U.S. CDC Committee of Independent Health Experts Recommends Vaccination with Pfizer and BioNTech COVID-19 Vaccine for Persons Ages 16 Years and Older

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Recommendation follows yesterday’s FDA authorization for emergency use of the Pfizer-BioNTech COVID-19 vaccine (BNT162b2), to address the crisis Based on urgent need, Committee recommends Pfizer-BioNTech COVID-19 vaccine for persons 16 years of age and older under U.S. FDA’s Emergency Use Authorization; earlier this month, the Committee recommended a phased allocation of vaccine distribution with Phase 1a to prioritize health care personnel treating patients, and residents in nursing homes and other long-term care facilities

NEW YORK & MAINZ, Germany--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) announced today that the U.S. Centers for Disease Control and Prevention’s (CDC) Advisory Committee on Immunization Practices (ACIP) voted today to recommend the use of the Pfizer-BioNTech COVID-19 vaccine in people 16 years of age and older under the Emergency Use Authorization (EUA) issued by the U.S. Food and Drug Administration (FDA). This ACIP vote follows the December 1, 2020, ACIP recommendation for a Phase 1a rollout where first priority of COVID-19 vaccines is given to health care personnel treating patients, and residents in nursing homes and other long-term care facilities.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20201212005026/en/

ACIP advises the CDC on the types of populations and circumstances for which vaccines should be used. The advisors based today's recommendation on the scientific evidence supporting the COVID-19 vaccine, including data from a Phase 3 clinical study announced last month and published in The New England Journal of Medicine on December 10, 2020, as well as on interim guidance that ACIP made on December 1, 2020 regarding the allocation of initial vaccine doses. The vaccine was authorized by the FDA on December 11, 2020 under an EUA while Pfizer and BioNTech gather additional data and prepare to file a planned Biologics License Application (BLA) with the FDA for a possible full regulatory approval in 2021.

"Today's ACIP recommendation marks a momentous step in this historic journey and the beginning of another, as we work jointly with the U.S. government, other vaccine companies and our many partners to execute the largest mass vaccination program in our nation's history. Collectively, we aim to vaccinate hundreds of millions of Americans by the end of 2021," said Albert Bourla, Chairman and Chief Executive Officer, Pfizer. "With vaccinations set to begin this week, I feel a sense of tremendous pride at what we have collectively achieved over the past nine months. I now look forward to the day that this devastating and deadly pandemic is finally behind us."

"We started our project to develop a potential COVID-19 vaccine in January because we felt we had a duty to leverage our mRNA technologies and fast vaccine development competences to help address the pandemic," said Ugur Sahin, M.D., CEO and Co-founder of BioNTech. "We have the greatest respect for all the healthcare workers and people working day and night in long-term care facilities and hospitals. They have been taking care of so many people who needed help the most. Now, we feel honored to be able to support them by providing this vaccine."

The first vaccine supplies are being prepared to ship from Pfizer's Kalamazoo, MI site, and will be distributed by the U.S. Department of Defense in partnership with agencies within the Department of Health and Human Services (HHS), including the CDC, to government-designated facilities across the country.

These ACIP recommendations will be forwarded to the director of the CDC and HHS for review and adoption.

AUTHORIZED USE:

The Pfizer-BioNTech COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

IMPORTANT SAFETY INFORMATION:

Do not administer Pfizer BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer BioNTech COVID-19 Vaccine Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer BioNTech COVID-19 Vaccine Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer BioNTech COVID-19 Vaccine The Pfizer BioNTech COVID-19 Vaccine may not protect all vaccine recipients In clinical studies, adverse reactions in participants 16 years of age and older included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%) Severe allergic reactions have been reported following the Pfizer-BioNTech COVID-19 Vaccine during mass vaccination outside of clinical trials. Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine Available data on Pfizer BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy Data are not available to assess the effects of Pfizer BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion There are no data available on the interchangeability of the Pfizer BioNTech COVID 19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer BioNTech COVID-19 Vaccine should receive a second dose of Pfizer BioNTech COVID-19 Vaccine to complete the vaccination series Vaccination providers must report Adverse Events in accordance with the Fact Sheet to VAERS at https://vaers.hhs.gov/reportevent.html or by calling 1-800-822-7967. The reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report Vaccination Providers should review the Fact Sheet for mandatory requirements and Information to Provide to Vaccine Recipients/Caregivers and the Full EUA Prescribing Information for Requirements and Instructions for Reporting Adverse Events and Vaccine Administration Errors

Please see Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including Full EUA Prescribing Information available at www.cvdvaccine.com.

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 December 12, 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, an Emergency Use Authorization in the U.S., other regulatory submissions, the anticipated timing of regulatory submissions (including the anticipated timing of filing of a Biologics License Application in the U.S.), regulatory approval or authorization 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 a Biologics License Application for BNT162b2 may be filed in the U.S. and whether and when other biologics license and/or emergency use authorization applications may be filed in particular jurisdictions for BNT162b2 or any other potential vaccines; whether and when any applications that may be pending or filed for BNT162b2 (including a potential Biologics License Application in the U.S.) may be approved by particular regulatory authorities, which will depend on myriad factors, including making a determination as to whether the vaccine's benefits outweigh its known risks and determination of the vaccine'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'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 our vaccine, which would negatively impact our ability to supply the estimated numbers of doses of our vaccine within the projected time periods indicated; whether and when additional supply agreements will be reached; uncertainties regarding the ability to obtain other 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 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 shelflife 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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Source: Pfizer Inc.