Pfizer and BioNTech Submitted Application for Conditional Marketing Authorization for COVID-19 Vaccine to the EMA

December 1, 2020

- *EMA confirms successful application for Conditional Marketing Authorization for BNT162b2, which Pfizer and BioNTech submitted yesterday*
- *In addition to submission to EMA, FDA and U.K. MHRA, the companies have also initiated additional rolling submissions across the globe including in Australia, Canada and Japan, and plan to submit applications to other regulatory agencies around the world*
- *Data from the Phase 3 clinical study demonstrated a vaccine efficacy rate for BNT162b2 of 95% against COVID-19, with no safety concerns observed to date*

NEW YORK and MAINZ, GERMANY, December 1, 2020 —Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) have submitted on Monday, November 30, 2020, a formal Application for Conditional Marketing Authorization (CMA) to the European Medicines Agency (EMA) for their mRNA vaccine candidate, BNT162b2, against COVID-19. This submission completes the rolling review process initiated on October 6, 2020, with nonclinical data and partial Chemistry, Manufacturing, and Controls (CMC) data, followed by emerging clinical data submitted by Pfizer and BioNTech. If EMA concludes that the benefits of the vaccine candidate outweigh its risks in protecting against COVID-19, it will recommend granting a CMA that could potentially enable use of BNT162b2 in Europe before the end of 2020.

The submitted clinical data demonstrated a vaccine efficacy rate of 95% ($p<0.0001$) in the companies' Phase 3 clinical study 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. Efficacy was consistent across age, gender, race and ethnicity demographics, with an observed efficacy in adults age 65 and over of more than 94%. The first primary objective analysis was based on 170 confirmed cases of COVID-19. In the trial, BNT162b2 also showed an overall favorable tolerability with no safety concerns reported by the Data Monitoring Committee to date. Approximately 42% of global participants and 30% of U.S. participants in the Phase 3 study have racially and ethnically diverse backgrounds, and 41% of global and 45% of U.S. participants are 56-85 years of age.

"Today's announcement marks another key milestone in our efforts to fulfill our promise to do everything we can to address this dire crisis given the critical public health need," said **Dr. Albert Bourla, Pfizer Chairman and CEO**. "We have known since the beginning of this journey that patients are waiting, and we stand ready to ship COVID-19 vaccine doses as soon as potential authorizations will allow us."

"As a company located in the heart of Europe, today's milestone is important to us as we continue to seek to enable a worldwide supply upon potential approval of BNT162b2," said **Ugur Sahin, M.D., CEO and Co-founder of BioNTech**. "We will continue to work with regulatory agencies around the world to enable the rapid distribution, should the vaccine receive the approval, contributing to the joint efforts to let the world heal and regain its normal pace of life."

The vaccine candidate will be assessed according to EMA's normal stringent standards for quality, safety and efficacy. The BNT162b2 vaccine candidate is currently not approved for distribution anywhere in the world.

In addition to submission to EMA, U.S. Food and Drug Administration (FDA) and U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), the companies have initiated rolling submissions across the globe including in Australia, Canada and Japan, and plan to submit applications to other regulatory agencies around the world.

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 December 1, 2020. 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 potential COVID-19 vaccine, the BNT162 mRNA vaccine program and modRNA candidate BNT162b2 (including qualitative assessments of available data, potential benefits, expectations for clinical trials, the submission of a formal application for Conditional Marketing Authorization to the EMA and other regulatory submissions, the anticipated timing of regulatory submissions, regulatory approval or authorization and anticipated manufacturing, distribution and supply), 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 risks associated with clinical data (including the 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 or in larger, more diverse populations upon commercialization; 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 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 any other biologics license and/or emergency use authorization applications may be filed in any jurisdictions for BNT162b2 or any other potential vaccine candidates; whether and when any applications that may be pending or filed may be approved by 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 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 candidate'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 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 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 timepoint for additional readouts on efficacy 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; the timing for submission of manufacturing data to the FDA; 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 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: 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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