



Single Dose of Johnson & Johnson COVID-19 Vaccine Candidate Demonstrates Robust Protection in Pre-clinical Studies

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Study published in *Nature* shows J&J's investigational SARS-CoV-2 vaccine elicits a strong immune response that protects against subsequent infection

First-in-human Phase 1/2a clinical trial now underway in United States and Belgium; Phase 3 clinical trial expected to commence in September

NEW BRUNSWICK, N.J., July 30, 2020 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) (the Company) today announced that its lead vaccine candidate protected against infection with SARS-CoV-2, the virus that causes COVID-19, in pre-clinical studies. The data, published in [Nature](#), show the Company's investigational adenovirus serotype 26 (Ad26) vector-based vaccine elicited a robust immune response as demonstrated by "neutralizing antibodies," successfully preventing subsequent infection and providing complete or near-complete protection in the lungs from the virus in non-human primates (NHPs) in the pre-clinical study. Based on the strength of the data, a Phase 1/2a first-in-human clinical trial of the vaccine candidate, Ad26.COVS, in healthy volunteers, [has now commenced](#) in the United States and Belgium.

"We are excited to see these pre-clinical data because they show our SARS-CoV-2 vaccine candidate generated a strong antibody response and provided protection with a single dose. The findings give us confidence as we progress our vaccine development and upscale manufacturing in parallel, having initiated a Phase 1/2a trial in July with the intention to move into a Phase 3 trial in September," said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer, Johnson & Johnson.

The robust Janssen COVID-19 clinical trial program, including the Phase 1/2a clinical trial and the Phase 3 clinical trial program, will evaluate both one- and two-dose regimens of Ad26.COVS in parallel studies. The Phase 1/2a trial will evaluate the safety, reactogenicity (expected reactions to vaccination, such as swelling or soreness), and immunogenicity of Ad26.COVS in over 1,000 healthy adults aged 18 to 55 years, as well as adults aged 65 years and older. Planning also is underway for a Phase 2a study in the Netherlands, Spain and Germany and a Phase 1 study in Japan. For more information about these studies, please visit www.clinicaltrials.gov.

As the Company plans its COVID-19 Phase 3 clinical development program, discussions are underway with partners with the objective to start a pivotal Phase 3 clinical trial of the single vaccine dose versus placebo in September, pending the interim data of the Phase 1 and 2 trials and approval of regulators. Simultaneously, the Company also is planning to start a parallel Phase 3 clinical trial of a two-dose regimen versus placebo.

The Company also will emphasize representation of populations that have been disproportionately impacted by the pandemic as it designs and implements its COVID-19 Phase 3 trial program. In the United States, this would include significant representation of Blacks, Hispanic/Latinx and participants over 65 years of age.

The pre-clinical studies were conducted by researchers from Beth Israel Deaconess Medical Center (BIDMC) in collaboration with the Janssen Pharmaceutical Companies of Johnson & Johnson and others as part of its ongoing [collaboration](#) to accelerate the development of a SARS-CoV-2 vaccine.

Dan Barouch, M.D., Ph.D., Director of the Center for Virology and Vaccine Research at BIDMC and the Ragon Institute, stated, "The pre-clinical data, generated in collaboration with the Johnson & Johnson team, highlights the potential of this SARS-CoV-2 vaccine candidate. Moreover, the data suggest that antibody levels may serve as a biomarker for vaccine-mediated protection."

In the studies, researchers first immunized the NHPs with a panel of vaccine prototypes, and then challenged them with SARS-CoV-2 infection. The scientists found that, of seven vaccine prototypes tested in the study, Ad26.COVS (referred to in the *Nature* article as Ad26-S.PP), elicited the highest levels of neutralizing antibodies to SARS-CoV-2. The level of antibodies correlated with the level of protection, confirming previous observations and suggesting they could be a potential biomarker for vaccine-mediated protection. The six NHPs that received a single immunization with Ad26.COVS showed no detectable virus in the lower respiratory tract after exposure to SARS-CoV-2, and only one of six showed very low levels of the virus in a nasal swab at two time points.

"As we collectively battle this pandemic, we remain deeply committed to our goal of providing a safe and effective vaccine to the world. Our pre-clinical results give us reason to be optimistic as we initiate our first-in-human clinical trial, and we are excited to enter the next stage in our research and development toward a COVID-19 vaccine. We know that, if successful, this vaccine can be rapidly developed, produced on a large scale and delivered around the world," said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, LLC, Johnson & Johnson.

The Company's fundamental responsibility is to provide patients, consumers and healthcare providers with products that are as safe and effective as possible. Johnson & Johnson takes an evidence- and science-based, ethics- and values-driven approach to medical safety, putting patient and consumer wellbeing first and foremost in its decision making and actions, with an emphasis on transparency.

As Johnson & Johnson progresses the clinical development of SARS-CoV-2, the Company continues to increase manufacturing capacity and is in active discussions with global strategic partners to support worldwide access. Johnson & Johnson aims to meet its goal to supply more than one billion doses globally through the course of 2021, provided the vaccine is safe and effective.

This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Other Transaction Agreement HHSO100201700018C.

For more information on Johnson & Johnson's multi-pronged approach to combatting the pandemic, visit: www.jnj.com/coronavirus.

About Johnson & Johnson

At Johnson & Johnson, we believe good health is the foundation of vibrant lives, thriving communities and forward progress. That's why for more than 130 years, we have aimed to keep people well at every age and every stage of life. Today, as the world's largest and most broadly-based healthcare company, we are committed to using our reach and size for good. We strive to improve access and affordability, create healthier communities, and put a healthy mind, body and environment within reach of everyone, everywhere. We are blending our heart, science and ingenuity to profoundly change the trajectory of health for humanity. Learn more at www.jnj.com. Follow us at [@JNJNews](https://twitter.com/JNJNews).

About the Janssen Pharmaceutical Companies

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension. Learn more at www.janssen.com. Follow us at [@JanssenGlobal](https://twitter.com/JanssenGlobal).

Notice to Investors Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding development of potential preventive and treatment regimens for COVID-19. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of the Janssen Research & Development LLC., and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 29, 2019, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.



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