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Pfizer and BioNTech to Submit Emergency Use Authorization Request Today to the U.S. FDA for COVID-19 Vaccine

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- *In addition to today's submission to the FDA, the companies have already initiated rolling submissions across the globe including in Australia, Canada, Europe, Japan and the U.K., and plan to submit applications immediately to other regulatory agencies around the world*
- *Based on current projections, the companies expect to produce globally up to 50 million doses in 2020 and up to 1.3 billion doses by the end of 2021; the companies will be ready to distribute the vaccine within hours after authorization*
- *BNT162b2 demonstrated a vaccine efficacy rate of 95%, with no serious safety concerns observed to date*

NEW YORK & MAINZ, Germany--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) announced they will submit a request today to the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) of their mRNA vaccine candidate, BNT162b2 against SARS-CoV-2, which will potentially enable use of the vaccine in high-risk populations in the U.S. by the middle to end of December 2020.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20201120005370/en/

The submission is based on a vaccine efficacy rate of 95% ($p<0.0001$) demonstrated 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. The first primary objective analysis was based on 170 confirmed cases of COVID-19. This submission also is supported by solicited safety data from a randomized subset of approximately 8,000 participants ?18 years of age and unsolicited safety data from approximately 38,000 trial participants who have been followed for a median of two months following the second dose of the vaccine candidate. The submission also includes solicited safety data on approximately 100 children 12-15 years of age. 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. To date, the Data Monitoring Committee (DMC) for the study has not reported any serious safety concerns related to the vaccine.

"Our work to deliver a safe and effective vaccine has never been more urgent, as we continue to see an alarming rise in the number of cases of COVID-19 globally. Filing in the U.S. represents a critical milestone in our journey to deliver a COVID-19 vaccine to the world and we now have a more complete picture of both the efficacy and safety profile of our vaccine, giving us confidence in its potential," said Dr. Albert Bourla, Pfizer

Chairman and CEO. “We look forward to the upcoming Vaccines and Related Biological Products Advisory Committee discussion and continue to work closely with the FDA and regulatory authorities worldwide to secure authorization of our vaccine candidate as quickly as possible.”

“Filing for Emergency Use Authorization in the U.S. is a critical step in making our vaccine candidate available to the global population as quickly as possible,” said Ugur Sahin, M.D., CEO and Co-founder of BioNTech. “We intend to continue to work with regulatory agencies worldwide to enable the rapid distribution of our vaccine globally. As a company located in Germany in the heart of Europe, our interactions with the European Medicines Agency (EMA) are of particular importance to us and we have continuously provided data to them as part of our rolling review process.”

The companieshave already initiated rolling submissions with several regulatory agencies around the world, including the EMA and the Medicines & Healthcare Products Regulatory Agency (MHRA) in the United Kingdom, and intend to submit applications to other regulatory agencies worldwide in the coming days. In some cases, governments may have regulatory pathways similar to an EUA. The companies will be ready to distribute the vaccine candidate within hours after authorization.

Pfizer and BioNTech are extremely grateful to the study volunteers and investigative site staff in the clinical trial program, as their involvement was crucial to today’s important milestone in the companies’ efforts to address the COVID-19 global pandemic.

The BNT162b2 vaccine candidate is not currently approved for distribution anywhere in the world. Both collaborators are committed to developing this novel vaccine with preclinical and clinical data at the forefront of all their decision making.

Manufacturing and Delivery Capabilities

While Pfizer and BioNTech await potential authorization or approval from regulatory agencies, the companies continue to work in collaboration with governments and Ministries of Health around the world that will distribute the vaccine, subject to authorization or approval, to help ensure it can reach those most in need as quickly as possible.

Pfizer is bringing its leading in-house manufacturing capabilities to this effort, with the ability and experience to quickly scale, manufacture and distribute large quantities of vaccine at high quality, leveraging multiple sites in the U.S. and Europe, and complementing the mRNA manufacturing expertise of BioNTech, gained over almost a decade. Pfizer and BioNTech’s combined manufacturing network has the potential to supply up to 50 million vaccine doses globally in 2020 and up to 1.3 billion doses by the end of 2021 (subject to clinical success, manufacturing capacity, and regulatory approval or authorization).

Pfizer has vast experience and expertise in cold-chain shipping and has an established infrastructure to supply the vaccine worldwide, including distribution hubs that can store vaccine doses for up to six months. The company has developed specially designed, temperature-controlled shippers for the BNT162b2 vaccine candidate, which can maintain recommended storage conditions (-70°C ±10°C) up to 15 days. Each shipper contains a GPS-enabled thermal sensor to track the location and temperature of each vaccine shipment. Once thawed, the vaccine vial can be stored for up to 5 days at refrigerated (2 - 8^{o}C) conditions.

From the start of the research program earlier this year, Pfizer and BioNTech have successfully supplied and distributed their investigational vaccine to more than 150 clinical trial sites across the U.S., as well as Europe, Latin America, and South Africa. Based on their collective experience, the companies believe in their capability to distribute the vaccine globally upon approval or authorization.

About the Study

The Phase 3 clinical trial of BNT162b2, which is based on BioNTech's proprietary mRNA technology, began on July 27 and has enrolled 43,661 participants to date, 41,135 of whom have received a second dose of the vaccine candidate as of November 13, 2020. A breakdown of the diversity of clinical trial participants can be found here from approximately 150 clinical trials sites in the U.S., Germany, Turkey, South Africa, Brazil and Argentina. Participants will continue to be monitored for long-term protection and safety for an additional two years after their second dose.

Pfizer and BioNTech plan to submit the efficacy and safety data from the study for peer-review in a scientific journal once analysis of the data is completed.

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 November 20, 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 request for Emergency Use Authorization 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 such applications 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 shelflife 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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