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Pfizer and BioNTech Choose Lead mRNA Vaccine Candidate Against COVID-19 and Commence Pivotal Phase 2/3 Global Study

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- *Companies advance nucleoside-modified messenger RNA (modRNA) candidate BNT162b2, which encodes an optimized SARS-CoV-2 full-length spike glycoprotein, at a 30 µg dose level in a 2 dose regimen into Phase 2/3 Study*
- *Candidate and dose level selection informed by preclinical and clinical data obtained in Phase 1/2 studies conducted in the U.S. (C4591001) and Germany (BNT162-01)*
- *The Phase 2/3 study protocol follows all the U.S. Food and Drug Administration (FDA) guidance on clinical trial design for COVID-19 vaccine studies.*
- *Phase 2/3 study of up to 30,000 participants aged 18 – 85 years started in the U.S. and expected to include approximately 120 sites globally*
- *Trial regions to include areas with significant expected SARS-CoV-2 transmission to assess whether investigational vaccine candidate, BNT162b2, is effective in preventing COVID-19*
- *Assuming clinical success, Pfizer and BioNTech on track to seek regulatory review as early as October 2020 and, if regulatory authorization or approval is obtained, plan to supply up to 100 million doses by the end of 2020 and approximately 1.3 billion doses by the end of 2021*

NEW YORK & MAINZ, Germany--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today announced the start of a global (except for China) Phase 2/3 safety and efficacy clinical study to evaluate a single nucleoside-modified messenger RNA (modRNA) candidate from their BNT162 mRNA-based vaccine program against SARS-CoV-2.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20200727005800/en/

After extensive review of preclinical and clinical data from Phase 1/2 clinical trials, and in consultation with the U.S. Food and Drug Administration's Center for Biologics Evaluation and Research (CBER) and other global regulators, Pfizer and BioNTech have chosen to advance their BNT162b2 vaccine candidate into the Phase 2/3 study, at a 30 *µg* dose level in a 2 dose regimen. BNT162b2, which recently received U.S. Food and Drug Administration (FDA) Fast Track designation, encodes an optimized SARS-CoV-2 full length spike glycoprotein (S), which is the target of virus neutralizing antibodies.

"Our selection of the BNT162b2 vaccine candidate and its advancement into a Phase 2/3 study are the culmination of an extensive, collaborative and unprecedented R&D program involving Pfizer, BioNTech, clinical investigators, and study participants with a singular focus of developing a safe and effective COVID-19 RNA vaccine. The Phase 2/3 study protocol follows all the U.S. Food and Drug Administration (FDA) guidance

on clinical trial design for COVID-19 vaccine studies," said Kathrin U. Jansen, Ph.D., Senior Vice President and Head of Vaccine Research & Development, Pfizer. "The initiation of the Phase 2/3 trial is a major step forward in our progress toward providing a potential vaccine to help fight the ongoing COVID-19 pandemic, and we look forward to generating additional data as the program progresses."

"Today, we are starting our late-stage global study, which will include up to 30,000 participants. We selected BNT162b2 as our lead candidate for this Phase 2/3 trial upon diligent evaluation of the totality of the data generated so far. This decision reflects our primary goal to bring a well-tolerated, highly effective vaccine to the market as quickly as possible, while we will continue to evaluate our other vaccine candidates as part of a differentiated COVID-19 vaccine portfolio," said Ugur Sahin, M.D., CEO and Co-Founder of BioNTech. "Many steps have been taken towards this important milestone and we would like to thank all those involved for their extraordinary commitment."

About the BNT162b2 Candidate

During preclinical and clinical studies of four BNT162 RNA vaccine candidates, BNT162b1 and BNT162b2 emerged as strong candidates based on assessments of safety and immune response. Pfizer and BioNTech selected BNT162b2 as the candidate to progress to a Phase 2/3 study based on the totality of available data from our preclinical and clinical studies, including select immune response and tolerability parameters.

In the preclinical studies, BNT162b1 and BNT162b2 candidates induced favorable viral antigen specific CD4+ and CD8+T cell responses, high levels of neutralizing antibody in various animal species, and beneficial protective effects in a primate SARS-CoV-2 challenge model.

Preliminary clinical Phase 1/2 data from nearly 120 patients demonstrated a favorable overall tolerability profile for BNT162b2, as compared to BNT162b1, with generally mild to moderate and transient (1-2 days) systemic events, such as fever, fatigue and chills and no serious adverse events. Two 30 μg doses of BNT162b2 elicited neutralizing geometric mean titers (GMTs) generally similar to the GMTs that were elicited by the BNT162b1 vaccine candidate, as reflected in data the companies have previously posted on a preprint server. In older adults (65-85 years of age), two 30 µg doses, spaced three weeks apart, elicited a neutralizing antibody GMT higher than the GMT in a panel of 38 sera from subjects who had contracted SARS-CoV-2. BNT162b2 vaccinated human participants displayed a favorable breadth of epitopes recognized in T cell responses specific to the SARS-CoV-2 antigen, as compared to the BNT162b1 candidate. BNT162b2 demonstrated concurrent induction of high magnitude CD4+ and CD8+ T cell responses. BNT162b2 elicited T cell responses against the receptor binding domain (RBD) and against the remainder of the spike glycoprotein that is not contained in the BNT162b1 vaccine candidate. The companies believe that immune recognition of more spike T cell epitopes may have the potential to generate more consistent responses across diverse populations and in older adults.

The companies are continuing to collect data from the Phase 1/2 trials for all four vaccine candidates and expect to submit data on BNT162b2 for peer review and potential publication in the near future. In keeping with their commitment to transparency, the companies intend to also post the manuscript on a preprint server at that time.

About the Phase 2/3 Study

Pfizer and BioNTech finalized the Phase 2/3 study protocol in response to feedback from global regulators, including the FDA and the German Paul-Ehrlich-Institut. The Phase 2/3 study is an event driven trial that is planned to enroll up to 30,000 participants between 18 and 85 years of age. The companies plan to enroll a diverse population, including participants in areas where there is significant expected SARS-CoV-2 transmission.

The Phase 2/3 trial is designed as a 1:1 vaccine candidate to placebo, randomized, observer-blinded study to obtain safety, immune response, and efficacy data needed for regulatory review. The trial's primary endpoints will be prevention of COVID-19 in those who have not been infected by SARS-CoV-2 prior to immunization, and prevention of COVID-19 regardless of whether participants have previously been infected by SARS-CoV-2. Secondary endpoints include prevention of severe COVID-19 in those groups. The study also will explore prevention of infection by SARS-CoV-2, the virus that causes COVID-19. The primary efficacy analysis will be an event-driven analysis based on the number of participants with symptomatic COVID-19 disease. The trial design allows for interim analyses and unblinded reviews by an independent external Data Monitoring Committee.

By the end of the trial, the Phase 2/3 study is expected to be active at approximately 120 clinical investigational sites around the world, including 39 states across the United States and countries including Argentina, Brazil, and Germany. Investigator sites are selected based on factors including scientific expertise and capabilities, the epidemiology of the disease, and prior experience conducting clinical trials. For further information about this trial, visit ClinicalTrials.gov using the number NCT04368728.

Pfizer and BioNTech are committed to decreasing health disparities in underrepresented populations through the clinical trial process. To that end, many investigator sites are in diverse communities that have been disproportionately affected by COVID-19 so that individuals who have been most impacted have the opportunity to participate. The companies are also working together with investigator sites and advocacy partners to raise awareness about the importance of participation in this trial.

BNT162b2 remains under clinical study and is not currently approved for distribution anywhere in the world. If the Phase 2/3 trial is successful, Pfizer and BioNTech expect to be ready to seek Emergency Use Authorization or some form of regulatory approval as early as October 2020. If authorization or approval is obtained, the companies currently aim to supply globally up to 100 million doses by the end of 2020 and approximately 1.3 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 27, 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 timing of regulatory submissions, and anticipated manufacturing, supply and distribution), 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 authorizationapplications 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, 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 anticipated publication of data from these clinical trials; the potential number of sites and participants in our Phase 2/3 trial; the timing for any potential emergency use authorizations or approvals; the collaboration between BioNTech and Pfizer to develop a potential COVID-19 vaccine; 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; and the ability of BioNTech to supply the quantities of BNT162 to support clinical development and, if approved, market demand, including our production estimates for 2020 and 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: 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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