UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

FOR THE MONTH OF DECEMBER 2020

COMMISSION FILE NUMBER 001-39081

BioNTech SE

(Translation of registrant's name into English)

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+49 6131-9084-0
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F: Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

DOCUMENTS INCLUDED AS PART OF THIS FORM 6-K

On December 11, 2020, BioNTech SE (the "Company") and Pfizer Inc. issued a press release announcing that the U.S. Food and Drug Administration (FDA) has authorized the emergency use of the mRNA vaccine, BNT162b2, against COVID-19 in individuals 16 years of age or older. The vaccine is now authorized under an Emergency Use Authorization (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. The press release is attached hereto as Exhibit 99.1

Additionally, on December 12, 2020, the Company and Pfizer Inc. issued a press release announcing that the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) voted on December 12th 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). The press release is attached hereto as Exhibit 99.2.

Lastly, on December 14, 2020, the Company and Pfizer Inc. issued a press release announcing additional data on neutralizing antibody and T cell responses from the Phase 1/2 trial with BNT162b2 conducted in Germany. The study results demonstrate that BNT162b2 elicits a combined adaptive humoral and cellular immune response against SARS-CoV-2 and provide insights into the composite nature of the BNT162b2-induced T cell immunity. The results were published on the preprint server MedRxiv and are available here. The press release is attached hereto as Exhibit 99.3.

SIGNATURE

Pursuant to the requirements of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BioNTech SE

By: /s/ Dr. Sierk Poetting
Name: Dr. Sierk Poetting
Title: Chief Financial Officer

Date: December 14, 2020

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	Press Release dated December 11, 2020 – Pfizer and BioNTech Celebrate Historical First Authorization in the U.S. of Vaccine to Prevent COVID-19.
99.2	Press Release dated December 12, 2020 – U.S. CDC Committee of Independent Health Experts Recommends Vaccination with Pfizer and BioNTech COVID-19 Vaccine for Persons Ages 16 Years and Older.
99.3	Press Release dated December 14, 2020 – Pfizer and BioNTech Provide Data from German Phase 1/2 Study Further Characterizing Immune Response Following Immunization with Lead COVID-19 Vaccine Candidate BNT162b2.

PFIZER AND BIONTECH CELEBRATE HISTORIC FIRST AUTHORIZATION IN THE U.S. OF VACCINE TO PREVENT COVID-19

- *U.S. FDA authorizes COVID-19 mRNA vaccine for emergency use; companies are prepared to deliver first doses in the U.S. immediately*
- *Pfizer and BioNTech previously announced an agreement with the U.S. Government to supply doses in 2020 & 2021*
- *In collaboration with Operation Warp Speed, Pfizer and BioNTech, as well as other vaccine companies are expected to deliver hundreds of millions of vaccine doses to Americans by the end of 2021*
- *Historic, science-driven efforts will seek to help bring an end to the most devastating pandemic in a century*
- *Pfizer and BioNTech expect to file a Biologics License Application for possible full regulatory approval in 2021*

NEW YORK and MAINZ, GERMANY, December 11, 2020 — Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) announced today that the U.S. Food and Drug Administration (FDA) has authorized the emergency use of the mRNA vaccine, BNT162b2, against COVID-19 in individuals 16 years of age or older. The vaccine is now authorized under an Emergency Use Authorization (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.

Under Operation Warp Speed, the Department of Defense (DoD) in partnership with agencies within the Department of Health and Human Services (HHS), including the U.S. Centers for Disease Control and Prevention (CDC), will manage allocation and distribution of the vaccine in the U.S. This will be prioritized according to the populations identified by the CDC's Advisory Committee on Immunization Practices (ACIP) guidelines.

"Pfizer's purpose is breakthroughs that change patients' lives, and in our 171-year history there has never been a more urgent need for a breakthrough than today with hundreds of thousands of people continuing to suffer from COVID-19," said Albert Bourla, Chairman and Chief Executive Officer, Pfizer. "As a U.S. company, today's news brings great pride and tremendous joy that Pfizer has risen to the challenge to develop a vaccine that has the potential to help bring an end to this devastating pandemic. We have worked tirelessly to make the impossible possible, steadfast in our belief that science will win."

"We founded BioNTech to develop new technologies and medicines that utilize the full potential of the immune system to fight serious diseases" said Ugur Sahin, M.D., CEO and Co-founder of BioNTech. "Today we are another step closer to our vision. We believe that today's Emergency Use Authorization, and the subsequent distribution of our vaccine that has demonstrated an efficacy rate of 95% and a favorable safety profile, will help to save lives across the United States and could accelerate a return to normality."

The FDA based its decision on the totality of scientific evidence shared by the companies, including data from a pivotal Phase 3 clinical study announced last month and published this week in *The New England Journal of Medicine*. The Phase 3 data demonstrated a vaccine efficacy rate of 95% 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 Data Monitoring Committee for the study has not reported any serious safety concerns related to the vaccine. Efficacy was consistent across age, gender, race and ethnicity demographics. All trial participants will continue to be monitored to assess long-term protection and safety for an additional two years after their second dose.

Pfizer and BioNTech appreciate the continued participation of the approximately 44,000 trial volunteers and remain committed to the companies' pledge to always make their safety and well-being the companies' top priority. The participants in our COVID-19 vaccine clinical trial are courageous volunteers who have made a personal and important choice to help make a difference during this pandemic. Pfizer and BioNTech plan to provide an option for trial participants who received the placebo to receive the vaccine at scheduled timepoints in the study. This vaccine transition option will be voluntary and will be implemented in alignment with the regulatory authorities where the trial is conducted.

In July 2020, Pfizer and BioNTech announced an agreement with the HHS and the DoD to meet the U.S. government's Operation Warp Speed program goal to deliver doses of a vaccine for COVID-19. With the vaccine being authorized for emergency use in the U.S., the companies will begin delivering the first doses in the U.S. immediately, with delivery fulfillment expected to be completed in 2021.

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

About the Phase 2/3 Study
The ongoing Phase 3 clinical trial of BNT162b2, which is based on BioNTech's proprietary mRNA technology, has enrolled more than 44,000 participants, the vast majority of whom have received their second dose. A breakdown of the diversity of clinical trial participants can be found here from more than 150 clinical trials sites in the U.S., Germany, Turkey, South Africa, Brazil and Argentina.

The Phase 3 trial is designed as a 1:1 vaccine candidate to placebo, randomized, observer-blinded study to obtain safety, immune response, and efficacy data needed for regulatory review. The trial's primary endpoints are prevention of COVID-19 in those who have not been infected by SARS-CoV-2 prior to immunization, and prevention of COVID-19 regardless of whether participants have previously been infected by SARS-CoV-2. Secondary endpoints include prevention of severe COVID-19 in those groups. The study also will explore prevention of infection by SARS-CoV-2, the virus that causes COVID-19.

Data from this study, including longer term safety, comprehensive information on duration of protection, efficacy against asymptomatic SARS-CoV-2 infection, and safety and immunogenicity in adolescents 12 to 17 years of age will be gathered in the months ahead. Additional studies are planned to evaluate BNT162b2 in pregnant women, children younger than 12 years, and those in special risk groups, such as the immunocompromised.

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 and terms of supply agreements, to help ensure it can reach those most in need as quickly as possible. The companies are leveraging Pfizer's leading vaccine manufacturing and distribution capabilities to quickly scale, manufacture and distribute large quantities of the vaccine at high quality, complementing BioNTech's mRNA manufacturing expertise 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. Pfizer and BioNTech are confident in their ability to deliver the vaccine to people in the U.S. Based on current projections, Pfizer's and BioNTech's combined manufacturing network has the potential to supply globally up to 50 million vaccine doses in 2020 and up to 1.3 billion doses by the end of 2021 (subject to manufacturing capacity and regulatory approval or authorization).

Pfizer is leveraging three of its U.S. manufacturing sites to produce the COVID-19 vaccine – Saint Louis, Missouri, Andover, Massachusetts, and Kalamazoo, Michigan. Pfizer's Pleasant Prairie, Wisconsin and Puurs, Belgium sites are also being used.

Pfizer has vast experience and expertise in cold-chain shipping and has an established infrastructure to supply the vaccine worldwide, including distribution hubs that can store vaccine doses for up to six months. The company's distribution is built on a flexible just-in-time system that can ship the frozen vials quickly to designated points of vaccination at the time of need, minimizing the need for long term storage. Vaccination in a pandemic situation is expected to be rapid, and we do not expect that the product will need to be stored at any location for more than 30 days. To assure product quality, the companies have developed specially designed, temperature-controlled shippers for the vaccine, which can maintain recommended storage conditions (-70°C ±10°C) for extended periods of time with dry ice. The shipper can maintain temperature for 10 days unopened which allows for transportation to markets globally. Once open, a vaccination center may use the specially designed shippers as a temporary storage solution to maintain the recommended storage conditions (-70°C ±10°C) up to 30 days with re-icing every five days in accordance with the handling instructions. Each shipper contains a GPS-enabled thermal sensor to track the location and temperature of each vaccine shipment 24 hours a day, seven days a week. Once thawed, the vaccine vial can be stored safely for up to five days at refrigerated (2-8°C) conditions.

From the start of the research program earlier this year, Pfizer and BioNTech have successfully supplied and distributed their investigational vaccine to more than 150 clinical trial sites across the U.S., as well as Europe, Latin America and South Africa reaching approximately 44,000 participants. Based on their collective experience, the companies believe in their capability to distribute the vaccine globally upon approval or authorization. BioNTech will hold the regulatory approvals in the U.S., U.K., Canada and, if authorized, in the EU, and other countries. Pfizer will have marketing and distribution rights worldwide with the exception of China, Germany, and Turkey.

AUTHORIZED USE:
The Pfizer-BioNTech COVID19 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 (SARSCoV2) 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) and 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 11, 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 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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U.S. CDC COMMITTEE OF INDEPENDENT HEALTH EXPERTS RECOMMENDS VACCINATION WITH PFIZER AND BIONTECH COVID-19 VACCINE FOR PERSONS AGES 16 YEARS AND OLDER

- *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 and MAINZ, GERMANY, December 12, 2020 — 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.

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

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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
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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.

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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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Pfizer and BioNTech Provide Data from German Phase 1/2 Study Further Characterizing Immune Response Following Immunization with Lead COVID-19 Vaccine Candidate BNT162b2

- *Analysis of 37 participants immunized with BNT162b2 showed a broad immune response with SARS-CoV-2-specific neutralizing antibodies, T_H1 type CD4+ T cells, and strong expansion of CD8+ T cells of the early effector memory phenotype*
- *All vaccinated participants demonstrated neutralizing antibody as well as T cell responses. T cell responses were directed against multiple regions of the spike protein, including the RBD, suggesting immune recognition of multiple independent epitopes*
- *Data confirm previous findings from the U.S. trial demonstrating a good safety profile and robust induction of antibody responses with a longer follow-up period of 85 days*
- *Antibodies generated in trial subjects were able to neutralize pseudo-viruses representing 19 diverse SARS-CoV-2 variants, indicating potential for broad protection against viruses with reported mutations*

NEW YORK and MAINZ, GERMANY, December 14, 2020 — Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today announced additional data on neutralizing antibody and T cell responses from the Phase 1/2 trial with BNT162b2 conducted in Germany. The study results demonstrate that BNT162b2 elicits a combined adaptive humoral and cellular immune response against SARS-CoV-2 and provide insights into the composite nature of BNT162b2-induced T cell immunity. The results were published on the preprint server MedRxiv and are available here. BNT162b2 is an investigational COVID-19 vaccine developed by Pfizer-BioNTech. It has been authorized for emergency use for individuals 16 years of age and older in several countries around the world.

“In parallel to working with regulators around the globe to make our vaccine available, we will continue to share important data from our ongoing studies with the global scientific community and the public in order to advance our collective understanding of the underlying vaccine mechanism of action,” said **Ugur Sahin, M.D., CEO and Co-Founder of BioNTech**. “While there is a broad consensus that vaccines should induce antibody responses against the virus, experiences from the prior SARS pandemic indicate that $CD8^+$ T cell responses may be of critical importance to achieve long-term protection.”

“These results from the ongoing German Phase 1/2 study help illustrate the multiple arms of the immune system that are activated to fight SARS-CoV-2 by the vaccine candidate BNT162b2. Advancing the understanding of the duration of antibody responses is critical as the global scientific community continues to look for potential vaccines to help overcome this pandemic,” said **Kathrin U. Jansen, Ph.D., Senior Vice President and Head of Vaccine Research & Development at Pfizer**. “We continue to add to the body of scientific evidence supporting BNT162b2 and are pleased to see the consistency in our findings across studies.”

The ongoing non-randomized open-label Phase 1/2 trial (NCT04380701) is being conducted in Germany in parallel to the Phase 1/2/3 trial (NCT04368728) that started in the U.S. The German study evaluated the safety and immunogenicity of BNT162b2 in different dose cohorts (1 µg, 10 µg, 20 µg and 30 µg) with 11-12 participants per cohort. BNT162b2 was administered in two doses 21 days apart to healthy adults between 18 and 55 years of age.

Overall, these results mirror those from the U.S. study (NCT04368728) that were previously published, and support the favorable safety profile and robust induction of virus-specific antibody responses. A longer follow-up period of 85 days showed sustained neutralizing antibody titers in the range of, or above, those in convalescent sera cohort. BNT162b2 immune sera efficiently

neutralized 19 pseudo-viruses, indicating the potential for broad BNT162b2-elicited protection against reported mutations.

All 37 participants vaccinated with BNT162b2 showed newly generated spike protein-specific CD4+ T cell responses, and almost 92% of participants demonstrated CD8+ T cell responses. The majority were strong T cell responses comparable to or significantly higher than memory responses of the same individuals against common viruses, such as cytomegalovirus (CMV), Epstein Barr virus (EBV) and the influenza virus. Even with the lowest dose of 1 µg BNT162b2, most of the vaccinated participants elicited robust expansion of CD4+ and CD8+ T cells. Expression of cytokines IFNγ and IL-2, but only low levels of IL-4 in BNT162b2-induced CD4+ T cells indicated a T_H1 profile. CD8+ T cell responses were directed against multiple regions of the spike protein, and several of the multiple epitopes recognized by BNT162b2-induced CD8+ T cells were molecularly identified.

Effectors of the adaptive immune system have complementary roles in defense against viral infections. While neutralizing antibodies are the first line of defense, CD8+ T cells contribute to virus clearance from intracellular compartments that are inaccessible to neutralizing antibodies. Antigen-specific CD4+ T cells have immune orchestrating functions, including support of memory generation. Therefore, detailed characterization of the cellular immune responses will be important in understanding the mechanisms contributing to protection against SARS-CoV-2.

As of today, BNT162b2, Pfizer-BioNTech Covid-19 vaccine candidate, has been authorized or approved for emergency use for individuals 16 years of age and older in the U.S, U.K., Bahrain, Canada, Saudi Arabia, and Mexico. Pfizer and BioNTech have submitted a final Conditional Marketing Authorization Application (CA) following rolling submissions with the European Medicines Agency (EMA) and several other regulatory agencies around the world.

U.S. 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.

U.S. 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.

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