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Pfizer and BioNTech Provide Data from German Phase 1/2 Study Further Characterizing Immune Response Following Immunization with Lead COVID-19 Vaccine Candidate BNT162b2

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- Analysis of 37 participants immunized with BNT162b2 showed a broad immune response with SARS-CoV-2-specific neutralizing antibodies, TH1 type CD4+ T cells, and strong expansion of CD8+ T cells of the early effector memory phenotype
- All vaccinated participants demonstrated neutralizing antibody as well as T cell responses. T cell responses were directed against multiple regions of the spike protein, including the RBD, suggesting immune recognition of multiple independent epitopes
- Data confirm previous findings from the U.S. trial demonstrating a good safety profile and robust induction of antibody responses with a longer follow-up period of 85 days
- Antibodies generated in trial subjects were able to neutralize pseudo-viruses representing 19 diverse SARS-CoV-2 variants, indicating potential for broad protection against viruses with reported mutations

Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today announced additional data on neutralizing antibody and T cell responses from the Phase 1/2 trial with BNT162b2 conducted in Germany. The study results demonstrate that BNT162b2 elicits a combined adaptive humoral and cellular immune response against SARS-CoV-2 and provide insights into the composite nature of BNT162b2-induced T cell immunity. The results were published on the preprint server MedRxiv and are available here. BNT162b2 is an investigational COVID-19 vaccine developed by Pfizer-BioNTech. It has been authorized for emergency use for individuals 16 years of age and older in several countries around the world.

“In parallel to working with regulators around the globe to make our vaccine available, we will continue to share important data from our ongoing studies with the global scientific community and the public in order to advance our collective understanding of the underlying vaccine mechanism of action,” said **Ugur Sahin, M.D., CEO and Co-Founder of BioNTech**. “While there is a broad consensus that vaccines should induce antibody responses against the virus, experiences from the prior SARS pandemic indicate that CD8+ T cell responses may be of critical importance to achieve long-term protection.”

“These results from the ongoing German Phase 1/2 study help illustrate the multiple arms of the immune system that are activated to fight SARS-CoV-2 by the vaccine candidate BNT162b2. Advancing the understanding of the duration of antibody responses is critical as the global scientific community continues to look for potential vaccines to help overcome this pandemic,” said **Kathrin U. Jansen, Ph.D., Senior Vice President and Head of Vaccine Research & Development at Pfizer**. “We continue to add to the body of scientific evidence supporting

BNT162b2 and are pleased to see the consistency in our findings across studies."

The ongoing non-randomized open-label Phase 1/2 trial (NCT04380701) is being conducted in Germany in parallel to the Phase 1/2/3 trial (NCT04368728) that started in the U.S. The German study evaluated the safety and immunogenicity of BNT162b2 in different dose cohorts (1 µg, 10 µg, 20 µg and 30 µg) with 11-12 participants per cohort. BNT162b2 was administered in two doses 21 days apart to healthy adults between 18 and 55 years of age.

Overall, these results mirror those from the U.S. study (NCT04368728) that were previously published, and support the favorable safety profile and robust induction of virus-specific antibody responses. A longer follow-up period of 85 days showed sustained neutralizing antibody titers in the range of, or above, those in convalescent sera cohort. BNT162b2 immune sera efficiently neutralized 19 pseudo-viruses, indicating the potential for broad BNT162b2-elicited protection against reported mutations.

All 37 participants vaccinated with BNT162b2 showed newly generated spike protein-specific CD4+ T cell responses, and almost 92% of participants demonstrated CD8+ T cell responses. The majority were strong T cell responses comparable to or significantly higher than memory responses of the same individuals against common viruses, such as cytomegalovirus (CMV), Epstein Barr virus (EBV) and the influenza virus. Even with the lowest dose of 1 µg BNT162b2, most of the vaccinated participants elicited robust expansion of CD4+ and CD8+ T cells. Expression of cytokines IFN? and IL-2, but only low levels of IL-4 in BNT162b2-induced CD4+ T cells indicated a TH1 profile. CD8+ T cell responses were directed against multiple regions of the spike protein, and several of the multiple epitopes recognized by BNT162b2-induced CD8+ T cells were molecularly identified.

Effectors of the adaptive immune system have complementary roles in defense against viral infections. While neutralizing antibodies are the first line of defense, CD8+ T cells contribute to virus clearance from intracellular compartments that are inaccessible to neutralizing antibodies. Antigen-specific CD4+ T cells have immune orchestrating functions, including support of memory generation. Therefore, detailed characterization of the cellular immune responses will be important in understanding the mechanisms contributing to protection against SARS-CoV-2.

As of today, BNT162b2, Pfizer-BioNTech Covid-19 vaccine candidate, has been authorized or approved for emergency use for individuals 16 years of age and older in the U.S, U.K., Bahrain, Canada, Saudi Arabia, and Mexico. Pfizer and BioNTech have submitted a final Conditional Marketing Authorization Application (CA) following rolling submissions with the European Medicines Agency (EMA) and several other regulatory agencies around the world.

U.S. AUTHORIZED USE:

The Pfizer-BioNTech COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

U.S. IMPORTANT SAFETY INFORMATION:

- Do not administer Pfizer BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer BioNTech COVID-19 Vaccine
- Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer BioNTech COVID-

19 Vaccine
- Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer BioNTech COVID-19 Vaccine
- The Pfizer BioNTech COVID-19 Vaccine may not protect all vaccine recipients
- In clinical studies, adverse reactions in participants 16 years of age and older included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%)
- Severe allergic reactions have been reported following the Pfizer-BioNTech COVID-19 Vaccine during mass vaccination outside of clinical trials. Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine
- Available data on Pfizer BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy
- Data are not available to assess the effects of Pfizer BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion
- There are no data available on the interchangeability of the Pfizer BioNTech COVID 19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer BioNTech COVID-19 Vaccine should receive a second dose of Pfizer BioNTech COVID-19 Vaccine to complete the vaccination series
- Vaccination providers must report Adverse Events in accordance with the Fact Sheet to VAERS at https://vaers.hhs.gov/reportevent.html or by calling 1-800-822-7967. The reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report
- Vaccination Providers should review the Fact Sheet for mandatory requirements and Information to Provide to Vaccine Recipients/Caregivers and the Full EUA Prescribing Information for Requirements and Instructions for Reporting Adverse Events and Vaccine Administration Errors

Please see Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including Full EUA Prescribing Information available at www.cvdvaccine.com.

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 December 14, 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, regulatory submissions, the anticipated timing of regulatory submissions, regulatory approvals or authorizations and anticipated manufacturing, distribution and supply) involving 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 clinical data (including the Phase 1/2 data discussed in this release and the Phase 3 data), including the possibility of unfavorable new preclinical or clinical trial data and further analyses of existing preclinical or clinical trial data; the ability to produce comparable clinical or other results, including the rate of vaccine effectiveness and safety and tolerability profile observed to date, in additional analyses of the Phase 3 trial and additional studies or in larger, more diverse populations upon commercialization; 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 additional 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 any future preclinical and clinical studies; whether and when any other biologics license and/or emergency use authorization applications may be filed in particular jurisdictions for BNT162b2 or any other potential vaccine candidates; whether and when any applications that may be pending or filed for BNT162b2 may be approved by particular 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; disruptions in the relationships between us and our collaboration partners or third-party suppliers; risks related to the availability of raw materials to manufacture a vaccine; challenges related to our vaccine candidate's ultra-low temperature formulation and attendant storage, distribution and administration requirements, including risks related to handling after delivery by Pfizer; the risk that we may not be able to successfully develop non-frozen formulations; the risk that we may not be able to create or scale up manufacturing capacity on a timely basis or have access to logistics or supply channels commensurate with global demand for any potential approved vaccine, which would negatively impact our ability to supply the estimated numbers of doses of our vaccine candidate 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; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; 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, Regeneron, 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 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; the expected timepoint for additional readouts on efficacy data of BNT162b2 in our Phase 2/3 trial; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; the timing for submission of data for, or receipt of, any marketing approval or Emergency Use Authorization; our contemplated shipping and storage plan, including our estimated product shelf life at various temperatures; 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: the ability to meet the pre-defined endpoints in clinical trials; competition to create a vaccine for COVID-19; the ability to produce comparable clinical or other results, including our stated rate of vaccine effectiveness and safety and tolerability profile observed to date, in the remainder of the trial or in larger, more diverse populations upon commercialization; 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 Quarterly Report for the Three and Nine Months Ended September 30, 2020, filed as Exhibit 99.2 to its Current Report on Form 6-K filed with the SEC on November 10, 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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