



Johnson & Johnson Initiates Pivotal Global Phase 3 Clinical Trial of Janssen's COVID-19 Vaccine Candidate

September 23, 2020

First participants dosed in Phase 3 trial (ENSEMBLE) evaluating safety and efficacy of Janssen's COVID-19 vaccine candidate, JNJ-78436735, also known as Ad26.COV2.S

NEW BRUNSWICK, N.J., Sept. 23, 2020 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) (the Company) today announced the launch of its large-scale, pivotal, multi-country Phase 3 trial (ENSEMBLE) for its COVID-19 vaccine candidate, JNJ-78436735, being developed by its Janssen Pharmaceutical Companies. The initiation of the ENSEMBLE trial follows positive interim results from the Company's Phase 1/2a clinical study, which demonstrated that the safety profile and immunogenicity after a single vaccination were supportive of further development. These results have been submitted to medRxiv and are due to be published online imminently. Based on these results and following discussions with the U.S. Food and Drug Administration (FDA), ENSEMBLE will enroll up to 60,000 volunteers across three continents and will study the safety and efficacy of a single vaccine dose versus placebo in preventing COVID-19.

Johnson & Johnson has continued the scaling up of its manufacturing capacity and remains on track to meet its goal of providing one billion doses of a vaccine each year. The Company is committed to bringing an affordable vaccine to the public on a not-for-profit basis for emergency pandemic use and anticipates the first batches of a COVID-19 vaccine to be available for emergency use authorization in early 2021, if proven to be safe and effective.

Johnson & Johnson will develop and test its COVID-19 vaccine candidate in accordance with high ethical standards and sound scientific principles. The Company is committed to transparency and sharing information related to the Phase 3 ENSEMBLE study – including the [study protocol](#).

"As COVID-19 continues to impact the daily lives of people around the world, our goal remains the same – leveraging the global reach and scientific innovation of our company to help bring an end to this pandemic," said Alex Gorsky, Chairman and Chief Executive Officer, Johnson & Johnson. "As the world's largest healthcare company, we are bringing to bear our best scientific minds, and rigorous standards of safety, in collaboration with regulators, to accelerate the fight against this pandemic. This pivotal milestone demonstrates our focused efforts toward a COVID-19 vaccine that are built on collaboration and deep commitment to a robust scientific process. We are committed to clinical trial transparency and to sharing information related to our study, including details of our study protocol."

"We remain fully focused on developing an urgently needed, safe and effective COVID-19 vaccine for people around the world," said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer, Johnson & Johnson. "We greatly value the collaboration and support from our scientific partners and global health authorities as our global team of experts work tirelessly on the development of the vaccine and scaling up our production capacity with a goal to deliver a vaccine for emergency use authorization in early 2021."

The Janssen COVID-19 vaccine candidate leverages the Company's [AdVac® technology](#) platform, which was also used to develop and manufacture Janssen's European Commission approved Ebola vaccine and construct its Zika, RSV, and HIV vaccine candidates. Janssen's AdVac® technology platform has been used to vaccinate more than 100,000 people to date across Janssen's investigational vaccine programs.

With Janssen's AdVac® technology, the vaccine, if successful, is estimated at launch to remain stable for two years at -20 °C and at least three months at 2-8° C. This makes the vaccine candidate compatible with standard vaccine distribution channels and would not require new infrastructure to get it to the people who need it.

PHASE 3 ENSEMBLE STUDY

The Phase 3 ENSEMBLE study is a randomized, double-blind, placebo-controlled clinical trial designed to evaluate the safety and efficacy of a single vaccine dose versus placebo in up to 60,000 adults 18 years old and older, including significant representation from those that are over age 60. The trial will include those both with and without comorbidities associated with an increased risk for progression to severe COVID-19, and will aim to enroll participants in Argentina, Brazil, Chile, Colombia, Mexico, Peru, South Africa and the United States. In order to evaluate the effectiveness of Janssen's COVID-19 vaccine, countries and clinical trial sites which have a high incidence of COVID-19 and the ability to achieve a rapid initiation will be activated.

Built on a legacy of purpose-driven actions and a commitment to diversity and inclusion, the Company aims to achieve representation of populations that have been disproportionately impacted by the pandemic in the implementation of its COVID-19 Phase 3 trial program. In the U.S., this includes significant representation of Black, Hispanic/Latinx, American Indian and Alaskan Native participants.

ENSEMBLE is being initiated in collaboration with the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services (HHS) under Other Transaction Agreement HHSO100201700018C, and the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH) at HHS.

In parallel, the Company has also agreed in principle to [collaborate](#) with the United Kingdom of Great Britain and Northern Ireland (the UK Government) on a separate Phase 3 clinical trial in multiple countries to explore a two-dose regimen of Janssen's vaccine candidate.

"With our vaccine candidate now in our global Phase 3 trial, we are one step closer to finding a solution for COVID-19. We used a highly scientific and evidence-based approach to select this vaccine candidate. We are extremely grateful for the tireless efforts of our researchers and for the vital contributions of those participants who have volunteered to take part in our studies. Together, we are working to help combat this pandemic," said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, LLC, Johnson & Johnson.

The Company is in ongoing discussions with many stakeholders, including national governments and global organizations, as part of its efforts to meet its commitment to make the vaccine candidate accessible globally, provided the vaccine is demonstrated to be safe and effective and following regulatory approval.

For more information on Johnson & Johnson's multi-pronged approach to helping combat 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 a potential preventive vaccine 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 Pharmaceutical Companies, 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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