



News Release

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Johnson & Johnson Announces Submission of Application to the U.S. FDA for Emergency Use Authorization of its Investigational Single-Shot Janssen COVID-19 Vaccine Candidate

Johnson & Johnson intends to distribute vaccine to the U.S. government immediately following authorization, and expects to supply 100 million doses to the U.S. in the first half of 2021

NEW BRUNSWICK, N.J., February 4, 2021 – Johnson & Johnson (NYSE: JNJ) (the Company) today announced that Janssen Biotech, Inc., has submitted an application to the U.S. Food and Drug Administration (FDA) requesting Emergency Use Authorization (EUA) for its investigational single-dose Janssen COVID-19 vaccine candidate. The Company's EUA submission is based on [topline efficacy and safety data](#) from the Phase 3 ENSEMBLE clinical trial, demonstrating that the investigational single-dose vaccine met all primary and key secondary endpoints. The Company expects to have product available to ship immediately following authorization.

"Today's submission for Emergency Use Authorization of our investigational single-shot COVID-19 vaccine is a pivotal step toward reducing the burden of disease for people globally and putting an end to the pandemic," said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer at Johnson & Johnson. "Upon authorization of our investigational COVID-19 vaccine for emergency use, we are ready to begin shipping. With our submission to the FDA and our ongoing reviews with other health authorities around the world, we are working with great urgency to make our investigational vaccine available to the public as quickly as possible."

The Company has initiated rolling submissions with several health agencies outside the U.S., and will submit a Conditional Marketing Authorisation Application (cMAA) with the European Medicines Agency in the coming weeks.

Manufacturing and Supply Chain Information

The Janssen investigational vaccine is compatible with standard vaccine distribution channels. If authorized, Janssen's investigational single-dose vaccine is estimated to remain stable for two years at -4°F (-20°C), at least three months of which can be stored in most standard refrigerators at temperatures of 36°F–46°F (2°-8°C). The Company will ship the vaccine using the same cold chain technologies it uses today to transport other innovative medicines.

Janssen's Investigational COVID-19 Vaccine

The Janssen investigational COVID-19 vaccine leverages the Company's [AdVac® vaccine platform](#), which was also used to develop and manufacture Janssen's European Commission-approved Ebola vaccine regimen and construct its investigational Zika, RSV, and HIV vaccines. The safety profile observed was consistent with other investigational vaccines using Janssen's AdVac® technology among more than 200,000 people to date.

Phase 3 ENSEMBLE Study Design

The Phase 3 [ENSEMBLE](#) study is a randomized, double-blind, placebo-controlled clinical trial in adults 18 years old and older. The study was designed to evaluate the safety and efficacy of the Janssen investigational vaccine in protecting against both moderate and severe COVID-19 disease, with assessment of efficacy as of day 14 and as of day 28 as co-primary endpoints.

The trial, conducted in eight countries across three continents, includes a diverse and broad population.

Research and development activities for the investigational Janssen COVID-19 vaccine including the ENSEMBLE clinical trial and the delivery of doses for the U.S. has been funded in whole or in part with federal funds from the U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority (BARDA), under Contract No. HHSO100201700018C, and in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH) at the U.S. Department of Health and Human Services (HHS).

Janssen has worked with BARDA since 2015 on innovative solutions for influenza, chemical, biological, radiation and nuclear threats and emerging infectious diseases such as Ebola. In February 2020, Janssen and BARDA began work on the development of a COVID-19 vaccine based on Janssen's AdVac® technology.

For more information on the Company's multi-pronged approach to helping combat the pandemic, visit: www.jnj.com/coronavirus.

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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 of Johnson & Johnson

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.