Pfizer and BioNTech Share Positive Early Data on Lead mRNA Vaccine Candidate BNT162b2 Against COVID-19

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- *In a Phase 1 study in the U.S., at 7 days after a second dose of 30ug, BNT162b2 elicited SARS-CoV-2–neutralizing geometric mean titers (GMTs) in younger adults (18-55 years of age) that were 3.8 times the GMT of a panel of 38 sera of SARS-CoV-2 convalescent patients, and in older adults (65-85 years of age) the vaccine candidate elicited a neutralizing GMT 1.6 times the GMT of the same panel, demonstrating strong immunogenicity in younger and older adults.*

- *The companies previously announced that BNT162b2-vaccinated human participants displayed a favorable breadth of epitopes recognized in T cell responses specific to the SARS-CoV-2 spike antigen, and that BNT162b2 demonstrated concurrent induction of high magnitude CD4+ and CD8+ T cell responses against the receptor binding domain (RBD) and against the remainder of the spike glycoprotein*

- *Across all populations, BNT162b2 administration was well tolerated with mild to moderate fever in fewer than 20% of the participants*

- *These results informed the selection of the BNT162b2 candidate for the pivotal Phase 2/3 global study in up to 30,000 participants that started in July 2020, which has to date enrolled more than 11,000 participants, including in areas with significant SARS-CoV-2 transmission*

- *Assuming clinical success, Pfizer and BioNTech are on track to seek regulatory review of BNT162b2 as early as October 2020 and, if regulatory authorization or approval is obtained, currently plan to supply up to 100 million doses worldwide by the end of 2020 and approximately 1.3 billion doses by the end of 2021*

NEW YORK and MAINZ, Germany, Aug. 20, 2020 (GLOBE NEWSWIRE) -- Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today shared additional Phase 1 safety and immunogenicity data from their ongoing U.S. study of the BNT162 mRNA-based vaccine program against SARS-CoV-2, which has advanced into Phase 2/3 evaluation. The newly released manuscript describes key safety and immunogenicity data from the U.S. Phase 1 trial for the BNT162b2 vaccine candidate, which at 30ug recorded 7 days after the second dose elicited SARS-CoV-2-neutralizing geometric mean titers (GMTs) in younger adults (18-55 years of age) that were 3.8 times the GMT of a panel of 38 sera of SARS-CoV2 convalescent patients, and in older adults (65-85 years of age) the vaccine candidate elicited a neutralizing GMT 1.6 times the GMT of the same 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. As previously announced, these data informed the companies' decision to advance a 2-dose regimen of the 30*μg* dose level of BNT162b2, which encodes an optimized SARS-CoV-2 full-length spike glycoprotein (S), into a Phase 2/3 evaluation. The manuscript is now available on an online preprint server at https://www.medrxiv.org/content/10.1101/2020.08.17.20176651v1 and is concurrently undergoing scientific peer review for potential publication.

The companies are continuing to analyze data from the Phase 1 trials in the U.S. and Germany. T cell immune responses elicited by BNT162b2 are being evaluated in the German study and the companies expect to submit the data for peer review and potential publication. The companies previously announced that BNT162b2-vaccinated human participants displayed a favorable breadth of epitopes recognized in T cell responses specific to the SARS-CoV-2 spike antigen, as compared to the BNT162b1 candidate, and that BNT162b2 demonstrated concurrent induction of high magnitude CD4+ and CD8+ 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 totality of the clinical and preclinical data informed Pfizer and BioNTech's decision to select BNT162b2 as the lead candidate to advance into pivotal trials. We are proud to share our findings with the scientific community as we continue our work to deliver a safe and effective vaccine to combat this devastating virus," said **Kathrin U. Jansen, Ph.D., Senior Vice President and Head of Vaccine Research & Development, Pfize**r. "We are especially pleased to offer these early data showing our vaccine candidate's promising safety and immunogenicity profile from the U.S. trial and we look forward to sharing T cell immune response data from the German trial in the near future."

"It is important to us to continue sharing data and related information on our COVID-19 vaccine lead candidate," said **Ugur Sahin, M.D., CEO and Co-Founder of BioNTech**. "The favorable safety profile of BNT162b2 and the breadth of T cell responses we previously announced have supported our decision to select this candidate for the pivotal Phase 2/3 study. As of today, we have already dosed more than 11,000 participants with BNT162b2 in that study."

The additional data from the ongoing U.S. Phase 1 randomized, placebo-controlled, observer-blinded study was utilized to evaluate the safety and immunogenicity of varying dose levels of BNT162b1 and BNT162b2 in 195 participants randomized into 13 groups of 15 participants (per group, 12 received the vaccine and 3 the placebo). Groups of participants 18 to 55 years of age and 65 to 85 years of age received 10*μg*, 20*μg*, or 30*μg* dose levels of BNT162b1 or BNT162b2 on a 2-dose schedule, 21 days apart.

In both younger and older adults, BNT162b1 and BNT162b2 elicited similar dose-dependent SARS-CoV-2–neutralizing antibody GMTs, which were substantially elevated after the second dose, showing clear benefit of a 2-dose regimen. Although both vaccine candidates elicited lower antigen-binding IgG (Immunoglobulin G) and neutralizing responses in older adults (65 to 85 years of age), compared to younger adults (18 to 55 years of age), the neutralizing antibody GMTs measured 7 days after Dose 2 of 30*μg* of BNT162b1 or BNT162b2 in participants 65 to 85 years old were

comparable to or higher than the GMT of a panel of SARS-CoV-2 convalescent sera from 38 patients (18 to 83 years of age) who had contracted SARS-CoV-2.

Participants 18 to 55 years old who received 10*μg*, 20*μg*, or 30*μg* of BNT162b1 reported mild to moderate local reactions, primarily pain at the injection site, within 7 days after an injection which were more frequent after Dose 2. In participants 65 to 85 years old, BNT162b1 elicited similar, but milder, local reactions, with mild to moderate injection site pain reported by 92% after Dose 1 and 75% after Dose 2. A similar pattern was observed after vaccination with BNT162b2. No older adult who received BNT162b2 reported redness or swelling. No participant who received either vaccine candidate reported a Grade 4 local reaction.

Systemic events after administration of BNT162b2 were milder than those with BNT162b1. Overall, after Dose 1, systemic events reported by participants 65 to 85 years old who received BNT162b2 were similar to those reported by those who received placebo. After Dose 2 of 30*μg* BNT162b2, only 17% of participants 18 to 55 years old and 8% of participants 65 to 85 years old reported fever (≥38.0 to 38.9 °C), compared to 75% of 18 to 55 year old participants and 33% of 65 to 85 year old participants administered a second dose of 30*μg* of BNT162b1. Severe systemic events (fatigue, headache, chills, muscle pain, and joint pain) were reported in small numbers of younger BNT162b2 recipients and were transient and manageable. No severe systemic events were reported by older BNT162b2 recipients. There were no reports of Grade 4 systemic events by any BNT162 recipient.

The totality of data contributed to the decision by Pfizer and BioNTech to commence the global (except for China) Phase 2/3 safety and efficacy portion of the clinical study to evaluate BNT162b2 against COVID-19. The study is now actively enrolling in the U.S., Argentina and Brazil. Additional enrollment is planned in Germany, Turkey and South Africa. The study is an event-driven trial that is planned to enroll up to 30,000 participants between 18 and 85 years of age. The Phase 2/3 trial enrollment to date has exceeded 11,000 participants with a second dose underway.

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. Assuming clinical success, Pfizer and BioNTech are on track to seek regulatory review for BNT162b2 as early as October 2020 and, if regulatory authorization or approval is obtained, currently plan to supply up to 100 million doses worldwide by the end of 2020 and approximately 1.3 billion doses by the end of 2021. Those interested in learning more about the study can visit 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 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 August 20, 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 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, 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 potential number of sites and participants in our Phase 2b/3 trial; the collaboration between BioNTech and Pfizer to develop a potential COVID-19 vaccine; our expectations regarding the potential characteristics of BNT162b2 in our Phase 2b/3 trial and/or in commercial use based on data observations to date, including expected advantages over BNT162b1; the timing for any potential emergency use authorizations or approvals; 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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