2L+					FPD in July 2022 ✓	
	iNeST	Autogene cevumeran (BNT122) ¹	1L melanoma					Data update exp. 2023	
			Adjuvant colorectal cancer						
			Solid tumors						
	Intratumoral immunotherapy	SAR441000 (BNT131)	Solid tumors (IL-12sc, IL15-sushi, GM-CSF, IFNα)					Start Phase 2 in 2023	
	RiboMabs		BNT141	Multiple solid tumors (CLDN18.2)					FPD in Jan. 2022 ✓
			BNT142	Multiple solid tumors (CD3×CLDN6)					FPD in July 2022 ✓
RiboCytokines		BNT151	Multiple solid tumors (optimized IL-2)						
		BNT152, BNT153	Multiple solid tumors (IL-7, IL-2)						
Cell therapies	CAR T cells + CARVac	BNT211	Multiple solid tumors (CLDN6)					Start Phase 2 in 2023	
		BNT212	Pancreatic, other cancers (CLDN18.2)						
	Neoantigen-based T cells	BNT221	Multiple solid tumors						
	TCR engineered T cells	To be selected	All tumors						
Antibodies	Next-gen immune checkpoint modulators	GEN1046 (BNT311) ³	Metastatic NSCLC (PD-L1×4-1BB)					Data update exp. in 2023	
		GEN1042 (BNT312) ³	Multiple solid tumors (PD-L1×4-1BB)					Data update exp. in 2023	
		GEN1053 (BNT313) ³	Malignant solid tumors (CD27)					Initiated in Nov. 2022 ✓	
	Targeted cancer antibodies	BNT321	Pancreatic cancer (sLea)						
SMIM	Toll-like receptor binding	BNT411	Solid tumors (TLR7)						

¹ Partnered with Genentech

² Investigator-initiated Phase 1 trial

³ Partnered with Genmab

FPD = First patient dosed, SMIM = small molecule immunomodulators, NSCLC = non-small cell lung cancer

