Harnessing The Power Of The Immune System To Fight Human Diseases

November 2022





# 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 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'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. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "expects," "intends," "plans," "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. 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# **Safety Information**

COMIRNATY® \(\bar{\text{the Pfizer-BioNTech COVID-19}\) vaccine)\) has been granted standard marketing authorization (MA) by the European Commission to prevent coronavirus disease 2019 (COVID-19) in people aged 5 years and older. The vaccine is administered as a 2-dose series, 3 weeks apart. 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. In addition, the MA has been expanded to include a booster dose (third dose) at least 3 months after the second dose in individuals 12 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 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.4-5 may be administered as a booster in people aged 12 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.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.
- There is an increased, but very rare risk (<1/10,000 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. The risk of myocarditis after a booster dose of COMIRNATY Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 has not yet been characterized.
- Rare cases of acute peripheral facial paralysis; uncommon incidence of insomnia, hyperhidrosis and night sweats; and unknown incidence of paraesthesia, 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 Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 may be lower in immunosuppressed individuals.
- As with any vaccine, vaccination with 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 (≥ 1/100 to < 1/100 to < 1/100, Common (≥ 1/10,000 to < 1/100), Rare (≥ 1/10,000 to < 1/1,000 to < 1/1,000), Very rare (< 1/10,000).</li>
- · 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, 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
- 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-feed newborn/infant are anticipated since the systemic exposure of breast-feeding woman 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-feed newborns/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 reactogenicity between those COMIRNATY variant adapted vaccines that have been clinically evaluated, 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-feed newborns/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 concomitant 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 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%) 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 69 (> 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.1. as well as for a booster dose of COMIRNATY Original/Omicron BA.1. as well as for a booster dose of COMIRNATY Original.
- 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
- 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  $\nabla$  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 <u>Eudra Vigilance</u> or directly to BioNTech using email medinfo@biontech.de. telephone +49 6131 9084 0. or via the website www.biontech.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 through 11 years of age
- · a third primary series dose to individuals 5 years through 11 years of age 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 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization 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 heart muscle); Pericarditis (inflammation of 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 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 1-800-822-7967 or report online to www.vaers.hhs.gov/reportevent.html. In addition, individuals can report side effects to Pfizer Inc. at www.pfizersafetyreporting.com or by calling 1-800-438-1985





# OUR VISION

Harnessing the power of the immune system to develop novel therapies against cancer, infectious diseases and other severe diseases.



# **BioNTech Today | A 21st Century Immunotherapy Powerhouse**





# 2021: Key Highlights of Progress Towards Vision

COMIRNATY - GLOBAL LEADERSHIP

~2.6 bn

doses delivered in 2021<sup>1</sup>

>165

Countries & territories<sup>1</sup>

>1 bn

to low- and middleincome countries<sup>1</sup>

#### DROVE ADVANCEMENT IN ONCOLOGY

to

Five randomized phase 2 trials

Four new platforms entered the clinic (FIH)

Three strategic M&As to complement existing technologies

#### **EXPANDED GLOBAL ORGANIZATION**

3,000+ team members

Increased footprint with new offices in U.S., Europe and Asia

#### STRONG FINANCIAL PERFORMANCE

€19.0 Bn

Total 2021 Revenues<sup>2</sup>

€39.63

Diluted EPS<sup>2</sup>



# 2021: A Year of Transformation & Progress



**Expansion of oncology** pipeline

Nine oncology clinical trials started; clinical results from six phase 1 studies



**Expansion of R&D and production teams** 

Increased R&D and production teams to >2,000 professionals<sup>1</sup>



**Production capacity** 

Expansion of commercial scale mRNA production and addition of US cell therapy manufacturing facility



**Global presence** 

Established offices in Singapore, China and Turkey



**Commercial infrastructure** 

Deployed commercial team in Germany



# **Diversity – Important Success Factor**





# Global Social Responsibility at Our Core

#### **Democratize Access to Novel Medicines**

#### COVID-19 vaccine pledge to COVAX and the world

 2+ bn doses to low- and middle-income countries by end of 2022

Development of new drugs for diseases with high unmet medical need in low-income countries

- Malaria
- Tuberculosis
- HIV

Start to establish mRNA production in Africa to ensure local vaccine supply

Modular "BioNTainer" mRNA production facilities as technological solution to democratize access to novel medicines



#### **Environmental & Climate Protection**

#### **Climate targets under SBTi**

 Scope 1 & 2: absolute emission reduction of 42% by 2030<sup>1</sup>



### Responsible Governance

Practice good corporate governance and social and societal responsibility

Signed UN Global Compact<sup>2</sup>



## **Attractive Employer**

#### Recruitment of qualified employees

 Specialists for scientific innovation and support of global growth



# We Collaborate with Global Leaders in Our Industry

# **Collaborations for clinical stage programs**

COVID-19 Vaccine 50:50 gross profit share<sup>1</sup> & NSCLC
Companies keep full

rights to own product

iNeST 50:50 cost & profit share Bi- and monospecific mABs 50:50 cost & profit share

Intra-tumoral mRNA cost & profit share

Seasonal Influenza royalties & milestones

Pfizer Fosur

REGENERON

Genentech







# **Pre-clinical collaborations**

**Shingles**Cost and gross profit share

Up to 10 Infectious
Disease Indications
worldwide opt-in right

HIV, Tuberculosis developed world rights

5 Rare Disease Indications 50:50 cost & profit share

**Pfizer** 

University of Pennsylvania

BILL & MELINDA GATES foundation **GENÈVANT** 





# MULTI-PLATFORM STRATEGY



# Multi-platform Strategy: Toolbox for Innovation







# DIVERSIFIED PRODUCT PIPELINE

# **Advancing Toward Our Vision**

Market leader in COVID-19 vaccines

3 marketed vaccines
First-to-market Omicron BA.4/BA.5-adapted
bivalent vaccine

19 programs in 24 clinical trials

5 randomized Phase 2 trials



1 Phase 3 program

10+ preclinical programs,
Up to 5 FIH trial initiations<sup>1</sup>



**Infectious diseases** 

**Driving transformation today** 

Next-gen or variant adapted COVID-19 vaccines

Multiple product launches in next 3-5 yrs

5-10 IND submissions per year

Mid-term goals

Maintain and deepen COVID-19 vaccine leadership

Approved products across various disease areas

Expand to new disease areas: autoimmune disease, regenerative medicine, cardiovascular diseases











**Long-term vision** 

Once in a generation opportunity to transform medicine



# Taking mRNA from vision to reality



First ever approved mRNA therapy<sup>1</sup>

Fastest vaccine development in medical history

One of the **most successful** pharmaceutical launches in history<sup>2</sup>

>1 bn individuals vaccinated in 2021

COMIRNATY market share<sup>3</sup>: USA: ~74%; EU: ~80%

Millions of cases of severe illness or death likely averted<sup>4</sup>

Trillions of dollars of global economic impact<sup>5</sup>





# **Rapid Omicron Response:**

# ~ 2 Months from Regulator Recommendation to Launch

CMC/Manufacturing of BA.1 and BA.4/BA.5 Vaccine Product

Ongoing Submissions, Approvals & Pediatric Label Expansion in Various Geographies

# FDA RECOMMENDS

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

June 30



# FIRST SHIPMENTS

COMIRNATY BA.4/BA.5-adapted bivalent vaccine

September 1



June 28

Clinical & preclinical data presented to VRBP Advisory Committee

July 01

recommends
adaption of COVID19 vaccines to
Omicron variant

July 19

BA.1-adapted vaccine **EMA** submission

August 24

BA.4/BA.5adapted **FDA and EMA** submission August 31

FDA EUA for BA.4/BA.5adapted vaccine (12+ yrs) September 01

EC approval for BA.1-adapted vaccine (12+ yrs) September 12

EC approval for BA.4/BA.5adapted vaccine (12+ yrs) October 12

FDA EUA for BA.4/BA.5adapted vaccine (5-11 yrs)

Rapid deployment supports framework for sustainable vaccine business for COVID-19 and other infectious diseases



# 2022: Success Through Further Development of the COVID-19 Vaccine

#### 2022: Strong market position



- Up to 2.1 bn doses expected to be invoiced in 2022<sup>1</sup>
- ~300 m doses of variant adapted vaccines invoiced in the first six week after product launch<sup>1</sup>

#### **Expansion of global market position**

- Pediatric label expansion for different age groups
- Evaluation and approval of booster
- Label expansion to additional at-risk groups
- ✓ Future pandemic preparedness
  - Monitoring of emerging variants
  - Rapid data-guided vaccine adaptation
- Development of variant-adapted and nextgeneration vaccines
  - First-to-market Omicron BA.4/BA.5-adapted bivalent vaccine in September 2022
  - Multipronged next-generation vaccine strategy designing and testing multiple constructs



# **Infectious Diseases: Important Area of Growth**

#### Addressing a high medical need

- Tackling global health problems (malaria, tuberculosis, and HIV)
- Combating diseases for which there is not yet a prophylactic vaccine or therapy



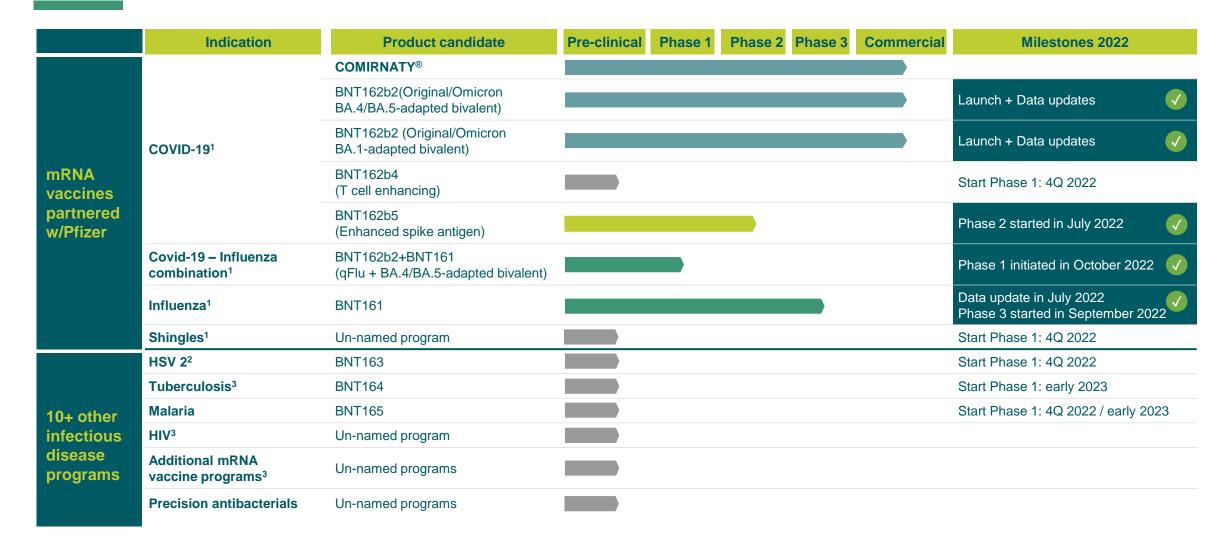
## Wide range of innovative technologies

- Applying new technologies, including
  - mRNA vaccines
  - trans-amplifying mRNA
  - Ribologicals
  - synthetic anti-bacterial agents (synthetic lysins)
- All methods to accelerate the development of new vaccines and therapies





# Infectious Disease Pipeline: Multiple Opportunities Built on Proven Platform



<sup>&</sup>lt;sup>1</sup> Collaboration with Pfizer

<sup>&</sup>lt;sup>2</sup> University of Pennsylvania collaboration

<sup>3</sup> Collaboration with Bill & Melinda Gates Foundation. BioNTech holds worldwide distribution rights except developing countries where BMG holds distribution rights.

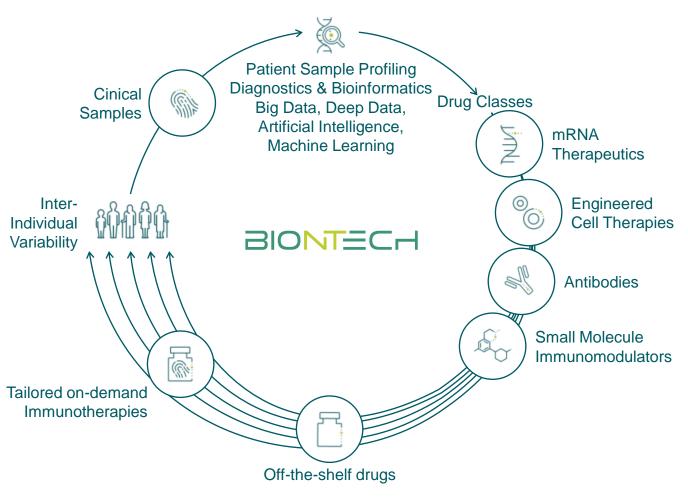
# **Oncology: New Precision Therapies with Scaling Potential**

# Our innovative approach

- Development of **precise** immunooncology therapies
- Individualized therapeutic approaches
- Scale of platforms across tumor indications
- Combination of different immunooncology mode of action

Overcoming therapeutic limitatons in the treatment of solid tumors

# A future model for immuno-oncology





# **Oncology: Potential To Tackle Multiple Diseases With Different Therapeutic Modalities**



#### **mRNA Cancer Vaccines**

# iNeST / FixVac

- Induces multi-specificity, multi-valency, high tumor-antigen specific T cell responses with unprecedented potency
- 4 Phase 2 randomized trials (2 iNeST and 2 FixVac)



#### **Cell Therapies**

Next Gen CAR-T Cell /
Neoantigen-based T Cell /
Personalized TCR-T Cell Therapy

2 Phase 1 FIH trials



#### **Antibodies**

# Targeted Cancer Antibodies

- Novel cancer cell surface targets for underserved high medical need cancers
- CA19-9 antibody in 1L pancreatic cancer in Phase 1/2 trial

#### Small Molecule Immunomodulators

#### **TLR-7 Agonist**

- Potently modulates innate immunity
- Phase 1 trial

#### Next Generation Immunomodulators



#### **Bispecific & monospecifc antibodies**

- Next-generation checkpoint inhibitors to address a broad range of cancers
- Phase 1/2 trials of 2 bispecific and 1 monospecific antibodies
- 1 Phase 2 randomized trial

#### Ribologicals



#### Ribocytokines, RiboMabs

- mRNA encoded cytokines or antibodies with potential for improved properties and half life
- Potential to amplify vaccines and CPIs
- 2 Phase 1 FIH RiboCytokine trials
- 2 Phase 1 FIH RiboMab trials

Multiple product opportunities with unique combination potential in clinical testing



# **Oncology Pipeline: Significant Progress and Expansion in 2022**

Drug class	Platform	Product candidate	Indication (targets)	Pre-clinical	Phase 1	Phase 2	Phase 3	Milestones	
	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) <sup>1</sup>	1L melanoma					Data update exp. 1H 202	23
			Adjuvant colorectal cancer						
mRNA			Solid tumors						
			Adjuvant pancreatic ductal adenocarcinoma <sup>2</sup>					Data update June 2022	$\checkmark$
	Intratumoral immunotherapy	SAR441000 (BNT131)	Solid tumors (IL-12sc, IL15-sushi, GM-CSF, IFN $\alpha$ )						
	RiboMabs	BNT141	Multiple solid tumors (CLDN18.2)					FPD in Jan. 2022	<b> ✓</b>
		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)				_		
	CAR T cells + CARVac	BNT211	Multiple solid tumors (CLDN6)					Data update Sept. 2022	
Cell		BNT212	Pancreatic, other cancers (CLDN18.2)						
therapies	Neoantigen-based T cells	BNT221	Multiple solid tumors						
	TCR engineered T cells	To be selected	All tumors						
	Next-gen immune checkpoint modulators	GEN1046 (BNT311)	Metastatic NSCLC (PD-L1x4-1BB)						
Antibodies			Multiple solid tumors (PD-L1x4-1BB)						
		GEN1042 (BNT312)	Multiple solid tumors (CD40x4-1BB)					Data update 4Q 2022	
		GEN1053 (BNT313)	Malignant solid tumors (CD27)					Initiated in Nov. 2022	
	Targeted cancer antibodies	BNT321	Pancreatic cancer (sLea)						
SMIM	Toll-like receptor binding	BNT411	Solid tumors (TLR7)						



# **Oncology Programs in Phase 2**

Platform	FixVac Off-the-shelf mRNA vaccine		iNeST Individualized mRNA immun	Bispecific Next-generation immunotherapy	
Program	BNT111 R/R Melanoma	BNT113 HPV16+ HNSCC	BNT122 Autogene cevumeran <sup>1</sup> 1L Melanoma	BNT122 Autogene cevumeran¹ Adjuvant colorectal cancer	BNT311 <sup>2</sup> R/R NSCLC
How	<ul> <li>Encodes 4 tumor- associated antigens U.S. Fast Track Designation and Orphan Drug Designation</li> </ul>	Encodes HPV16 oncoproteins	Targets 20 neo-antigens unique to each patient	Targets 20 neo-antigens unique to each patient	Conditional 4-1BB co- stimulation while blocking PD(L)1 axis
Why	Potential to improve outcomes in combo with anti-PD1	Potential for synergistic anti-tumor effect in combination with anti-PD1	Trial success may unlock 1L use of iNeST as combination therapy with anti-PD(L)1 in anti-PD1- naive advanced cancers	Potential to address residual cancer cells that remain – focus on recurrence free survival	Enhances T-cell and NK cell function and targets them to tumor lesions





# **OUTLOOK 2022**



# **Select COVID-19 and Infectious Disease Pipeline Milestones**

	Program	Milestone	Anticipated Timeline
	Covid-19 – Influenza combination: BNT162b2 + BNT161 (BA.4/BA.5-adapted bivalent + qIRV) <sup>1</sup>	Phase 1 FPD	Started November 2022
COVID-19	Next-generation COVID-19 vaccine: BNT162b5 (Enhanced spike antigen) <sup>1</sup>	Phase 2 data	Data expected 4Q 2022
	Next-generation COVID-19 vaccine: BNT162b4 (T cell enhancing) <sup>1</sup>	Phase 1 FPD	FPD expected 4Q 2022
	Additional next-generation vaccines <sup>1</sup>	Multiple Phase 1 trials	FPD expected 4Q 2022
Other BioNTech-Pfizer collaboration program	mRNA Shingles vaccine <sup>1</sup>	Phase 1 FPD	FPD expected 4Q 2022
BioNTech	BNT163 (mRNA HSV2 vaccine) <sup>2</sup>	Phase 1 FPD	FPD expected 4Q 2022
Infectious Disease	BNT164 (mRNA tuberculosis vaccine) <sup>3</sup>	Phase 1 FPD	FPD expected early 2023
vaccine programs	BNT165 (mRNA malaria vaccine)	Phase 1 FPD	FPD expected 4Q 2022 / early 2023

## 2023 Outlook

Up to 5 new Infectious Disease trial initiations



<sup>&</sup>lt;sup>1</sup> Partnered with Pfizer

<sup>&</sup>lt;sup>2</sup> University of Pennsylvania collaboration

# **Select Oncology Pipeline Milestones**

	Program	Milestone	Anticipated Timeline		
First-in-Human	BNT313 (GEN1053) <sup>1</sup> - Monospecific HexaBody <sup>2</sup>	Phase 1/2 in solid tumors FPD	Started in November 2022		
<b>Trial Starts</b>	BNT116 - FixVac <sup>3</sup>	Phase 1/2 in 1L NSCLC in combo with cemiplimab FPD	FPD expected 4Q 2022		
	BNT312 (GEN1042) <sup>1</sup> – Bispecific antibody	Phase 1/2 in solid tumors data	Data expected at ESMO IO 2022		
Data Updates	Autogene cevumeran / BNT122 - iNeST <sup>4</sup>	Phase 2 in combo with pembrolizumab in frontline melanoma data	Data expected 1H 2023		

# 2023 Outlook Up to 10 Oncology clinical trial updates



<sup>&</sup>lt;sup>2</sup> HexaBody® technology owned by Genmab



Trial sponsored by Regeneron

<sup>&</sup>lt;sup>4</sup> Collaboration with Genentech, a member of the Roche group

# **2022 Strategic Priorities**

#### **Continue COVID-19 Vaccine Leadership**



- Label & geographic expansion
- Variant-adapted and nextgeneration vaccines
- Innovations for pandemic preparedness

## **Execute** in Oncology



- Prepare for registrational trials
- Additional data for CAR-T cell therapy against solid tumors

#### **Expand in** Infectious Disease



- Up to 5 FIH vaccine trial initiations
- 10+ additional mRNA vaccine programs
- Precision antibacterials

## Advance into **New Therapeutic Areas**



- Autoimmune disease
- Regenerative medicine
- Cardiovascular disease

# Invest in Foundation to Enable Accelerated Innovation and Expansion

Digital & Al Capabilities | Technologies | Development Team | Manufacturing

| Global Footprint





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