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Pfizer and BioNTech Announce Early Positive Data from an Ongoing Phase 1/2 study of mRNA-based Vaccine Candidate Against SARS-CoV-2

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- *In an ongoing U.S. Phase 1/2 placebo-controlled, observer-blinded clinical trial, nucleoside-modified messenger RNA vaccine candidate (BNT162b1) expressing the* SARS-CoV-2 *receptor binding domain (RBD) is being evaluated in 45 subjects*
- *At day 28 (7 days after dose 2), all subjects who received 10 or 30 µg of BNT162b1 had significantly elevated RBD-binding IgG antibodies with geometric mean concentrations (GMCs) of 4,813 and 27,872 units/ml which are 8- and 46.3-times, respectively, the GMC of 602 units/ml in a panel of 38 sera of convalescent patients who had contracted SARS-CoV-2*
- *At day 28 (7 days after dose 2), all subjects who received 10 or 30 µg of BNT162b1 had SARS-CoV-2 neutralizing antibodies with geometric mean titers (GMTs) of 168 and 267, which are 1.8- and 2.8-times, respectively, the GMT of the convalescent serum panel*
- *Local reactions and systemic events after immunization with 10 µg and 30 µg* of *BNT162b1 were dose-dependent, generally mild to moderate, and transient. No serious adverse events were reported*
- *Further data from the ongoing Phase 1/2 clinical trial of four vaccine candidates will enable selection of a lead candidate and dose level for a large, global Phase 2b/3 safety and efficacy study that may begin as early as July 2020*
- *Efforts to manufacture the leading candidates, at risk, are gearing up. In case the safety and efficacy study is successful, and the vaccine receives regulatory approval, the companies are expecting to manufacture up to 100 million doses by the end of 2020 and potentially more than 1.2 billion doses by the end of 2021*

NEW YORK & MAINZ, Germany--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today announced preliminary data from the most advanced of four investigational vaccine candidates from their BNT162 mRNA-based vaccine program, Project Lightspeed, against SARS-CoV-2, the virus causing the current global pandemic. The BNT162 program is evaluating at least four experimental vaccines, each of which represents a unique combination of mRNA format and target antigen. The manuscript describing the preliminary clinical data for the nucleoside-modified messenger RNA (modRNA) candidate, BNT162b1, which encodes an optimized SARS-CoV-2 receptor binding domain (RBD) antigen, is available on an online preprint server at https://www.medrxiv.org/content/10.1101/2020.06.30.20142570v1 and is concurrently undergoing scientific peer-review for potential publication. Overall, the preliminary data demonstrated that BNT162b1 could be administered in a dose that was well tolerated and generated dose dependent immunogenicity, as measured by RBD-binding IgG concentrations and SARS-CoV-2 neutralizing antibody titers.

This press release features multimedia. View the full release here:
https://www.businesswire.com/news/home/20200701005576/en/

“We are encouraged by the clinical data of BNT162b1, one of four mRNA constructs we are evaluating clinically, and for which we have positive, preliminary, topline findings,” said Kathrin U. Jansen, Ph.D., Senior Vice President and Head of Vaccine Research & Development, Pfizer. “We are dedicated to develop potentially groundbreaking vaccines and medicines, and in the face of this global health crisis, we approach this goal with the utmost urgency. We look forward to publishing our clinical data in a peer-reviewed journal as quickly as possible.”

“These preliminary data are encouraging in that they provide an initial signal that BNT162b1 targeting the RBD SARS-CoV-2 is able to produce neutralizing antibody responses in humans at or above the levels observed in convalescent sera – and that it does so at relatively low dose levels. We look forward to providing further data updates on BNT162b1,” said Ugur Sahin, M.D., CEO and Co-founder of BioNTech.

The ongoing U.S. Phase 1/2 randomized, placebo-controlled, observer-blinded study is evaluating the safety, tolerability, and immunogenicity of escalating dose levels of BNT162b1. The initial part of the study included 45 healthy adults 18 to 55 years of age. Preliminary data for BNT162b1 was evaluated for 24 subjects who received two injections of 10 µg and 30 µg, 12 subjects who received a single injection of 100 µg, and 9 subjects who received 2 doses of placebo control.

The participants received two doses, 21 days apart, of placebo, 10 µg or 30 µg of BNT162b1, or received a single dose of 100 µg of the vaccine candidate. Because of a strong vaccine booster effect, the highest neutralizing titers were observed seven days after the second dose of 10 µg or 30 µg on day 28 after vaccination. The neutralizing GMTs were 168 and 267 for the 10 µg and 30 µg dose levels, respectively, corresponding to 1.8- and 2.8-times the neutralizing GMT of 94 observed in a panel of 38 sera from subjects who had contracted SARS-CoV-2.

In all 24 subjects who received 2 vaccinations at 10 µg and 30 µg dose levels of BNT162b1, elevation of RBD-binding IgG concentrations was observed after the second injection with respective GMCs of 4,813 and 27,872 units/ml at day 28, seven days after immunization. These concentrations are 8- and 46.3-times the GMC of 602 units/ml in a panel of 38 sera from subjects who had contracted SARS-CoV-2.

At day 21 after a single injection, the 12 subjects who received 100 µg of BNT162b1 had an RBD-binding IgG GMC of 1,778 units/ml and a SARS-CoV neutralizing GMT of 33, which are 3-times and 0.35-times, respectively, the GMC and GMT of the convalescent serum panel.

At the 10 µg or 30 µg dose levels, adverse reactions, including low grade fever, were more common after the second dose than the first dose. Following dose 2, 8.3% of participants who received 10 µg and 75.0% of participants who received 30 µg BNT162b1 reported fever ? 38.0 °C. Local reactions and systemic events after injection with 10 µg and 30 µg of BNT162b1 were dose-dependent, generally mild to moderate, and transient. The most commonly reported local reaction was injection site pain, which was mild to moderate, except in one of 12 subjects who received a 100 µg dose, which was severe. No serious adverse events were reported. Given higher numbers of subjects experiencing local reactions and systemic events after a single 100 µg dose with no significant increases in immunogenicity compared to the 30 µg dose level, the 12 participants in the 100 µg group were not administered a second dose.

These preliminary data, together with additional preclinical and clinical data being generated, will be used by the two companies to determine a dose level and select among multiple vaccine candidates to seek to progress to a large, global Phase 2b/3 safety and efficacy trial. That trial may involve up to 30,000 healthy participants and is anticipated to begin in late July 2020, if regulatory approval to proceed is received. The preliminary clinical data from this ongoing study have been submitted for potential publication in a peer-reviewed journal and is available on an online preprint manuscript server.

The BNT162b1 candidate remains under clinical study and is not currently approved for distribution anywhere in the world. If the ongoing studies are successful and the vaccine candidate receives regulatory approval, the companies expect to manufacture up to 100 million doses by the end of 2020 and potentially more than 1.2 billion doses by the end of 2021. In that event, BioNTech and Pfizer would work jointly to distribute the potential COVID-19 vaccine worldwide (excluding China, where BioNTech has a collaboration with Fosun Pharma for BNT162 for both clinical development and commercialization). The development of the vaccine is also supported by partners like Acuitas Therapeutics. The Canadian company provides lipid nanoparticles (LNP) for the formulation of various mRNA vaccines.

Pfizer Conference Call and Webcast Information

Pfizer Inc. invites investors and the general public to view and listen to a webcast of a conference call with investment analysts at 2 p.m. EDT today, Wednesday, July 1, 2020.

To view and listen to the webcast, visit our web site at www.pfizer.com/investors. Participants are advised to pre-register in advance of the conference call.

You can also listen to the conference call by dialing either (866) 669-8582 in the United States and Canada or (702) 495-1304 outside of the United States and Canada. The password is “PFIZER 2020”.

BioNTech Conference Call and Webcast Information

BioNTech SE will host a conference call and webcast today at 11:00 a.m. EDT (5:00 p.m. CET) to review the Phase 1/2 clinical results for BNT162.

To participate in the conference call, please dial the following numbers 10-15 minutes prior to the start of the call and provide the Conference ID: 7176269.

United States international:	+1 646 741 3167
United States domestic (toll-free):	+1 877 870 9135
Germany:	+49 692 2222 625

Participants may also access the slides and the webcast of the conference call via the “Events & Presentations” page of the Investor Relations section of the Company’s website at https://biontech.de/. A replay of the webcast will be available shortly after the conclusion of the call and archived on the Company’s website for 30 days following the call.

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 1, 2020. Pfizer assumes no obligation to update information or 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 BNT162 mRNA vaccine program, and a collaboration between BioNTech and Pfizer to develop a potential COVID-19 vaccine, including their potential benefits, and anticipated publication of data, manufacturing and distribution and the expected timing of clinical trials, 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 preclinical or clinical trial data and further analyses of existing preclinical or clinical trial data; risks associated with preliminary data; 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 the scientific journal publications referenced above will occur 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 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; including whether the estimated numbers of doses can be manufactured within the projected time periods indicated; 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 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; 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 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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