Pfizer Logo

Pfizer and BioNTech Submit Application to U.S. FDA for Emergency Use Authorization of Omicron BA.4/BA.5-Adapted Bivalent COVID-19 Vaccine

Monday, August 22, 2022 - 10:30am

- *Data support request for Emergency Use Authorization of a 30-µg booster dose of an Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine for individuals 12 years of age and older*
- *Companies have rapidly scaled production and stand ready to deliver doses of Omicron BA.4/BA.5-adapted bivalent vaccines for September, and will begin shipping immediately pending authorization*
- *Rolling submission for Omicron BA.4/BA.5-adapted bivalent vaccine to be completed with the European Medicines Agency in the coming days*

NEW YORK & MAINZ, Germany--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today announced they have completed a submission to the U.S. Food and Drug Administration (FDA) requesting Emergency Use Authorization (EUA) of a booster dose of an Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine for individuals 12 years of age and older. The application follows guidance from the FDA to include clinical data from the companies' bivalent Omicron BA.1-adapted vaccine and pre-clinical and manufacturing data from the companies' bivalent Omicron BA.4/BA.5-adapted vaccine to address the continued evolution of SARS-CoV-2. Pending authorization, the Omicron BA.4/BA.5-adapted bivalent vaccine will be available to ship immediately.

This press release features multimedia. View the full release here:
https://www.businesswire.com/news/home/20220822005376/en/

A conditional marketing authorization application has also been initiated with the European Medicines Agency (EMA) for the Omicron BA.4/BA.5-adapted bivalent vaccine and is expected to be completed in the coming days.

"The agility of the mRNA platform, together with extensive clinical experience with the Pfizer-BioNTech COVID-19 Vaccine, has allowed us to develop, test and manufacture updated, high-quality vaccines that align to circulating strains with unprecedented speed," said Albert Bourla, Chairman and Chief Executive Officer, Pfizer. "Having rapidly scaled up production, we are positioned to immediately begin distribution of the bivalent Omicron BA.4/BA.5 boosters, if authorized, to help protect individuals and families as we prepare for potential fall and winter surges."

"Given the ongoing evolution of SARS-CoV-2 and its variants, it's of great importance that vaccines can be rapidly adapted to the major circulating Omicron lineages," said Prof. Ugur Sahin, M.D., CEO and Co-founder of BioNTech. "In less than three months after the FDA provided its guidance for adapted vaccines in the U.S., we are ready to ship the first doses of our Omicron BA.4/BA.5-adapted bivalent vaccine, pending regulatory

authorization, to provide people in the U.S. with the possibility to get a booster adapted to the currently most dominant strain of the virus."

The bivalent vaccine contains mRNA encoding the original SARS-CoV-2 spike protein, which is present in the original Pfizer-BioNTech COVID-19 Vaccine, together with mRNA encoding the spike protein of the Omicron BA.4/BA.5 variant. Pre-clinical data showed a booster dose of Pfizer and BioNTech's Omicron BA.4/BA.5-adapted bivalent vaccine generated a strong neutralizing antibody response against Omicron BA.1, BA.2 and BA.4/BA.5 variants, as well as the original wild-type strain. A clinical study investigating the safety, tolerability and immunogenicity of the Omicron BA.4/BA.5-adapted bivalent vaccine in individuals 12 years of age and older is expected to start this month.

The companies previously announced safety, tolerability and immunogenicity data from a Phase 2/3 trial of a 30-µg booster dose of their Omicron BA.1-adapted bivalent vaccine candidate, which combines the existing vaccine and a vaccine targeting the Omicron BA.1 variant spike protein. The Omicron BA.1-adapted bivalent vaccine elicited a superior immune response against the Omicron BA.1 variant compared to the companies' current COVID-19 vaccine. The Omicron BA.1-adapted bivalent vaccine was well-tolerated with a favorable safety profile.

Following guidance from the EMA and International Coalition of Medicines Regulatory Authorities (ICMRA), Pfizer and BioNTech submitted an application for the Omicron BA.1-adapted bivalent COVID-19 vaccine in July.

The Pfizer-BioNTech COVID-19 Vaccine, which is based on BioNTech's proprietary mRNA technology, was developed by both BioNTech and Pfizer. BioNTech is the Marketing Authorization Holder for BNT162b2 (Comirnaty®) in the United States, the European Union, the United Kingdom, Canada and other countries, and the holder of emergency use authorizations or equivalents in the United States (jointly with Pfizer) and other countries. Submissions to pursue regulatory approvals in those countries where emergency use authorizations or equivalent were initially granted are planned.

U.S. Indication & Authorized Use

Pfizer-BioNTech COVID-19 Vaccine is FDA authorized under Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 6 months of age and older.

Pfizer-BioNTech COVID-19 Vaccine is FDA authorized to provide:

Primary Series

- A 3-dose primary series to individuals 6 months through 4 years of age
- a 2-dose primary series to individuals 5 years through 11 years of age
- a 2-dose primary series to individuals 12 years of age and older
- a third primary series dose to individuals 5 years of age and older with certain kinds of immunocompromise

Booster Series

- a single booster dose to individuals 5 through 11 years of age who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine

- 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® (COVID-19 Vaccine, mRNA)
- a first booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized or approved COVID-19 vaccine. The booster schedule is based on the labeling information of the vaccine used for the primary series
- a second booster dose to individuals 50 years of age and older who have received a first booster dose of any authorized or approved COVID-19 vaccine
- a second booster dose to individuals 12 years of age and older with certain kinds of immunocompromise and who have received a first booster dose of any authorized or approved COVID-19 vaccine

COMIRNATY® INDICATION

COMIRNATY® (COVID-19 Vaccine, mRNA) is a vaccine approved 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.

HOW IS COMIRNATY ® GIVEN?

COMIRNATY® is administered as an injection into the muscle as a 2-dose primary series, 3 weeks apart.

COMIRNATY® AUTHORIZED USES

COMIRNATY® (COVID-19 Vaccine, mRNA) is FDA authorized under Emergency Use Authorization (EUA) to provide:

Primary Series

- a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise

Booster Dose

- 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 years of age and older who have completed primary vaccination with another authorized or approved COVID-19 vaccine. The booster schedule is based on the labeling information of the vaccine used for the primary series
- a second booster dose to individuals 50 years of age and older who have received a first booster dose of any authorized or approved COVID-19 vaccine
- a second booster dose to individuals 12 years of age and older with certain kinds of immunocompromise and who have received a first booster dose of any authorized or approved COVID-19 vaccine

Emergency Use Authorization

Emergency uses of the vaccine 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 6 months of age and older. 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.

INTERCHANGEABILITY

FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine FDA authorized for Emergency Use Authorization (EUA) for individuals 12 years of age and older can be used interchangeably by a vaccination provider when prepared according to their respective instructions for use.

The formulation of the Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 6 months through 4 years of age, 5 through 11 years of age, and 12 years of age and older are different and should therefore **not** be used interchangeably.

IMPORTANT SAFETY INFORMATION

Tell your vaccination provider about all of the vaccine recipient's medical conditions, including if the vaccine recipient:

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

- Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY® (COVID-19 Vaccine, mRNA) may not protect all vaccine recipients

- The vaccine recipient should not receive Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY® (COVID-19 Vaccine, mRNA) if the vaccine recipient has had a severe allergic reaction to any of its ingredients or had a severe allergic reaction to a previous dose of Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY®

- There is a remote chance that Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY® (COVID-19 Vaccine, mRNA) could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to 1 hour after getting a dose of the vaccine. For this reason, your vaccination provider may ask you to stay at the place where the vaccine was administered for monitoring after vaccination. If the vaccine recipient experiences a severe allergic reaction, call 9-1-1 or go to the nearest hospital

    - **Seek medical attention right away if the vaccine recipient has any of the following symptoms:** difficulty breathing, swelling of the face and throat, a fast heartbeat, a bad rash all over the body, dizziness, and weakness

- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine, more commonly in males under 40 years 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

Seek medical attention right away if the vaccine recipient has any of the following symptoms after receiving the vaccine, particularly during the 2 weeks after receiving a vaccine dose:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart
- Fainting
- Unusual and persistent irritability
- Unusual and persistent poor feeding
- Unusual and persistent fatigue or lack of energy
- Persistent vomiting
- Persistent pain in the abdomen
- Unusual and persistent cool, pale skin

- Fainting can happen after getting injectable vaccines, including Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY® (COVID-19 Vaccine, mRNA). Sometimes people who faint can fall and hurt themselves. For this reason, your vaccination provider may ask the vaccine recipient to sit or lie down for 15 minutes after receiving the vaccine

- Some people with weakened immune systems may have reduced immune responses to Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY® (COVID-19 Vaccine, mRNA)

- Additional side effects include rash, itching, hives, swelling of the face, 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 and irritability

These may not be all the possible side effects of the vaccine. Call the vaccination provider or healthcare provider about bothersome side effects or side effects that do not go away.

- You should always ask your healthcare providers for medical advice about adverse events. Report vaccine side effects to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1 ?800?822?7967 or report online to www.vaers.hhs.gov/reportevent.html. You can also report side effects to Pfizer Inc. at www.pfizersafetyreporting.com or by calling 1-800-438-1985

Click for Fact Sheets and Prescribing Information for individuals 5 years of age and older:

Recipients and Caregivers Fact Sheet (6 months through 4 years of age)
Recipients and Caregivers Fact Sheet (5 through 11 years of age)
Recipients and Caregivers Fact Sheet (12 years of age and older)
COMIRNATY® Full Prescribing Information (12 years of age and older), DILUTE BEFORE USE, Purple Cap
COMIRNATY® Full Prescribing Information (12 years of age and older), DO NOT DILUTE, Gray Cap
EUA Fact Sheet for Vaccination Providers (6 months through 4 years of age), DILUTE BEFORE USE, Maroon Cap
EUA Fact Sheet for Vaccination Providers (5 through 11 years of age), DILUTE BEFORE USE, Orange Cap
EUA Fact Sheet for Vaccination Providers (12 years of age and older), DILUTE BEFORE USE, Purple Cap
EUA Fact Sheet for Vaccination Providers (12 years of age and older), DO NOT DILUTE, Gray Cap

About Pfizer: Breakthroughs That Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Pfizer Disclosure Notice

The information contained in this release is as of August 22, 2022. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about Pfizer's efforts to combat COVID-19, the collaboration between BioNTech and Pfizer to develop a COVID-19 vaccine, the BNT162b2 mRNA vaccine program, and the Pfizer-BioNTech COVID-19 Vaccine, also known as COMIRNATY (COVID-19 Vaccine, mRNA) (BNT162b2) (including an Omicron-adapted bivalent COVID-19 vaccine candidate, for the BA.4/BA.5 subvariants, including a submission to the U.S. Food and Drug Administration (FDA) for an Omicron-adapted bivalent COVID-19 vaccine, for the BA.4/BA.5 subvariants, planned regulatory submissions, qualitative assessments of available data, potential benefits, expectations for clinical trials, potential regulatory submissions, the anticipated timing of data readouts, regulatory submissions, regulatory approvals or authorizations and anticipated manufacturing, distribution and supply) involving substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preclinical and clinical data (including Phase 1/2/3 or Phase 4 data), including the data discussed in this release for BNT162b2, any monovalent, bivalent or variant-adapted vaccine candidates or any other vaccine candidate in the BNT162 program in any of our studies in pediatrics, adolescents, or adults or real world evidence, including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the ability to produce comparable clinical or other results, including the rate of vaccine effectiveness and safety and tolerability profile observed to date, in additional analyses of the Phase 3 trial and additional studies, in real world data studies or in larger, more diverse populations following commercialization; the ability of BNT162b2, any monovalent, bivalent or variant-adapted vaccine candidates or any future vaccine to prevent COVID-19 caused by emerging virus variants; the risk that more widespread use of the vaccine will lead to new information about efficacy, safety, or other developments, including the risk of additional adverse reactions, some of which may be serious; the risk that preclinical and clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; whether and when additional data from the BNT162 mRNA vaccine program will be published in scientific journal publications and, if so, when and with what modifications and interpretations; whether regulatory authorities will be satisfied with the design of and results from these and any future preclinical and clinical studies; whether and when submissions to request emergency use or conditional marketing authorizations for BNT162b2 in additional populations, for a potential booster dose for BNT162b2, any monovalent or bivalent vaccine candidates or any potential future vaccines (including potential

future annual boosters or re-vaccination), and/or other biologics license and/or emergency use authorization applications or amendments to any such applications may be filed in particular jurisdictions for BNT162b2, any monovalent or bivalent vaccine candidates or any other potential vaccines that may arise from the BNT162 program, including a potential variant-based, higher dose, or bivalent vaccine, and if obtained, whether or when such emergency use authorizations or licenses will expire or terminate; whether and when any applications that may be pending or filed for BNT162b2 (including any requested amendments to the emergency use or conditional marketing authorizations), any monovalent or bivalent vaccine candidates (including the submission to the FDA for an Omicron-adapted bivalent COVID-19 vaccine candidate, for the BA.4/BA.5 subvariants), or other vaccines that may result from the BNT162 program may be approved by particular regulatory authorities, which will depend on myriad factors, including making a determination as to whether the vaccine's benefits outweigh its known risks and determination of the vaccine's efficacy and, if approved, whether it will be commercially successful; decisions by regulatory authorities impacting labeling or marketing, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of a vaccine, including development of products or therapies by other companies; disruptions in the relationships between us and our collaboration partners, clinical trial sites or third-party suppliers; the risk that demand for any products may be reduced or no longer exist which may lead to reduced revenues or excess inventory; risks related to the availability of raw materials to manufacture a vaccine; challenges related to our vaccine's formulation, dosing schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery by Pfizer; the risk that we may not be able to successfully develop other vaccine formulations, booster doses or potential future annual boosters or re-vaccinations or new variant-based or next generation vaccines; the risk that we may not be able to maintain or scale up manufacturing capacity on a timely basis or maintain access to logistics or supply channels commensurate with global demand for our vaccine, which would negatively impact our ability to supply the estimated numbers of doses of our vaccine within the projected time periods as previously indicated; whether and when additional supply agreements will be reached; uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; challenges related to public vaccine confidence or awareness; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

About BioNTech

Biopharmaceutical New Technologies is a next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. The Company exploits a wide array of computational discovery and therapeutic drug platforms for the rapid development of novel biopharmaceuticals. Its broad portfolio of oncology product candidates includes individualized and off-the-shelf mRNA-based therapies, innovative chimeric antigen receptor T cells, bispecific immune checkpoint modulators, targeted cancer antibodies and small molecules. Based on its deep expertise in mRNA vaccine development and in-house manufacturing capabilities, BioNTech and its collaborators are developing multiple mRNA vaccine candidates for a range of infectious diseases alongside its diverse oncology pipeline. BioNTech has established a broad set of relationships with multiple global pharmaceutical collaborators, including Genmab, Sanofi, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma, and Pfizer. For more information, please visit www.BioNTech.de.

BioNTech Forward-looking Statements

This press release contains “forward-looking statements” of BioNTech within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may include, but may not be limited to, statements concerning: BioNTech’s efforts to combat COVID-19; the collaboration between BioNTech and Pfizer including the program to develop a COVID-19 vaccine and COMIRNATY (COVID-19 Vaccine, mRNA) (BNT162b2) (including an Omicron-adapted bivalent COVID-19 vaccine candidate based on the BA.4/5 subvariant, including a submission to the Food and Drug Administration (FDA) for an Omicron-adapted bivalent COVID-19 vaccine based on the BA.4/5 subvariant, planned regulatory submissions, qualitative assessments of available data, potential benefits, expectations for clinical trials, the anticipated timing of regulatory submissions, regulatory approvals or authorizations and anticipated manufacturing, distribution and supply); our expectations regarding the potential characteristics of BNT162b2 in our clinical trials and/or in commercial use based on data observations to date; the ability of BNT162b2, any monovalent or bivalent vaccine candidates or any future vaccine, to prevent COVID-19 caused by emerging virus variants; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preclinical and clinical data (including Phase 1/2/3 or Phase 4 data), including the data discussed in this release for BNT162b2, any monovalent or bivalent vaccine candidates or any other vaccine candidate in BNT162 program in any of our studies in pediatrics, adolescents, or adults or real world evidence, including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the expected time point for additional readouts on efficacy data of BNT162b2 in our clinical trials; the risk that more widespread use of the vaccine will lead to new information about efficacy, safety, or other developments, including the risk of additional adverse reactions, some of which may be serious; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; the timing for submission of data for, or receipt of, any marketing approval or Emergency Use Authorization; our contemplated shipping and storage plan, including our estimated product shelf life at various temperatures; the ability of BioNTech to supply the quantities of BNT162, any monovalent or bivalent vaccine candidates or any future vaccine, to support clinical development and market demand, including our production estimates for 2022; that demand for any products may be reduced or no longer exist which may lead to reduced revenues or excess inventory; the availability of raw materials to manufacture a vaccine; our vaccine’s formulation, dosing schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery by Pfizer; the ability to successfully develop other vaccine formulations, booster doses or potential future annual boosters or re-vaccinations or new variant-adapted vaccines; the ability to maintain or scale up manufacturing capacity on a timely basis or maintain access to logistics or supply channels commensurate with global demand for our vaccine, which would negatively impact our ability to supply the estimated numbers of doses of our vaccine within the projected time periods as previously indicated; whether and when additional supply agreements will be reached; the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; challenges related to public vaccine confidence or awareness; and uncertainties regarding the impact of COVID-19 on BioNTech’s trials, business and general operations. Any forward-looking statements in this press release are based on BioNTech current expectations and beliefs of future events, and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: the ability to meet the pre-defined endpoints in clinical trials; competition to create a vaccine for COVID-19; the ability to produce comparable clinical or other results, including our stated rate of vaccine effectiveness and safety and tolerability profile observed to date, in the remainder of the trial or in larger, more diverse populations upon commercialization; the ability to effectively scale our productions capabilities; and other potential difficulties.

For a discussion of these and other risks and uncertainties, see BioNTech's quarterly report on Form 6-K for the quarter ended June 30, 2022 and in subsequent filings made by BioNTech with the SEC, which are available on the SEC's website at www.sec.gov. All information in this press release is as of the date of the release, and BioNTech undertakes no duty to update this information unless required by law.

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Pfizer:
Media Relations
+1 (212) 733-7410
PfizerMediaRelations@pfizer.com

Investor Relations
+1 (212) 733-4848
IR@pfizer.com

BioNTech:
Media Relations
Jasmina Alatovic
+49 (0)6131 9084 1513
Media@biontech.de

Investor Relations
Sylke Maas, Ph.D.
+49 (0)6131 9084 1074
Investors@biontech.de

Source: Pfizer Inc.