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Pfizer and BioNTech to Supply Canada with their BNT162 mRNA- Based Vaccine Candidate

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- *Supply to be provided over the course of 2021, subject to Health Canada 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*

KIRKLAND, QC , and MAINZ, Germany , Aug. 5, 2020 /CNW/ - Pfizer Canada and BioNTech SE today announced an agreement with the Government of Canada to supply their BNT162 mRNA-based vaccine candidate against SARS-CoV2, subject to clinical success and Health Canada approval.

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 Canada , deliveries of the vaccine candidate are planned for over the course of 2021.

"We continue to be committed to partnering with the Canadian government to help fight this pandemic and are pleased with their collaborative approach to addressing a national COVID-19 immunization strategy with public health officials," said Cole C. Pinnow , President, Pfizer Canada . "With our combined efforts, we know there is no health challenge that we cannot address."

"As the development of effective COVID-19 vaccines continues around the world, we commend the work of Pfizer and BioNTech , which will provide Canadians access to a vaccine candidate for the virus. This agreement is another critical step in our government's efforts to keep Canadians safe and healthy as the pandemic continues to evolve," said The Honourable Anita Anand, Minister of Public Services and Procurement, Government of Canada .

"In the face of this global health crisis, Pfizer's purpose – breakthroughs that change patients' lives – has taken on an even greater urgency," said Albert Bourla , Chairman and CEO, Pfizer. "We're harnessing our scientific expertise, and we're marshaling our manufacturing resources in an effort to ensure that the vaccine would be available as soon as possible, if our clinical trials prove successful and regulatory approval is granted."

"This agreement is part of our commitment to address the pandemic by supporting global supply of our vaccine candidate. Our teams are working diligently to advance the lead product candidate through clinical development in order to seek regulatory review as early as October. At the same time, Pfizer and BioNTech continue to scale up manufacturing capacities to be able to produce up to 100m doses in 2020 and more than one billion doses in 2021. Since we initiated Project Lightspeed our aim has always been clear: Making a potential vaccine available to the public as quickly as possible – worldwide. This agreement is yet another step in that direction," said Sean Marett , Chief Business and Chief Commercial Officer at 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. BNT162b2 has received Fast Track designation from the U.S. Food and Drug Administration (FDA).

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 Canada

Pfizer Canada ULC is the Canadian operation of Pfizer Inc., one of the world's leading biopharmaceutical companies. Our diversified health care portfolio includes some of the world's best known and most prescribed medicines and vaccines. We apply science and our global resources to improve the health and well-being of Canadians at every stage of life. Our commitment is reflected in everything we do, from our disease awareness initiatives to our community partnerships. To learn more about Pfizer Canada , visit pfizer.ca or you can follow us on LinkedIn , Facebook , Twitter or YouTube .

Pfizer Disclosure Notice

The information contained in this release is as of August 5, 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 Canada 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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