Pfizer and BioNTech Receive Health Canada Authorization for XBB.1.5-Adapted Monovalent COVID-19 Vaccine

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- *COMIRNATY Omicron XBB.1.5-adapted monovalent COVID-19 vaccine is now authorized in Canada for individuals 6 months of age and older*
- *New Omicron XBB.1.5-adapted COVID-19 vaccine is administered as a single dose for individuals 5 years of age and older, regardless of COVID-19 vaccination history. In children 6 months through 4 years of age the vaccine is administered as a three-dose series in those without a history of completion of a COVID-19 primary vaccination course, or as a single dose in those with a history of completion of a COVID-19 primary vaccination course*
- *The updated vaccine is expected to be available in Canada in the coming weeks*

KIRKLAND, QUEBEC and MAINZ, GERMANY, September 28, 2023 — Pfizer Canada ULC and BioNTech SE (Nasdaq: BNTX, "BioNTech") announced today that Health Canada has authorized the companies' Omicron XBB.1.5-adapted monovalent COVID-19 vaccine (COMIRNATY® Omicron XBB.1.5) for ages 6 months and older. The updated vaccine will be available in Canada as a single dose for individuals 5 years of age and older, regardless of prior COVID-19 vaccination history. For children 6 months through 4 years of age the updated vaccine is authorized for administration as a three-dose series in those without a history of completion of a COVID-19 primary vaccination course, or as a single dose for those with a history of completion of a COVID-19 primary vaccination course.

The authorization of is based on the full body of previous clinical, non-clinical, and real-world evidence supporting the safety and efficacy of the Pfizer-BioNTech COVID-19 Vaccines. Further, the application included pre-clinical data on the neutralization potential of serum antibodies induced by the updated monovalent COVID-19 vaccine against multiple XBB-related sublineages, including XBB.1.5, XBB.1.16, XBB.2.3 and EG.5.1 (Eris).

Pfizer and BioNTech continue to monitor emerging SARS-CoV-2 strains and continue to conduct studies to monitor the vaccine's effectiveness, including the recently emerged Omicron BA.2.86 (Pirola) variant and the globally dominant EG.5.1 (Eris) subvariant.[1]

"With today's Health Canada authorization, individuals 6 months and older in Canada are eligible to receive the XBB.1.5-adapted COVID-19 vaccine, even if they have never been vaccinated against COVID-19 before," said Andréa Mueller, Primary Care Portfolio Lead, Pfizer Canada. "We are proud of this achievement that empowers Canadians to protect themselves against the XBB sublineages, which are currently the most dominant strains in Canada. We expect the newly formulated vaccine to be available in Canada in the coming weeks to ensure people can get their updated COVID-19 vaccine ahead of the fall/winter season when respiratory viruses are expected to peak."

"As COVID 19 is expected to become a seasonal disease, similar to influenza, it remains our goal to provide COVID-19 vaccines that are adapted to the respective circulating virus variants or sublineages to the people worldwide," said Prof. Ugur Sahin, M.D., CEO and Co-founder of BioNTech. "The new variant-adapted monovalent vaccine aims to further improve protection against severe illness and hospitalization caused by Omicron XBB descendent sublineages that are antigenically distant from prior Omicron strains."

The COVID-19 vaccines (COMIRNATY®) by Pfizer and BioNTech are based on BioNTech's proprietary mRNA technology and were developed by both companies. BioNTech is the Marketing Authorization Holder for COMIRNATY and its adapted vaccines (COMIRNATY Original/Omicron BA.1; COMIRNATY Original/Omicron BA.4/BA.5; COMIRNATY Omicron XBB.1.5) in the United States, the European Union, the United Kingdom, Canada and other countries, and the holder of emergency use authorizations or equivalents in the United States (jointly with Pfizer) and other countries.

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 (BioNTech) 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 (CAR) T cells, several protein-based therapeutics, including bispecific immune checkpoint modulators, targeted cancer antibodies and antibody-drug conjugate (ADC) therapeutics, as well as 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 DualityBio, Fosun Pharma, Genentech, a member of the Roche Group, Genevant, Genmab, OncoC4, Regeneron, Sanofi, and Pfizer.

For more information, please visit www.BioNTech.com.

BioNTech Forward-Looking Statements
This press release may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not be limited to, statements concerning: BioNTech's efforts to combat COVID-19; the collaboration between BioNTech and Pfizer; the rate and degree of market acceptance of BioNTech's COVID-19 vaccine, including the Omicron XBB.1.5-adapted monovalent COVID-19 vaccine; qualitative assessments of available data and expectations of potential benefits; regulatory submissions and regulatory approvals or authorizations

and expectations regarding manufacturing, distribution and supply; expectations regarding anticipated changes in COVID-19 vaccine demand, including changes to the ordering environment; and expected regulatory recommendations to adapt vaccines to address new variants or sublineages. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond BioNTech's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to: BioNTech's pricing and coverage negotiations with governmental authorities, private health insurers and other third-party payors after BioNTech's initial sales to national governments; the future commercial demand and medical need for initial or booster doses of a COVID-19 vaccine; competition from other COVID-19 vaccines or related to BioNTech's other product candidates, including those with different mechanisms of action and different manufacturing and distribution constraints, on the basis of, among other things, efficacy, cost, convenience of storage and distribution, breadth of approved use, side-effect profile and durability of immune response; the timing of and BioNTech's ability to obtain and maintain regulatory approval for BioNTech's product candidates; the ability of BioNTech's COVID-19 vaccines to prevent COVID-19 caused by emerging virus variants; BioNTech's and its counterparties' ability to manage and source necessary energy resources; BioNTech's ability to identify research opportunities and discover and develop investigational medicines; the ability and willingness of BioNTech's third-party collaborators to continue research and development activities relating to BioNTech's development candidates and investigational medicines; the impact of the COVID-19 pandemic on BioNTech's development programs, supply chain, collaborators and financial performance; unforeseen safety issues and potential claims that are alleged to arise from the use of BioNTech's COVID-19 vaccine and other products and product candidates developed or manufactured by BioNTech; BioNTech's and its collaborators' ability to commercialize and market BioNTech's COVID-19 vaccine and, if approved, its product candidates; BioNTech's ability to manage its development and expansion; regulatory developments in the United States and other countries; BioNTech's ability to effectively scale BioNTech's production capabilities and manufacture BioNTech's products, including BioNTech's target COVID-19 vaccine production levels, and BioNTech's product candidates; risks relating to the global financial system and markets; and other factors not known to BioNTech at this time.

You should review the risks and uncertainties described under the heading "Risk Factors" in BioNTech's Report on Form 6-K for the period ended June 30, 2023 and in subsequent filings made by BioNTech with the U.S. Securities and Exchange Commission ("SEC"), which are available on the SEC's website at www.sec.gov. Except as required by law, BioNTech disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on BioNTech's current expectations and speak only as of the date hereof.

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[1] World Health Organization. EG.5 Initial Risk Evaluation, 9 August 2023. Available at: https://www.who.int/docs/default-source/coronaviruse/09082023eg.5_ire_final.pdf?sfvrsn=2aa2daee_1