



## Pfizer-BioNTech Announce Positive Topline Results of Pivotal COVID-19 Vaccine Study in Adolescents

March 31, 2021

- In participants aged 12-15 years old, BNT162b2 demonstrated 100% efficacy and robust antibody responses, exceeding those reported in trial of vaccinated 16-25 year old participants in an earlier analysis, and was well tolerated
- The companies plan to submit these data to the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) as soon as possible to request expansion of the Emergency Use Authorization (EUA) and EU Conditional Marketing Authorization for BNT162b2
- The companies also provided an update on the Phase 1/2/3 study of BNT162b2 in children aged 6 months to 11 years

**New York and Mainz, Germany, March 31, 2021** —Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today announced that, in a Phase 3 trial in adolescents 12 to 15 years of age with or without prior evidence of SARS-CoV-2 infection, the Pfizer-BioNTech COVID-19 vaccine BNT162b2 demonstrated 100% efficacy and robust antibody responses, exceeding those recorded earlier in vaccinated participants aged 16 to 25 years old, and was well tolerated. These are topline results from a pivotal Phase 3 trial in 2,260 adolescents.

"We share the urgency to expand the authorization of our vaccine to use in younger populations and are encouraged by the clinical trial data from adolescents between the ages of 12 and 15," said **Albert Bourla, Chairman and Chief Executive Officer, Pfizer**. "We plan to submit these data to FDA as a proposed amendment to our Emergency Use Authorization in the coming weeks and to other regulators around the world, with the hope of starting to vaccinate this age group before the start of the next school year."

"Across the globe, we are longing for a normal life. This is especially true for our children. The initial results we have seen in the adolescent studies suggest that children are particularly well protected by vaccination, which is very encouraging given the trends we have seen in recent weeks regarding the spread of the B.1.1.7 UK variant. It is very important to enable them to get back to everyday school life and to meet friends and family while protecting them and their loved ones," said **Ugur Sahin, CEO and Co-founder of BioNTech**.

### About the Phase 3 Data from Adolescents 12-15 Years of Age

The trial enrolled 2,260 adolescents 12 to 15 years of age in the United States. In the trial, 18 cases of COVID-19 were observed in the placebo group (n=1,129) versus none in the vaccinated group (n=1,131). Vaccination with BNT162b2 elicited SARS-CoV-2-neutralizing antibody geometric mean titers (GMTs) of 1,239.5, demonstrating strong immunogenicity in a subset of adolescents one month after the second dose. This compares well (was non-inferior) to GMTs elicited by participants aged 16 to 25 years old (705.1 GMTs) in an earlier analysis. Further, BNT162b2 administration was well tolerated, with side effects generally consistent with those observed in participants 16 to 25 years of age.

The companies plan to submit these data to the FDA and EMA for a requested amendment to the Emergency Use Authorization of BNT162b2 and the EU Conditional Marketing Authorization for COMIRNATY® to expand use in adolescents 12-15 years of age as quickly as possible. All participants in the trial will continue to be monitored for long-term protection and safety for an additional two years after their second dose.

Pfizer and BioNTech plan to submit the data for scientific peer review for potential publication.

### Update on the Phase 1/2/3 Study in Children 6 months to 11 years old

Last week, Pfizer and BioNTech dosed the first healthy children in a global Phase 1/2/3 seamless study to further evaluate the safety, tolerability, and immunogenicity of the Pfizer-BioNTech COVID-19 vaccine in children 6 months to 11 years of age. The study is evaluating the safety, tolerability, and immunogenicity of the Pfizer-BioNTech COVID-19 vaccine on a two-dose schedule (approximately 21 days apart) in three age groups: children aged 5 to 11 years, 2 to 5 years, and 6 months to 2 years. The 5 to 11 year-old cohort started dosing last week and the companies plan to initiate the 2 to 5 year-old cohort next week.

The Pfizer-BioNTech COVID-19 vaccine, BNT162b2, has not been approved or licensed by the U.S. Food and Drug Administration (FDA), but has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 16 years of age and older. 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. Please see Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including Full EUA Prescribing Information available at [www.cvdvaccine.com](http://www.cvdvaccine.com).

The vaccine, which is based on BioNTech proprietary mRNA technology, was developed by both BioNTech and Pfizer. BioNTech is the Marketing Authorizations Holder in the European Union, and the holder of emergency use authorizations or equivalent in the United States, United Kingdom, Canada and other countries in advance of a planned application for full marketing authorizations in these countries.

### AUTHORIZED USE IN THE U.S.:

The Pfizer-BioNTech COVID-19 vaccine is authorized for use under an 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 16 years of age and older.

### IMPORTANT SAFETY INFORMATION FROM U.S. FDA EMERGENCY USE AUTHORIZATION PRESCRIBING INFORMATION:

- Do not administer Pfizer-BioNTech COVID-19 vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 vaccine



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 or third-party suppliers; risks related to the availability of raw materials to manufacture a vaccine; challenges related to our vaccine's ultra-low temperature 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; 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 technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; 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](http://www.sec.gov) and [www.pfizer.com](http://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](http://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 to develop a COVID-19 vaccine (including a potential second booster dose of BNT162b2 and/or a potential booster dose of a variation of BNT162b2 having a modified mRNA sequence); 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 on 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](http://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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