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Pfizer and BioNTech Announce Early Positive Update from German Phase 1/2 COVID-19 Vaccine Study, Including First T Cell Response Data

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- *The data further demonstrated the ability of BNT162b1 to elicit high SARS-CoV-2 neutralizing titers*
- *BNT162b1 elicited strong $CD4^+$ and $CD8^+$ T cell responses against SARS-CoV-2- receptor binding domain (RBD), compared to baseline*
- *The RBD-specific, interferon-?$^+$, IL-2$^+$, $CD8^+$ T cells elicited by BNT162b1 in immunized participants indicate a strong potential for cell mediated anti-viral activity*
- *T cell cytokine profile shows vaccine elicited T cells exhibit a Th1 phenotype, which is associated with antiviral properties*
- *BNT162b1 induced antibodies had broadly neutralizing activity in pseudovirus neutralization assays across a panel of sixteen SARS-CoV-2 RBD variants identified in published SARS-CoV-2 sequences and against the newly dominant D614G strain*
- *Robust specific antibody and T cell responses, (both of which are considered by experts as key to a vaccine ensuring protection against disease) elicited by the BNT162b1 mRNA vaccine against RBD suggest a potential for multiple beneficial protective mechanisms against COVID-19*
- *Local reactions and systemic events after immunization with BNT162b1 were dose-dependent, generally mild to moderate and transient, with occasional severe adverse events (Grade 3, e.g. flu-like symptoms and injection site reactions) that resolved spontaneously or could be managed with simple measures - no serious adverse events were reported*

MAINZ, Germany & NEW YORK--(BUSINESS WIRE)-- BioNTech SE (Nasdaq: BNTX, “BioNTech” or “the Company”) and Pfizer Inc. (NYSE: PFE) today announced initial data from their ongoing German Phase 1/2, open-label, non-randomized, non-placebo-controlled, dose-escalation trial, that is part of the global mRNA-based vaccine program against SARS-CoV-2. The data are available on an online preprint server at medrxiv and are concurrently undergoing scientific peer-review for potential publication.

This press release features multimedia. View the full release here:
https://www.businesswire.com/news/home/20200720005408/en/

The preliminary clinical results are for the most advanced investigational vaccine candidate in Pfizer’s and BioNTech’s BNT162 mRNA-based vaccine program against SARS-CoV-2, BNT162b1. This vaccine candidate is a lipid nanoparticle formulated, nucleoside-modified messenger RNA that encodes an optimized SARS-CoV-2 receptor binding domain (RBD) antigen. Overall, the new preliminary data from this German study support and expand upon the recently disclosed early results from the corresponding U.S. trial with BNT162b1.

Preliminary data for BNT162b1 in the German Phase 1/2 trial were evaluated with a total of 60 healthy adults 18 to 55 years of age enrolled in the study. Of these 60 participants, 12 subjects per dose level (1 µg, 10 µg, 30 µg, and 50 µg; 48 participants in total) were vaccinated with BNT162b1 on day 1 and day 22 (n=12 per prime-boost cohort, except n=11 for the 10 µg and 50 µg cohorts from day 22 on). Furthermore, 12 participants received a single injection of 60 µg.

The vaccine elicited high, dose level-dependent SARS-CoV-2-neutralizing titers and RBD-binding IgG concentrations after the second dose. Day 43 SARS-CoV-2 neutralizing geometric mean titers were in the range of 0.7-fold (1 µg) to 3.2-fold (50 µg) compared to that of a panel of SARS-CoV-2 infection convalescent human sera. Furthermore, sera of vaccinated subjects displayed broadly neutralizing activity in pseudovirus neutralization assays across a panel of sixteen SARS-CoV-2 RBD variants represented in publicly available SARS-CoV-2 sequences and against the newly dominant D614G strain.

In addition, the initial German trial results demonstrate, for the first time for the BNT62b1 candidate, a concurrent induction of high level $CD4^+$ and $CD8^+$ T cell responses against the SARS-CoV-2 RBD.

The strength of T cell responses varied between subjects. There was no clear dose level dependency of the T cell response between 1 µg to 50 µg, indicating that stimulation and robust expansion of T cells might be accomplished at low mRNA dose levels.

All subjects in the prime-boost cohorts, except for two at the lowest dose level, had $CD4^+$ T cell responses. Cytokine profiling of the RBD-specific $CD4^+$ T cells demonstrated a T_H1-dominant profile for these cells. 29 of the 36 tested subjects also mounted an RBD-specific functional, $CD8^+$ T cell response that was comparable to memory responses observed against cytomegalovirus (CMV), Epstein Barr virus (EBV) and influenza virus.

Overall, the data suggested that BNT162b1 could potentially be administered safely, with a manageable tolerability profile. Local reactions and systemic events after injection with BNT162b1 at all dose levels were transient, generally mild to moderate, with occasional severe events (Grade 3) of flu-like symptoms and injection site reactions. All adverse events resolved spontaneously and were managed with simple measures. No serious adverse events (SAEs) were reported, and there were no withdrawals due to adverse events related to the vaccine.

“It is encouraging that the data on BNT162b1 from the German study cohort are very much in line with what we have seen in the U.S. study cohort. The preliminary data indicate that our mRNA-based vaccine was able to stimulate antibody as well as T-cell responses at remarkably low dose levels. We believe both may play an important role in achieving effective clearance of a pathogen such as SARS-CoV-2,” said **Özlem Türeci, M.D., CMO and Co-founder of BioNTech.**

“These interim results from the German study, combined with initial data from the U.S. study, highlight the potential of this mRNA-based vaccine approach and represent an important step forward in our development efforts for the BNT162 program,” said **Kathrin U. Jansen, Ph.D., Senior Vice President and Head of Vaccine Research & Development, Pfizer.** “We remain dedicated to developing an effective vaccine to fight the COVID-19 pandemic, with safety at the forefront and look forward to sharing additional data as the program progresses.”

Preliminary data from both the German and U.S. Phase 1/2 studies, 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 an anticipated 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 is received.

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 1.3 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).

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 collaboration between BioNTech and Pfizer, and BioNTech and Fosun Pharma, to develop a potential COVID-19 vaccine; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; 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 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.

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 20, 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, 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 http://www.sec.gov/ and www.pfizer.com.

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