Janssen investigational COVID-19 vaccine: Interim analysis of phase 3 clinical data released

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An investigational COVID-19 vaccine developed by Janssen Pharmaceuticals appears to be safe and effective at preventing moderate and severe COVID-19 in adults, according to an interim analysis of Phase 3 clinical data conducted Jan. 21. The vaccine, called Ad.26.COV2.S or JNJ-78436725, requires only a single injection and can be stored in a refrigerator for months.

The interim analysis assessed 468 cases of symptomatic COVID-19 among 44,325 adult volunteers in Argentina, Brazil, Chile, Colombia, Mexico, Peru, South Africa, and the United States. The investigational vaccine was reportedly 66% effective at preventing the study's combined endpoints of moderate and severe COVID-19 at 28 days post-vaccination among all volunteers, including those infected with an emerging viral variant. Moderate COVID-19 was defined as laboratory-confirmed SARS-CoV-2 plus either one of the following: evidence of pneumonia; deep vein thrombosis; difficulty breathing; abnormal oxygen saturation or a respiratory rate equal to or greater than 20; or two or more signs or symptoms suggestive of COVID-19, such as cough, sore throat, fever or chills. Severe COVID-19 was defined as laboratory-confirmed SARS-CoV-2 plus evidence of clinical signs at rest indicative of severe systemic illness, respiratory failure, shock, significant organ dysfunction, hospital intensive care unit admission or death.

Geographically, the level of protection for the combined endpoints of moderate and severe disease varied: 72% in the United States; 66% in Latin American countries; and 57% in South Africa, 28 days post-vaccination. The investigational vaccine was reportedly 85% effective in preventing severe/critical COVID-19 across all geographical regions. No deaths related to COVID-19 were reported in the vaccine group, while five deaths in the placebo group were related to COVID-19. Overall, there were 16 deaths in the placebo group, and three deaths in the vaccine group.

The Janssen Pharmaceutical Companies of Johnson & Johnson developed the experimental vaccine and served as the regulatory sponsor of the Phase 3 clinical study known as ENSEMBLE. Janssen; the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health; and the Biomedical Advanced Research and Development Authority (BARDA), part of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response, funded approximately 55% of the trial through a cost-sharing agreement. The ENSEMBLE trial, which began Sept. 23, 2020, is being conducted as part of the federal COVID-19 response.

The Janssen vaccine is a recombinant vector vaccine that uses a human adenovirus to express

the SARS-CoV-2 spike protein. SARS-CoV-2 is the virus that causes COVID-19. Adenoviruses are a group of viruses that cause infections in the respiratory and gastrointestinal tracts; the adenovirus vector used in the experimental vaccine has been modified, so that it can no longer replicate in humans and cause illness. In developing the vaccine, Janssen employed the same vector used in the first dose of its prime-boost vaccine regimen against Ebola virus disease (Ad26 ZEBOV and MVN-BN-Filo), developed under a long-standing partnership with BARDA and granted marketing authorization by the European Commission in July 2020. Unlike the two COVID-19 vaccines currently authorized by the U.S. Food and Drug Administration for emergency use (Pfizer and Moderna vaccines), the Janssen investigational vaccine requires only a single vaccination.

The principal investigators for the ENSEMBLE clinical trial include: Paul A. Goepfert, M.D., director of the Alabama Vaccine Research Clinic at the University of Alabama in Birmingham; Beatriz Grinsztejn, M.D., Ph.D., director of the Laboratory of Clinical Research on HIV/AIDS at the Evandro Chagas National Institute of Infectious Diseases-Oswaldo Cruz Foundation in Rio de Janeiro, Brazil; and Glenda E. Gray, M.B.B.Ch., president and chief executive officer of the South African Medical Research Council and co-principal investigator of the HIV Vaccine Trials Network (HVTN). The NIAID-supported clinical trial sites in the ENSEMBLE study were part of the COVID-19 Prevention Network (CoVPN).

As part of Janssen's collaboration with the federal COVID-19 response effort, representatives from NIAID, BARDA and Janssen are included in the oversight group that receives recommendations from the trial's independent data and safety monitoring board (DSMB). The same DSMB also oversees the other federally supported Phase 3 clinical trials evaluating COVID-19 vaccine candidates.

More information: A Study of Ad26.COV2.S for the Prevention of SARS-CoV-2-Mediated COVID-19 in Adult Participants (ENSEMBLE). www.clinicaltrials.gov/ct2/sho … 505722&draw=2&rank=1

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