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Pfizer and BioNTech Granted FDA Fast Track Designation for Two Investigational mRNA-based Vaccine Candidates Against SARS-CoV-2

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Anticipated large, global Phase 2b/3 safety and efficacy study may begin as early as July 2020

NEW YORK & MAINZ, Germany--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX, "BioNTech") today announced that two of the companies' four investigational vaccine candidates from their BNT162 mRNA-based vaccine program (BNT162b1 and BNT162b2) being developed to help protect against SARS-CoV-2 (the virus that causes COVID-19), received Fast Track designation from the U.S. Food and Drug Administration (FDA). BNT162b1 and BNT162b2 are the two most advanced vaccine candidates in the BNT162 program currently being evaluated in ongoing Phase 1/2 clinical studies in the United States and Germany.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20200713005168/en/

Fast Track is a process designed to facilitate the development, and expedite the review, of new drugs and vaccines that are intended to treat or prevent serious conditions that have the potential to address an unmet medical need.[i] This designation was granted based on preliminary data from Phase 1/2 studies that are currently ongoing in the United States and Germany as well as animal immunogenicity studies. The companies released early data from the ongoing U.S. Phase 1/2 study for the product candidate BNT162b1 on July 1, 2020. The manuscript is available on the online preprint server medRxiv and is concurrently undergoing scientific peer-review for potential publication. Early data from the German trial of BNT162b1 are expected to be released in July.

The BNT162 program is evaluating at least four experimental vaccines, each of which represent a unique combination of messenger RNA (mRNA) format and target antigen. BNT162b1 and BNT162b2 are both nucleoside modified RNAs, formulated in lipid nanoparticles. BNT162b1 encodes an optimized SARS-CoV-2 receptor-binding domain (RBD) antigen, while BNT162b2 encodes an optimized SARS-CoV-2 full-length spike protein antigen.

"The FDA's decision to grant these two COVID-19 vaccine candidates Fast Track designation signifies an important milestone in the efforts to develop a safe and effective vaccine against SARS-CoV-2," said **Peter Honig, Senior Vice President, Global Regulatory Affairs, Pfizer**. "We look forward to continue working closely with the FDA throughout the clinical development of this program, Project Lightspeed, to evaluate the safety and efficacy of these vaccine candidates."

“We are pleased to have received Fast Track designation from the FDA for two of our vaccine candidates and look forward to working closely with the FDA, along with our partner Pfizer, to expedite the clinical development path forward,” said **Özlem Türeci, Chief Medical Officerat BioNTech**.

The Project Lightspeed vaccine development program is based on BioNTech’s proprietary mRNA-based technology platforms and supported by Pfizer’s global vaccine development capabilities. The BNT162 vaccine candidates are undergoing clinical studies and are not currently approved for distribution anywhere in the world. Pfizer and BioNTech are committed to developing these novel vaccines with pre-clinical and clinical data at the forefront of all decision-making of both companies. Subject to regulatory approval, the companies are expecting to start a Phase 2b/3 trial as soon as later this month and are anticipating enrolling up to 30,000 subjects. If the ongoing studies are successful, and the vaccine candidate receives regulatory approval, the companies currently expect to manufacture up to 100 million doses by the end of 2020 and potentially more than 1.2 billion doses by the end of 2021.

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 150 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.

Pfizer Disclosure Notice

The information contained in this release is as of July 13, 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 BNT162 mRNA vaccine program, and a collaboration between BioNTech and Pfizer to develop a potential COVID-19 vaccine, including their potential benefits, and anticipated publication of data, manufacturing and distribution and the expected timing of 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 the possibility of unfavorable new preclinical or clinical trial data and further analyses of existing preclinical or clinical trial data; risks associated with preliminary data; 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 the scientific journal publications referenced above will occur 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 applications may be filed in any jurisdictions for any potential vaccine candidates under the collaboration; 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 product’s benefits outweigh its known risks and determination of the product’s

efficacy and, if approved, whether any such vaccine candidates 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 any such vaccine candidates, 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; uncertainties regarding the ability to obtain recommendations from vaccine technical committees and other public health authorities regarding any such vaccine candidates 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, 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 timing to initiate clinical trials of BNT162 and any expedited review resulting from Fast Track designation; collaborations between BioNTech and Pfizer, and BioNTech and Fosun Pharma, to develop a potential COVID-19 vaccine; and the ability of BioNTech to supply the quantities of BNT162 to support clinical development and, if approved, market demand. 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 and 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 has been filed with the SEC and 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.

[i] U.S. Food and Drug Administration Fast Track
https://www.fda.gov/ForPatients/Approvals/Fast/ucm405399.htm

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