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# Pfizer and BioNTech Reach an Agreement to Supply the EU With 200 Million Doses of Their BNT162b2 mRNA-Based Vaccine Candidate Against SARS-CoV-2

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- *Agreement provides a supply of 200 million doses and an option to request additional 100 million doses, with deliveries anticipated to start by the end of 2020, subject to regulatory approval*
- *The vaccine supply for the EU will be produced by BioNTech's manufacturing sites in Germany and Pfizer's manufacturing site in Belgium and based on current projections, the companies expect to produce globally up to 1.3 billion doses in 2021*
- *Pfizer and BioNTech initiated a rolling submission to the European Medicines Agency (EMA) in October, and will continue regular and open dialogue with the EMA providing results from their ongoing Phase 3 study*

NEW YORK & MAINZ, Germany--(BUSINESS WIRE)-- Pfizer (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today announced that they have reached an agreement with the European Commission to supply 200 million doses of their investigational BNT162b2 mRNA-based vaccine candidate against SARS-CoV-2 to European Union (EU) Member States, with an option for the European Commission to request an additional 100 million doses. Deliveries are anticipated to start by the end of 2020, subject to clinical success and regulatory authorization.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20201111005405/en/

Vaccine doses for Europe will be produced in BioNTech's German manufacturing sites, as well as in Pfizer's manufacturing site in Belgium. If the BNT162b2 vaccine candidate receives approval from the European Medicines Agency (EMA), then doses will be ordered by the EU Member States who have elected to receive the vaccine as part of this agreement.

"Since the onset of the pandemic, Pfizer's priority has been to develop a safe and effective vaccine, while simultaneously scaling up our manufacturing to deliver doses before the end of the year. This is an ambitious goal but critical to halting this global pandemic," said Albert Bourla, Chairman and CEO, Pfizer. "Today's finalized supply agreement with the European Commission represents the largest initial order of vaccine doses for Pfizer and BioNTech to date and a major step toward our shared goal of making a COVID-19 vaccine available to vulnerable populations."

"As a company founded in the heart of Europe, we are looking forward to supplying millions of people upon regulatory approval. We would like to thank the Commission and the Member States for their support and trust in our COVID-19 vaccine candidate. Our aim is to develop a safe and effective vaccine to contribute to bringing

this pandemic to an end. Only through joint efforts will we be able to do so," said Ugur Sahin, M.D., CEO and Co-founder of BioNTech.

Pfizer and BioNTech announced the conclusion of exploratory talks with the European Commission to supply doses of the BNT162b2 vaccine candidate, if approved, on September 9, 2020. The proposed supply agreement is now final.

On November 9, 2020, Pfizer and BioNTech announced their mRNA-based vaccine candidate, BNT162b2, against SARS-CoV-2 has demonstrated evidence of efficacy against COVID-19 in participants without prior evidence of SARS-CoV-2 infection, based on the first interim efficacy analysis conducted on November 8, 2020 by an external, independent Data Monitoring Committee (DMC) from the Phase 3 clinical study. The DMC reviewed 94 cases. The case split between vaccinated individuals and those who received the placebo indicates a vaccine efficacy rate above 90%, at 7 days after the second dose. This means that protection is achieved 28 days after the initiation of the vaccination, which consists of a 2-dose schedule. As the study continues, the final vaccine efficacy percentage may vary. The DMC has not reported any serious safety concerns and recommends that the study continue to collect additional safety and efficacy data as planned. The data will be discussed with regulatory authorities worldwide. Pfizer and BioNTech plan to submit data from the full Phase 3 trial for scientific peer-review publication.

In addition to engagements with governments, Pfizer and BioNTech have provided an expression of interest for possible supply to the COVAX Facility, a mechanism established by Gavi, the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations (CEPI) and World Health Organization (WHO) that, using a range of technology platforms, aims to provide governments, including those in the emerging markets, with early access to a large portfolio of COVID-19 candidate vaccines produced by multiple manufacturers across the world.

**About the BNT162 Vaccine Candidate Program**

The BNT162 program is based on BioNTech's proprietary mRNA technology and supported by Pfizer's global vaccine development and manufacturing capabilities. Two of the companies' four investigational vaccine candidates – BNT162b1 and BNT162b2 – received Fast Track designation from the U.S. Food and Drug Administration (FDA), based on preliminary data from Phase 1/2 studies that are currently ongoing in the U.S. and Germany as well as animal immunogenicity studies. During preclinical and clinical studies, BNT162b1 and BNT162b2 emerged as strong candidates based on assessments of safety and immune response.

On July 27, 2020, Pfizer and BioNTech announced that following extensive review of preclinical and clinical data from Phase 1/2 clinical trials, and in consultation with the FDA's Center for Biologics Evaluation and Research (CBER) and other global regulators, the companies selected the BNT162b2 vaccine candidate to move forward into a Phase 2/3 study. BNT162b2 encodes an optimized SARS-CoV-2 full-length spike glycoprotein (S), which is the target of virus neutralizing antibodies.

**About the Study**

The Phase 3 clinical trial of BNT162b2 began on July 27, 2020 and has enrolled 43,538 participants to date, 38,955 of whom have received a second dose of the vaccine candidate as of November 8, 2020. Approximately 42% of global participants and 30% of U.S. participants have racially and ethnically diverse backgrounds. The trial is continuing to enroll and is expected to continue through the final analysis when a total of 164 confirmed COVID-19 cases have accrued. The study also will evaluate the potential for the vaccine candidate to provide protection against COVID-19 in those who have had prior exposure to SARS-CoV-2, as well as vaccine prevention against severe COVID-19 disease. In addition to the primary efficacy endpoints evaluating confirmed COVID-19 cases accruing from 7 days after the second dose, the final analysis now will also include, with the

approval of the U.S. Food and Drug Administration (FDA), new secondary endpoints evaluating efficacy based on cases accruing 14 days after the second dose. The companies believe that the addition of these secondary endpoints will help align data across all COVID-19 vaccine studies and allow for cross-trial learnings and comparisons between these novel vaccine platforms. The companies have posted an updated version of the study protocol at https://www.pfizer.com/science/coronavirus.

Pfizer and BioNTech are continuing to accumulate safety data and currently estimate that a median of two months of safety data following the second (and final) dose of the vaccine candidate – the amount of safety data specified by the FDA in its guidance for potential Emergency Use Authorization – will be available by the third week of November. Additionally, participants will continue to be monitored for long-term protection and safety for an additional two years after their second dose. Along with the efficacy data generated from the clinical trial, Pfizer and BioNTech are working to prepare the necessary safety and manufacturing data to submit to the FDA to demonstrate the safety and quality of the vaccine product produced.

Assuming positive data and availability of the necessary safety and manufacturing data, and based on current projections, Pfizer and BioNTech expect to produce globally up to 50 million vaccine doses in 2020 and up to 1.3 billion doses in 2021. To meet those anticipated quantities and milestones, the companies have produced sufficient supply for their Phase 2/3 clinical trial and have begun to produce and stockpile their pandemic supply.

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

**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 11, 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, an agreement with the European Commission to supply BNT162 and other potential agreements, and modRNA candidate BNT162b2 (including qualitative assessments of available data, potential benefits, expectations for clinical trials, anticipated timing of clinical trial readouts and regulatory submissions, the rolling submission to the EMA 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 preliminary and interim data, (including the Phase 3 interim data discussed in this release), including the possibility of unfavorable new preclinical or clinical trial data and further analyses of existing preclinical or clinical trial data; 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 future preclinical and clinical studies; whether and when any 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; 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 potential Emergency Use Authorization; the timing for submission of manufacturing data to the FDA; 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, 2020, 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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**Pfizer Contacts:**
**Media Relations**
Andrew Widger
+44797 0149098
andrew.widger@pfizer.com

**Investor Relations**
Chuck Triano
+1 (212) 733-3901
Charles.E.Triano@Pfizer.com

**BioNTech Contacts:**
**Media Relations**
Jasmina Alatovic
+49 (0)6131 9084 1513 or +49 (0)151 1978 1385
Media@biontech.de

**Investor Relations**
Sylke Maas, Ph.D.
+49 (0)6131 9084 1074
Investors@biontech.de

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