



Pfizer and BioNTech Initiate a Study as Part of Broad Development Plan to Evaluate COVID-19 Booster and New Vaccine Variants

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- *The evaluation is part of the Phase 1/2/3 trial and will study a third dose of the Pfizer-BioNTech COVID-19 vaccine, BNT162b2, at 30 µg that will be given to Phase 1 participants to evaluate the safety and tolerability of a booster vaccine*
- *Discussions with regulatory authorities are ongoing regarding an additional registration-enabling study using an mRNA vaccine with a variant sequence; this would provide a flexible solution for rapidly adapting the vaccine for use against the B.1.351 lineage or other new strains that may emerge as possible immune escape virus variants*
- *Based on in-vitro studies conducted to date and observations from real world evidence, the Companies have not observed changes to neutralizing antibody levels that would predict a significant reduction in protection provided by two doses of BNT162b2*

New York and Mainz, Germany, February 25, 2021 — [Pfizer Inc.](#) (NYSE: PFE) and [BioNTech SE](#) (Nasdaq: BNTX) announced today they have begun an evaluation of the safety and immunogenicity of a third dose of the Pfizer-BioNTech COVID-19 vaccine (BNT162b2) to understand the effect of a booster on immunity against COVID-19 caused by the circulating and potential newly emerging SARS-CoV-2 variants. The study will draw upon participants from the [Phase 1](#) study in the United States who will be offered the opportunity to receive a 30 µg booster of the current vaccine 6 to 12 months after receiving their initial two-dose regimen. The study is part of the Companies' clinical development strategy to determine the effectiveness of a third dose against evolving variants.

Separately, in order to be prepared for any potential future strain changes, Pfizer and BioNTech are in ongoing discussions with regulatory authorities, including the U.S. Food and Drug Administration (FDA) and the European Medicines Agency, regarding a registration-enabling clinical study to evaluate a variant-specific vaccine having a modified mRNA sequence. This study would use a new construct of the Pfizer-BioNTech vaccine based on the B.1.351 lineage, first identified in South Africa. This could position the Companies to update the current vaccine quickly if the need arises to protect against COVID-19 from circulating strains. In alignment with the updated guidance issued by the FDA regarding emergency use of vaccines to prevent COVID-19 which provides recommendations for evaluating a modified vaccine to address variants, the Companies are hoping to pursue the validation of future modified mRNA vaccines with a regulatory pathway similar to what is currently in place for flu vaccines.

"While we have not seen any evidence that the circulating variants result in a loss of protection provided by our vaccine, we are taking multiple steps to act decisively and be ready in case a strain becomes resistant to the protection afforded by the vaccine. This booster study is critical to understanding the safety of a third dose and immunity against circulating strains," said **Albert Bourla, Chairman and Chief Executive Officer, Pfizer**. "At the same time, we are making the right investments and engaging in the appropriate conversations with regulators to help position us to potentially develop and seek authorization for an updated mRNA vaccine or booster if needed."

"Our proactive clinical development strategy aims to create the foundation today, that will enable us to address the challenges of tomorrow. We want to be prepared for different scenarios," said **Ugur Sahin, CEO and Co-founder of BioNTech**. "Therefore, we will be evaluating a second booster in the current regimen as well as preparing for a potential rapid adaptation of the vaccine to address new variants which might escape the current version of our mRNA-based vaccine. The flexibility of our proprietary mRNA vaccine platform allows us to technically develop booster vaccines within weeks, if needed. This regulatory pathway is already established for other infectious diseases like influenza. We take these steps in order to ensure a long-term immunity against the virus and its variants."

Administering a third dose will provide an early assessment of the safety of a third dose of BNT162b2, as well as its immunogenicity. The study will evaluate up to 144 Phase 1 participants in two age cohorts, 18-55 and 65-85 years of age. This study will include trial participants who received the two doses in the Phase 1 study 6 to 12 months ago in order to assess the boostability of BNT162b2. Thus, the study will evaluate the safety and tolerability of a third vaccination irrespective of the level of antibody titers of the trial participant. Participants will be assessed at the time they receive the third dose, then one week and one month after, and Pfizer and BioNTech plan to study the ability of the sera from those participants to neutralize SARS-CoV-2 strains of interest. The participants will continue being followed in the study for up to 2 years as originally planned.

The Pfizer-BioNTech COVID-19 Vaccine 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.

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.,

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 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, 2019 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 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 Quarterly Report for the Three and Nine Months Ended September 30, 2020, filed as Exhibit 99.2 to its Current Report on Form 6-K filed with the SEC on November 10, 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.

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