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Pfizer and BioNTech Announce Data from Preclinical Studies of mRNA-based Vaccine Candidate Against COVID-19

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- *Immunization of non-human primates (rhesus macaques) with BNT162b2, a nucleoside-modified messenger RNA (modRNA) candidate that expresses the SARS-CoV-2 spike glycoprotein, resulted in strong anti-viral effects against an infectious SARS-CoV-2 challenge*
- *BNT162b2 immunization prevented lung infection in 100% of the SARS-CoV-2 challenged rhesus macaques, with no viral RNA detected in the lower respiratory tract of immunized and challenged animals. The BNT162b2 vaccination also cleared the nose of detectable viral RNA in 100% of the SARS-CoV-2 challenged rhesus macaques within 3 days after the infection*
- *The BNT162b2 vaccine candidate induced SARS-CoV-2 neutralizing antibodies in rhesus macaques, pseudovirus neutralizing antibodies in mice, and strong, antigen-specific CD4+ and CD8+ T cells in mice and macaques*

NEW YORK & MAINZ, Germany--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today announced preliminary preclinical data in mouse and non-human primate models from their BNT162b2 mRNA-based vaccine program against SARS-CoV-2, the virus that causes COVID-19 disease. In a non-human primate preclinical study, immunization with the BNT162b2, a nucleoside-modified messenger RNA (modRNA) candidate, protected rhesus macaques against SARS-CoV-2 infection. The manuscript describing these preclinical data is available on a preprint server at https://www.biorxiv.org/content/10.1101/2020.09.08.280818v1 and is concurrently undergoing scientific peer-review for potential publication.

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“Collectively, these preclinical results, combined with our clinical data collected to date, continue to support the promise and validity of our mRNA-based vaccine program against SARS-CoV-2 and selection of the BNT162b2 candidate, which we believe has the potential to prevent many millions of COVID-19 cases,” said **Kathrin U. Jansen, Ph.D., Senior Vice President and Head of Vaccine Research & Development, Pfizer.** “We are encouraged by the data thus far and confident in our progress towards developing a safe and effective vaccine candidate to help address this current pandemic.”

“The data we have shared today include the characterization of our lead candidate BNT162b2, as well as key animal studies that were the basis for our clinical programs. They have enabled us to advance BNT162b2 into

Phase 3 evaluation," said **Ugur Sahin, M.D., CEO and Co-founder of BioNTech.** "This is another development milestone for providing a safe and effective potential vaccine to the global community to help end this pandemic."

In the preclinical study, BNT162b2 demonstrated protective anti-viral effects in rhesus macaques, with concomitant high neutralizing antibody titers and a TH1-biased cellular response in rhesus macaques and mice. In a viral infection model, macaques that received two injections with 100 µg BNT162b2 and macaques that received saline control injections were challenged 55 days after the second immunization with a very high viral inoculum of approximately 1 million plaque forming units of SARS-CoV-2, via both intranasal (nose) and intratracheal (lung) routes. Immunization with BNT162b2 reduced viral infection with no viral RNA detected in the lower respiratory tract of the immunized animals, while in most non-immunized (saline) animals, there was evidence of viral RNA.

Importantly, BNT162b2 induced potent SARS-CoV-2 neutralizing antibodies in vaccinated-macaques, and viral antigen-specific CD4+ and CD8+ T cells. Rhesus macaques (2-4-year-old males) were immunized by intramuscular (IM) immunization with 30 µg or 100 µg of BNT162b2 or saline control on Days 0 and 21 (2 doses). After two immunizations, neutralization titers were detectable in rhesus macaques sera with geometric mean titers of 962 (on Day 35 for the 30 µg group) or 1,689 (on Day 28 for the 100 µg group). Neutralizing antibody titers persisted to at least day 56, with higher geometric mean titers (GMTs) than those in a panel of human convalescent sera. BNT162b2 vaccination elicited a high frequency of CD4+ T cells that produced IFN-? , IL-2, and TNF-?, and almost no IL-4 producing CD4+ cells were detectable, indicating a TH1-biased response, which is an immune profile thought to promote vaccine safety. BNT162b2 also elicited spike-specific IFN-? producing CD8+ T cell responses, which is thought to promote an anti-viral effect.

In a preclinical murine model, a single IM immunization of BNT162b2 (0.2, 1, or 5 µg) generated B-cell and T-cell immune responses in BALB/c mice, and SARS-CoV-2 pseudovirus neutralizing activity increased steadily to Day 28, the last day for which titers are reported. CD4+ and CD8+ T-cells from splenocytes isolated from BNT162b2-immunized mice were strongly positive for IFN? and IL-2, producing high levels of the TH1 cytokines but minute amounts of TH2 cytokines, suggesting a robust, TH1-biased T cell adaptive immune response.

Many of these preclinical data and the Phase 1 clinical results 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 potential prevention of COVID-19 disease by BNT162b2. The Phase 2/3 study has enrolled over 25,000 participants 18 to 85 years of age in the U.S., Argentina and Brazil. Additional enrollment is planned in Germany, Turkey and South Africa. The study is an event-driven trial.

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.

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 September 9, 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 candidate BNT162b2 (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 locations 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; 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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