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Pfizer and BioNTech to Supply Japan with 120 Million Doses of their BNT162 mRNA-based Vaccine Candidate

Friday, July 31, 2020 - 05:15am

- *Supply of 120 million doses to be provided in the first half of 2021, subject to regulatory approval*
- *Agreement is part of Pfizer's and BioNTech's global commitment to help address the pandemic*
- *Pfizer and BioNTech began a Phase 2b/3 safety and efficacy trial and remain on track to seek regulatory review as early as October 2020, and manufacture globally up to 100 million doses by the end of 2020 and approximately 1.3 billion doses by the end of 2021*

NEW YORK & MAINZ, Germany--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today announced an agreement with the Ministry of Health, Labour and Welfare (MHLW) in Japan to supply 120 million doses of BNT162 mRNA-based vaccine candidate against SARS-CoV2, subject to clinical success and regulatory approval, beginning in 2021.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20200731005116/en/

Financial details of the agreement were not disclosed, but the terms were based on the timing of delivery and the volume of doses. As requested by the Government of Japan, deliveries of the vaccine candidate are planned for the first half of 2021.

"We are deeply honored to work with the Japanese government and to marshal our scientific and manufacturing resources toward our shared goal of bringing millions of doses of a potential COVID-19 vaccine to the Japanese people as quickly as possible," said Albert Bourla, Chairman and CEO, Pfizer. "In the face of this global health crisis, Pfizer's purpose – breakthroughs that change patients' lives – has taken on an even greater urgency. Under these difficult circumstances, we are proud to help support Japan in its steadfast determination to bring the world together at the 2020 Tokyo Olympics, in a celebration of solidarity, friendship and the power of sport as a global force for good. Our hope is that, subject to clinical and regulatory success, our potential vaccine will help make this happen."

"In bringing the world together at one place, for centuries, the Olympic Games have been a symbol of a global community. As a renewed version of that very spirit, the 2020 Tokyo Olympics may become a symbol for all of us for how all nations around the world can overcome a global pandemic threat together. We are proud and honored that our vaccine candidate may contribute to the efforts undertaken by the government of Japan to turn this vision into reality," said Ugur Sahin, M.D., CEO and Co-founder of BioNTech.

The BNT162 program is based on BioNTech's proprietary mRNA technology and supported by Pfizer's global vaccine development and manufacturing capabilities. The vaccine development program is evaluating at least four experimental vaccine candidates, each of which represents a unique combination of messenger RNA (mRNA) format and target antigen. The BNT162 vaccine candidates are undergoing clinical studies and are not

currently approved for distribution anywhere in the world. Both collaborators are committed to developing these novel vaccines with pre-clinical and clinical data at the forefront of all their decision-making.

Recently, two of the companies' four investigational vaccine candidates – BNT162b1 and BNT162b2 – received Fast Track designation from the U.S. Food and Drug Administration (FDA). This designation was granted based on preliminary data from Phase 1/2 studies that are currently ongoing in the United States and Germany as well as animal immunogenicity studies.

On July 27, 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. In the late-stage trial, the companies will study a 30 µg dose level in a 2 dose regimen among up to 30,000 participants aged 18 – 85 years. It is expected to include approximately 120 sites globally including in regions with significant expected SARS-CoV-2 transmission.

Assuming clinical success, Pfizer and BioNTech are on track to seek regulatory review for BNT162b2 as early as October 2020 and, if regulatory authorization or approval is obtained, plan to supply up to 100 million doses worldwide by the end of 2020 and approximately 1.3 billion doses by the end of 2021.

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 aims to provide governments, including those in the emerging markets, with early access to a large portfolio of COVID-19 candidate vaccines using a range of technology platforms, produced by multiple manufacturers across 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 July 31, 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, an agreement with the government of Japan to supply BNT162 and other potential agreements, the BNT162 mRNA vaccine program, and modRNA candidates BNT162b2 and BNT162b1 (including qualitative assessments of available data, potential benefits, expectations for clinical trials and timing of regulatory submissions, anticipated manufacturing, supply and

distribution), 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 data, including the possibility of unfavorable new preclinical or clinical trial data and further analyses of existing preclinical or clinical trial data that may be inconsistent with the data used for selection of the BNT162b2 vaccine candidate and dose level for the Phase 2/3 study; 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; manufacturing capabilities or capacity, including whether the estimated numbers of doses can be manufactured 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, 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 timing to initiate clinical trials of BNT162 and anticipated publication of data from these clinical trials; the timing for any potential emergency use authorizations or approvals; the potential to enter into additional supply agreements with other jurisdictions or the COVAX Facility; the potential safety and efficacy of BNT162; the collaboration between BioNTech and Pfizer to develop a potential COVID-19 vaccine; 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: competition to create a vaccine for COVID-19; the ability to produce comparable clinical results in larger and more diverse clinical trials; 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 Annual Report on Form 20-F filed with the SEC on March 31, 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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Source: Pfizer Inc.