# 2nd Quarter 2022 Financial Results & Corporate Update

August 8, 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: our expected revenues and net profit related to sales of our COVID-19 vaccine, referred to as COMIRNATY® where approved for use under full or conditional marketing authorization, in territories controlled by our collaboration partners, particularly for those figures that are derived from preliminary estimates provided by our partners; our pricing and coverage negotiations with governmental authorities, private health insurers and other third-party payors after our 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 our 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 our COVID-19 vaccine and, if approved, our investigational medicines; the initiation, timing, progress, results, and cost of our research and development programs, including those relating to additional formulations of our COVID-19 vaccine, and our 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 our research and development programs; the timing of and our ability to obtain and maintain regulatory approval for our product candidates; the ability of BNT162b2 to prevent COVID-19 caused by emerging virus variants; our and our counterparties' ability to manage and source necessary energy resources; our ability to identify research opportunities and discover and develop investigational medicines; the ability and willingness of our third-party collaborators to continue research and development activities relating to our development candidates and investigational medicines; the impact of the COVID-19 pandemic on our development programs, supply chain, collaborators and financial performance; unforeseen safety issues and claims for personal injury or death arising from the use of our COVID-19 vaccine and other products and product candidates developed or manufactured by us; our ability to progress our Malaria, Tuberculosis and HIV programs, including timing for selecting clinical candidates for these programs and the commencement of a clinical trial, as well as any data readouts; the nature and duration of support from the World Health Organization, the European Commission and other organizations with establishing infrastructure; the development of sustainable vaccine production and supply solutions on the African continent, including our BioNTainers, and the nature and feasibility of these solutions; our estimates of research and development revenues, commercial revenues, cost of sales, research and development expenses, sales and marketing expenses, general and administrative expenses, capital expenditures, income taxes, shares outstanding; our ability and that of our collaborators to commercialize and market our product candidates, if approved, including our COVID-19 vaccine; our ability to manage our development and expansion; regulatory developments in the United States and foreign countries; our ability to effectively scale our production capabilities and manufacture our products, including our target COVID-19 vaccine production levels, and our product candidates; and other factors not known to us at this time. In some cases, forward-looking statements can be identified by terminology such as “will,” “may,” “should,” “expects,” “intends,” “plans,” “aims,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue,” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. The forward-looking statements in this presentation are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond BioNTech’s control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. You should review the risks and uncertainties described under the heading “Risk Factors” in our quarterly report for the three months ended June 30, 2022 and in subsequent filings made by BioNTech with the SEC, which are available on the SEC’s website at https://www.sec.gov/. Except as required by law, BioNTech disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this presentation in the event of new information, future developments or otherwise. These forward-looking statements are based on BioNTech’s current expectations and speak only as of the date hereof.



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# Safety Information

**COMIRNATY® ▼(the Pfizer-BioNTech COVID-19 vaccine)** has been granted conditional marketing authorization (CMA) by the European Commission to prevent coronavirus disease 2019 (COVID-19) in people from 5 yrs of age. The vaccine is administered as a 2-dose series, 3 weeks apart. In addition, the CMA has been expanded to include a booster dose (third dose) at least 6 months after the second dose in individuals 18 yrs of age and older. For immunocompromised individuals, the third dose may be given at least 28 days after the second dose. The European Medicines Agency's (EMA's) human medicines committee (CHMP) has completed its rigorous evaluation of COMIRNATY®, concluding by consensus that sufficiently robust data on the quality, safety and efficacy of the vaccine are now available.

**IMPORTANT SAFETY INFORMATION:**

- 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.
- Very rare cases of myocarditis and pericarditis have been observed following vaccination with Comirnaty. These cases have primarily occurred within 14 days following vaccination, more often after the second vaccination, and more often in younger men. Available data suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis or pericarditis in general.
- 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.
- The efficacy, safety and immunogenicity of the vaccine has not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy. The efficacy of COMIRNATY® may be lower in immunosuppressed individuals.
- As with any vaccine, vaccination with COMIRNATY® may not protect all vaccine recipients. Individuals may not be fully protected until 7 days after their second dose of vaccine.
- In clinical studies, adverse reactions in participants 16 yrs of age and older were injection site pain (> 80%), fatigue (> 60%), headache (> 50%), myalgia and 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 overall safety profile of COMIRNATY® in participants 5 to 15 yrs of age was similar to that seen in participants 16 yrs of age and older.
- The most frequent adverse reactions in children 5 to 11 yrs of age were injection site pain (>80%), fatigue (>50%), headache (>30%), injection site redness and swelling (>20%), myalgia and chills (>10%).
- The most frequent adverse reactions in clinical trial participants 12 to 15 yrs of age were injection site pain (> 90%), fatigue and headache (> 70%), myalgia and chills (> 40%), arthralgia and pyrexia (> 20%).
- There is limited experience with use of COMIRNATY® in pregnant women. Administration of COMIRNATY® in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and fetus.
- It is unknown whether COMIRNATY® is excreted in human milk.
- Interactions with other medicinal products or concomitant administration of COMIRNATY® with other vaccines has not been studied.
- For complete information on the safety of COMIRNATY® always make reference to the approved Summary of Product Characteristics and Package Leaflet available in all the languages of the European Union on the EMA website.

The black equilateral triangle ▼ denotes that additional monitoring is required to capture any adverse reactions. This will allow quick identification of new safety information. 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, telephone +49 6131 9084 0, or via the website www.biontech.de



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# Safety Information

**AUTHORIZED USE IN THE U.S.**

- COMIRNATY® (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 yrs of age and older. It is also authorized under EUA to provide a 3-dose primary series to individuals 6 months through 4 yrs of age, 2-dose primary series to individuals 5 yrs of age and older, a third primary series dose to individuals 5 yrs of age and older who have been determined to have certain kinds of immunocompromise, a single booster dose to individuals 5 through 11 yrs of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY®, a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise, a first booster dose to individuals 12 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY®, a first booster dose to individuals 18 yrs of age and older who have completed primary vaccination with a different authorized COVID-19 vaccine, a second booster dose to individuals 50 yrs of age and older who have received a first booster dose of any authorized COVID-19 vaccine; and a second booster dose to individuals 12 yrs of age and older who have been determined to have certain kinds of immunocompromise and who have received a first booster dose of any authorized COVID-19 vaccine.

The booster schedule is based on the labeling information of the vaccine used for the primary series.

**IMPORTANT SAFETY INFORMATION**

Individuals should not get the vaccine if they:
- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

Individuals should tell the vaccination provider about all of their medical conditions, including if they:
- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects the immune system
- are pregnant, plan to become pregnant, or are breastfeeding
- have received another COVID-19 vaccine
- have ever fainted in association with an injection

The vaccine may not protect everyone. Side effects reported with the vaccine include:
- There is a remote chance that the vaccine could cause a severe allergic reaction
  - A severe allergic reaction would usually occur within a few minutes to 1 hour after getting a dose of the vaccine. For this reason, vaccination providers may ask individuals to stay at the place where they received the vaccine for monitoring after vaccination
  - Signs of a severe allergic reaction can include difficulty breathing, swelling of the face and throat, a fast heartbeat, a bad rash all over the body, dizziness, and weakness
  - If an individual experiences a severe allergic reaction, they should call 9-1-1 or go to the nearest hospital



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# Safety Information

- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine, more commonly in males under 40 yrs of age than among females and older males. In most of these people, symptoms began within a few days following receipt of the second dose of the vaccine. The chance of having this occur is very low. Individuals should seek medical attention right away if they have any of the following symptoms after receiving the vaccine:
  - chest pain
  - shortness of breath
  - feelings of having a fast-beating, fluttering, or pounding heart

- Additional side effects that have been reported with the vaccine include:
  - severe allergic reactions; non-severe allergic reactions such as 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; and fainting in association with injection of the vaccine
- These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials. Call the vaccination provider or healthcare provider about bothersome side effects or side effects that do not go away

Data on administration of this vaccine at the same time as other vaccines have not yet been submitted to FDA. Individuals considering receiving this vaccine with other vaccines should discuss their options with their healthcare provider.

Patients should always ask their healthcare providers for medical advice about adverse events. Individuals are encouraged to report negative side effects of vaccines to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Visit https://www.vaers.hhs.gov or call 1-800- 822-7967. In addition, side effects can be reported to Pfizer Inc. at www.pfizersafetyreporting.
com or by calling 1-800-438-1985.



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# Agenda

**01** **2nd Quarter 2022 Highlights**
Ugur Sahin, CEO

**02** **Pipeline Update**
Özlem Türeci, CMO

**03** **Financial Results**
Jens Holstein, CFO

**04** **Corporate Outlook**
Ryan Richardson, Chief Strategy Officer

# Advancing Toward Our Vision

**1 marketed vaccine**
**Market leader in COVID-19 vaccines**

**18 programs in 23 clinical trials**

**5 randomized Phase 2 trials**

**1 Phase 1 program**

**10+ preclinical programs, 4 FIH trials to start**

**Oncology**

**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**

**Long-term vision**

## Immunotherapy powerhouse expanding into multiple therapeutic areas



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# Highlights in Q2: Corporate & Oncology Pipeline

## Corporate Updates

- Reported Q2 total revenues of €3.2 bn[1] and year-to-date revenues of €9.6 bn[1]
- Began construction of first BioNTainer mRNA vaccine manufacturing facility in Africa
- Signed new equal share cost/profit collaboration agreement with Genmab for joint development of an antibody targeting CD27

## Oncology: Pipeline Advancement

- BNT122 (iNeST): Positive data from Phase 1 trial in patients with resected pancreatic cancer showing favorable safety profile and encouraging signs of clinical activity[2]
- BNT116 (FixVac): FPD in Phase 1 trial in advanced NSCLC
- BNT142 (RiboMab): FPD in Phase 1/2 trial in CLDN6 positive solid tumors
- BNT211 (CLDN6 CAR-T cell therapy): EMA Priority Medicines (PRIME) designation for 3rd or later-line treatment of testicular cancer

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, 2021 as well as the Quarterly Report as of and for the three and six months ended June 30, 2022, filed as an exhibit to BioNTech's Current Report on Form 6-K filed on August 8,2022. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively.
2 Investigator-initiated trial

# Highlights in Q2:
# COVID-19 Vaccine / COMIRNATY

**Broad label across age groups**

- FDA granted EUA for primary series in children 6 months through 4 yrs of age and for booster dose in children 5 through 11 yrs of age

Pediatric label now includes[1]:

- 6 mo. to <5 yrs (3 µg)
- 5 yrs to <12 yrs (10 µg)
- 12 yrs+ (30 µg)

**Strong global distribution**

- More than 3.6 bn doses delivered to 180 countries and territories since launch Dec. 2020[2]
- Order book 2022: ~2.5 bn doses[2]
  - New agreement with U.S. government to provide additional 105m doses of COVID-19 vaccine with option for another 195m doses
- Fostering global health equity: On track to deliver a total of 2 bn doses to low- and middle-income countries by end of 2022

**Variant adapted & next-gen vaccines**

**Variant adapted vaccines:**

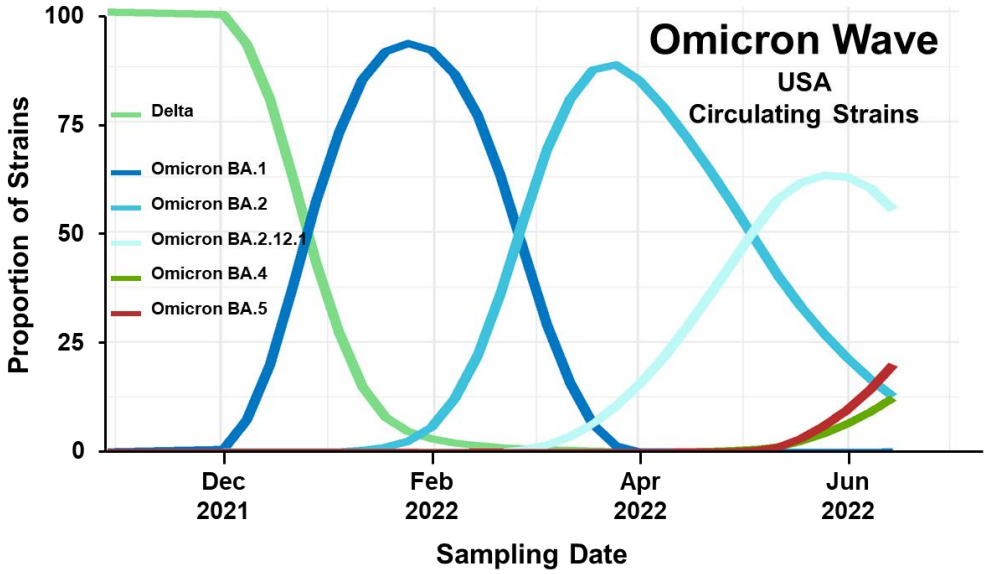
- Omicron BA.1 adapted vaccine candidates demonstrated high immunogenicity and tolerable safety profile
- Regulatory submissions of Omicron BA.1- and BA.4/5-adapted bivalent vaccines are ongoing worldwide

**Next-gen vaccines:**

- Initiated Phase 2 trial of BNT162b5: bivalent vaccine candidate based on enhanced versions of SARS-CoV-2 ancestral strain and Omicron BA.2 variant spike proteins engineered for broader immunity

1 Approved as a 2-dose series for prevention of COVID-19 in individuals 12 yrs of age and older; 2-dose series under Emergency Use Authorization for individuals 5–11 yrs old, and 3-dose series under emergency use authorization for children 6 months through 4 yrs of age
2 As of beginning of July 2022

# SARS-CoV-2 Epidemiology Changes Quickly: Vaccine Updates Need Timely Adaptation With the Pace of Virus




**SARS-CoV-2 virus continues to evolve:**

Currently seeing new variant waves every ~3 months

## Variant vaccine adaptation timelines

| | |
|---|---|
| **Clinical (current)** | **~8 months** |
| **Pre-clinical/CMC (proposed)** | **~3 months** |

CMC, chemistry, manufacturing and controls

GISAID Initiative database: https://www.gisaid.org/ (accessed June 20, 2022).

# Preparing for Launch of Omicron-Adapted Bivalent Vaccines in Early October 2022

**Regulatory Engagement**

FDA, EMA and other regulators recommended Omicron-adapted bivalent vaccines

Submissions ongoing worldwide for both BA.1- and BA.4/5-adapted bivalent vaccines

- FDA: Provided guidance for bivalent vaccine encoding Omicron BA.4/5 spike protein
- EMA: Omicron BA.1-adapted bivalent vaccine submission finalized; preparing submission of preclinical and CMC data package for Omicron BA.4/5-adapted bivalent vaccine

**Clinical Development**

- Clinical trial of Omicron BA.4/5-adapated bivalent vaccine expected to initiate in August

**Manufacturing Scale-Up**

- BA.1- and BA.4/5-adapted bivalent vaccines manufacturing initiated
- Planning to supply both vaccines in time for fall booster campaign

**Planned Launch**

**First shipments expected as early as October subject to regulatory approval**



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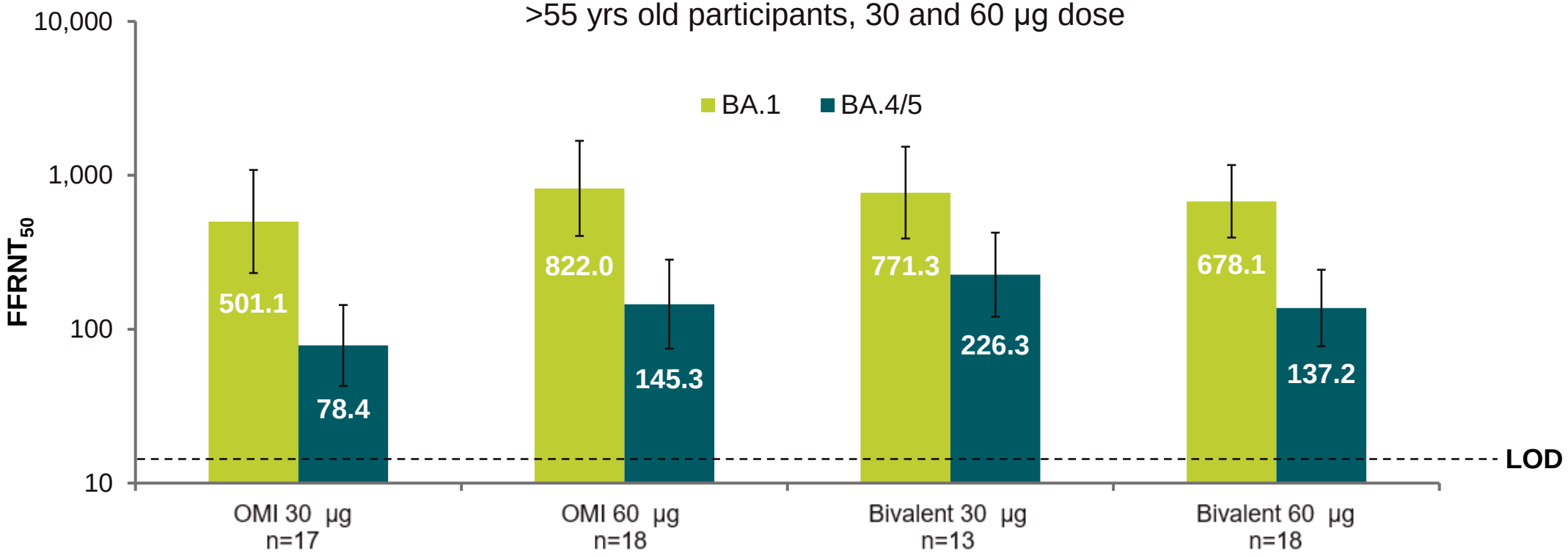
# Omicron-BA.1 Adapted Vaccines as 4th Dose Elicit Improved Omicron Neutralization Response

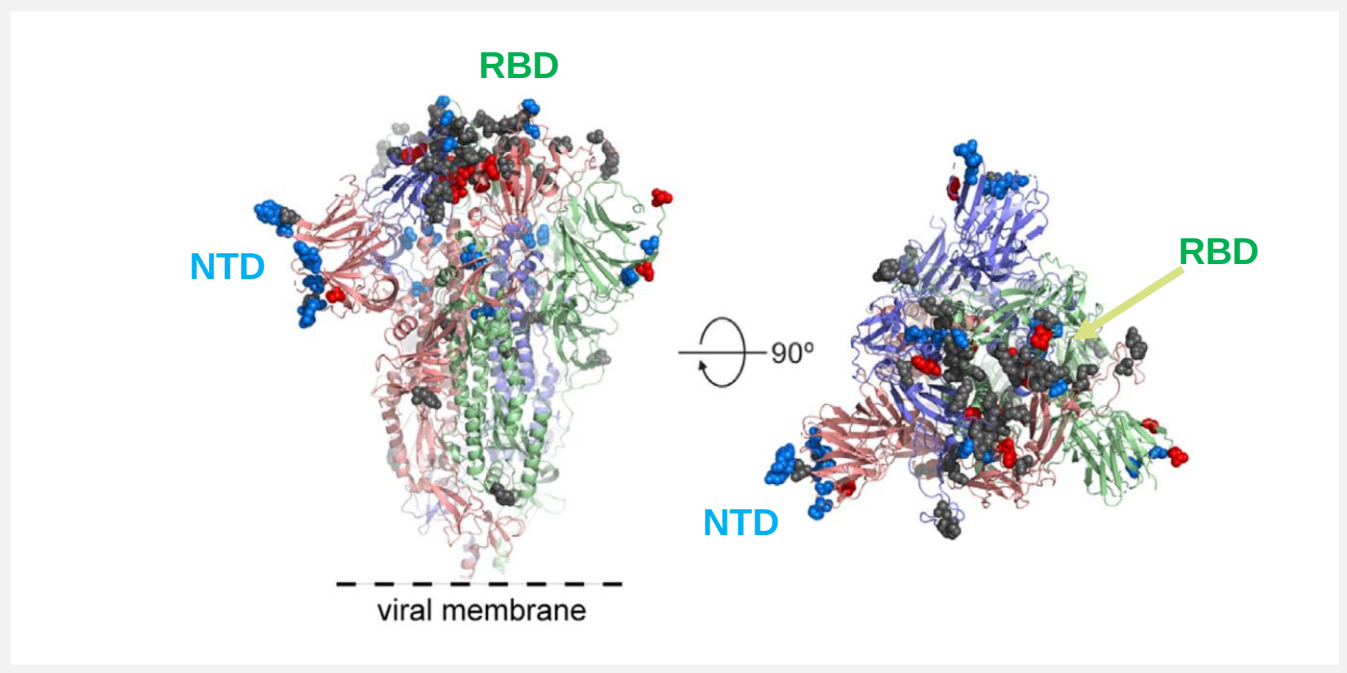
**Participants WITHOUT evidence of infection up to 1 month after first study vaccination**
>55 yrs old participants, 30 and 60 µg dose




**Superiority[1] for GMR and non-inferiority[2] for seroresponses (monovalent and bivalent vaccines)**
**"Super" superiority[3] for GMR (monovalent vaccines); Neutralization activity against BA.4/5 reduced**

Internal data.
FFRNT, fluorescent foci reduction neutralization test; LOD, limit of detection. GMR, geometric mean ratio
1 GMR superiority criterion: the lower bound of 95% confidence interval for GMR is >1.0
2 Non-inferiority criterion: the lower bound of 95% confidence interval for interval for the percentage difference is >-5
3 GMR "super" superiority criterion: the lower bound of 95% confidence interval for GMR is >1.5

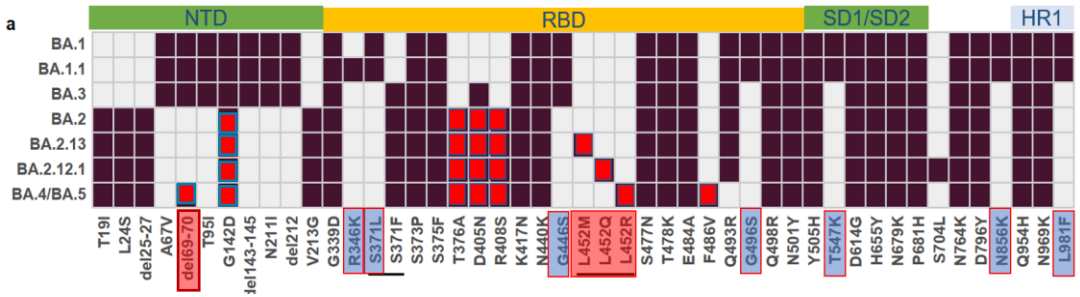
# Omicron BA.4/5 RBD and NTD Sequences are distinct From BA.1 and BA.2




Omicron-BA.2 unique mutations

Omicron-BA.2 common mutations

Omicron-BA.1 unique mutations

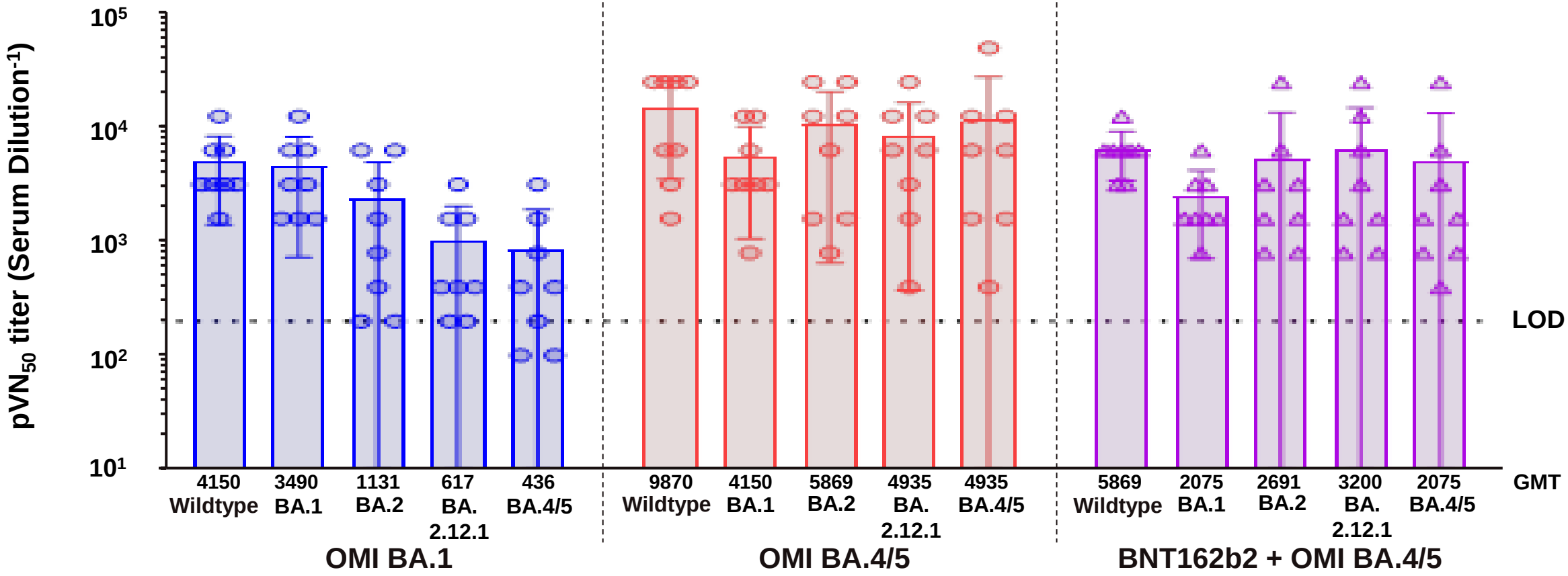



RBD, receptor binding domain; NTD, N-terminal domain

Stalls et al., Cryo-EM structures of SARS-CoV-2 Omicron BA.2 spike. Cell reports, 2022

# Omicron BA.4/5 Monovalent and Bivalent Boosters in Mice Substantially Increase Omicron Neutralization Responses to All Tested Omicron Variants

**Compared to Monovalent OMI BA.1, BA.4/5 neutralizing titers increase by ~11.3 fold (mono BA.4/5) or ~4.8 fold (bivalent BA.4/5)**




15 N=8 mice Balb/c mice. Mice preimmunized with 2 doses of BNT162b2; boosters given at day 104
Pseudovirus neutralization assay; LOD, Limit of Detection; GMT, geometric mean titers

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# Pursuing Multiple Novel COVID-19 Vaccine Approaches to Provide Durable and High-Level Protection against Evolving Variants

## Long-term: Next-Generation Vaccine Approaches

### Next generation SARS-CoV-2 spike antigen

Engineered for optimized immunogenicity

- Increase prefusion stability
- Expose more neutralizing-sensitive epitopes

### BNT162b5: bivalent vaccine candidate

Enhanced SARS-CoV-2 spike protein of ancestral strain and Omicron BA.2 sublineage

**Phase 2:**
FPD in July

### T cell enhancing vaccine candidate

Designed to stimulate and enhance T cell immunity

**Clinical trial start expected 2H 2022**

### Pan-SARS-CoV-2 vaccine candidate

Potential for greater, more durable protection to manage future variants of concern

**Proof-of-concept trial expected 2H 2022**

**Long-term strategy comprises multipronged approach designing and testing multiple constructs with the aim to engage different arms of the immune system including antibodies and T cells**



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# Oncology Pipeline: Significant Progress and Expansion in 2022

| Drug class | Platform | Product candidate | Indication (targets) | Pre-clinical | Phase 1 | Phase 2 | Phase 3 | Milestones |
|---|---|---|---|---|---|---|---|---|
| mRNA | FixVac | BNT111 | Advanced and R/R melanoma | | | | | |
| | | BNT112 | Prostate cancer | | | | | |
| | | BNT113 | HPV16+ head and neck cancer | | | | | |
| | | BNT115[1] | Ovarian cancer | | | | | |
| | | BNT116 | NSCLC | | | | | FPD in July 2022 ✓ |
| | iNeST | Autogene cevumeran (BNT122)[2] | 1L melanoma | | | | | Data update: 1H 2023 |
| | | | Adjuvant colorectal cancer | | | | | |
| | | | Solid tumors | | | | | |
| | | | Adjuvant pancreatic ductal adenocarcinoma[1] | | | | | |
| | Intratumoral immunotherapy | SAR441000 (BNT131)[3] | Solid tumors (IL-12sc, IL15-sushi, GM-CSF, IFNα) | | | | | |
| | RiboMabs | BNT141 | Multiple solid tumors (CLDN18.2) | | | | | FPD in Jan. 2022 ✓ |
| | | BNT142 | Multiple solid tumors (CD3×CLDN6) | | | | | FPD in July 2022 ✓ |
| | RiboCytokines | BNT151 | Multiple solid tumors (optimized IL-2) | | | | | |
| | | BNT152, BNT153 | Multiple solid tumors (IL-7, IL-2) | | | | | |
| Cell therapies | CAR T cells + CARVac | BNT211 | Multiple solid tumors (CLDN6) | | | | | Data update: 2H 2022 |
| | | BNT212 | Pancreatic, other cancers (CLDN18.2) | | | | | |
| | Neoantigen-based T cells | BNT221 (NEO-PTC-01) | Multiple solid tumors | | | | | |
| | TCR engineered T cells | To be selected | All tumors | | | | | |
| Antibodies | Next-gen immune checkpoint modulators | GEN1046 (BNT311)[4] | Metastatic NSCLC (PD-L1×4-1BB) | | | | | |
| | | | Multiple solid tumors (PD-L1×4-1BB) | | | | | |
| | | GEN1042 (BNT312)[4] | Multiple solid tumors (CD40×4-1BB) | | | | | |
| | | GEN1053 (BNT313)[4] | Malignant solid tumors (CD27) | | | | | Start Phase 1: 2H 2022 |
| | Targeted cancer antibodies | BNT321 (MVT-5873) | Pancreatic cancer (sLea) | | | | | |
| SMIM | Toll-like receptor binding | BNT411 | Solid tumors (TLR7) | | | | | |



SMIM, small molecule immunomodulators.
1 Investigator-initiated Phase 1 trial; 2 Collaboration with Genentech; 3 Collaboration with Sanofi; 4 Collaboration with Genmab.

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# FixVac | BNT116: Phase 1 Trial in Patients with Advanced NSCLC


| Key endpoints | Status |
|---|---|
| **Primary: Safety and tolerability**<br>Secondary: Clinical activity | FPD in July 2022 |

NSCLC, non-small-cell lung cancer; TPS, tumor proportion score
*Regeneron's Libtayo®
Clinicaltrials.gov: NCT05142189.

# RiboMabs: Nucleoside-modified mRNA Encoding Variable Antibody Formats for *in vivo* Translation

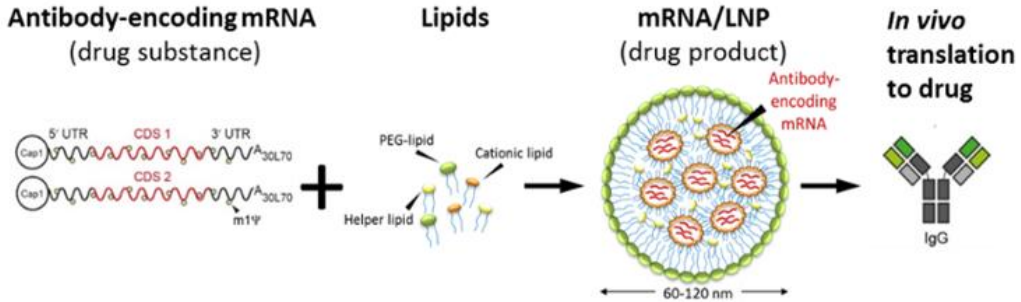
### *In vivo* translation and systemic availability of active drug at therapeutically relevant plasma concentrations

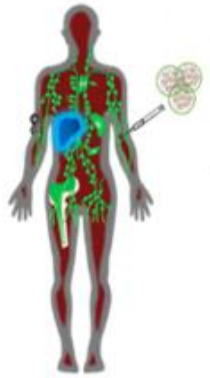
- mRNA backbone designed for minimal immunogenicity
- Encoded antibodies target tumor-associated antigens
- Sustained *in vivo* production may result in prolonged serum half-life

### Shared LNP formulation across platform candidates

- Liver-targeting LNP formulation for intravenous delivery

### Encouraging preclinical data[1]



(1) Intravenous injection

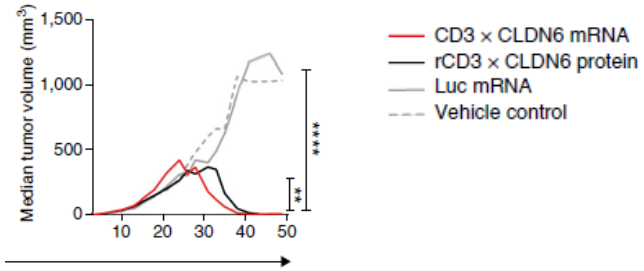
(2) LNP target site: liver

(3) Translation and systemic availability of active drug

nature medicine

Elimination of large tumors in mice by mRNA-encoded bispecific antibodies

Christiane R Stadler[1], Hayat Bähr-Mahmud[1], Leyla Celik[1], Bernhard Hebich[1,5], Alexandra S Roth[1,5], René P Roth[1,5], Katalin Karikó[1], Özlem Türeci[2] & Ugur Sahin[1,3,4]




| Product Candidate | Indication (Targets) | Pre-clinical | Phase 1 | Phase 2 |
|---|---|---|---|---|
| BNT141 | Solid Tumors (CLDN18.2) | | | |
| BNT142 | Solid Tumors (CD3+CLDN6) | | | |

IgG, immunoglobulin G; LNP, lipid nanoparticles; TAA; CLDN18.2, Claudin-18.2; CD3 cluster of differentiation 3 (protein complex); CLDN, Claudin

1 Stadler, C.R. et al. Nature Medicine 2017 https://www.nature.com/articles/nm.4356



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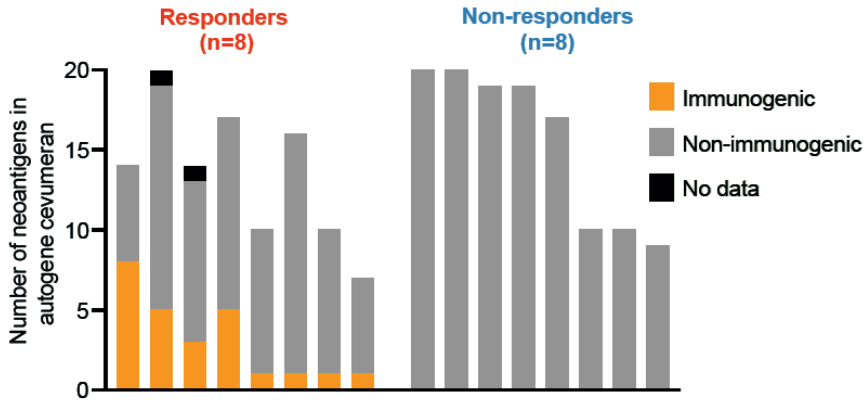
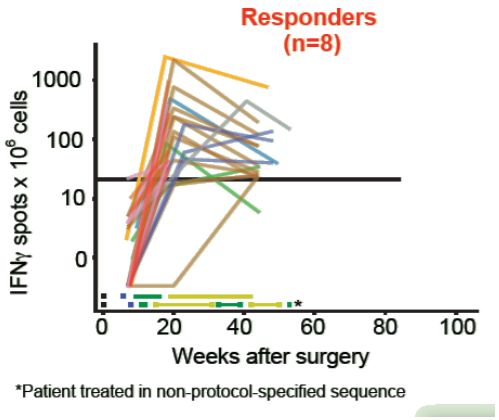
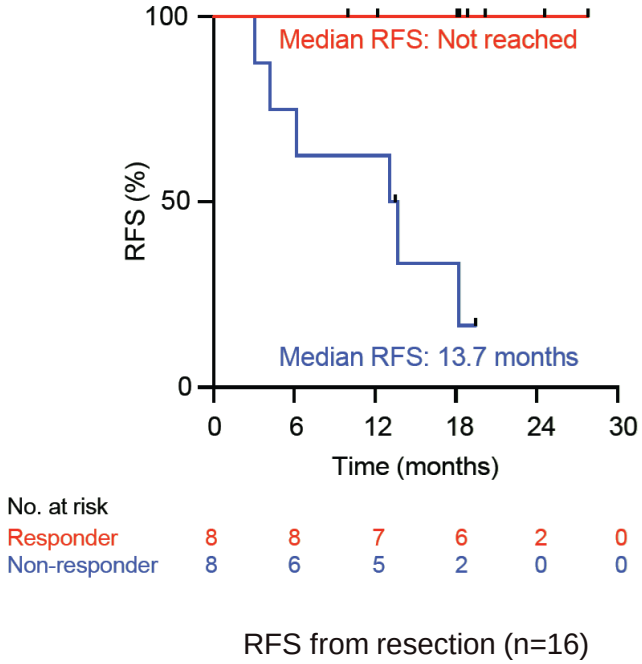
# iNeST | Autogene Cevumeran (BNT122)
# Phase 1 for Adjuvant Treatment of Pancreatic Cancer

Vaccine-induced Neoantigen-specific immune responses of high magnitude against at least one of the neoantigens by *ex vivo* IFNγ ELISPOT in half of the patients.

Prolonged Relapse free survival in patients who have high magnitude Immune responses.



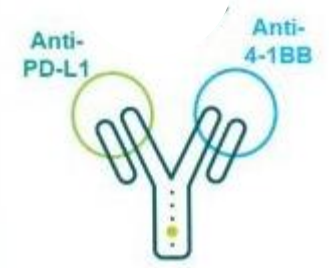




RFS from resection (n=16)

iNeST is being developed in collaboration with Genentech.
RFS, recurrence-free survival
Balachandran VP, *et al.* ASCO Annual Meeting 2022; Poster presentation 2516.
Investor-initiated single-center study sponsored by Memorial Sloan Kettering Cancer Center

# Expanding Strategic Collaboration With Genmab

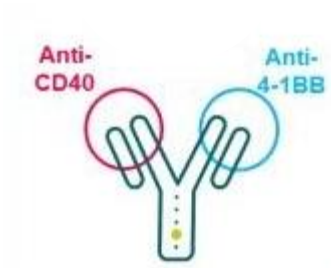
## GEN1046 / BNT311[1]




**Phase 2: R/R NSCLC**
**Phase 1/2: Advanced solid tumors**

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

## GEN1042 / BNT312[1]




**Phase 1/2: Advanced solid tumors**

Bispecific antibody: Combines targeting and conditional activation of CD40 and 4-1BB on immune cells

## GEN1053 / BNT313[1]


**Phase 1/2: Solid tumors**
**FPD expected in 2H 2022**

Monospecific HexaBody[2] targeting CD27 on naïve and activated T cells

**Next-generation immunomodulators designed to prime and activate anti-tumor T cell and Natural Killer cell function**



1 Collaboration with Genmab based on 50/50 sharing of costs and profits
2 HexaBody® technology owned by Genmab

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Özlem Türeci, CMO

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Jens Holstein, CFO

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Ryan Richardson, Chief Strategy Officer

# Key Highlights for Q2 2022

## Total Revenues[1]

**€3.2 bn**

## Operating Result

**€2.2 bn**

## Diluted EPS

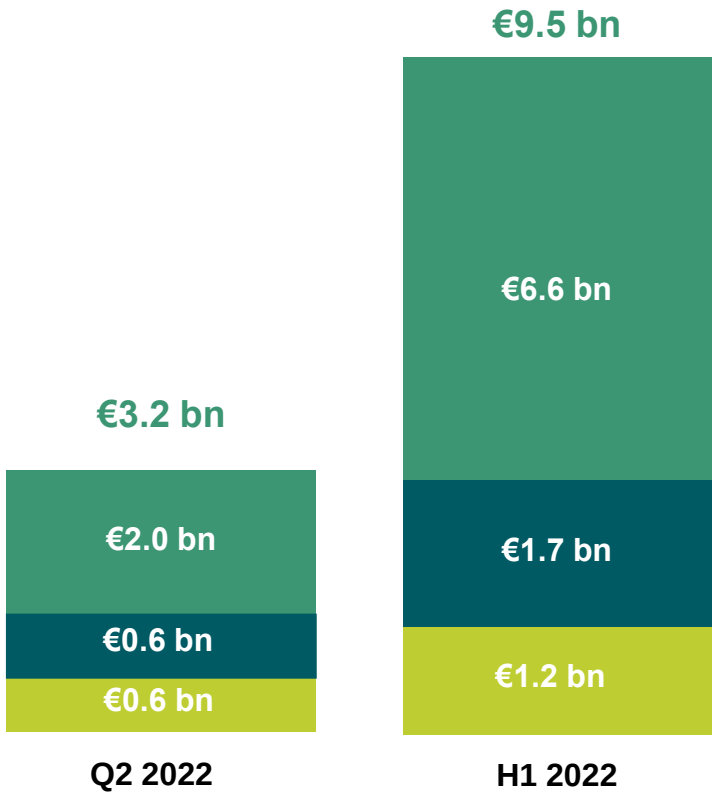
**€6.45**

## Cash and Trade Receivables

**€9.3 bn + €10.4 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, 2021 as well as the Quarterly Report as of and for the three and six months ended June 30, 2022, filed as an exhibit to BioNTech's Current Report on Form 6-K filed on August 8, 2022. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively.

# Q2 and H1 2022 COVID-19 Vaccine Revenues




- Share of gross profit from COVID-19 vaccine sales in the Pfizer and Fosun Pharma territory (100% gross margin)
- Direct COVID-19 vaccine sales to customers in BioNTech's territory
- COVID-19 vaccine sales to collaboration partners of products manufactured by BioNTech

**Q2 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, 2021 as well as the Quarterly Report as of and for the three and six months ended June 30, 2022, filed as an exhibit to BioNTech's Current Report on Form 6-K filed on August 8, 2022. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively.

# Q2 and H1 2022 Financial Results – Profit or Loss

| *(in millions, except per share data)*[1] | *Three months ended June 30,* | | *Six months ended June 30,* | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Commercial revenues[2] | €3,166.3 | €5,280.5 | €9,528.5 | €7,308.0 |
| Research & development revenues | 30.2 | 28.0 | 42.6 | 48.9 |
| **Total revenues** | **€3,196.5** | **€5,308.5** | **€9,571.1** | **€7,356.9** |
| Cost of sales | (764.6) | (883.8) | (2,058.7) | (1,116.9) |
| Research and development expenses | (399.6) | (201.1) | (685.4) | (417.3) |
| Sales and marketing expenses | (17.8) | (13.3) | (32.1) | (22.0) |
| General and administrative expenses | (130.0) | (47.8) | (220.8) | (86.7) |
| Other operating income less expenses | 325.1 | 35.9 | 388.2 | 146.6 |
| **Operating income** | **€2,209.6** | **€4,198.4** | **€6,962.3** | **€5,860.6** |
| Finance income less expenses | 109.7 | (175.6) | 375.1 | (195.5) |
| Income taxes | (647.3) | (1,235.6) | (1,966.6) | (1,749.8) |
| **Profit for the period** | **€1,672.0** | **€2,787.2** | **€5,370.8** | **€3,915.3** |
| **Earnings per share** | | | | |
| Basic profit for the period per share | €6.86 | €11.42 | €22.00 | €16.07 |
| Diluted profit for the period per share | €6.45 | €10.77 | €20.69 | €15.14 |

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, 2021 as well as the Quarterly Report as of and for the three and six months ended June 30, 2022, filed as an exhibit to BioNTech's Current Report on Form 6-K filed on August 8, 2022. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively.

# 2022 Financial Year Guidance Reiterated

| COVID-19 Vaccine Revenues for FY 2022[1] | |
|---|---|
| Estimated BioNTech COVID-19 vaccine revenues | **€ 13 – 17 bn** |

| Planned FY 2022 Expenses and Capex[1] | |
|---|---|
| R&D expenses | **€ 1,400 - 1,500 m** |
| SG&A expenses | **€ 450 - 550 m** |
| Capital expenditure | **€ 450 - 550 m** |

| Estimated FY 2022 Tax Assumptions | |
|---|---|
| BioNTech Group estimated annual effective income tax rate | **~28%[2]** |



1 Ranges reflect current base case projections and do not include potential effects caused by or driven from additional collaborations or potential M&A transactions.
2 BioNTech Group estimated annual effective income tax rate decreased from 31.6% (FY 2021) to ~28% (FY 2022) due to decreasing average trade tax rates.

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# Strong Position and Outlook for Global COVID-19 Vaccine Franchise

**>3.6 bn doses shipped to 180 countries or territories since product launch[1]**

**Increasing market share since January 2022[2]**

- All markets[3]: increase from 52% to 63%
- Developed markets[4]: increase from 59% to 68%

**2022 order book: ~2.5 bn doses**

- U.S. government ordered additional 105 m doses with value of $3.2 bn
  - Option for another 195 m doses
- EC order of 650 m doses for delivery in 2022
  - Amended contract for rephasing deliveries toward Q4 2022

**Shipment volumes expected to increase with planned launch of Omicron variant-adapted vaccines in the late fall[5]**

1 As of beginning of July 2022
2 Cumulative Share of Doses from January 1, 2022 to July 20, 2022 in markets in which Pfizer and BioNTech operate and that report market share data
3 Incl. all markets in Developed Markets(4) plus Emerging Markets (Argentina, Chile, Ecuador, Hong Kong, Nepal, Peru, South Africa, Uruguay)
4 Includes the U.S., EU/EEA, other Int'l Developed markets (Japan, South Korea, Switzerland, Ukraine)
5 Starting date of January 1, 2022 for this data set is from Q1 2022 earnings presentation
5 Pending regulatory approval
Distribution of COVID-10 vaccine in collaboration with Pfizer



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# Delivering on Commitment to Provide Equitable Access to Medicines

**>1.5 bn COVID-19 vaccine doses shipped to low-and-middle income countries of 2 bn doses pledged[1]**

## BioNTainer Launch in Africa

- End-to-end mRNA production units with capacity of up to >50 million doses/year
- First manufacturing facility to become a node in decentralized and robust African end-to-end manufacturing network
- Construction of facility underway following groundbreaking in Rwanda
- Potential additional sites for Senegal and South Africa

**Potential Manufacturing Sites in Africa**

**Senegal, Rwanda, & South Africa**
Groundbreaking for Rwanda in June 2022



1 Between Dec 2020 and Jul 17, 2022 via bi-lateral and donation agreements

# Selected 2022 Pipeline Milestones

| | Milestones | Anticipated Timing |
|---|---|---|
| **COVID-19 vaccine: Follow on and Next Gen Vaccines** | Omicron BA.4/5-adapted bivalent vaccine trial start | August 2022 |
| | BNT162b5: Next-generation bivalent vaccine, enhanced SARS-CoV-2 encoding ancestral and BA.2 spike antigen | ✓ Phase 2: FPD in July 2022 |
| | T cell enhancing vaccine trial start | 2H 2022 |
| | Additional next-generation vaccine trial starts, including pan-SARS-CoV-2 vaccine | 2H 2022 |
| | Multiple data updates | 2H 2022 |
| **4 Infectious Disease First-In-Human Trial Starts** | Shingles vaccine[1] | 2H 2022 |
| | BNT163 HSV2 vaccine | 2H 2022 |
| | BNT164 tuberculosis vaccine[2] | 2H 2022 / early 2023 |
| | BNT165 malaria vaccine | 2H 2022 / early 2023 |
| **4 Oncology First-in-Human Trial Starts** | BNT141 RiboMab in solid tumors (CLDN18.2) | ✓ FPD in Jan. 2022 |
| | BNT142 RiboMab in solid tumors (CD3×CLDN6) | ✓ FPD in July 2022 |
| | BNT116 FixVac in combo with Cemiplimab in NSCLC | ✓ FPD in July 2022 |
| | BNT313 (GEN1053) in solid tumors[3] | 2H 2022 |
| **3 Data Updates** | BNT161 influenza mRNA vaccine[1] | ✓ July 2022 |
| | BNT122[4] Phase 2 iNeST in combo with Pembro in frontline melanoma | now in 1H 2023 |
| | BNT211 Phase 1/2 CAR-T/CLDN6+ in multiple solid tumors | 2H 2022 |



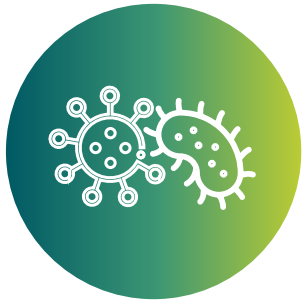
HSV 2, Herpes simplex virus type 2; FPD, first patient dosed; CLDN, Claudin; NSCLC, non-small cell lung cancer
1 Partnered with Pfizer; 2 Collaboration with BMGF; 3 Collaboration with Genmab 4 Partnered with Genentech

# Outlook 2022 and Beyond

## Once in a generation opportunity to transform medicine

Further development of COVID-19 vaccine

Accelerate late-stage oncology programs



Advance infectious disease portfolio

Pursue complementary acquisitions

Transform & expand global organization

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



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# THANK YOU

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