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Pfizer and BioNTech Achieve First Authorization in the World for a Vaccine to Combat COVID-19

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- *U.K. regulator, MHRA, authorizes supply of COVID-19 mRNA vaccine for emergency supply under Regulation 174; Companies are ready to deliver the first doses to the U.K. immediately*
- *First authorization for a COVID-19 vaccine represents a breakthrough scientific achievement to help combat this devastating pandemic*
- *The companies previously signed an agreement to supply a total of 40 million doses to the U.K. with delivery in 2020 and 2021*
- *U.S. FDA and EU EMA decisions on authorization are expected in December*

NEW YORK & MAINZ, Germany--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) announced today that the Medicines & Healthcare Products Regulatory Agency (MHRA) in the U.K. has granted a temporary authorization for emergency use for their COVID-19 mRNA vaccine (BNT162b2), against COVID-19. This constitutes the first Emergency Use Authorization following a worldwide Phase 3 trial of a vaccine to help fight the pandemic. Pfizer and BioNTech are anticipating further regulatory decisions across the globe in the coming days and weeks and are ready to deliver vaccine doses following potential regulatory authorizations or approvals. The distribution of the vaccine in the U.K. will be prioritized according to the populations identified in guidance from the Joint Committee on Vaccination and Immunisation (JCVI).

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“Today’s Emergency Use Authorization in the U.K. marks a historic moment in the fight against COVID-19. This authorization is a goal we have been working toward since we first declared that science will win, and we applaud the MHRA for their ability to conduct a careful assessment and take timely action to help protect the people of the U.K.,” said Albert Bourla, Chairman and Chief Executive Officer, Pfizer. “As we anticipate further authorizations and approvals, we are focused on moving with the same level of urgency to safely supply a high-quality vaccine around the world. With thousands of people becoming infected, every day matters in the collective race to end this devastating pandemic.”

“The Emergency Use Authorization in the U.K. will mark the first time citizens outside of the trials will have the opportunity to be immunized against COVID-19,” said Ugur Sahin, M.D., CEO and Co-founder of BioNTech. “We believe that the roll-out of the vaccination program in the U.K. will reduce the number of people in the high-risk population being hospitalized. Our aim is to bring a safe and effective vaccine upon approval to the people who need it. The data submitted to regulatory agencies around the world are the result of a scientifically rigorous and highly ethical research and development program.”

The MHRA’s decision is based on a rolling submission, including data from the Phase 3 clinical study, which demonstrated a vaccine efficacy rate of 95% ($p<0.0001$) 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 is based on 170 cases of COVID-19, as specified in the study protocol. Efficacy was consistent across age, gender, race and ethnicity demographics, with an observed efficacy in adults age 65 and over of more than 94%. In the trial, BNT162b2 was generally well tolerated with no serious safety concerns reported by the Data Monitoring Committee to date. Today's decision also is based on a review of Pfizer's and BioNTech's Chemistry, Manufacturing and Control (CMC) data for BNT162b2.

In July 2020, Pfizer and BioNTech announced an agreement with the U.K. to supply 30 million doses of the BNT162b2 mRNA-based vaccine, once authorized for emergency use. That agreement was increased to 40 million doses in early October. The delivery of the 40 million doses will occur throughout 2020 and 2021, in stages, to ensure an equitable allocation of vaccines across the geographies with executed contracts. Now that the vaccine is authorized in the U.K., the companies will take immediate action to begin the delivery of vaccine doses. The first doses are expected to arrive in the U.K. in the coming days, with complete delivery fulfilment expected in 2021.

The companies have filed a request for Emergency Use Authorization with the U.S. Food and Drug Administration (FDA) and have submitted the final Conditional Marketing Authorization Application (CA) following rolling submissions with the European Medicines Agency (EMA) and several other regulatory agencies around the world.

Manufacturing and Delivery Capabilities

Pfizer and BioNTech continue to work in collaboration with governments and Ministries of Health around the world that will distribute the vaccine, subject to country authorization or approval, to help ensure it can reach those most in need as quickly as possible. The companies are leveraging leading vaccine manufacturing and distribution capabilities to quickly scale, manufacture and distribute large quantities of the vaccine at high quality, complementing the mRNA manufacturing expertise of BioNTech gained over almost a decade. Pfizer has a 171-year track record of researching, developing, manufacturing and delivering innovative medicines and vaccines to patients in need. Pfizer and BioNTech are confident in their ability to safely and effectively deliver the vaccine to the people in the U.K. Based on current projections, Pfizer's and BioNTech's combined manufacturing network has the potential to supply globally up to 50 million vaccine doses in 2020 and up to 1.3 billion doses by the end of 2021 (subject to manufacturing capacity and regulatory approval or authorization).

Through its existing mRNA production sites in Mainz and Idar-Oberstein, Germany, BioNTech is able to produce mRNA for commercial supply after having already produced the vaccine candidate doses for the clinical trials. BioNTech will also increase its manufacturing capacity in 2021, once a third site in Germany will start manufacturing to provide further capacities for a global supply of the potential vaccine. Critical to distribution in the U.K. will be Pfizer's manufacturing site in Puurs, Belgium, one of Pfizer's largest sterile injectable sites. The Puurs site is being used primarily for European supply but will also serve as back up supply to Kalamazoo, Michigan, for the U.S. market.

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's distribution is built on a flexible just-in-time system that can ship the frozen vials quickly to designated points of vaccination at the time of need. So, this will minimize the need for long term storage anywhere. Vaccination in a pandemic situation is expected to be rapid, with high demand, and we do not expect that the product will need to be stored at any location for more than 30 days.

To assure product quality, the companies have developed specially designed, temperature-controlled shippers for the BNT162b2 vaccine candidate, which can maintain recommended storage conditions (-70°C ±10°C) for extended periods of time without any additional equipment but dry ice. The shipper can maintain temperature for 10 days unopened which allows for transportation to markets globally. Once open, a vaccination center may use the specially designed shippers as a temporary storage solution to maintain the recommended storage conditions (-70°C ±10°C) up to 30 days with re-icing every five days in accordance with the handling instructions. Each shipper contains a GPS-enabled thermal sensor to track the location and temperature of each vaccine shipment 24 hours a day, seven days a week. Once thawed, the vaccine vial can be stored for up to five days at refrigerated (2-8°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 reaching approximately 44,000 participants. Based on their collective experience, the companies believe in their capability to distribute the vaccine globally upon approval or authorization. BioNTech will hold the regulatory authorization in the U.K., and, if granted, in the U.S., the EU, Canada and other countries. Pfizer will have the commercialization right worldwide with the exception of China, Germany and Turkey.

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 2, 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, a temporary authorization for emergency use in the U.K., regulatory submissions, including a pending request for Emergency Use Authorization in the U.S. and rolling submissions with the EMA and several other regulatory agencies around the world, the anticipated timing of regulatory submissions, regulatory approvals or authorizations 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 for BNT162b2 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; whether and when the U.K. temporary use authorization may be superseded by the grant of a Marketing Authorisation; 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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