



In Vitro Studies Demonstrate Pfizer and BioNTech COVID-19 Vaccine Elicits Antibodies that Neutralize SARS-CoV-2 with Key Mutations Present in U.K. and South African Variants

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NEW YORK and MAINZ, Germany, January 27, 2021 — [Pfizer Inc.](#) (NYSE: PFE) and [BioNTech SE](#) (Nasdaq: BNTX) announced results from in vitro neutralization studies of sera from individuals vaccinated with the Pfizer-BioNTech COVID-19 vaccine. The sera neutralized SARS-CoV-2 with key mutations present in the United Kingdom (U.K.) and South Africa variants, as measured by studies conducted by Pfizer and the University of Texas Medical Branch (UTMB). The results were published on the preprint server [bioRxiv](#) and submitted to a peer-reviewed journal.

To study the effect of these mutations, three engineered viruses with key mutations were tested against the panel of human sera from 20 participants in the [previously reported](#) Phase 3 trial who had been immunized with the Pfizer-BioNTech COVID-19 vaccine. Of the three recombinant variants, one has a mutation common to both the U.K. and South Africa variants (N501Y), one has mutations common to the U.K. variant ($\Delta 69/70+N501Y+D614G$), and the third has mutations common to the South Africa variant (E484K+N501Y+D614G). The sera from individuals vaccinated with the Pfizer-BioNTech COVID-19 vaccine neutralized all the SARS-CoV-2 strains tested.

Consistent with recent reports of the neutralization of variant SARS-CoV-2 or corresponding pseudoviruses by convalescent or post-immunization sera,^{i,ii} neutralization against the virus with the three key mutations present in the South African variant (E484K+N501Y+D614G) was slightly lower when compared to neutralization of virus containing the other mutations that were evaluated. However, the Companies believe the small differences in viral neutralization observed in these studies are unlikely to lead to a significant reduction in the effectiveness of the vaccine.

Pfizer and BioNTech are encouraged by these early in vitro study findings and are currently evaluating the full set of mutations in the spike protein of the South African variant. While these findings do not indicate the need for a new vaccine to address the emerging variants, the Companies are prepared to respond if a variant of SARS-CoV-2 demonstrates evidence of escaping immunity by the COVID-19 vaccine. Pfizer and BioNTech will continue to monitor emerging SARS-CoV-2 strains and continue to conduct studies to monitor the vaccine's real-world effectiveness. Pfizer and BioNTech believe that the flexibility of BioNTech's proprietary mRNA vaccine platform is well suited to develop new vaccine variants if required.

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.

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 ability of BNT162b2 to prevent COVID-19 caused by new virus variants; 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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ⁱ Wibmer CK, Ayres F, Hermanus T, et al. SARS-CoV-2 501Y.V2 escapes neutralization by South African COVID-19 donor plasma. bioRxiv 2021:doi: <https://doi.org/10.1101/2021.01.18.427166>.

ⁱⁱ Wang Z, Schmidt F, Weisblum Y, et al. mRNA vaccine-elicited antibodies to SARS-CoV-2 and circulating variants. bioRxiv 2021:doi: <https://doi.org/10.1101/2021.01.15.426911>.