Pfizer Logo

Pfizer and BioNTech Receive Authorization in the European Union for COVID-19 Vaccine

Monday, December 21, 2020 - 02:09pm

- *COMIRNATY® (also known as BNT162b2) receives conditional marketing authorization from the European Commission; this milestone represents a global joint effort to advance the first authorized mRNA vaccine*
- *Pfizer and BioNTech are ready to immediately ship initial doses to the 27 EU member states*
- *Pfizer and BioNTech previously announced an agreement with the European Commission to supply 200 million vaccine doses to EU member states; the EU also has an option to purchase an additional 100 million doses in 2021*
- *The vaccine has now been granted a conditional marketing authorization, emergency use authorization, or temporary authorization in more than 40 countries worldwide, including all 27 EU member states*

NEW YORK & MAINZ, Germany--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) announced today that the European Commission (EC) has granted a conditional marketing authorization (CMA) to Pfizer and BioNTech for COMIRNATY® (also known as BNT162b2), for active immunization to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 16 years of age and older. This follows the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) positive opinion to authorize the vaccine earlier today. The EC granted this CMA in the interest of public health to help address the COVID-19 pandemic. The CMA is valid in all 27 member states of the European Union (EU).

This press release features multimedia. View the full release here:
https://www.businesswire.com/news/home/20201221005672/en/

The vaccine will be marketed in the EU under the brand name COMIRNATY, which represents a combination of the terms COVID-19, mRNA, community, and immunity, to highlight the first authorization of a messenger RNA (mRNA) vaccine, as well as the joint global efforts that made this achievement possible with unprecedented rigor and efficiency – and with safety at the forefront – during this global pandemic. COMIRNATY is the first COVID-19 vaccine to receive CMA in the EU. The distribution of COMIRNATY by the EU member states will be determined according to the populations identified in EU and national guidance.

"The conditional marketing authorization by the European Commission is an historic achievement. It is the first vaccine which has been developed in a large-scale trial with more than 44,000 participants and approved in less than a year to address this pandemic. This is based on the decade-long pioneering work by many scientists from all over the world. This achievement is also a testament to the successful collaboration with our partner Pfizer," said Ugur Sahin, M.D., CEO and Co-founder of BioNTech. "As a company founded and headquartered in the heart of Europe, we are looking forward to delivering the vaccine to Europeans in the upcoming days. We believe that vaccinations may help reduce the number of people in high-risk populations being hospitalized. Moving forward, we will continue to collect efficacy and safety data in participants for an additional two years

and test the vaccine against additional mutations that might occur."

"With the pandemic still raging in many countries, we are continuing to work around the clock to bring this vaccine to the world as quickly, efficiently and equitably as possible," said Albert Bourla, Chairman and Chief Executive Officer, Pfizer. "I am truly grateful for the collaboration with our partner BioNTech, and to the European Medicines Agency and European Commission for their thorough and efficient review to help us defeat a virus that has already claimed the lives of hundreds of thousands of people in Europe. We are grateful that this authorization is bringing hope to people across the continent, as we hopefully turn the corner of this crisis and approach the new year."

The EU authorization is based on the totality of scientific evidence shared by the companies as part of the EMA's rolling review process and the application for CMA, which the companies submitted on December 1, 2020. This included data from a pivotal Phase 3 clinical study announced last month and published recently 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 (DMC) for the study has not reported 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 the duration of protection and safety for an additional two years after their second dose.

Following today's CMA, Pfizer and BioNTech will initiate delivery of the first vaccine doses immediately across the EU based on a distribution plan defined by the EC and contract terms. In November 2020, Pfizer and BioNTech reached an agreement with the EC to supply 200 million doses of a vaccine for COVID-19 in 2020 and 2021, with the option for up to 100 million additional doses, subject to agreement of the parties. Delivery will begin immediately, and occur in stages, throughout 2020 and 2021, to ensure an equitable allocation of vaccines according to contract terms across the EU. Vaccine doses for Europe will be produced in BioNTech's manufacturing sites in Germany, and Pfizer's manufacturing site in Puurs, Belgium.

Pfizer and BioNTech appreciate the continued participation of the more than 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 the companies' 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 are providing a vaccine transition option that enables trial participants 16 years and over who received the placebo to receive the vaccine as part of the study. This option is voluntary and is being implemented in a phased manner.

With this EU authorization in all 27 EU member states, the COVID-19 vaccine has now been granted a conditional marketing authorization, emergency use authorization or a temporary authorization in a total of more than 40 countries.[1] Regulatory reviews are underway in several countries, with more authorizations anticipated in the coming weeks.

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 which includes information 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 EU. 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).

Through its existing mRNA production sites in Germany, BioNTech is able to produce the Pfizer-BioNTech COVID-19 Vaccine for commercial supply after having already produced the vaccine candidate doses for the clinical trials. BioNTech will also increase its manufacturing capacity in 2021, once a third site in Marburg, Germany will start manufacturing to provide further capacities for a global supply of the vaccine. Critical to distribution in Europe will be Pfizer's manufacturing site in Puurs, Belgium, one of Pfizer's largest sterile injectable sites. The Puurs site is being used primarily for European supply but will also serve as back up supply to Kalamazoo, Michigan, for the U.S. market.

Pfizer has vast experience and expertise in cold-chain shipping and has an established infrastructure to supply the vaccine worldwide, including distribution hubs where vaccine can be stored until its expiration. 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 shipping conditions (-90ºC to -60ºC (-130ºF to -76ºF)) 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 store the vaccine in an Ultra-Low Temperature freezer at (-70°C ±10°C) for up to six months, or use the specially designed shippers as a temporary storage solution to maintain the required temperatures for 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 more than 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 authorization in the U.S., U.K., Canada, EU, and, if authorized, in other countries. Pfizer will have marketing and distribution rights worldwide with the exception of China, Germany, and Turkey.

The Pfizer-BioNTech COVID-19 Vaccine has not been approved or licensed by the U.S. Food and Drug Administration (FDA), but has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 16 years of age and older. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564 (b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner. 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.

AUTHORIZED USE IN THE U.S.:
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 FROM U.S. FDA EMERGENCY USE AUTHORIZATION PRESCRIBING 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 21, 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 the EU, other regulatory submissions, the anticipated timing of regulatory submissions, regulatory approval or authorization and anticipated manufacturing, distribution and supply), that involves 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 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'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; 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.

---

[1] This number includes all 27 EU member states.

View source version on businesswire.com: https://www.businesswire.com/news/home/20201221005672/en/

Pfizer Contacts:
Andy Widger
+44 (0)1737 330909
eupress@pfizer.com

Investor Relations
Chuck Triano
+1 (212) 733-3901
Charles.E.Triano@Pfizer.com

BioNTech Contacts:
Media Relations
Jasmina Alatovic
+49 89 62 81 75 46
Media@biontech.de

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

Source: Pfizer Inc.