Pfizer and BioNTech Announce Positive Topline Results from Pivotal Trial of COVID-19 Vaccine in Children 5 to 11 Years

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- Results are the first from a pivotal trial of any COVID-19 vaccine in children under 12 years of age
- In participants 5 to 11 years of age, the vaccine was safe, well tolerated and showed robust neutralizing antibody responses
- Companies plan to submit these data to the FDA, EMA and other regulatory agencies around the world as soon as possible
- Results in children under 5 years of age are expected as soon as later this year

NEW YORK and MAINZ, Germany, September 20, 2021 – Pfizer Inc. (NYSE: PFE, “Pfizer”) and BioNTech SE (Nasdaq: BNTX, “BioNTech”) today announced results from a Phase 2/3 trial showing a favorable safety profile and robust neutralizing antibody responses in children 5 to 11 years of age using a two-dose regimen of 10 µg administered 21 days apart, a smaller dose than the 30 µg dose used for people 12 and older. The antibody responses in the participants given 10 µg doses were comparable to those recorded in a previous Pfizer-BioNTech study in people 16 to 25 years of age immunized with 30 µg doses. The 10 µg dose was carefully selected as the preferred dose for safety, tolerability and immunogenicity in children 5 to 11 years of age. These are the first results from a pivotal trial of a COVID-19 vaccine in this age group.

“Over the past nine months, hundreds of millions of people ages 12 and older from around the world have received our COVID-19 vaccine. We are eager to extend the protection afforded by the vaccine to this younger population, subject to regulatory authorization, especially as we track the spread of the Delta variant and the substantial threat it poses to children,” said Albert Bourla, Chairman and Chief Executive Officer, Pfizer. “Since July, pediatric cases of COVID-19 have risen by about 240 percent in the U.S. – underscoring the public health need for vaccination. These trial results provide a strong foundation for seeking authorization of our vaccine for children 5 to 11 years old, and we plan to submit them to the FDA and other regulators with urgency.”

“We are pleased to be able to submit data to regulatory authorities for this group of school-aged children before the start of the winter season,” said Dr. Ugur Sahin, CEO and co-founder of BioNTech. “The safety profile and immunogenicity data in children aged 5 to 11 years vaccinated at a lower dose are consistent with those we have observed with our vaccine in other older populations at a higher dose.”

The data summarized from this Phase 2/3 study, which is enrolling children 6 months to 11 years of age, was for 2,268 participants who were 5 to 11 years of age and received a 10 µg dose level in a two-dose regimen. In the trial, the SARS-CoV-2–neutralizing antibody geometric mean titer (GMT) was 1,197.6 (95% confidence interval [CI, 1106.1, 1296.6]), demonstrating strong immune response in this cohort of children one month after the second dose. This compares well (was non-inferior) to the GMT of 1146.5 (95% CI: 1045.5, 1257.2) from participants ages 16 to 25 years old, used as the control group for this analysis and who were administered a two-dose regimen of 30 µg. Further, the COVID-19 vaccine was well tolerated, with side effects generally comparable to those observed in participants 16 to 25 years of age.

Pfizer and BioNTech plan to share these data with the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and other regulators as soon as possible. For the United States, the companies expect to include the data in a near-term submission for Emergency Use Authorization (EUA) as they continue to accumulate the safety and efficacy data required to file for full FDA approval in this age group. A request to the EMA to update the EU Conditional Marketing Authorization is also planned. Topline readouts for the other two age cohorts from the trial – children 2-5 years of age and children 6 months to 2 years of age – are expected as soon as the fourth quarter of this year.

Pfizer and BioNTech plan to submit data from the full Phase 3 trial for scientific peer-review publication.

About the Phase 1/2/3 Trial in Children
The Phase 1/2/3 trial initially enrolled up to 4,500 children ages 6 months to 11 years of age in the United States, Finland, Poland, and Spain from more than 90 clinical trial sites. It was designed to evaluate the safety, tolerability, and immunogenicity of the Pfizer-BioNTech vaccine on a two-dose schedule (approximately 21 days apart) in three age groups: ages 5 to 11 years; ages 2 to 5 years; and ages 6 months to 2 years. Based on the Phase 1 dose-escalation portion of the trial, children ages 5 to 11 years received two-dose schedule of 10 µg each while children under age 5 received a lower 3 µg dose for each injection in the Phase 2/3 study. The trial enrolled children with or without prior evidence of SARS-CoV-2 infection.

COMIRNATY, 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 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
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 Emergency Use Authorization (EUA) to be administered for emergency use to:
  - prevent COVID-19 in individuals 12 through 15 years, and
  - provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise

The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA to:
• prevent COVID-19 in individuals 12 years of age and older, and
• provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise

The FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series. An individual may be offered either COMIRNATY® (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2.

EUA Statement
This emergency use of the product has not been approved or licensed by FDA, but has been authorized by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 12 years of age and older; and the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

Important Safety Information
Individuals should not get the Pfizer-BioNTech COVID-19 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 one 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. 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

• 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); diarrhea; vomiting; arm pain
• These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The vaccine is 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

There is no information on the use of the vaccine with other vaccines.

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 http://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.
This press release contains “forward-looking statements” of BioNTech within the meaning of the Private Securities Litigation Reform Act of 1995.

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 potential in children 5 to 11 years of years of age and an ongoing study in children 6 months to 5 years of age, a BLA to support potential full FDA approval of BNT162b2 in individuals 12 through 15 years, 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 to prevent COVID-19 caused by 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; 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; and the ability of BioNTech to supply the quantities of BNT162 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. 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 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.

CONTACTS

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

Investor Relations
Christopher Stevo
+1 (212) 733-0437
Christopher.Stevo@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