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www.reachmd.com
info@reachmd.com
(866) 423-7849

A Look into the Development of a COVID-19 Vaccine

Announcer:
You're listening to The Drug Report on ReachMD, hosted by Linda Bernstein, Pharm.D., Clinical Professor on the Volunteer Faculty of the School of Pharmacy, University of California, San Francisco.

Dr. Bernstein:
Welcome to the Drug Report. After a ten-month effort, Pfizer and BioNTech announced this week that their SARS-CoV-2 mRNA vaccine candidate was found to be 90 percent effective at seven days after the second dose in preventing COVID-19 in participants with no evidence of prior SARS-COV-2 infection. Thus, protection is achieved 28 days after the start of the vaccine, which must be administered in a 2-dose schedule.

These results come from the first interim efficacy analysis which studied 94 confirmed cases of the virus in trial participants. The analysis was done on November 8, 2020 by an external independent Data Monitoring Committee from the Phase 3 clinical trial.

The companies plan to apply for Emergency Use Authorization (EUA) to the U.S. Food and Drug Administration shortly after the required safety milestone is reached. The clinical trial will continue until the required 164 confirmed cases are accrued and through final analysis to collect the necessary data in order to evaluate the vaccine's performance against other study endpoints.

And now, some further background on this Phase 3 clinical trial of the Pfizer/ BioNTech vaccine candidate, BNT162b2. The study began on July 27, 2020 and has enrolled 43,538 participants to date. Almost 39,000 of these have received a second dose of the vaccine candidate as of November 8. People as young as 12 years old and those with chronic, stable HIV, Hepatitis C or B viral infections were also included. Forty percent of the study population worldwide and 30 percent of the United States participants are racially and ethnically diverse. The study evaluates the vaccine's efficacy and safety in those who have had prior exposure to SARS-CoV-2, as well as its role in prevention of severe COVID-19 disease. The FDA has given approval for the evaluation of new secondary endpoints beyond its primary efficacy from 7 days after the second dose. Efficacy will also be assessed based on cases accruing 14 days after the second dose. By adding these additional secondary endpoints, the study data will provide a better means of comparison to other COVID-19 studies and enhance cross-trial learning between these novel vaccine platforms. The companies will continue to gather safety data and estimate they will achieve the necessary median of two months of safety data following the second (and final) dose of the vaccine candidate that is required by the FDA in its guidance for potential Emergency Use Authorization by the third week of November. Participants will continue to undergo long term monitoring of their level of viral protection and safety for an additional two years after their second dose.

Besides efficacy data, the companies are preparing the necessary safety and manufacturing data required by the FDA to show the safety and quality of the vaccine product produced. The current projections are that up to 50 million vaccine doses will be produced globally in 2020 and up to 1.3 billion doses in 2021. The final report of this Phase 3 trial will be submitted for publication to a scientific peer-review journal.

According to the Regulatory Affairs Professionals Society COVID-19 vaccine tracker, there are currently nine Phase 3 vaccine clinical trials worldwide and one in Phase 2/3. Both Moderna and the Pfizer/BioNTech candidate are mRNA-based vaccines. Moderna just announced that it has completed case accrual for the first interim analysis of their Phase 3 COVE study of mRNA-1273, its COVID-19 vaccine candidate. The Company expects the first interim analysis will include substantially more than 53 cases, the targeted trigger point for the analysis. The data on these cases is being prepared for submission to the independent Data Safety Monitoring Board (DSMB) for analysis and recommendation. Moderna's study population in the Phase 3 trial includes participants historically underrepresented in clinical research but who are significantly affected by COVID-19, namely, participants over age 65, those under age

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65 with chronic diseases that make them high risk for severe COVID-19, and communities of color reflecting the diversity of the United States as a whole. Moderna has said it expects to be able to produce about 20 million doses of mRNA-1273 in 2020 and from 500 million up to one billion doses worldwide in 2021.

Other types of vaccines in Phase 3 trials are a recombinant vaccine by CanSino Biologics in Wuhan China; a replication-deficient viral vector vaccine trial sponsored by the University of Oxford in conjunction with AstraZeneca and others; three inactivated vaccines under study by Sinovac Research and Development, Bharat Biotech, and Henan Provincial Center for Disease Control and Prevention; a non-replicating viral vector by Johnson & Johnson; a nanoparticle vaccine by Novavax, and a live-attenuated vaccine by University of Melbourne and others.

For the Drug Report, I'm Pharmacist, Dr. Linda Bernstein.

Announcer:
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