Pfizer and BioNTech's Omicron BA.4/BA.5-Adapted Bivalent COVID-19 Vaccine Booster Receives Health Canada Authorization for Individuals 12 Years of Age and Older

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- *COMIRNATY Original & Omicron BA.4/BA.5 now authorized in Canada as a booster dose for individuals 12 years of age and older*
- *Authorization is based on clinical, pre-clinical and manufacturing data for Omicron-adapted bivalent vaccines as well as data from the monovalent ("original" vaccine)*
- *COMIRNATY Original & Omicron BA.4/BA.5 combines 15-µg of mRNA encoding the spike protein of the wild-type of SARS-CoV-2 and 15-µg of mRNA encoding the spike protein of the Omicron BA.4/BA.5 subvariants*

KIRKLAND, QUEBEC and MAINZ, GERMANY, October 7, 2022 —Pfizer Canada ULC and BioNTech SE today announced that Health Canada has authorized COMIRNATY Original & Omicron BA.4/BA.5 as a 30-µg booster dose for individuals ages 12 years and older. An application for an Omicron BA.4/BA.5-adapted bivalent vaccine for children 5 through 11 years of age is also being planned for submission to Health Canada for review.

The authorization of COMIRNATY Original & Omicron BA.4/BA.5 is based on clinical data from Pfizer and BioNTech's monovalent ("original" vaccine), Omicron BA.1-adapted bivalent vaccine as well as pre-clinical and manufacturing data from their Omicron BA.4/BA.5-adapted bivalent vaccine. A clinical study investigating the safety, tolerability, and immunogenicity of the Omicron BA.4/BA.5-adapted bivalent vaccine in individuals 12 years of age and older is currently underway. This data will be provided to the authorities in the coming months.

Pfizer and BioNTech's bivalent COVID-19 vaccine contains 15-µg of mRNA encoding the spike protein of the wild-type of SARS-CoV-2, and 15-µg of mRNA encoding the spike protein of the Omicron BA.4/BA.5 subvariants. Because the Omicron BA.4 and BA.5 variants contain identical spike protein amino acid sequences, both can be targeted with a single mRNA strand. Apart from the addition of the mRNA sequence of the Omicron BA.4/BA.5 spike protein, all other components of the vaccine remain unchanged.

"As we head into another fall and winter with COVID-19, we are pleased to offer Canadians our Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine," said **Fabien Paquette, mRNA Vaccines & Antiviral Portfolio Lead, Pfizer Canada**. "This is another important milestone in our ongoing efforts to provide protection against this virus. Pfizer will be making significant volumes of the vaccine available in the coming days."

"Today's approval allows us to make our Omicron BA.4/BA.5-adapted bivalent vaccine available to the people in Canada to support the continued vaccination program in advance of the winter season," said **Prof. Ugur Sahin, M.D., CEO and Co-founder of BioNTech**. "The bivalent BA.4/BA.5 vaccine aims to provide broader immunization against COVID-19 caused by the current dominant Omicron sublineages and previous variants of concern. It marks a further milestone in addressing this continuously evolving virus."

COMIRNATY and COMIRNATY Original & Omicron BA.4/BA.5, which are based on BioNTech's proprietary mRNA technology, were developed by both BioNTech and Pfizer. BioNTech is the Marketing Authorization Holder for BNT162b2 in Canada, the United States, the European Union, the United Kingdom and other countries, and the holder of emergency use authorizations or equivalents in the United States (jointly with Pfizer) and other countries. Submissions to pursue regulatory approvals in those countries where emergency use authorizations or equivalent were initially granted are planned.

About Pfizer Canada
Pfizer Canada ULC is the Canadian operation of Pfizer Inc., one of the world's leading biopharmaceutical companies. Our diversified healthcare 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.

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, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma, and Pfizer. For more information, please visit www.BioNTech.com.

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 including the program to develop a COVID-19 vaccine and COMIRNATY (COVID-19 vaccine, mRNA) (BNT162b2) (including authorization in Canada for persons 12 years of age and older of an Omicron-adapted COVID-19 bivalent vaccine based on the BA.4/BA.5 subvariant and planned regulatory submissions, qualitative assessments of available data, potential benefits, expectations for clinical trials, the anticipated timing of regulatory submissions, regulatory approvals or authorizations and anticipated manufacturing, distribution and supply); our expectations regarding the potential characteristics of BNT162b2, any monovalent or bivalent vaccine candidates or any future vaccine, in our clinical trials and/or in commercial use based on data observations to date; the ability of BNT162b2, any monovalent or bivalent vaccine candidates or any future vaccine, to prevent COVID-19 caused by emerging virus variants; 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 preclinical and clinical data (including Phase 1/2/3 or Phase 4 data), including the data discussed in this release for BNT162b2, any monovalent or bivalent vaccine candidates or any other vaccine candidate in BNT162 program in any of our studies in pediatrics, adolescents, or adults or real world evidence, including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the expected time point for additional readouts on efficacy data of BNT162b2, or any monovalent or bivalent vaccine candidates or any future vaccine, in our clinical trials; the risk that more widespread use of the vaccine will lead to new information about efficacy, safety, or other developments, including the risk of additional adverse reactions, some of which may be serious; 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; our contemplated shipping and storage plan, including our estimated product shelf life at various temperatures; the ability of BioNTech to supply the quantities of BNT162, any monovalent or bivalent vaccine candidates or any future vaccine, to support clinical development and market demand, including our production estimates for 2022; that demand for any products may be reduced or no longer exist which may lead to reduced revenues or excess inventory; the availability of raw materials to manufacture a vaccine; our vaccine's formulation, dosing schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery by Pfizer; the ability to successfully develop other vaccine formulations, booster doses or potential future annual boosters or re-vaccinations or new variant-based vaccines; the ability to maintain or scale up manufacturing capacity on a timely basis or maintain access to logistics or supply channels commensurate with global demand for our vaccine, which would negatively impact our ability to supply the estimated numbers of doses of our vaccine within the projected time periods as previously indicated; whether and when additional supply agreements will be reached; the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; challenges related to public vaccine confidence or awareness; and uncertainties regarding the impact of COVID-19 on BioNTech's trials, business and general operations. 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 on Form 6-K for the quarter ended June 30, 2022, and in subsequent filings made by BioNTech with the SEC, which are 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.

CONTACT:

Pfizer:
Pfizer Canada Corporate Affairs
1-866-9-PFIZER (1 866 973-4937)
corporate.affairs.canada@pfizer.com

BioNTech:
Media Relations
Jasmina Alatovic
+49 (0)6131 9084 1513
Media@biontech.de

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