Pfizer and BioNTech Receive Conditional Marketing Authorization by Swissmedic for COVID-19 Vaccine

December 19, 2020

- *Authorization follows previously signed agreement with Switzerland to supply vaccine doses through 2021*

ZURICH, SWITZERLAND and MAINZ, GERMANY, December 19, 2020 —Pfizer AG and BioNTech SE today announced that Swissmedic in Switzerland has granted a Conditional Marketing Authorization for their COVID-19 mRNA vaccine COMIRNATY® (BNT162b2). COMIRNATY® is the brand name under which the vaccine will be marketed in Switzerland. The distribution of the vaccine in Switzerland will be prioritized by the Federal Office of Public Health (FOPH) according to the populations identified in guidance from the Federal Vaccination Commission (EKIF).

"Today's Conditional Marketing Authorization in Switzerland marks a historic moment in the fight against this deadly disease, further affirming Pfizer's commitment to deliver on its promise to provide the public with a vaccine against this virus," said **Sabine Bruckner, Pfizer Country Manager Switzerland**. "We commend Swissmedic for its careful assessment of our COVID-19 vaccine and timely action to help protect the people of Switzerland."

"It is encouraging to see that our mRNA vaccine is now approved in Switzerland. The number of countries authorizing the use of our vaccine is steadily increasing. This is important in order to support addressing this pandemic," said **Sean Marett, Chief Business Officer and Chief Commercial Officer at BioNTech**. "Together with our partner Pfizer, we are looking forward to shipping the vaccines to Switzerland."

The Swissmedic decision is based on a rolling submission, including data from the Phase 3 clinical study, which demonstrated a vaccine efficacy rate of 95% ($p<0.0001$) in participants without prior SARS-CoV-2 infection (first primary objective) and also in participants with and without prior SARS-CoV-2 infection (second primary objective), in each case measured from 7 days after the second dose. The first primary objective analysis is based on 170 cases of COVID-19, as specified in the study protocol. Efficacy was consistent across age, gender, race and ethnicity demographics, with an observed efficacy in adults age 65 and over of more than 94%. In the trial, the vaccine was generally well tolerated with no safety concerns reported by the Data Monitoring Committee to date. Today's decision also is based on a review of Pfizer's and BioNTech's Chemistry, Manufacturing and Control (CMC) data.

Pfizer and BioNTech previously announced an agreement with Switzerland to supply the vaccine, once authorized or approved. Deliveries will start in 2020 and will occur throughout 2021 in accordance with terms of the supply agreement.

Pfizer AG is the Marketing Authorization Holder in Switzerland. To date, the vaccine has been authorized or approved for emergency use in more than 15 countries. The companies have also submitted the final Conditional Marketing Authorization Application (CA) following rolling submissions with the European Medicines Agency (EMA) and several other regulatory agencies around the world.

Manufacturing and Delivery Capabilities

Pfizer and BioNTech continue to work in collaboration with governments and Ministries of Health around the world that will distribute the vaccine, subject to country authorization or approval, to help ensure it can reach those most in need as quickly as possible. The companies are leveraging leading vaccine manufacturing and distribution capabilities to quickly scale, manufacture and distribute large quantities of the vaccine at high quality, complementing the mRNA manufacturing expertise of BioNTech 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. Based on current projections, Pfizer's and BioNTech's combined manufacturing network has the potential to supply up to 1.3 billion doses by the end of 2021 (subject to manufacturing capacity and regulatory approval or authorization).

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 19, 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 COVID-19 vaccine, the BNT162 mRNA vaccine program and modRNA candidate BNT162b2 (including qualitative assessments of available data, potential benefits, expectations for clinical trials, a Conditional Marketing Authorization in Switzerland, regulatory submissions, including pending requests for emergency use authorization and other marketing applications, the anticipated timing of regulatory submissions, regulatory approvals or authorizations and anticipated manufacturing, distribution and supply), involving 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 clinical data (including the Phase 3 data), including the possibility of unfavorable new preclinical or clinical trial data and further analyses of existing preclinical or clinical trial data; the ability to produce comparable clinical or other results, including the rate of vaccine effectiveness and safety and tolerability profile observed to date, in additional analyses of the Phase 3 trial and additional studies or in larger, more diverse populations upon commercialization; 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 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 additional 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 any future preclinical and clinical studies; whether and when any other biologics license and/or emergency use authorization applications may be filed in any particular jurisdictions for BNT162b2 or any other potential vaccine candidates; whether and when any applications that may be pending or filed for BNT162b2 may be approved by particular 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; disruptions in the relationships between us and our collaboration partners or third-party suppliers; risks related to the availability of raw materials to manufacture a vaccine; challenges related to our vaccine candidate's ultra-low temperature formulation and attendant storage, distribution and administration requirements, including risks related to handling after delivery by Pfizer; the risk that we may not be able to successfully develop non-frozen formulations; the risk that we may not be able to create or scale up manufacturing capacity on a timely basis or have access to logistics or supply channels commensurate with global demand for any potential approved vaccine, which would negatively impact our ability to supply the estimated numbers of doses of our vaccine candidate 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; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; 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, Regeneron, 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 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; a Conditional Marketing Authorization in Switzerland; 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; 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.

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