



Pfizer and BioNTech Publish Results of Study Showing COVID-19 Vaccine Elicits Antibodies that Neutralize Pseudovirus Bearing the SARS-CoV-2 U.K. Strain Spike Protein in Cell Culture

New York and Mainz, Germany, January 20, 2021 — Today, [Pfizer Inc.](#) (NYSE: PFE) and [BioNTech SE](#) (Nasdaq: BNTX) announced results from an in vitro study that provides additional data on the capability of sera from individuals immunized with the Pfizer-BioNTech COVID-19 vaccine, BNT162b2, to neutralize the SARS-CoV-2 U.K. strain, also known as B.1.1.7 lineage or VOC 202012/01. The results were published on the preprint server [bioRxiv](#) and submitted to a peer-reviewed journal.

The B.1.1.7 lineage is a rapidly spreading variant of SARS-CoV-2 initially detected in the U.K. that carries a larger than usual number of genetic changes with 10 mutations located in the spike protein. BioNTech and Pfizer have previously published [data](#) from an in vitro study that evaluated one of the key mutations (N501Y) in the U.K. strain, which is also shared by the South African strain. That study showed efficient neutralization of the N501Y mutated spike bearing virus by sera of individuals who had received the Pfizer-BioNTech COVID-19 vaccine.

The current in-vitro study investigated the full set of UK strain spike mutations. To this aim, a pseudovirus featuring the U.K. strain spike protein was generated. The pseudovirus recapitulates SARS-CoV-2 virus binding and cell entry. Sera of participants from the [previously reported](#) German Phase 1/2 trial inhibited pseudovirus bearing the U.K. strain SARS-CoV-2 spike in a neutralization range that is regarded as biologically equivalent to the unmutated Wuhan SARS-CoV-2 spike.

While the pseudovirus system used is a surrogate for authentic SARS-CoV-2, previous studies have shown excellent concordance between pseudotype neutralization and SARS-CoV-2 neutralization assays.¹ The preserved neutralization of the pseudovirus bearing the U.K. strain spike by BNT162b2-immune sera makes it likely that COVID-19 caused by the U.K. virus variant will also be prevented by immunization with BNT162b2.

Pfizer and BioNTech are encouraged by these early in vitro study findings. Further data are needed to monitor the Pfizer-BioNTech COVID-19 vaccine's effectiveness in preventing COVID-19 caused by new virus variants. So far, for COVID-19 vaccines, it has not been established what reduction in neutralization might indicate the need for a vaccine strain change. Should a vaccine strain change be required to address virus variants in the future, the Companies believe that the flexibility of BioNTech's proprietary mRNA vaccine platform is well suited to enable such adjustment.

The Pfizer-BioNTech COVID-19 Vaccine has not been approved or licensed by the U.S. Food and Drug Administration (FDA), but has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 16 years of age and older. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564 (b) (1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner. 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](#).

AUTHORIZED USE IN THE U.S.:

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.

IMPORTANT SAFETY INFORMATION FROM U.S. FDA EMERGENCY USE AUTHORIZATION PRESCRIBING 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.

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 in vitro and 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 ability of BNT162b2 to prevent COVID-19 caused by new virus variants; the risk that more widespread use of the vaccine will lead to new information about efficacy, safety, or other developments, including the risk of additional adverse reactions, some of which may be serious; 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 a Biologics License Application for BNT162b2 may be filed in the U.S. and whether and when other biologics license and/or emergency use authorization applications may be filed in particular jurisdictions for BNT162b2 or any other potential vaccines; whether and when any other applications that may be pending or filed for BNT162b2 (including a potential Biologics License Application in the U.S.) may be approved by particular regulatory authorities, which will depend on myriad factors, including making a determination as to whether the vaccine's benefits outweigh its known risks and determination of the vaccine'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'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 our vaccine, which would negatively impact our ability to supply the estimated numbers of doses of our vaccine 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 time point for additional readouts on efficacy data of BNT162b2 in our Phase 2/3 trial; the nature of non-clinical and 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 market demand, including our production estimates for 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 production 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.

Pfizer:

Media Relations
Amy Rose
+1 (212) 733-1226
PfizerMediaRelations@pfizer.com

Investor Relations
Chuck Triano
+1 (212) 733-3901
Charles.E.Triano@Pfizer.com

BioNTech:

Media Relations
Jasmina Alatovic
+49 89 62 81 75 46
Media@biontech.de

Investor Relations
Sylke Maas, Ph.D.
+49 (0)6131 9084 1074
Investors@biontech.de

¹J. B. Case et al., Neutralizing Antibody and Soluble ACE2 Inhibition of a Replication-Competent VSV-SARS-CoV-2 and a Clinical Isolate of SARS-CoV-2. *Cell host & microbe*. 28, 475-485.e5 (2020)

A. B. Vogel et al., BNT162b vaccines are immunogenic and protect non-human primates against SARS-CoV-2. *bioRxiv* (2020)