



Pfizer and BioNTech Announce New England Journal of Medicine Publication of Phase 1 Data on Lead mRNA Vaccine Candidate BNT162b2 Against COVID-19

October 14, 2020

NEW YORK and MAINZ, GERMANY, October 14, 2020 — [Pfizer Inc.](#) (NYSE: PFE) and [BioNTech SE](#) (Nasdaq: BNTX) today announced that preliminary, peer-reviewed data from the Phase 1 portion of their ongoing U.S. study of BNT162b2 were published online in the [New England Journal of Medicine \(NEJM\)](#). BNT162b2, which has advanced into a global Phase 3 study, is part of the companies' mRNA-based vaccine development program against COVID-19. The publication describes key safety and immunogenicity data from the Phase 1 portion of the U.S. trial for the BNT162b2 and BNT162b1 vaccine candidates. Among the Phase 1 study participants aged 18 to 55 years, the 50% neutralizing geometric mean titers (GMTs) for the two vaccine candidates at the 30-µg dose level on day 28 or day 35 ranged from 1.7 to 4.6 times the GMT of a panel of SARS-CoV-2 human convalescent sera (HCS). In addition, 50% neutralizing GMTs among participants 65 to 85 years of age ranged from 1.1 to 2.2 times the GMT of the HCS panel, demonstrating strong immunogenicity in younger and older adults. Further, across all populations, BNT162b2 administration was well tolerated with mild to moderate fever in fewer than 20% of the participants. Data were initially made available to the public on August 20, 2020 via the online preprint server, medRxiv. For additional details, please read the previously issued [press release](#).

[As previously announced](#), BNT162b2 was selected as the vaccine candidate to advance into a global Phase 2/3 study based on the totality of available data from preclinical and clinical studies. As of today, the trial has enrolled over 37,000 participants. For further information about this trial, visit www.ClinicalTrials.gov using the number NCT04368728.

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](https://www.facebook.com/Pfizer).

Pfizer Disclosure Notice

The information contained in this release is as of October 14, 2020. 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 potential COVID-19 vaccine, the BNT162 mRNA vaccine program, and modRNA candidates BNT162b2 and BNT162b1 (including qualitative assessments of available data, potential benefits, and expectations for clinical trials), that involves 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 preliminary data, including the possibility of unfavorable new preclinical or clinical trial data and further analyses of existing preclinical or clinical trial data that may be inconsistent with the data used for selection of the BNT162b2 vaccine candidate and dose level for the Phase 2/3 study; the risk that 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; whether regulatory authorities will be satisfied with the design of and results from these and future preclinical and clinical studies; whether and when any biologics license and/or emergency use authorization applications may be filed in any jurisdictions for BNT162b2 or any other potential vaccine candidates; whether and when any such applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the vaccine candidate's benefits outweigh its known risks and determination of the vaccine candidate's efficacy and, if approved, whether it will be commercially successful; decisions by regulatory authorities impacting labeling, 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; manufacturing capabilities or capacity, including whether the estimated numbers of doses can be manufactured within the projected time periods 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; 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 potential COVID-19 vaccine; and our expectations regarding the potential characteristics of BNT162b2 in our Phase 2/3 trial and/or in commercial use based on data observations to date, including expected advantages over BNT162b1; the expected timepoint for readout on efficacy data of BNT162b2 in our Phase 2/3 trial; and the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation. 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: competition to create a vaccine for COVID-19; the ability to produce comparable clinical results in larger and more diverse clinical trials; 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 filed with the SEC on March 31, 2020, 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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