



Pfizer and BioNTech Achieve Authorization by the Ministry of Health of Vietnam to Supply their Vaccine to Combat COVID-19

- *The companies will supply 31 million doses to Vietnam through 2021 following the Emergency Use Authorization for pandemic supply*
- *Agreement is part of Pfizer's and BioNTech's global commitment to help address the COVID-19 pandemic*
- *The Emergency Use Authorization for our COVID-19 vaccine represents a breakthrough scientific achievement to help address this devastating pandemic*

VIETNAM and MAINZ, GERMANY, June 17, 2021 — Pfizer Vietnam and BioNTech SE today announced an agreement with the Ministry of Health in VIETNAM to supply their COVID-19 mRNA vaccine (BNT162b2) - Comirnaty™. Deliveries are planned in Q3 and Q4 2021, following the Emergency Use Authorization for Comirnaty™ which has been granted in June 12, 2021 by the Ministry of Health in Vietnam. The distribution of the vaccine in Vietnam will be led by the Ministry of Health and its system.

Financial details of the agreement were not disclosed, but the terms were based on the timing of delivery and the volume of doses.

We are honoured to have been working with the Government of Vietnam to marshal our scientific and manufacturing resources toward our shared goal of supplying the COVID-19 vaccine (BNT162b2) to the people in Vietnam as quickly as possible said John Paul Pullicino, Pfizer Vietnam General Director. "We also want to commend The Ministry of Health of Vietnam for its fast-track assessment of our COVID-19 vaccine to grant the Emergency Use Authorization to provide the Vietnamese public with our vaccine. In the face of this global health crisis, Pfizer's purpose – breakthroughs that change patients' lives – has taken on an even greater urgency and meaning. Our hope is that, subject to the necessary regulatory approvals, our vaccine will help to change patients' lives in Vietnam."

"I would like to thank the Government of Vietnam for its support and putting trust in our ability to develop a vaccine that, we believe, has the potential to help address this global pandemic threat. It is encouraging to see that our mRNA vaccine is now approved in Vietnam. Our goal remains to deliver a global supply of a well-tolerated and effective COVID-19 vaccine for many people around the world, as quickly as we can," said Sean Marett, Chief Business and Chief Commercial Officer at BioNTech.

The vaccine, which is based on BioNTech's proprietary mRNA technology, was developed by both BioNTech and Pfizer. BioNTech is the Marketing Authorization Holder in the European Union, and the holder of emergency use authorizations or equivalent in the United States (jointly with Pfizer), Canada and other countries in advance of a planned application for full marketing authorizations in these countries.

The Ministry of Health of Vietnam decision is based on the totality of scientific evidence shared by the companies as part of The Ministry of Health of Vietnam's review process. This included data from a pivotal Phase 3 clinical study [announced](#) in November 2020 and published in [The New England Journal of Medicine](#). The Phase 3 data demonstrated a vaccine efficacy rate of 95% in participants without prior SARS-CoV-2 infection (first primary objective) and also in participants with and without prior SARS-CoV-2 infection (second primary objective), in each case measured from 7 days after the second dose. The Data Monitoring Committee (DMC) for the study has not reported safety concerns related to the vaccine. Efficacy was consistent across age, gender, race and ethnicity demographics. All trial participants will continue to be monitored to assess the duration of protection and safety for an additional two years after their second dose.



some of which may be serious; the risk that pre-clinical and 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 and interpretations; whether regulatory authorities will be satisfied with the design of and results from these and any future preclinical and clinical studies; whether and when any other biologics license and/or emergency use authorization applications may be filed in any particular jurisdictions for BNT162b2 or any other potential vaccine candidates, and if obtained, whether or when such emergency use authorization or licenses will expire or terminate; whether and when any applications that may be pending or filed for BNT162b2 may be approved by particular regulatory authorities, which will depend on myriad factors, including making a determination as to whether the vaccine candidate's benefits outweigh its known risks and determination of the vaccine candidate's efficacy and, if approved, whether it will be commercially successful; decisions by regulatory authorities impacting labelling or marketing, 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 candidate's ultra-low temperature formulation, two-dose schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery by Pfizer; the risk that we may not be able to successfully develop other vaccine 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 any potential approved vaccine, which would negatively impact our ability to supply the estimated numbers of doses of our vaccine candidate within the projected time periods as previously 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 regarding a 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 ability of BNT162b2 to prevent COVID-19 caused by emerging virus variants; the expected time point for additional readouts on trial data of BNT162b2 in our Phase 2/3 trial; the nature of the 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, if approved, market demand, including our production estimate 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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