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 VOC202012/01. 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. 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.
• 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.
• Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/).
• 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 Information to Provide to Vaccine Recipients/Caregivers and Mandatory Requirements for Pfizer-BioNTech COVID-19 Vaccine Administration Under Emergency Use Authorization.


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 January 20, 2021. 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 COVID-19 vaccine, the BNT162 mRNA vaccine program and the Pfizer-BioNTech COVID-19 Vaccine (BNT162b2) (including qualitative assessments of available data, potential benefits, expectations for clinical trials, the anticipated timing of regulatory submissions, regulatory approval or authorization and anticipated manufacturing, distribution and
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
Biotherapeutic 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 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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