

October 01, 2020 | By Scott LaFee

UC San Diego Health Joins International Clinical Trial to Test Coronavirus Vaccine

Janssen trial will recruit up to 60,000 participants around the world to assess safety and efficacy of a single-dose vaccine to prevent COVID-19

UC San Diego Health will be a test site for a third, major Phase III clinical trial to assess a vaccine candidate for SARS-CoV-2, the novel coronavirus that causes COVID-19.

Sponsored by Janssen Pharmaceuticals Companies of Johnson & Johnson, the trial will recruit up to 60,000 participants at sites in the United States, Brazil, Chile, Colombia, Mexico, Peru, Argentina, Philippines, South Africa and Ukraine to test a single-dose investigational vaccine injection. Dubbed ENSEMBLE, the trial in San Diego officially launches October 7, 2020.

Like the [Moderna](#) and [AstraZeneca](#) COVID-19 vaccine trials already underway at UC San Diego Health and elsewhere, the Janssen trial will be a randomized, double-blind, placebo-controlled study. It will assess the efficacy, safety and immunogenicity (the ability to provoke an immune response) of the investigational drug Ad.26-COV2.S.

The Janssen trial employs an older, well-tested vaccine development approach: A deactivated common cold virus is modified to carry the SARS-CoV-2's characteristic spike protein, which the virus uses to enter host cells. This vaccine "vector" is injected, and the presence of the spike protein prompts the human immune system to create neutralizing antibodies to block the targeted pathogen, essentially rendering subsequent exposures to the coronavirus as non-infectious.



False color scanning electron micrograph of SARS-CoV-2 virus, which causes COVID-19. Photo credit: NIAID

“The Janssen vaccine strategy builds upon their extensive experience using the same vaccine platform for many other infectious diseases, including HIV, Ebola and malaria,” said Susan Little, MD, professor of medicine at UC San Diego School of Medicine and principal investigator of the UC San Diego trial. “No significant safety issues have been identified in studies of more than 90,000 people using this same vaccine platform for other infectious diseases.”

In late-July, researchers published online pre-clinical data in the journal [Nature](#) showing that a single injection of Ad.26-COV2.S produced a “robust immune response” in rhesus macaques. In other words, it generated levels of neutralizing antibodies that provides near- or complete protection from COVID-19 infections in the lungs of the monkeys.

The early findings were encouraging enough for Janssen to immediately announce the launch a two-year-long Phase I/IIa first-in-human clinical trial in the United States and Belgium. Interim, non-peer-reviewed results of that study, published September 25, 2020 on the preprint site [medRxiv](#), found that safety and immunogenicity supported further clinical development.

Participation Protocol

The Phase III ENSEMBLE trial at UC San Diego Health will recruit an estimated 2,000 participants. Half of the participants will receive a single injection of the Ad.26-COV2.S investigational vaccine and the other half will receive a placebo; all will be regularly monitored for signs of infection and COVID-19 over the next two years. Qualifying participants must be 18 or older and in reasonably good health.

Like the other trials, researchers are especially interested in participants at increased risk of SARS-CoV-2 infection due to where they live (higher community spread of the virus), age or personal circumstances, such as working in essential jobs like first responders, health care, maintenance, construction, grocery stores or assisted living facilities.

There is an emphasis upon participation in underserved communities, particularly those of color, that have shown higher rates of both hospitalization and death due to COVID-19.

According to the latest available data from the County of San Diego’s [Health and Human Services Agency](#), the countywide rate of SARS-CoV-2 infection is 1,442 cases per 100,000 population. In the southern half of the county, however, the rate is measurably higher: Chula Vista — 2,207; Imperial Beach — 2,189; National City — 2,598.

To permit easier access to the study in these communities, UC San Diego trial coordinators have contracted with National City to establish a testing location in trailers that will be set up in the parking lot of Toyon Park. The site is scheduled to operate through October 2022.

Additional outreach efforts are planned.

“Many communities of color are experiencing higher rates of hospitalization related to COVID-19 than are observed in White, non-Hispanic people,” said Little. “It is important that these communities are represented in COVID-19 vaccine clinical trials so that we understand if the vaccine will work well within these groups.”

The Janssen trial is part of the National Institutes of Health’s (NIH) COVID-19 Prevention Network (CoVPN) and Operation Warp Speed, a program sponsored by the U.S. Department of Health and Human Services, with a goal to deliver 300 million doses of a safe, effective vaccine for COVID-19 by end of year or early 2021. Currently, Operation Warp Speed has now committed a reported \$8 billion to development and/or purchase of different vaccines under investigation by AstraZeneca, Moderna, Janssen/Johnson & Johnson, Pfizer/BioNTech SE, NovaVax, Merck and Sanofi/GSK, the last a European-based partnership.



Susan Little, MD, professor of medicine at UC San Diego School of Medicine and principal investigator of the UC San Diego trial.

Belgium-based Janssen Pharmaceutica was purchased by the American health conglomerate Johnson & Johnson in 1961. Janssen opened a 122,000-square-foot life sciences facility in San Diego in 2012; Johnson & Johnson has maintained a research center in in the region for more than two decades. Both entities have had long and varied research collaborations with UC San Diego.

For more information about participating in the Janssen trial at UC San Diego, visit www.covidvaccinesd.com or call 619-742-0433.

For information on other COVID-19 clinical trials at UC San Diego, visit clinicaltrials.ucsd.edu/covid-19.

MEDIA CONTACT

Scott LaFee, 858-249-0456, slafee@ucsd.edu

UC San Diego's Studio Ten 300 offers radio and television connections for media interviews with our faculty, which can be coordinated via studio@ucsd.edu. To connect with a UC San Diego faculty expert on relevant issues and trending news stories, visit <https://ucsdnews.ucsd.edu/media-resources/faculty-experts>.