



News Release

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Johnson & Johnson COVID-19 Vaccine Authorized by U.S. FDA For Emergency Use

First Single-Shot Vaccine in Fight Against Global Pandemic

Data demonstrated protection against COVID-19 related hospitalization and death, across countries with different variants

Available on not-for-profit basis for emergency pandemic use

Shipping vaccine immediately, delivering more than 20 million doses to U.S. in March, 100 million doses in first half of 2021

NEW BRUNSWICK, N.J., February 27, 2021 – Johnson & Johnson (NYSE: JNJ) (the Company) today announced that the U.S. Food and Drug Administration (FDA) has issued Emergency Use Authorization (EUA) for its single-dose COVID-19 vaccine, developed by the Janssen Pharmaceutical Companies of Johnson & Johnson, to prevent COVID-19 in individuals 18 years of age and older.

This decision was based on the totality of scientific evidence, including data from the Phase 3 ENSEMBLE study that demonstrated the vaccine was 85 percent effective in preventing severe disease across all regions studied, and showed protection against COVID-19 related hospitalization and death, beginning 28 days after vaccination.

The terms of the EUA allow use of the vaccine while more data are gathered. The Company plans to file for a Biologics License Application (BLA) with the FDA later in 2021.

“This milestone follows a year of incredible work by our dedicated teams and unprecedented collaboration with health leaders around the world – all of whom shared a goal of bringing a single-shot vaccine to the public,” said Alex Gorsky,

Chairman and Chief Executive Officer at Johnson & Johnson. “We will do everything we can to help bring this pandemic to an end, in the United States and throughout the world.”

“We believe the Johnson & Johnson single-shot COVID-19 vaccine is a critical tool for fighting this global pandemic, particularly as it shows protection across countries with different variants. A vaccine that protects against COVID-19, especially against the most dire outcomes of hospitalization and death, will help ease the burden on people and the strain on health systems worldwide,” said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer, Johnson & Johnson. “We look forward to our continued efforts around the world as we collectively aim to change the trajectory of this global pandemic.”

Johnson & Johnson is committed to making its COVID-19 vaccine available on a not-for-profit basis for emergency pandemic use. The Company has begun shipping its COVID-19 vaccine and expects to deliver enough single-shot vaccines by the end of March to enable the full vaccination of more than 20 million people in the U.S. The Company plans to deliver 100 million single-shot vaccines to the U.S. during the first half of 2021. The U.S. government will manage allocation and distribution of the vaccine in the U.S. This will be prioritized according to the populations identified by the CDC’s Advisory Committee on Immunization Practices (ACIP) guidelines.

Johnson & Johnson also recently [announced its submission](#) of a European Conditional Marketing Authorisation Application to the European Medicines Agency as well as its [filing for an Emergency Use Listing \(EUL\)](#) with the World Health Organization for its COVID-19 vaccine candidate. In addition, rolling submissions for the single-dose COVID-19 vaccine candidate have been initiated in several countries worldwide.

The EUA follows a [unanimous vote](#) by the U.S. FDA’s Vaccines and Related Biological Products Advisory Committee (VRBPAC) on February 26, 2021.

“We are thankful for the efforts of all those who have volunteered to participate in our clinical trials, our scientists, collaborators, clinical trial sites and investigators. Through the combined commitment of everyone involved, we have been able to discover, develop and manufacture a single-shot COVID-19 vaccine to protect people around the world,” said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, Johnson & Johnson.

Manufacturing and Supply Chain Information

The Johnson & Johnson COVID-19 single-dose vaccine is compatible with standard vaccine storage and distribution channels with ease of delivery to remote areas. The vaccine is estimated to remain stable for two years at -4°F (-20°C), and a maximum of three months at routine refrigeration at temperatures of 36-46°F (2 to 8°C). The Company will ship the vaccine using the same cold chain technologies it uses today to transport treatments for cancer, immunological disorders and other medicines. The COVID-19 vaccine should not be re-frozen if distributed at temperatures of 36°F–46°F (2°-8°C).

Johnson & Johnson’s COVID-19 Vaccine

The Company’s COVID-19 vaccine leverages the [AdVac® vaccine platform](#), a unique and proprietary technology that 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 Janssen COVID-19 vaccine has not been approved or licensed by the U.S. Food and Drug Administration (FDA), but has been authorized by FDA through an Emergency Use Authorization (EUA) for active immunization to prevent Coronavirus

Disease 2019 (COVID-19) in individuals 18 years of age and older. There is no FDA-approved vaccine to prevent COVID-19.

The FDA EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and full EUA Prescribing Information are available at:

<https://www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-HCP-fact-sheet.pdf>

Phase 3 ENSEMBLE Study Design

The Phase 3 [ENSEMBLE](#) study is a randomized, double-blind, placebo-controlled clinical trial in individuals 18 years of age and older. The study was designed to evaluate the safety and efficacy of the Company's vaccine candidate 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 study enrolled a total of 43,783 participants.

The trial, conducted in eight countries across three continents, includes a diverse and broad population including 34 percent of participants over age 60.

The study enrolled 44 percent of participants in the United States. Seventy-four percent of participants in the U.S. are White/Caucasian; 15 percent are Hispanic and/or Latinx; 13 percent are Black/African American; 6 percent are Asian and 1 percent are Native American.

Forty-one percent of participants in the study had comorbidities associated with an increased risk for progression to severe COVID-19.

Research and development activities for the Company's COVID-19 vaccine, including the ENSEMBLE clinical trial and the delivery of doses for the U.S., have been funded 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).

Johnson & Johnson has worked with BARDA since 2015 on innovative solutions for influenza, chemical, biological, radiation and nuclear threats and emerging infectious diseases such as Ebola.

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

Authorized Use

The Janssen COVID-19 vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

Important Safety Information

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE JANSSEN COVID-19 VACCINE?

Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have a fever
- have a bleeding disorder or are on a blood thinner

- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine

WHO SHOULD NOT GET THE JANSSEN COVID-19 VACCINE?

You should not get the Janssen COVID-19 Vaccine if you:

- had a severe allergic reaction to any ingredient of this vaccine.

HOW IS THE JANSSEN COVID-19 VACCINE GIVEN?

The Janssen COVID-19 Vaccine will be given to you as an injection into the muscle. The Janssen COVID-19 Vaccine vaccination schedule is a single dose.

WHAT ARE THE RISKS OF THE JANSSEN COVID-19 VACCINE?

Side effects that have been reported with the Janssen COVID-19 Vaccine include:

- Injection site reactions: pain, redness of the skin, and swelling.
- General side effects: headache, feeling very tired, muscle aches, nausea, fever.

There is a remote chance that the Janssen COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Janssen COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

These may not be all the possible side effects of the Janssen COVID-19 Vaccine. Serious and unexpected effects may occur. The Janssen COVID-19 Vaccine is still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital. Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to <https://vaers.hhs.gov/reportevent.html>. Please include "Janssen COVID-19 Vaccine EUA" in the first line of box #18 of the report form. In addition, you can report side effects to Janssen Biotech, Inc. at 1-800-565-4008.

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.

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).

Cautions 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 January 3, 2021, 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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