Pfizer Logo

BioNTech and Pfizer Announce Nature Publication of German Phase 1/2 Study Data from mRNA-based Vaccine Candidate BNT162b1 Against SARS-CoV-2

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MAINZ, GERMANY and NEW YORK, September 30, 2020 — BioNTech SE (Nasdaq: BNTX) and Pfizer Inc. (NYSE: PFE) today announced that preliminary, peer-reviewed data from their ongoing German Phase 1/2 Study of BNT162b1 were published online in the journal Nature. BNT162b1 is part of the companies' mRNA-based vaccine development program against SARS-CoV-2. The preliminary clinical data from the German study of BNT162b1, a nucleoside-modified messenger RNA (modRNA) candidate that encodes an optimized SARS-CoV-2 receptor binding domain (RBD) antigen, supported and expanded the data from the Phase 1/2 US study. BNT162b1 administered at dose levels that were well tolerated, generated dose level-dependent immunogenicity, as measured by RBD-binding IgG concentrations and SARS-CoV-2 neutralizing titers. In addition, the initial German trial results demonstrated, for the first time for the BNT62b1 candidate, a concurrent induction of high magnitude CD4+ and CD8+ T cell responses against the SARS-CoV-2 RBD. The data were initially made available to the public on July 20, 2020 via the online preprint server, medRxiv. For additional details, please read the previously issued press release.

The companies are also continuing the peer-review process for other previously announced results from their BNT162b2 studies. As previously announced, BNT162b2 has been selected as the vaccine candidate to advance into a Phase 2/3 study based on the totality of available data from preclinical and clinical studies. As of today, the trial has enrolled over 35,000 participants, and the companies continue to expect that a conclusive readout on efficacy is likely by the end of October.

The Phase 2/3 study is an event-driven trial that is planned to enroll up to 44,000 participants between 16 and 85 years of age. The companies are enrolling a diverse population, including participants in areas where there is significant expected SARS-CoV-2 transmission. For further information about this trial, visit www.ClinicalTrials.gov using the number NCT04368728.

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 2 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.

Pfizer Disclosure Notice:The information contained in this release is as of September 30, 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, expectations for clinical trials and anticipated timing of clinical trial readouts and regulatory submissions), 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 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. BioNTech Contacts: Media Relations Jasmina Alatovic +49 (0)6131 9084 1513 or +49 (0)151 1978 1385 Media@biontech.de Investor Relations Sylke Maas, Ph.D. +49 (0)6131 9084 1074 Investors@biontech.de Pfizer Contacts: Media Relations Jerica Pitts +1 (212) 733-5060 Jerica.Pitts@pfizer.com Investor Relations Chuck Triano +1 (212) 733-3901 Charles.E.Triano@Pfizer.com