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Pfizer and BioNTech Dose First Participants in the U.S. as Part of Global COVID-19 mRNA Vaccine Development Program

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Multimedia Materials

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Pfizer COVID-19 Vaccine Clinical Trial Manufacturing Infographic

Pfizer COVID-19 mRNA Vaccine Infographic

First participants dosed at NYU Grossman School of Medicine and University of Maryland School of Medicine

Pfizer and BioNTech ramping up manufacturing capabilities to further increase production capacity in 2020/2021

NEW YORK & MAINZ, Germany--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) announced today that the first participants have been dosed in the U.S. in the Phase 1/2 clinical trial for the BNT162 vaccine program to prevent COVID-19. The trial is part of a global development program, and the dosing of the first cohort in Germany was completed last week.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20200505005474/en/

The Phase 1/2 study is designed to determine the safety, immunogenicity and optimal dose level of four mRNA vaccine candidates evaluated in a single, continuous study. The dose level escalation portion (Stage 1) of the Phase 1/2 trial in the U.S. will enroll up to 360 healthy subjects into two age cohorts (18-55 and 65-85 years of age). The first subjects immunized in Stage 1 of the study will be healthy adults 18-55 years of age. Older adults will only be immunized with a given dose level of a vaccine candidate once testing of that candidate and dose level in younger adults has provided initial evidence of safety and immunogenicity. Sites currently dosing participants include NYU Grossman School of Medicine and the University of Maryland School of Medicine, with the University of Rochester Medical Center/Rochester Regional Health and Cincinnati Children’s Hospital Medical Center to begin enrollment shortly.

“With our unique and robust clinical study program underway, starting in Europe and now the U.S., we look forward to advancing quickly and collaboratively with our partners at BioNTech and regulatory authorities to bring a safe and efficacious vaccine to the patients who need it most. The short, less than four-month timeframe in which we’ve been able to move from pre-clinical studies to human testing is extraordinary and further demonstrates our commitment to dedicating our best-in-class resources, from the lab to manufacturing and beyond, in the battle against COVID-19,” said Albert Bourla, Chairman and CEO, Pfizer.

Pfizer and BioNTech’s development program includes four vaccine candidates, each representing a different combination of mRNA format and target antigen. The novel design of the trial allows for the evaluation of the various mRNA candidates simultaneously in order to identify the safest and potentially most efficacious candidate in a greater number of volunteers, in a manner that will facilitate the sharing of data with regulatory authorities in real time.

“It is encouraging that we have been able to leverage more than a decade of experience in developing our mRNA platforms to initiate a global clinical trial in multiple regions for our vaccine program in such a short period. We are optimistic that advancing multiple vaccine candidates into human trials will allow us to identify the safest, most effective vaccination options against COVID-19,” said CEO and Co-founder of BioNTech, Ugur Sahin.

During the clinical development stage, BioNTech will provide clinical supply of the vaccine from its GMP-certified mRNA manufacturing facilities in Europe.

In anticipation of a successful clinical development program, Pfizer and BioNTech are working to scale up production for global supply. Pfizer plans to activate its extensive manufacturing network and invest at risk in an effort to produce an approved COVID-19 vaccine as quickly as possible for those most in need around the world. The breadth of this program should allow production of millions of vaccine doses in 2020, increasing to hundreds of millions in 2021. Pfizer-owned sites in three U.S. states (Massachusetts, Michigan and Missouri) and Puurs, Belgium have been identified as manufacturing centers for COVID-19 vaccine production, with more sites to be selected. Through its existing mRNA production sites in Mainz and Idar-Oberstein, Germany, BioNTech plans to ramp up its production capacity to provide further capacities for a global supply of the potential vaccine.

BioNTech and Pfizer will work jointly to commercialize the vaccine worldwide upon regulatory approval (excluding China, where BioNTech has a collaboration with Fosun Pharma for BNT162 for both clinical development and commercialization).

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.

Pfizer Disclosure Notice

The information contained in this release is as of May 5, 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, BioNTech's mRNA vaccine program, BNT162, a collaboration between BioNTech and Pfizer to develop a potential COVID-19 vaccine and manufacturing capacity, including their potential benefits, and the expected timing of clinical trials and potential supply, 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 clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from the 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; 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 (BioNTech) 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 Eli Lilly and Company, 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; 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.

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