Pfizer and BioNTech Provide Update on Omicron Variant

Wednesday, December 08, 2021 - 06:54am

.q4default .bwalignc { text-align: center; list-style-position: inside }.q4default .bwlistcircle { list-style-type: circle }.q4default .bwlistdisc { list-style-type: disc }.q4default .bwuline { text-decoration: underline }

Preliminary laboratory studies demonstrate that three doses of the Pfizer-BioNTech COVID-19 Vaccine neutralize the Omicron variant (B.1.1.529 lineage) while two doses show significantly reduced neutralization titers Data indicate that a third dose of BNT162b2 increases the neutralizing antibody titers by 25-fold compared to two doses against the Omicron variant; titers after the booster dose are comparable to titers observed after two doses against the wild-type virus which are associated with high levels of protection As 80% of epitopes in the spike protein recognized by CD8+ T cells are not affected by the mutations in the Omicron variant, two doses may still induce protection against severe disease The companies continue to advance the development of a variant-specific vaccine for Omicron and expect to have it available by March in the event that an adaption is needed to further increase the level and duration of protection – with no change expected to the companies' four billion dose capacity for 2022
NEW YORK & MAINZ, Germany--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today announced results from an initial laboratory study demonstrating that serum antibodies induced by the Pfizer-BioNTech COVID-19 Vaccine (BNT162b2) neutralize the SARS-CoV-2 Omicron variant after three doses. Sera obtained from vaccinees one month after receiving the booster vaccination (third dose of BNT162b2 vaccine) neutralized the Omicron variant to levels that are comparable to thoseobserved for the wild-type SARS-CoV-2 spike protein after two doses.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20211208005542/en/

Sera from individuals who received two doses of the current COVID-19 vaccine did exhibit, on average, more than a 25-fold reduction in neutralization titers against the Omicron variant compared to wild-type, indicating that two doses of BNT162b2 may not be sufficient to protect against infection with the Omicron variant. However, as the vast majority of epitopes targeted by vaccine-induced T cells are not affected by the mutations in Omicron, the companies believe that vaccinated individuals may still be protected against severe forms of the disease and are closely monitoring real world effectiveness against Omicron, globally.

A more robust protection may be achieved by a third dose as data from additional studies of the companies indicate that a booster with the current COVID-19 vaccine from Pfizer and BioNTech increases the antibody titers by 25-fold. According to the companies' preliminary data, a third dose provides a similar level of neutralizing antibodies to Omicron as is observed after two doses against wild-type and other variants that emerged before Omicron. These antibody levels are associated with high efficacy against both the wild-type virus and these variants. A third dose also strongly increases CD8+ T cell levels against multiple spike protein epitopes which are considered to correlate with the protection against severe disease. Compared to the wild-type virus, the vast majority of these epitopes remain unchanged in the Omicron spike variant.

"Although two doses of the vaccine may still offer protection against severe disease caused by the Omicron strain, it's clear from these preliminary data that protection is improved with a third dose of our vaccine," said Albert Bourla, Chairman and Chief Executive Officer, Pfizer. "Ensuring as many people as possible are fully vaccinated with the first two dose series and a booster remains the best course of action to prevent the spread of COVID-19."

"Our preliminary, first dataset indicate that a third dose could still offer a sufficient level of protection from disease of any severity caused by the Omicron variant," said Ugur Sahin, M.D., CEO and Co-Founder of BioNTech. "Broad vaccination and booster campaigns around the world could help us to better protect people everywhere and to get through the winter season. We continue to work on an adapted vaccine which, we believe, will help to induce a high level of protection against Omicron-induced COVID-19 disease as well as a prolonged protection compared to the current vaccine."

While these results are preliminary, the companies will continue to collect more laboratory data and evaluate real-world effectiveness to assess and confirm protection against Omicron and inform the most effective path forward. On November 25, the companies started to develop an Omicron-specific COVID-19 vaccine. The development

will continue as planned in the event that a vaccine adaption is needed to increase the level and duration of protection against Omicron. First batches of the Omicron-based vaccine can be produced and are planned to be ready for deliveries within 100 days, pending regulatory approval. Pfizer and BioNTech have tested other variant-specific vaccines as well, which have produced very strong neutralization titers and a tolerable safety profile. Based on this experience the companies have high confidence that if needed they can deliver an Omicron-based vaccine in March 2022. The companies have also previously initiated clinical trials with variant-specific vaccines (Alpha, Beta, Delta & Alpha/Delta Mix) and data from these studies will be submitted to regulatory agencies around the world to help accelerate the process of adapting the vaccine and gaining regulatory authorization or approval of an Omicron-specific vaccine, if needed. The companies have previously announced that they expect to produce four billion doses of BNT162b2 in 2022, and this capacity is not expected to change if an adapted vaccine is required.

About the Pfizer-BioNTech Laboratory Studies

To evaluate the effectiveness of BNT162b2 against the Omicron variant, Pfizer and BioNTech immediately tested a panel of human immune sera obtained from the blood of individuals that received two or three 30-µg doses of the current Pfizer-BioNTech COVID-19 vaccine, using a pseudovirus neutralization test (pVNT). The sera were collected from subjects 3 weeks after receiving the second dose or one month after receiving the third dose of the Pfizer-BioNTech COVID-19 vaccine. Each serum was tested simultaneously for its neutralizing antibody titer against the wild-type SARS-Cov-2 spike protein, and the Omicron spike variant. The third dose significantly increased the neutralizing antibody titers against the Omicron strain spike by 25-fold. Neutralization against the Omicron variant after three doses of the Pfizer-BioNTech COVID-19 vaccine was comparable to the neutralization against the wild-type strain observed in sera from individuals who received two doses of the companies' COVID-19 vaccine: The geometric mean titer (GMT) of neutralizing antibody against the Omicron variant measured in the samples was 154 (after three doses), compared to 398 against the Delta variant (after three doses) and 155 against the ancestral strain (after two doses). Data on the persistence of neutralizing titers over time after a booster dose of BNT162b2 against the Omicron variant will be collected.

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 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

HOW IS THE VACCINE GIVEN?

The vaccine will be given as an injection into the muscle.

Primary Series:

In individuals 5 years of age and older, the vaccine is administered as a 2-dose series, 3 weeks apart. In individuals 12 years of age and older, a third primary series dose may be administered at least 4 weeks after the second dose to individuals who are determined to have certain kinds of immunocompromise.

Booster Dose:

A single booster dose of the vaccine may be administered at least 6 months after completion of a primary series to individuals 18 years of age and older A single booster dose of the vaccine may be administered to individuals 18 years of age and older who have completed primary vaccination with a different authorized COVID-19 vaccine. Individuals should check with their healthcare provider regarding timing of the booster dose
WHAT IS THE INDICATION AND AUTHORIZED USE?

The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA to provide:

a 2-dose primary series to individuals 5 years of age and older a third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise a single booster dose to individuals 18 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY® a single booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized COVID-19 vaccine. The booster schedule is based on the labeling information of the vaccine used for the primary series COMIRNATY® (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech.

It is approved as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older It is also authorized under EUA to provide: a 2-dose primary series to individuals 12 through 15 years of age a third primary series dose to individuals 12 years

of age and older who have been determined to have certain kinds of immunocompromise a single booster dose to individuals 18 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY® a single booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized COVID-19 vaccine. The boosterschedule is based on the labeling information of the vaccine used for the primary series

EUA Statement

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 5 years 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. Please see EUA Fact Sheets at www.cvdvaccine-us.com.

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 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. 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 rash, itching, hives, or swelling of the face; myocarditis (inflammation of the heart muscle); pericarditis (inflammation of the lining outside the heart); injection site pain; tiredness; headache; muscle pain; chills; joint pain; fever; injection site swelling; injection site redness; nausea; feeling unwell; swollen lymph nodes (lymphadenopathy); decreased appetite;diarrhea; vomiting; arm pain; fainting in association with injection of the vaccine 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.

Click for

Fact Sheets and Prescribing Information for individuals 12 years of age and older

Full Prescribing Information (16 years of age and older)

EUA Fact Sheet for Vaccination Providers (12 years of age and older), Purple Cap

EUA Fact Sheet for Vaccination Providers (12 years of age and older), Gray Cap

Recipients and Caregivers Fact Sheet (12 years of age and older)

Fact Sheets for individuals 5 through 11 years of age

EUA Fact Sheet for Vaccination Providers (5 through 11 years of age), Orange Cap

Recipients and Caregivers Fact Sheet (5 through 11 years of age)

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 December 8, 2021. 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 (BNT162b2) (including its potential against the Omicron variant, a potential variant-specific vaccine for Omicron, qualitative assessments of available data, potential benefits, expectations for clinical trials, 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 the preliminary laboratory data included in this release), 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 or in larger, more diverse populations following commercialization; the ability of BNT162b2 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 a potential booster dose, pediatric populations 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 or any other potential vaccines that may arise from the BNT162 program, including a potential variant-specific 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) 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; risks related to the availability of raw materials to manufacture a vaccine; challenges related to our vaccine's formulation, two-dose 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 new variant-specific vaccines; the risk that we may not be able to create 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, 2020 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, bi-specific checkpoint immuno-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, Bayer Animal Health, 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 the potential of a Omicron-specific COVID-19 vaccine candidate, the potential timing for the development of a Omicron-specific COVID-19 vaccine candidate, the testing of BNT162b2 against the Omicron variant, the effectiveness of a third booster dose of BNT162b2 to induce protection against Omicron-induced COVID-19 disease, and the timing for assessment of the effectiveness of a variant-specific COVID-19 vaccine, 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 or variant-specific COVID-19 vaccine candidates in our clinical trials and/or in commercial use based on data observations to date; the ability of BNT162b2 to prevent COVID-19 caused by the Omicron and other emerging virus variants; the expected time point for additional readouts on efficacy data of BNT162b2 in our clinical trials; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; further widespread use of our 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; decisions by regulatory authorities that may impact labeling or marketing, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of our vaccine, including development of products or therapies by other companies; the timing for submission of data for, or receipt of, any marketing authorisation or Emergency Use Authorization; our contemplated shipping and storage plan, including our estimated product shelf life at various temperatures; disruptions in the relationships between us and our collaboration partners, clinical trial sites or other third-parties; risks related to the availability of raw materials to manufacture a vaccine; challenges related to our vaccine’s formulation, two-dose and booster schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery by BioNTech and third-party providers; and the ability of BioNTech to supply the quantities of BNT162 or variant-specific COVID-19 vaccine candidates to support clinical development and market demand, including our production

estimates for 2021. 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.

For a discussion of these and other risks and uncertainties, see BioNTech’s Annual Report as Form 20-F for the Year Ended December 31, 2020, filed with the SEC on March 30, 2021, which is 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20211208005542/en/

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.