Pfizer Logo

Pfizer Update On Our U.S. COVID-19 Vaccine Candidate Distribution Preparedness

Monday, November 16, 2020 - 08:00am

- *Actions include Pfizer's S. COVID-19 Immunization Pilot Program, that aims to help inform vaccine deployment and delivery logistics nationally*
- *Pfizer has been preparing for S. distribution for a vaccine, if authorized or approved, including coordinating with the U.S. Centers for Disease Control and Prevention and Operation Warp Speed*

NEW YORK, 16 November 2020 — Pfizer (NYSE: PFE) today announced the U.S. COVID-19 Immunization Pilot Program with four states, to help refine the plan for the delivery and deployment of the company's COVID-19 vaccine candidate that is being co-developed with BioNTech.

To build on our coordination with the relevant U.S. agencies, Pfizer launched this pilot program to help better support the states' planning, deployment, and administration of the COVID-19 vaccine candidate. Learnings from this program will be adapted for usage across other states to help them create effective immunization programs for this vaccine. The four states – Rhode Island, Texas, New Mexico, and Tennessee – were selected for the program because of their differences in overall size, diversity of populations, and immunization infrastructure, as well as the states' need to reach individuals in varied urban and rural settings. The four states included in this pilot program will not receive vaccine doses earlier than other states by virtue of this pilot, nor will they receive any differential consideration.

Pfizer has been working with U.S. officials in Operation Warp Speed (OWS) and the U.S. Centers for Disease Control and Prevention (CDC) to help ensure that after potential authorization or approval, the Pfizer-BioNTech COVID-19 vaccine can reach those in most need as quickly and equitably as possible. The company believes this ongoing coordination is critical to help ensure an efficient vaccine distribution as soon as possible after the vaccine receives regulatory authorization or approval, if received.

"This pilot program and our collaboration with U.S. and state officials will help us prepare for broader vaccine deployment in the near future, subject to authorization or approval, as we work to address this urgent public health need," said Angela Hwang, Group President, Pfizer Bio Group President, Pfizer Biopharmaceuticals Group. "We are hopeful that results from this vaccine delivery pilot will serve as the model for other U.S. states and international governments, as they prepare to implement effective COVID-19 vaccine programs."

In July, Pfizer and BioNTech announced the execution of an agreement with the U.S. Department of Health and Human Services and the Department of Defense to meet the U.S. government's OWS program goal to begin delivering 300 million doses of a vaccine for COVID-19 in 2021. Under the agreement, the U.S. government will first receive 100 million doses of the Pfizer-BioNTech COVID-19 vaccine after Pfizer successfully manufactures and obtains approval or emergency use authorization from the U.S. Food and Drug Administration (FDA). The U.S. government will pay $1.95 billion for those first 100 million doses, with the option to acquire up to an additional 500 million doses.

Pfizer's COVID-19 vaccine development and manufacturing costs have been entirely self-funded, with billions of dollars already invested at risk. The company will continue bearing all the costs of development and manufacturing in an effort to help find a solution to this pandemic as fast as possible.

The BNT162b2 COVID-19 vaccine development program is a collaboration between Pfizer and BioNTech. It is not currently approved for distribution anywhere in the world. Both collaborators are committed to developing these novel vaccines with preclinical and clinical data at the forefront of all their decision making.

About the BNT162 Vaccine Candidate Program

The BNT162 program is based on BioNTech's proprietary mRNA technology and supported by Pfizer's global vaccine development and manufacturing capabilities. Two of the companies' four investigational vaccine candidates – BNT162b1 and BNT162b2 – received Fast Track designation from the U.S. Food and Drug Administration (FDA), based on preliminary data from Phase 1/2 studies that are currently ongoing in the U.S. and Germany as well as animal immunogenicity studies. During preclinical and clinical studies, BNT162b1 and BNT162b2 emerged as strong candidates based on assessments of safety and immune response.

On November 9, 2020, Pfizer and BioNTech announced their mRNA-based vaccine candidate, BNT162b2, against SARS-CoV-2 has demonstrated evidence of efficacy against COVID-19 in participants without prior evidence of SARS-CoV-2 infection, based on the first interim efficacy analysis conducted on November 8, 2020 by an external, independent Data Monitoring Committee (DMC) from the Phase 3 clinical study. The DMC reviewed 94 cases. The case split between vaccinated individuals and those who received the placebo indicates a vaccine efficacy rate above 90%, at 7 days after the second dose. This means that protection is achieved 28 days after the initiation of the vaccination, which consists of a 2-dose schedule. As the study continues, the final vaccine efficacy percentage may vary. The DMC has not reported any serious safety concerns and recommends that the study continue to collect additional safety and efficacy data as planned. The data will be discussed with regulatory authorities worldwide. Pfizer and BioNTech plan to submit data from the full Phase 3 trial for scientific peer-review publication.

On July 27, 2020, Pfizer and BioNTech announced that following extensive review of preclinical and clinical data from Phase 1/2 clinical trials, and in consultation with the FDA's Center for Biologics Evaluation and Research (CBER) and other global regulators, the companies selected the BNT162b2 vaccine candidate to move forward into a Phase 2/3 study. BNT162b2 encodes an optimized SARS-CoV-2 full-length spike glycoprotein (S), which is the target of virus neutralizing antibodies.

About the Study

The Phase 3 clinical trial of BNT162b2 began on July 27, 2020 and has enrolled 43,661 participants to date, 41,135 of whom have received a second dose of the vaccine candidate as of November 8, 2020. Approximately 42% of global participants and 30% of U.S. participants have racially and ethnically diverse backgrounds. The trial is continuing to enroll and is expected to continue through the final analysis when a total of 164 confirmed COVID-19 cases have accrued. The study also will evaluate the potential for the vaccine candidate to provide protection against COVID-19 in those who have had prior exposure to SARS- CoV-2, as well as vaccine prevention against severe COVID-19 disease. In addition to the primary efficacy endpoints evaluating confirmed COVID-19 cases accruing from 7 days after the second dose, the final analysis now will also include, with the approval of the U.S. Food and Drug Administration (FDA), new secondary endpoints evaluating efficacy based on cases accruing 14 days after the second dose. The companies believe that the addition of these secondary endpoints will help align data across all COVID-19 vaccine studies and allow for cross-trial learnings and comparisons between these novel vaccine platforms. The companies have posted an updated version of the study protocol at https://www.pfizer.com/science/coronavirus.

Pfizer and BioNTech are continuing to accumulate safety data and currently estimate that a median of two months of safety data following the second (and final) dose of the vaccine candidate – the amount of safety data specified by the FDA in its guidance for potential Emergency Use Authorization – will be available by the third week of November. Additionally, participants will continue to be monitored for long-term protection and safety for an additional two years after their second dose. Along with the efficacy data generated from the clinical trial, Pfizer and BioNTech are working to prepare the necessary safety and manufacturing data to submit to the FDA to demonstrate the safety and quality of the vaccine product produced.

Assuming positive data and availability of the necessary safety and manufacturing data, and based on current projections, Pfizer and BioNTech expect to produce globally up to 50 million vaccine doses in 2020 and up to 1.3 billion doses in 2021. To meet those anticipated quantities and milestones, the companies have produced sufficient supply for their Phase 2/3 clinical trial and have begun to produce and stockpile their pandemic supply.

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 November 16 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 potential COVID-19 vaccine, the BNT162 mRNA vaccine program, the U.S. COVID-19 Immunization Pilot Program, an agreement with the U.S. Department of Health and Human Services and the Department of Defense to supply BNT 162, and modRNA candidate BNT162b2 (including qualitative assessments of available data, potential benefits, expectations for clinical trials, anticipated timing of clinical trial readouts and regulatory submissions, 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 preliminary and interim data, (including the Phase 3 interim data discussed in this release), including the possibility of unfavorable new preclinical or clinical trial data and further analyses of existing preclinical or clinical trial data; 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 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 future preclinical

and clinical studies; whether and when any biologics license and/or emergency use authorization applications may be filed in any jurisdictions for BNT162b2 or any other potential vaccine candidates; whether and when any such applications may be approved by 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; 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.

Pfizer Media Relations:

Steven Danehy

+1 (978)-273-3946

Steven.Danehy@pfizer.com