Pfizer and BioNTech Achieve Health Canada Authorization for Their Vaccine to Combat COVID-19

December 9, 2020

- *Health Canada authorizes supply of COVID-19 mRNA vaccine under Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19*
- *The companies will supply a minimum of 20 million doses to Canada through 2021*

KIRKLAND, QUEBEC, CANADA and MAINZ, GERMANY, December 9, 2020 (GLOBE NEWSWIRE) —Pfizer Canada and BioNTech SE (Nasdaq: BNTX) today announced that Health Canada has granted Authorization under Interim Order for the emergency use of their mRNA COVID-19 vaccine (BNT162b2). The distribution of the vaccine in Canada will be prioritized according to the populations identified in guidance from the National Advisory Committee on Immunizations (NACI). BioNTech will hold the regulatory approval in Canada, while Pfizer Canada will have the commercialization rights.

"Today's decision from Health Canada is a historic moment in our collective fight against the COVID-19 pandemic and is a major step towards returning to normalcy in Canada. I'd like to acknowledge the tremendous efforts of Pfizer and BioNTech colleagues around the world who have contributed to the development of this vaccine," says **Cole Pinnow, President, Pfizer Canada.** "We commend Health Canada for its careful and thorough assessment of our COVID-19 vaccine and timely action to help protect Canadians."

"It is encouraging to see that our mRNA vaccine is now authorized in Canada. Following U.K. and Bahrain, it is the third country to approve use of our vaccine within a week," said **Sean Marett, BioNTech's Chief Business and Chief Commercial Officer** . "Together with our partner Pfizer, we are ready to ship the vaccines to Canada as soon as we receive the green light from the regulatory authority to start with the distribution."

Health Canada's decision is based on data that was filed through the rolling submission regulatory pathway, and includes data from the Phase 2/3 clinical trial, which began recruiting in late-July 2020, and enrolled approximately 44,000 people across approximately 150 sites in multiple countries. Pfizer Canada and BioNTech will supply the Government of Canada a minimum of 20 million doses (and up to 76 million doses) of the vaccine through 2021.

Manufacturing and Delivery Capabilities
Pfizer and BioNTech continue to work in collaboration with governments and health authorities around the world to help ensure BNT162b2 can reach those most in need as quickly as possible, subject to country authorization or approval. The companies are taking a phased approach to quickly scale, manufacture and distribute large quantities of the vaccine at high quality, complementing the mRNA manufacturing expertise that BioNTech has 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. BioNTech will hold the regulatory approvals in the U.K. and Canada, and, if granted, in the U.S., the EU and other countries. Pfizer will have the marketing and distribution rights worldwide with the exception of China, Germany and Turkey.

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 December 9, 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, anticipated timing of clinical trial readouts and regulatory submissions and the rolling submission to Heath Canada), 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 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.

Pfizer Contacts:

COVID-19 Media Relations Team
1-866-9-PFIZER (1-866-973-4937)
pfizercanadamedia@national.ca

BioNTech Contacts:

Media Relations
Jasmina Alatovic
+49 6131 9084-0
Media@biontech.de

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