

A large, semi-transparent, teal-colored image of a virus particle, likely SARS-CoV-2, serves as the background. The virus is shown in a 3D perspective, highlighting its spherical shape and the dense, spiky surface of its envelope.

# Financial Results & Corporate Update

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4<sup>th</sup> Quarter and Full Year 2022

27.03.2023

BIONTECH

## 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; 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 and the availability of results; and BioNTech's estimates of commercial and other revenues, cost of sales, research and development expenses, sales and marketing expenses, general and administrative expenses, capital expenditures, income taxes, and shares outstanding. 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. These risks and uncertainties include, but are not limited to: 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 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 and its collaborators' ability to commercialize and market BioNTech's COVID-19 vaccine and, if approved, its product candidates; BioNTech's ability to manage its 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, risks relating to the global financial systems and markets; and other factors not known to BioNTech at this time. You should review the risks and uncertainties described under the heading "Risk Factors" in BioNTech's annual report on Form 20-F for the full year ended December 31, 2022 and in subsequent filings made by BioNTech with the SEC, which are available on the SEC's website [at https://www.sec.gov/](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 the population aged 6 months and older. In people from 5 years of age 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. There is a pediatric formulation containing 3 micrograms per dose available for infants and children 6 months to 4 years of age. In this age group, COMIRNATY can be given as primary vaccination consisting of three doses (of 3 micrograms each); the first two doses are given 3 weeks apart, followed by a third dose given at least 8 weeks after the second dose. In addition, the MA has been expanded to include a booster dose (third dose) of 30 micrograms at least 3 months after the second dose in individuals 12 years of age and older. A booster dose of COMIRNATY 10 micrograms may be given to children from 5 to 11 years of age at least 6 months after the primary vaccination course. 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. **COMIRNATY® ▼ (the Pfizer-BioNTech COVID-19 vaccine), Bivalent: COMIRNATY Original/Omicron BA.1, COMIRNATY Original/Omicron BA.4-5** In addition, COMIRNATY has also been granted standard MA for two Omicron subvariant 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 or COMIRNATY Original/Omicron BA.4-5 (30 micrograms per dose) 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. A booster dose of COMIRNATY Original/Omicron BA.4-5 (10 micrograms per dose) may be given to people aged from 5 years to 11 years after primary vaccination or a booster dose with a COVID-19 vaccine. 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.
- 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. From post-marketing experience very rare adverse reactions of myocarditis and pericarditis, Rare cases of acute peripheral facial paralysis; uncommon incidence of insomnia, hyperhidrosis and night sweats, dizziness common incidence of vomiting, very common diarrhoea and unknown incidence (wcan not be estimated from available data) anaphylaxis, of paraesthesia, hypoaesthesia and erythema multiforme, extensive swelling of vaccinated limb, facial swelling (in vaccine recipients with a history of injection of dermatological fillers) and heavy menstrual bleeding (most case appeared to be non-serious and temporary in nature) have been identified after 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, paresthesia, hypoaesthesia 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 and identified after post authorization experience 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),
- Very common side effects: injection site pain, injection site swelling, , headache, muscle pain, chills, joint pain, diarrhea, fever, chills, fatigue
- 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, dizziness, injection site itching, allergic reactions such as rash, itching, urticaria or angioedema, feeling weak or lack of energy/sleepy, decreased appetite, excessive sweating, night sweats
- Rare side effects: temporary one-sided facial drooping
- 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 incidence (cannot be estimated from the available data): 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 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-fed 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.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 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.
- In an analysis of Study 3 (Phase 2/3), 1,776 infants (1,178 Comirnaty 3 mcg and 598 placebo) were 6 to 23 months of age. The most frequent adverse reactions in infants 6 to 23 months of age that received any primary course dose included irritability (> 60%), drowsiness (> 40%), decreased appetite (> 30%), tenderness at the injection site (> 20%), injection site redness and fever (> 10%).
- The most frequent adverse reactions in children 2 to 4 years of age that received any primary course dose included pain at injection site and fatigue (> 40%), injection site redness and fever (> 10%).
- The overall safety profile of Comirnaty in participants 5 to 11 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 that received 2 doses were injection site pain (> 80%), fatigue (> 50%), headache (> 30%), injection site redness and swelling (≥ 20%), myalgia, chills, and diarrhoea (> 10%).
- The overall safety profile for the booster dose was similar to that seen after the primary course. The most frequent adverse reactions in children 5 to 11 years of age were injection site pain (> 70%), fatigue (> 40%), headache (> 30%), myalgia, chills, injection site redness and swelling (> 10%)
- The overall safety profile of Comirnaty in adolescents 12 to 15 years of age was similar to that seen in participants 16 years of age and older. 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%)
- 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.
- 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 Study 4 (Phase 3), 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 in individuals 18 years of age and older, as well as for a booster dose of COMIRNATY Original in individuals 5 years of age and older.
- 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 ▼ 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 EudraVigilance or directly to BioNTech using email [medinfo@biontech.de](mailto:medinfo@biontech.de), telephone +49 6131 9084 0, or via the website [www.biontech.de](http://www.biontech.de)

# Safety Information

## AUTHORIZED USE IN THE U.S.

### 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 years 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:
  - the first 2 doses of the 3-dose primary series for children 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 and older with certain kinds of immunocompromise

### 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) to prevent COVID-19 as:
  - the third dose of the 3-dose primary series following 2 doses of the monovalent\* Pfizer-BioNTech COVID-19 Vaccine in children 6 months through 4 years of age; or
  - a single booster dose in children 6 months through 4 years of age at least 2 months after completion of primary vaccination with 3 doses of the monovalent Pfizer-BioNTech COVID-19 Vaccine; or
  - a single booster dose at least 2 months after completion of either primary vaccination with any authorized or approved COVID-19 vaccine or receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine in individuals 5 years of age and older.

## 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


- Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.
- Warnings:
  - Management of Acute Allergic Reactions: Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.
  - Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (<https://www.cdc.gov/vaccines/covid-19/clinicalconsiderations/managing-anaphylaxis.html>)
  - Myocarditis and Pericarditis: Postmarketing safety data with Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent are relevant because these vaccines are manufactured using the same process.
  - Postmarketing data with authorized or approved Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent, demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following receipt of the second primary series dose or first booster dose, with most booster doses likely administered at least 5 months after completing primary vaccination. For the 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. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html>).
  - Syncope
  - Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting.
  - Altered Immunocompetence
  - Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.
- Limitation of Effectiveness
  - Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent may not protect all vaccine recipients.
- Adverse reactions reported with the vaccine include:
  - Adverse Reactions in Clinical Trials
  - Adverse reactions following administration of a booster dose of the Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent that have been reported in clinical trials include injection site pain, fatigue, headache, muscle pain, chills, joint pain, injection site swelling, fever, injection site redness, lymphadenopathy, nausea, malaise, pain in extremity, rash, decreased appetite, vomiting, diarrhea (see Full EUA Prescribing Information).
  - Adverse Reactions Identified in Post Authorization Experience
  - Severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions (e.g., rash, pruritus, urticaria, angioedema), diarrhea, vomiting, pain in extremity (arm), syncope, and dizziness have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine.
  - Myocarditis and pericarditis have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.
  - Additional adverse reactions, some of which may be serious, may become apparent with post-authorization use of the Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.
- Use with Other Vaccines
  - There is no information on the co-administration of the Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent, with other vaccines.



**1** 4th Quarter and Full Year 2022 Highlights  
Ugur Sahin, Chief Executive Officer



**2** Pipeline & COVID-19 Vaccines Update  
Özlem Türeci, Chief Medical Officer



**3** Financial Results  
Jens Holstein, Chief Financial Officer



**4** Strategic Outlook  
Ryan Richardson, Chief Strategy Officer





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# 4th Quarter and Full Year 2022 Highlights

Ugur Sahin, Chief Executive Officer

BIONTECH

# Continued Leadership against COVID-19 in 2022



**~2 billion  
doses**

invoiced in 2022<sup>1</sup>

**~550 million  
doses**

of variant adapted vaccines shipped<sup>2</sup>

**>60%**

market share<sup>3</sup>

**Broadest label**

amongst COVID-19 vaccines<sup>4</sup>

1. Partnered with Pfizer, 2. As of Dec. 16, 2022, 3. Pfizer/BioNTech cumulative global COVID-19 market share across reporting countries; CDC, ECDC OWID data as of Nov 2022, 4. in the USA, EU and UK.

# Continued Execution in Oncology and Infectious Diseases R&D in 2022



## Clinical data updates across platforms:

- BNT211** cell therapy for solid tumors
- BNT312**<sup>1</sup> next-gen immune checkpoint modulator
- BNT122**<sup>2</sup> individualized mRNA immunotherapy
- BNT113** FixVac in HPV16+ HNSCC

## 5 new clinical programs

First-in-human:

- BNT116** Lung cancer FixVac
- BNT141** Ribomab CLDN18.2
- BNT142** Ribomab CD3xCLDN6
- BNT313**<sup>1</sup> Hexabody CD27
- BNT322**<sup>1</sup> Antibody Undisclosed target

## 3 COVID-19 vaccine trials<sup>3</sup>

- BNT162b2, BA.1-adapted vaccine
- BNT162b2, BA.4-5-adapted vaccine
- BNT162b4 + BNT162b2

## Phase 1 trials for 4 mRNA vaccines

including first-in-human against multiple pathogens:

- |                                  |                           |                |                              |
|----------------------------------|---------------------------|----------------|------------------------------|
| <b>COVID-19+Flu</b> <sup>4</sup> | <b>HSV-2</b> <sup>5</sup> | <b>Malaria</b> | <b>Shingles</b> <sup>3</sup> |
| BNT162b2+BNT161                  | BNT163                    | BNT165         | BNT167                       |

Immuno-oncology

Infectious diseases

1. Partnered with Genmab, 2. Partnered with Genentech, member of Roche Group, 3. Partnered with Pfizer, 4. Collaboration with PFE and subject to reaching agreement with our partners, 5. Partnered with University of Pennsylvania  
CLDN = Claudin, NSCLC = Non-small cell lung cancer, HNSCC = head and neck squamous cell carcinoma, HSV = Herpes simplex virus, HPV = Human papillomaviruses



# Continued to Transform BioNTech



Broadened pipeline<sup>1</sup>

Oncology:

**20 programs in  
24 ongoing trials**

Infectious disease:

**6 programs in  
10 ongoing trials**

Grew team by<sup>2</sup>

**>1,500  
employees**

Strong financials

**€13.9 bn**

Cash and cash equivalents<sup>3</sup>

Expanded partnerships

**4 new collaborations**

accessing a variety of technologies<sup>2</sup>

<sup>1</sup> As of February 2023, <sup>2</sup> As of December 31, 2022

<sup>3</sup> The payment settling our gross profit share for the third quarter of 2022 (as defined by the contract) in the amount of €1,816.5 million was received from our collaboration partner subsequent to the end of the reporting period as of January 12, 2023.

# Enhancing Our Disruptive Technology Toolkit to Fight Human Diseases

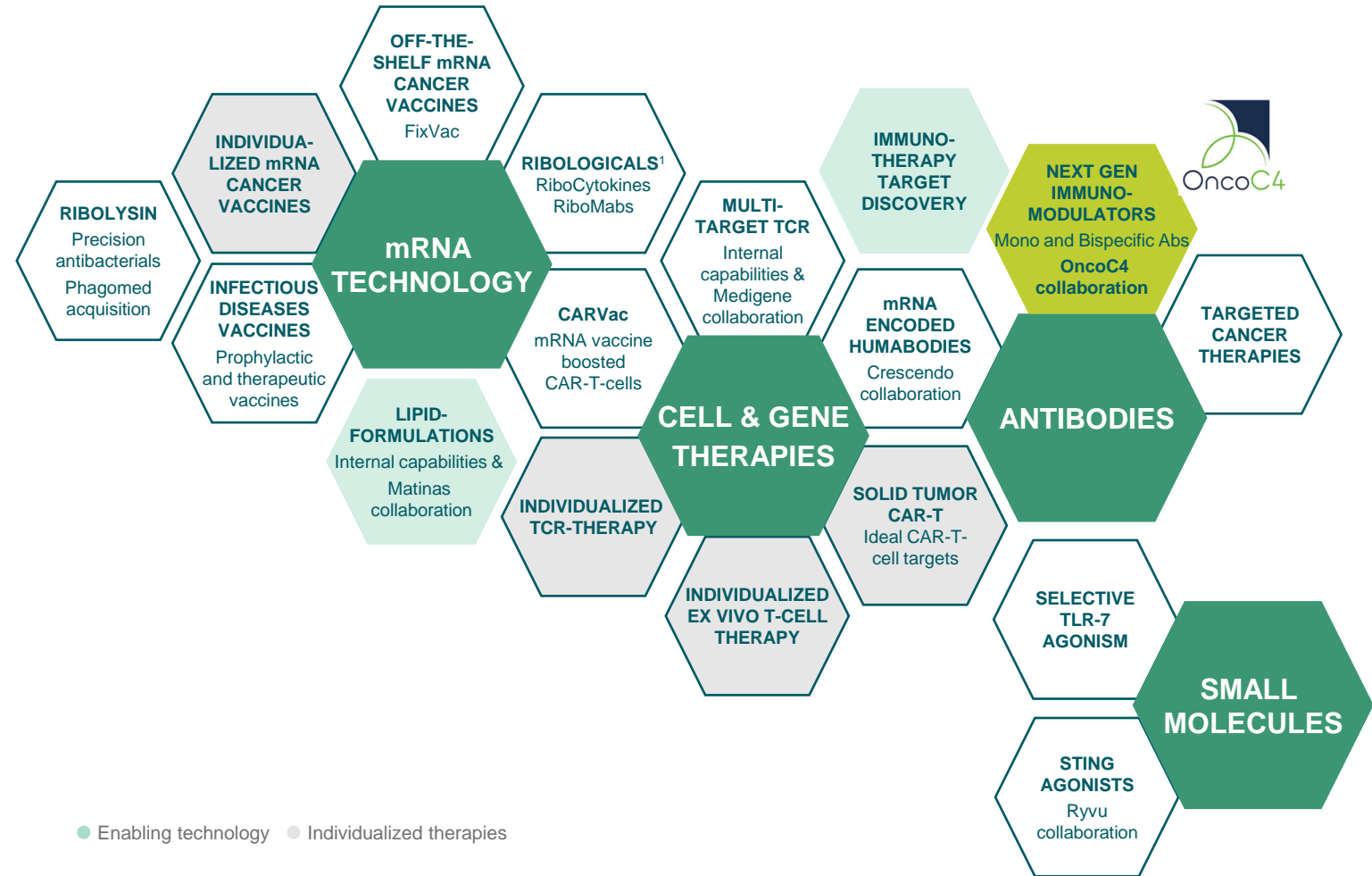
## Core principles of our technology strategy

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



1. mRNA encoded cancer-targeting antibodies and cytokines

# 2023 Strategic Priorities

## COVID-19 franchise<sup>1</sup>

Sustain leadership in COVID-19  
Advance next-gen vaccines

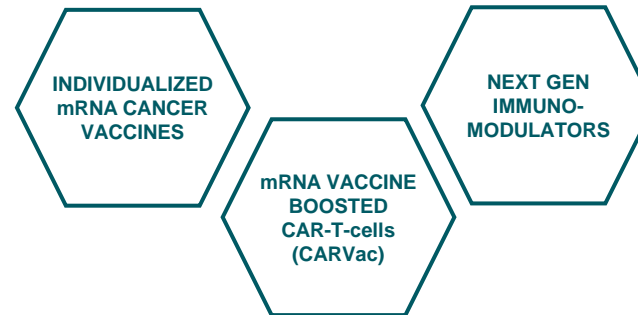


### Next-generation vaccine candidate programs:

Variant-adapted <b>BNT162b2<sup>1</sup></b>	T-cell enhancing <b>BNT162b4 +BNT162b2</b>	Combination <b>COVID-19+Flu<sup>2</sup></b> BNT162b2+BNT161
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## Immuno-oncology

Advance disruptive platforms for solid tumors  
Initiate multiple potentially registrational trials



### Focus programs:

<b>BNT122<sup>3</sup></b> adj. CRC 1L Melanoma	<b>BNT211</b> CLDN6+ tumors	<b>BNT312<sup>4</sup></b> <b>BNT311<sup>4</sup></b> <b>ONC-392<sup>5</sup></b> Solid tumors
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## Infectious diseases

Initiate and accelerate clinical programs for high need indications



### Ongoing clinical trials:

<b>HSV-2<sup>6</sup></b> BNT163	<b>Malaria</b> BNT165	<b>Shingles<sup>1</sup></b> BNT167
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### Program advancing to clinic:

Tuberculosis<sup>7</sup>  
BNT164

1. Partnered with Pfizer, 2. Collaboration with PFE and subject to reaching agreement with our partners, 3. Partnered with Genentech, member of Roche Group, 4. Partnered with Genmab, 5. Partnered with OncoC4, 6. Collaboration with University of Pennsylvania, 7. Collaboration with Bill & Melinda G. Foundation, 6.

# Anti-CTLA-4 Antibody: A Promising New Addition to our Growing Immuno-Oncology Checkpoint Portfolio

## Phase 3-Ready Program & Broad Combination Potential with BioNTech mRNA Vaccine Candidate Programs

- First FDA approval of ipilimumab in 2011
- Today 2 products approved in 7 cancer indications<sup>1</sup>
- Approved as monotherapy and/or combination therapy
- Lasting remissions observed in a fraction of responding patients<sup>2</sup>
- Narrow therapeutic window: Toxicities limit dose and duration needed for optimal efficacy<sup>2</sup>



### ONC-392: a differentiated anti-CTLA-4 antibody program

- Designed to preserve CTLA-4 recycling and regulatory T-cell function in healthy tissue
- Could allow for more effective dosing regimen and more successful tumor killing leading to potentially improved therapeutic index
- Planned to be developed as monotherapy in some advanced solid tumor indications

1. As of March 2023; 2. Refers to approved anti-CTLA-4 monoclonal antibodies. CTLA-4 = cytotoxic T-lymphocyte protein 4, FDA = Food and Drug Administration

The transaction is expected to close in the first half of 2023, subject to customary closing conditions and regulatory clearance.

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# Pipeline & COVID-19 Vaccines Update

Özlem Türeci, Chief Medical Officer

BIONTECH



















# Multiple Clinical Data Readouts Reported at Major Medical Meetings in 2022

Platform	iNeST	CARVac	FixVac	Next-generation immuno-modulators
Program	<b>BNT122<sup>1</sup></b> Pancreatic ductal adenocarcinoma <sup>2</sup>	<b>BNT211</b> CLDN6+ solid tumors	<b>BNT113</b> HPV16+ HNSCC	<b>BNT312 (GEN1042)<sup>3</sup></b> Multiple solid tumors
Data update	<b>ASCO</b> Ph1 in adjuvant PDAC: <ul style="list-style-type: none"> <li>A fraction of patients have high magnitude de-novo, neoantigen-specific T-cell responses which are associated with significantly longer RFS.</li> </ul>	<b>ESMO</b> Ph1/2: <ul style="list-style-type: none"> <li>Manageable safety profile</li> <li>Objective responses across different tumor types</li> <li>Patients with testicular cancer reached an ORR of 57% and a DCR of 85% (1CR, 3PR, 2SD)</li> </ul>	<b>ESMO IMMUNO-ONCOLOGY</b> Ph2 (Part A): <ul style="list-style-type: none"> <li>Safety profile acceptable and in line with BNT113 and pembrolizumab monotherapy</li> </ul>	<b>ESMO IMMUNO-ONCOLOGY</b> Ph1/2: <ul style="list-style-type: none"> <li>BNT312 + PEM ± CTx was well tolerated</li> <li>Early activity in advanced/metastatic HNSCC (2CR, 2PR)</li> </ul>
Next steps	<ul style="list-style-type: none"> <li>Ph2 trial in adjuvant PDAC to start in 2023</li> </ul>	<ul style="list-style-type: none"> <li>Data update from Ph1/2 trial in CLDN6+ advanced solid tumors in 2023</li> <li>Ph2 trial in 2L platinum resistant testicular cancer to start in 2024</li> </ul>	<ul style="list-style-type: none"> <li>Ph2 trial (Part B) is ongoing</li> </ul>	<ul style="list-style-type: none"> <li>Data update from Ph1/2 trial in multiple solid tumors expected in 2023</li> </ul>

1. Partnered with Genentech, member of Roche Group, 2. Investigator initiated study, 3. Partnered with Genmab  
 HPV = Human papilloma virus, HNSCC = Head and neck squamous-cell carcinoma, PDAC = Pancreatic ductal adenocarcinoma, RFS = Relapse-free survival, ORR = Objective response rate, DCR = Disease control rate, CR = Clinical response, PR = Partial response, SD = Stable disease, PEM = Pembrolizumab, CTx = Chemotherapy

# Oncology Pipeline: Significant Progress and Expansion in 2022

Drug Class	Phase 1 (5 First-in-Human)	Phase 1/2	Phase 2
mRNA	<b>BNT111</b> Advanced melanoma	<b>BNT112</b> Prostate cancer	<b>BNT111</b> aPD1-R/R melanoma, + Pembro
	<b>BNT116</b> NSCLC 	<b>BNT113<sup>1</sup></b> HPV16+ head and neck cancer	<b>BNT113</b> 1L rec./met. HPV16+ PDL1+ head and neck cancer, + Pembro 
	<b>Autogene cevumeran (BNT122)<sup>2</sup></b> Multiple solid tumors	<b>BNT141 (CLDN18.2)</b> Multiple solid tumors 	<b>Autogene cevumeran (BNT122)<sup>2</sup></b> 1L Adv. melanoma, + Pembro
	<b>Autogene cevumeran (BNT122)<sup>1</sup></b> PDAC 	<b>BNT142 (CLDN6)</b> Multiple solid tumors 	<b>Autogene cevumeran (BNT122)<sup>2</sup></b> Adjuvant colorectal cancer
	<b>BNT131 (SAR441000)<sup>3</sup></b> Solid tumors (IL-12sc, IL15-sushi, GM-CSF, IFN $\alpha$ )	<b>BNT151 (optimized IL-2)</b> Multiple solid tumors	
	<b>BNT152 + BNT153</b> Multiple solid tumors (IL-7, IL-2)		
Cell therapy	<b>BNT221 (NEO-PTC-0)</b> Multiple solid tumors	<b>BNT211 (CLDN6)</b> Multiple solid tumors 	
Antibodies	<b>BNT321 (MVT-5873)</b> Pancreatic cancer (sLea)	<b>BNT311 (GEN1046)<sup>4</sup></b> (PD-L1x4-1BB) Multiple solid tumors	<b>BNT311 (GEN1046)<sup>4</sup></b> (PD-L1x4-1BB) aPD1-R/R NSCLC, + Pembro  
	<b>BNT322 (GEN1056)<sup>4</sup></b> Multiple solid tumors (undisclosed) 	<b>BNT312 (GEN1042)<sup>4</sup></b> (CD40x4-1BB) Multiple solid tumors 	<b>ONC-392<sup>5</sup></b> (CTLA-4) Multiple solid tumors  
SMIM		<b>BNT411 (TLR7)</b> Multiple solid tumors	<b>ONC-392<sup>5</sup></b> (CTLA-4) Plat.-R ovarian cancer, + Pembro 

 = First Patient Dosed  
 = Data update  
 = New strategic collaboration

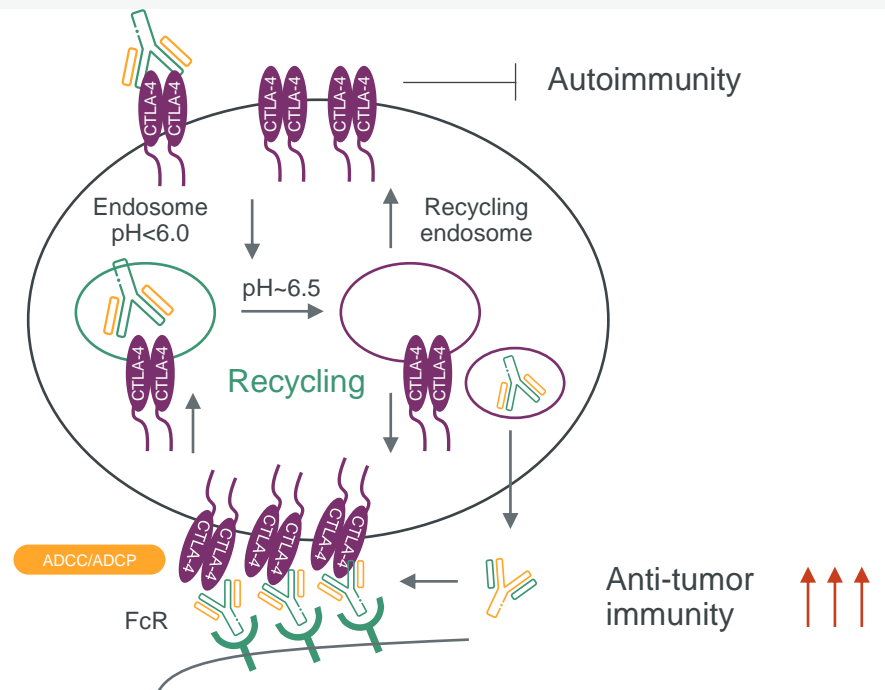
1. Investigator-initiated / Investigator-initiated and sponsored trial, 2. Partnered with Genentech, member of Roche Group, 3. Partnered with Sanofi, 4. Partnered with Genmab, 5. Partnered with OncoC4  
 NSCLC = Non-small cell lung cancer, HPV16 = Human papillomavirus 16, CLDN = Claudin, IL = Interleukin, PDAC = Pancreatic ductal adenocarcinoma, Pembro = Pembrolizumab, 1L = first line, TLR = Toll-like receptor, R/R = Relapsed/Refractory, Plat.-R. = Platinum-resistant, SMIM = small molecule immunomodulator

# Differentiated Mechanism with Potential to Become Best-in-Class Anti-CTLA-4 Antibody

Avoiding lysosomal degradation of CTLA-4 for safer and more effective immunotherapy may lead to an uncoupling of cancer therapeutic effect from immunotherapy-related adverse effects

## ONC-392 designed to:

- Allow regular recycling of antibody and CTLA-4 molecule
- Enhance anti-tumor immunity
- Reduce immune-related adverse events



Liu Y. et al. Abstract # 231, SITC 2021. Du et al. Uncoupling therapeutic from immunotherapy-related adverse effects for safer and effective anti-CTLA-4 antibodies in CTLA4 humanized mice. *Cell Res.* 2018 Apr; 28(4): 416–432. Du et al. A reappraisal of CTLA-4 checkpoint blockade in cancer immunotherapy. *Cell Res.* 2018 Apr; 28(4): 433–447.

FcR = fragment crystallizable region, CTLA-4 = cytotoxic T-lymphocyte-associated protein 4, ADCC = antibody-dependent cell-mediated cytotoxicity, ADCP = antibody-dependent cellular phagocytosis

# MoA Designed to Allow Higher Dosing & Longer Duration of Treatment with ONC-392

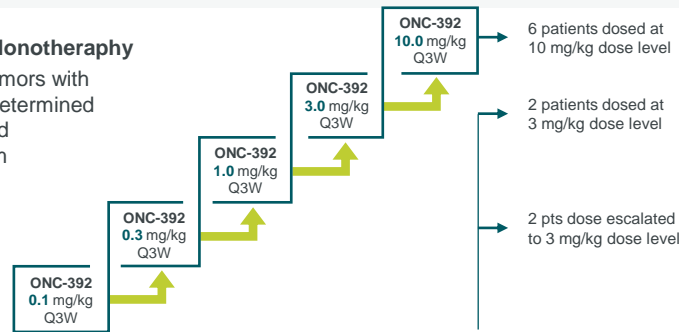
## PRESERVE-001: Study Design and Safety (NCT04140526)

### Monotherapy: Dose Finding

(Li T. et al. Poster #949, Presented at SITC 2021)

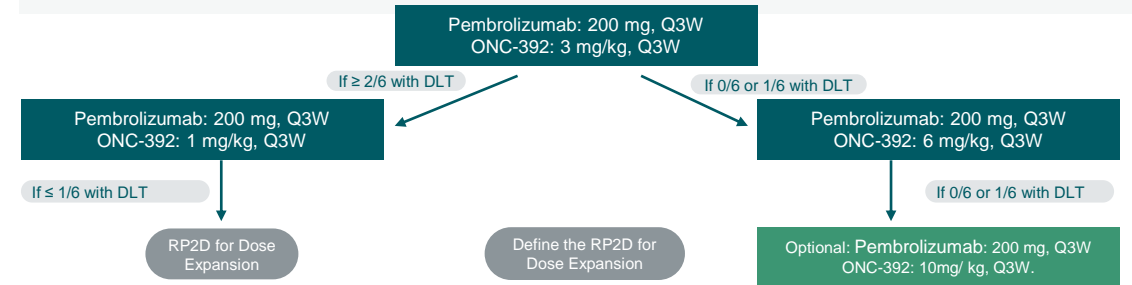
#### Objective: To estimate MTD or RP2D for Monotherapy

Patients with advanced or metastatic solid tumors with measurable or non-measurable disease as determined by RECIST version 1.1, who have progressed despite standard of care therapy, or for whom no standard therapies exist



### Combination: Dose Escalation

(Hu-Lieskovan et al. Poster #594. Presented at SITC 2022)



Dose expansion tested in multiple cancer types including:

IO naive NSCLC    IO R/R NSCLC    IO naive Melanoma    IO R/R Melanoma

## Safety data and study conclusions

- ONC-392 dosed as mono-therapy and in combination with pembrolizumab were well tolerated
  - TRAE were manageable, no DLTs, MTD not reached
  - Monotherapy RP2D: 10 mg/kg, Combination RP2D: 6 mg/kg
- Preliminary data demonstrated lower irAE rate than observed for comparable IO or IO-IO combinations
- Safety profile of ONC-392 allows for higher dosing and longer duration of treatment in monotherapy and in combination with pembrolizumab

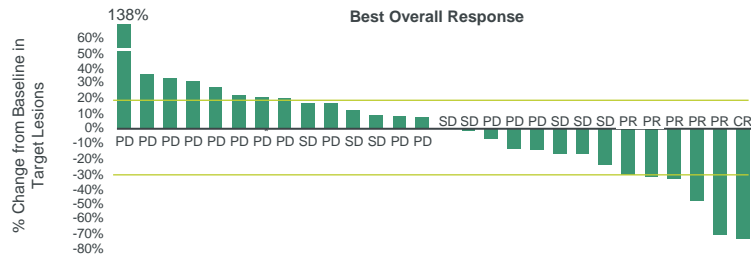
Q3W = Every three weeks; MTD = Maximum tolerated dose; RP2D = Recommended phase 2 dose; DLT = Dose-limiting toxicity; TRAE = Treatment related adverse event; NSCLC = Non-small cell lung cancer; irAE = immune-related adverse event, IO = immuno-oncologic, R/R = relapsed/refractory

# ONC-392 as a Single Agent and Combination Therapy in Multiple Solid Tumors

## PRESERVE-001: Clinical Efficacy (NCT04140526)

### Monotherapy (10 mg/kg) in platinum-resistant ovarian cancer patients

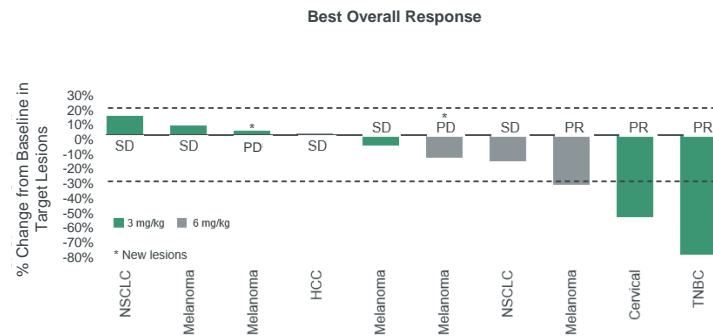
Hays J et al. Poster #564. Presented at SITC 2022



- 14/28 pts. with clinical activity
  - CR/PR/SD/PD = 1/5/8/14
  - ORR=21%, DCR=50%

### ONC-392 (3 or 6 mg/kg) in combination with pembrolizumab

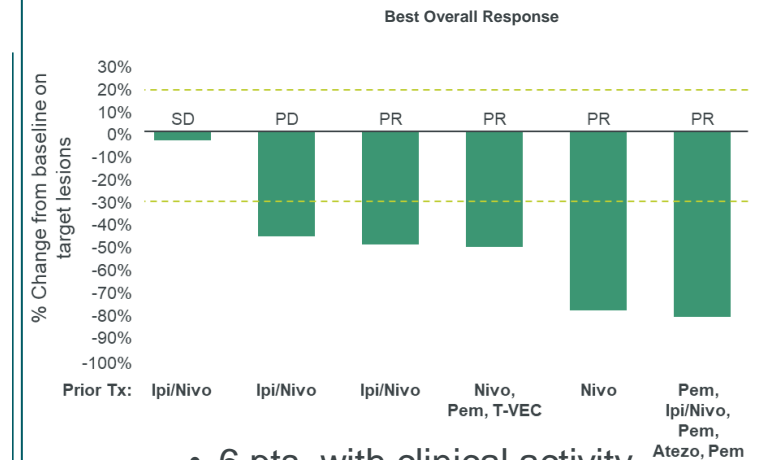
Hu-Lieskovan et al. Poster #594. Presented at SITC 2022



- 8/10 pts. with clinical activity
  - At 3 mg/kg (6 pts.): 2 PR, 3 SD
  - At 6 mg/kg (4 pts.): 1 PR, 2 SD

### ONC-392 (6mg/kg) in combination with pembro in R/R Melanoma

Hu-Lieskovan et al., Poster #594. Presented at SITC 2022



- 6 pts. with clinical activity
  - 5 PR, 1 SD

## ONC-392 Development Plan

### Phase 2 ongoing

ONC-392 (CTLA-4), NCT05446298

Plat.-resistant ovarian cancer + pembrolizumab

### Phase 3 planned

ONC-392 (CTLA-4), NCT05671510

aPD1-R/R NSCLC, Monotherapy

\*irAE= immune-related adverse event, CR = Complete remission; PR = Partial response; SD = Stable disease; PD = Progressive Disease; ORR = Objective response rate; DCR = Disease control rate, Ipi = Ipilimumab, Nivo = Nivolumab, Pem = Pemetrexed, Tx = Treatment, T-VEC = Talimogen laherparepvec, Atezo = atezolizumab, R/R = Relapsed/Refractory



# Infectious Disease Pipeline: Expansion in 2022



1. Collaboration with PFE and subject to reaching agreement with our partners, 2. Exclusive license to Pfizer, 3. Collaboration with University of Pennsylvania, HSV = Herpes simplex virus

# Broadest Label of COVID-19 Vaccines

Vaccine	Strain	Use	Europe (full MA)			U.S. (BLA and EUA)		
			Population			Population		
			≥ 6 months	≥ 5 years	≥ 12 years	≥ 6 months	≥ 5 years	≥ 12 years
COMIRNATY <sup>1</sup>	Original strain	Primary	✓	✓	✓	✓	✓	✓
	Original strain + Omicron BA.4-5 variant adapted	Booster		✓	✓	✓*	✓	✓
	Original strain + Omicron BA.1 variant adapted	Booster			✓			

■ MA/BLA Approval granted

■ EUA granted

\* As third dose following 2 x Original

1. Partnered with Pfizer  
MA = Marketing authorization, BLA = Biologics license application, EUA = Emergency use application

# Initiated Phase 1/2 Trial of Varicella Zoster Virus modRNA Vaccine Candidate<sup>1</sup>



mRNA VZV vaccine groups:  
N~50 adults aged 50-69

Shingrix group 0, 2- month group:  
N~60, 0, 6 month group: N~50

Primary endpoints:  
safety, tolerability and immunogenicity



## Varicella Zoster Virus (VZV) modRNA vaccine candidate

↓	↓	↓	↓	↓	↓	↓	↓	↓
Dose Level 1	Dose Level 2	Dose Level 3	Dose Level 2	Dose Level 3	-	-	Shingrix Dose: n/a	Shingrix Dose: n/a
Candidate 1	Candidate 1	Candidate 1	Candidate 1	Candidate 1	Candidate 2	Candidate 3	(Lyophilized) 0, 2 month	(Lyophilized) 0,6 month
(Lyophilized) 0, 2 month	(Lyophilized) 0, 2 month	(Lyophilized) 0, 2 month	(Frozen) 0, 2 month	(Frozen) 0, 6 month	(Frozen) 0, 2 month	(Frozen) 0, 2 month		

Potential benefit of mRNA  
vaccine for Shingles:

High efficacy

Well-tolerated

Efficient production, globally

<sup>1</sup> Trial being conducted by Pfizer as part of the ongoing collaboration, NCT05703607



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# 3

## Financial Results

Jens Holstein, Chief Financial Officer

## FY 2022 Key Highlights

Total revenues<sup>1</sup> € **17.3** bn

Operating cashflow € **13.6** bn

Diluted EPS € **37.77**

Cash and cash equivalents<sup>2</sup> € **13.9** bn

1. BioNTech's profit share is estimated based on preliminary data shared between Pfizer and BioNTech as further described in the Annual Report on Form 20-F for the year ended December 31, 2022 filed on March 27, 2023 with the SEC. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively.

2. The payment settling our gross profit share for the third quarter of 2022 (as defined by the contract) in the amount of €1,816.5 million was received from our collaboration partner subsequent to the end of the reporting period as of January 12, 2023.



# FY Financial Year Guidance vs. Actuals

		<b>Guidance update</b> (as published in Q3 2022 Financial Results and Corporate Update)	<b>Actuals FY 2022</b>
<b>FY 2022 COVID-19 vaccine revenues</b>	Estimated BioNTech COVID-19 vaccine revenues <sup>1</sup>	€16 – 17 bn	<b>€17.1 bn</b>
<b>FY 2022 expenses and capex</b>	R&D expenses	€1,400 – 1,500 m	<b>€1,537 m</b>
	SG&A expenses	€450 – 550 m	<b>€544 m</b>
	Capital expenditure	€450 – 550 m	<b>€363 m</b>
<b>FY 2022 tax assumptions</b>	BioNTech Group estimated annual effective income tax rate	~ 27%	(IFRS) ~ <b>27%</b> (cash-effective) <sup>2</sup> ~ <b>24%</b>

1. BioNTech's profit share is estimated based on preliminary data shared between Pfizer and BioNTech as further described in the Annual Report on Form 20-F for the year ended December 31, 2022 filed on March 27, 2023 with the SEC. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively.

2. Reduction in cash effective tax rate due to IAS 12.68c as a result of tax deductibility of share-based payment settlement.

# Full Year 2022 COVID-19 Vaccine Revenues

€17.1 bn



FY 2022

- Share of gross profit from COVID-19 vaccine sales in the Pfizer and Fosun Pharma territory (100% gross margin)<sup>1</sup>
- Direct COVID-19 vaccine sales to customers in BioNTech's territory
- COVID-19 vaccine sales to collaboration partners<sup>2</sup>

FY 2022 revenues in line with our expectations

1. BioNTech's profit share is estimated based on preliminary data shared between Pfizer and BioNTech as further described in the Annual Report on Form 20-F for the year ended December 31, 2022 filed on March 27, 2023 with the SEC. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively.

2. Represents sales to collaboration partners of products manufactured by BioNTech and reflects manufacturing costs and variances to the extent identified.

# Q4 and FY 2022 Financial Results – Profit or Loss

(in millions, except per share data) <sup>1</sup>	Three months ended December 31		Years ended December 31	
	2022	2021	2022	2021
Commercial revenues <sup>2</sup>	€4,271.3	€5,525.9	€17,194.6	€18,874.0
Research & development revenues	7.0	6.6	116.0	102.7
<b>Total revenues</b>	<b>€4,278.3</b>	<b>€5,532.5</b>	<b>€17,310.6</b>	<b>€18,976.7</b>
Cost of sales	(183.5)	(583.2)	(2,995.0)	(2,911.5)
Research and development expenses	(509.8)	(271.5)	(1,537.0)	(949.2)
Sales and marketing expenses	(14.6)	(17.9)	(59.5)	(50.4)
General and administrative expenses	(122.9)	(130.9)	(484.7)	(285.8)
Other operating income less expenses	(154.6)	170.7	408.3	504.0
<b>Operating income</b>	<b>€3,292.9</b>	<b>€4,699.7</b>	<b>€12,642.7</b>	<b>€15,283.8</b>
Finance income less expenses	(120.3)	14.2	311.4	(237.4)
Income taxes	(893.9)	(1,547.7)	(3,519.7)	(4,753.9)
<b>Profit for the period</b>	<b>€2,278.7</b>	<b>€3,166.2</b>	<b>€9,434.4</b>	<b>€10,292.5</b>
<b>Earnings per share</b>				
Basic profit for the period per share	€9.38	€12.96	€38.78	€42.18
Diluted profit for the period per share	€9.26	€12.18	€37.77	€39.63

1. Numbers have been rounded, numbers presented may not add up precisely to the totals and may have been adjusted in the table context. Presentation of the consolidated statements of profit or loss has been condensed.

2. BioNTech's profit share is estimated based on preliminary data shared between Pfizer and BioNTech as further described in the Annual Report on Form 20-F for the year ended December 31, 2022 filed on March 27, 2023 with the SEC. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively.

# Full Year 2022 Return to Shareholders

## Dividend 2022

**Dividend** in the amount of €0.5 bn paid

## Share Repurchase Program

**Repurchase American Depositary Shares** (ADS) in the amount of up to \$1.5 bn

**Repurchased ADSs** are to be used in whole or in part to satisfy upcoming settlement obligations under share-based payment arrangements

**First tranche worth up to \$1.0 bn** began May 2, 2022, and ended October 10, 2022 amounting to \$1.0 bn

**Second tranche worth up to \$0.5 bn** commenced on December 7, 2022, and ended on March 17, 2023 amounting to \$0.3 bn

**Total net consideration** of approximately \$1.3 bn under the program

Period	Number of acquired ADSs	Percentage of share capital <sup>1</sup>	Average price (in \$)	Volume (in million \$)
May 2, 2022 to March 17, 2023	9,166,684	3.7%	142.04	1,302

1. For the share repurchase, the "percentage of share capital" ratio is calculated based on the shares issued as of April 30, 2022 (248,552,200 ordinary shares).

## 2023 Financial Guidance Key Assumptions and Considerations

- Expected transition from an advanced purchased agreement environment to commercial market ordering starting in 2023 and a regulatory recommendation to adapt the COVID-19 vaccines to newly circulating variants or sublineages of SARS-CoV-2
- Revenue guidance reflects expected deliveries under existing or committed supply contracts and anticipated sales through traditional commercial orders
- Re-negotiation of the existing supply contract with the European Commission is ongoing with the potential for a rephasing of dose deliveries across multiple years and/or volume reduction
- While need for a new variant-adapted vaccine increasing the demand is expected, fewer primary vaccinations and lowered population-wide levels of boosting are anticipated
- Seasonal demand assumed, moving expected revenue generation significantly to the second half of the year 2023

## 2023 Financial Year Guidance

<b>COVID-19 vaccine revenues for FY 2023<sup>1</sup></b>	Estimated BioNTech COVID-19 vaccine revenues	~ €5 bn
<b>Planned FY 2023 expenses and capex<sup>1</sup></b>	R&D expenses	€2,400 – 2,600 m
	SG&A expenses	€650 – 750 m
	Capital expenditure	€500 – 600 m
<b>Estimated FY 2023 tax assumptions</b>	BioNTech Group estimated annual cash effective income tax rate	~ 27%

1. Numbers reflect current base case projections, include potential effects caused by or driven from additional collaborations or potential M&A transactions to the extent they have been disclosed and are calculated based on constant currency rates.

# Capital Allocation Framework

## R&D activities

**Main focus remains the acceleration of our R&D activities** in oncology and infectious diseases

## M&A and business development

**Strengthen pipeline, technology platforms and digital capabilities** by collaborations and potential complementary M&A

## Return capital to shareholders

**Expect to authorize a share repurchase program** of up to \$0.5 bn during the year 2023



# 4

## Strategic Outlook

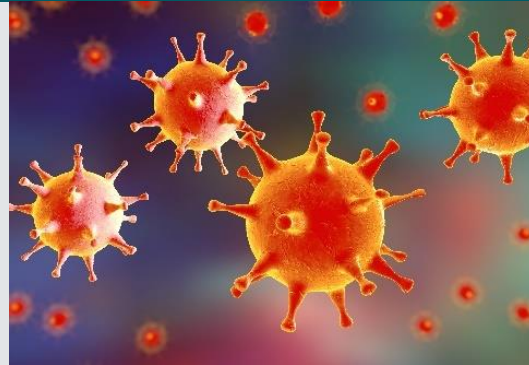
Ryan Richardson, Chief Strategy Officer

# 2023 Strategic Outlook

COVID-19 franchise



Infectious disease pipeline



Oncology pipeline



# Mid-term Growth Potential for COVID-19 Vaccine Franchise

- First commercial market opening expected in 2H 2023 in the United States, likely to be shaped by ACIP and VRBPAC recommendations
  - Assume that VRBPAC strain selection in May/June will be relevant for 2H booster supply in 2023
- Transition from pandemic to steady state market expected to take several years
- Growth potential for COVID-19 franchise from 2025, driven by shift to commercial market and the potential introduction of next-generation vaccines and novel combinations

## COVID-19 vaccine pipeline

BNT162b4 + BNT162b2  
(T-cell enhancing)  
COVID-19<sup>1</sup>



BNT162b2+BNT161  
(qFlu + BA.4-5-adapted bivalent)  
COVID-19/Influenza combination<sup>2</sup>



Additional variant-adapted vaccine  
COVID-19<sup>1</sup>

✓ = Data update expected in 2023

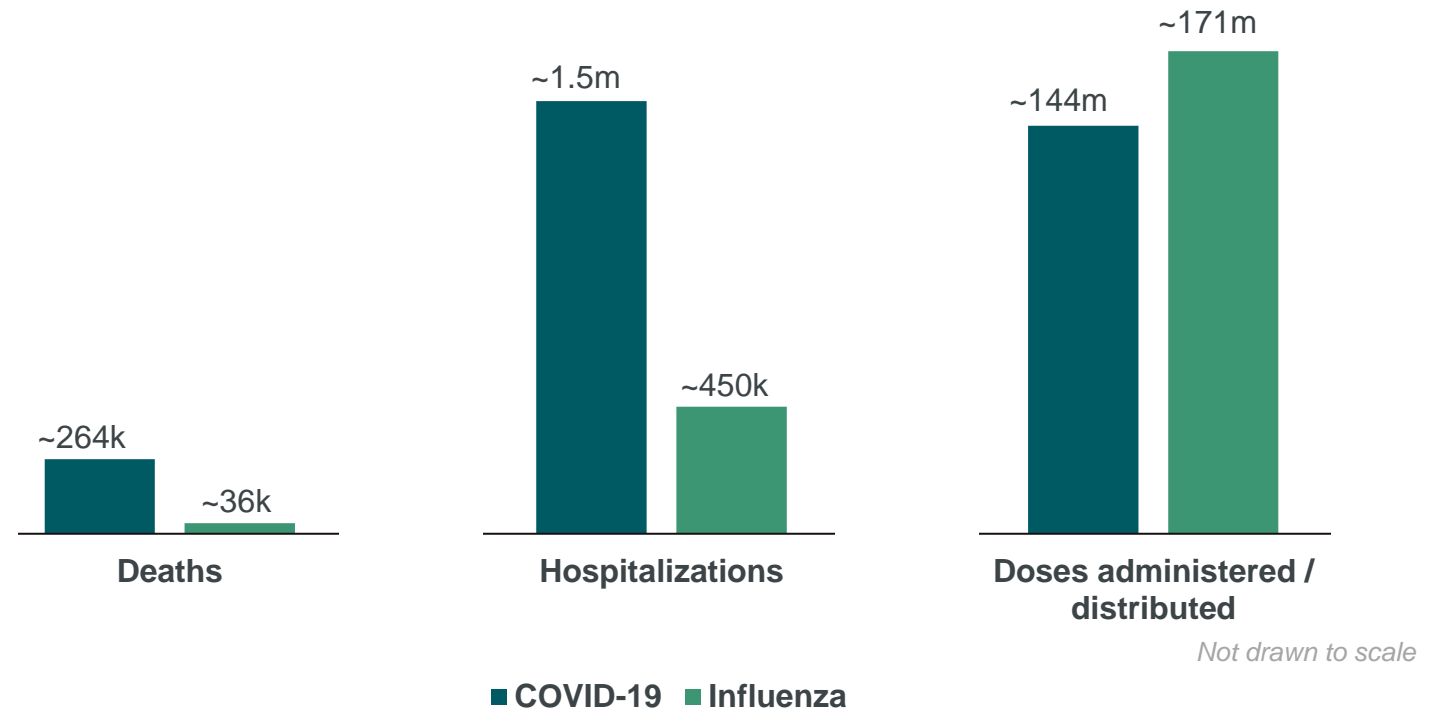
1. Partnered with Pfizer, 2. Collaboration with PFE and subject to reaching agreement with our partners  
ACIP = Advisory Committee on Immunization Practices; VRBPAC = Vaccines and Related Biological Products Advisory Committee

# 2022 COVID-19 Deaths and Hospitalizations Greatly Exceeded Those from Influenza in the United States

## COVID-19 continues to cause mortality, hospitalization and long-term complications

- A leading cause of death worldwide, estimated to exceed 6.8 million deaths<sup>1</sup>
- A leading cause for respiratory disease hospitalization in the United States<sup>2</sup>
- Evidence suggesting that patients with the SARS-CoV-2 Omicron variant had a higher risk of in-hospital mortality than those with influenza<sup>3</sup>
- Estimated to be >65 million long COVID sufferers worldwide (more than 10% of COVID survivors)<sup>4,5</sup>

Death, hospitalizations and administered/distributed vaccine doses in the U.S.:  
COVID-19 vs. Influenza in 2022<sup>6-8</sup>



1. WHO Coronavirus (COVID-19) Dashboard 2. Since October 2022: <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html>; 3. Portmann et al. Jama Netw Open. 2023;6(2):e2255599; 4. Huerne K, Filion KB, Grad R, Ernst P, Gershon AS, Eisenberg MJ. Epidemiological and Clinical Perspectives of Long COVID Syndrome. Am J Med Open. 2023 Jan 18;9:100033. doi: 10.1016/j.ajmo.2023.100033. 5. Davis H et al. Nature Reviews Microbiology. 2023.21,133-146; 6. <https://www.cdc.gov/flu/about/burden/preliminary-in-season-estimates.htm>; 7. <https://www.cdc.gov/flu/fluview/dashboard/vaccination-doses-distributed.html>; 8. [https://gis.cdc.gov/grasp/covidnet/covid19\\_5.html](https://gis.cdc.gov/grasp/covidnet/covid19_5.html)

# Advancing Broader Infectious Disease Vaccine Portfolio

- Advancing 2 additional clinical stage mRNA vaccine programs partnered with Pfizer and multiple wholly owned infectious disease vaccines
- Focused on prophylactic vaccines against diseases of high global incidence and causing significant mortality and/or morbidity
- Targeting diseases with no marketed vaccine or room for differentiation over existing vaccines
- Multiple additional trial starts expected in the next 12 months

## Infectious disease pipeline

BNT161  
Influenza<sup>1</sup>



BNT167  
Shingles<sup>2</sup>



BNT163  
HSV-2<sup>3</sup>



BNT165  
Malaria



Preclinical program  
Tuberculosis<sup>4</sup>



✓ = Data update expected in 2023

= First Patient Dosed expected in 2023

1. Licenced to Pfizer, 2. Partnered with Pfizer, 3. Collaboration with University of Pennsylvania, 4. Collaboration with Bill & Melinda Gates Foundation  
HSV-2 = Herpes Simplex Virus 2,

# 2023 Strategic Outlook in Oncology

- Multiple trials with registrational potential expected to be initiated in 2023-2024
- Build-out of oncology commercial capabilities to accelerate in 2023-2024
- Goal of commercial readiness in the United States, European Union and other selected regions to support first potential oncology launches from 2026 onwards, subject to regulatory approvals
- Anticipate further M&A and/or product candidate in-licensing to complement organic pipeline advancement
- Aim to deliver multiple oncology product approvals from 2026 onwards

## Mid-stage oncology pipeline

**BNT111**  
aPD1-R/R melanoma, + Pembro

**BNT113**  
1L rec./met. HPV16+ head and neck cancer, + Pembro

**Autogene cevumeran (BNT122)<sup>1</sup>**  
1L Adv. melanoma, + Pembro ✓

**Autogene cevumeran (BNT122)<sup>1</sup>**  
Adjuvant colorectal cancer

**BNT311 (GEN1046) (PD-L1x4-1BB)<sup>2</sup>**  
aPD1-R/R NSCLC, + Pembro

**ONC-392<sup>3</sup> (CTLA-4)**  
Plat.-R ovarian cancer, + Pembro

**BNT211 (CLDN6)**  
Multiple solid tumors ✓

**BNT312 (GEN1042)<sup>2</sup> (CD40x4-1BB)**  
**BNT311 (GEN1046)<sup>2</sup> (PD-L1x4-1BB)** ✓  
Multiple solid tumors

1. Partnered with Genentech, member of Roche Group, 2. Partnered with Genmab, 3. Partnered with OncoC4  
NSCLC = Non-small cell lung cancer, CLDN = Claudin, HPV16 = Human papillomavirus 16, 1L = first line, R/R = Relapsed/Refractory, Plat.-R = Platinum-resistant

Phase 1 Phase 2 ✓ = Data update expected in 2023



# Multiple Late- and Early-Stage Pipeline Milestones Expected in 2023

Modality	Indication	Program	Select milestones	Anticipated timing
mRNA vaccines for infectious disease	COVID-19 <sup>1</sup>	BA.4-5-adapted bivalent	Pediatric label expansion	2H 2023
	COVID-19 – influenza Combination <sup>1,2</sup>	BA.4-5-adapted bivalent+ BNT161	Phase 1 data update	2023
	Malaria	BNT165	Phase 1 data update	2H 2023
	HSV-2 <sup>3</sup>	BNT163	Phase 1 data update	2H 2023
	Shingles <sup>1</sup>	BNT167	Phase 1 FPD	FPD in February 2023
	Tuberculosis <sup>4</sup>	BNT164	Phase 1 FPD	H1 2023
iNeST individualized mRNA vaccines	1L melanoma <sup>5</sup>	Autogene Cevumeran (BNT122)	Phase 2 data update	2023
	Adjuvant CRC <sup>5</sup>	Autogene Cevumeran (BNT122)	Phase 2 data update	-
	Adjuvant PDAC <sup>6</sup>	Autogene Cevumeran (BNT122)	Phase 2 FPD	2023
Next-gen immune checkpoint modulators	Multiple solid tumors <sup>7</sup>	BNT311 (PD-L1x4-1BB)	Expansion cohort data update	2023
	Multiple solid tumors <sup>7</sup>	BNT312 (CD40x4-1BB)	Expansion cohort data update	2023
	2L NSCLC <sup>8</sup>	ONC-392 (CTLA-4)	Phase 3 FPD	2023
Cell therapies	CLDN6+ solid tumors	BNT211	Phase 1 data update	2023
	2L+ testicular cancer	BNT211	Phase 2 FPD	2024

1. Partnered with Pfizer; 2. Collaboration with Pfizer and subject to reaching agreement with our partners, 3. Partnered with University of Pennsylvania; 4. Collaboration with Bill & Melinda Gates Foundation; 5. Partnered with Genentech, a member of Roche Group; 6. Investigator-initiated trial, 7. Collaboration with Genmab, 8. Collaboration with OncoC4  
 FPD = First Patient Dosed, CRC = Colorectal cancer, PDAC = Pancreatic ductal adenocarcinoma, HSV = Herpes simplex virus, NSCLC = Non-small cell lung cancer, CLDN6 = Claudin 6, 1L = first line, 2L = second line

# SAVE THE DATE

## BIONTECH



Annual General Meeting  
**May 25, 2023**



Innovation Series Day  
**November 7, 2023**



Thank you

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BIONTECH