



## News Release

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## **Johnson & Johnson Announces U.S. CDC Advisory Committee Recommends First Single-Shot COVID-19 Vaccine for Adults 18 and Older in U.S.**

**NEW BRUNSWICK, N.J., February 28, 2021** – Johnson & Johnson (NYSE: JNJ) (the Company) today announced that the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) has recommended the first single-shot COVID-19 vaccine, developed by the Janssen Pharmaceutical Companies of Johnson & Johnson, for individuals 18 years of age and older under the Emergency Use Authorization (EUA) issued by the U.S. Food and Drug Administration (FDA).

"For more than 130 years, Johnson & Johnson has come to the aid of people during times of crisis, and we believe today's recommendation from the CDC to begin use of our vaccine as part of the U.S. national immunization program will add a critical tool in the fight against COVID-19," said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer at Johnson & Johnson. "This recommendation follows the FDA's decision to grant an Emergency Use Authorization for our single-shot vaccine, which has the potential to play a pivotal role in helping to end the COVID-19 pandemic."

ACIP is a body of independent health experts that advises the CDC on the types of populations and circumstances for which vaccines should be used. The ACIP recommendation will be forwarded to the Director of the CDC and the U.S. Department of Health and Human Services (HHS) for review and adoption.

The Company's single-shot COVID-19 vaccine [received EUA from the FDA](#) on February 27, 2021. 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.

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.

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](#) 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.

### **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 Candidate**

The Company's Janssen 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 the FDA through an Emergency Use Authorization (EUA).

The FDA EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and full EUA Prescribing Information are available [here](#).

For more information on the single-dose Janssen COVID-19 vaccine, visit: [www.janssencovid19vaccine.com](http://www.janssencovid19vaccine.com).

### **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](http://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](http://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](http://www.janssen.com). Follow us at @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](http://www.sec.gov), [www.jnj.com](http://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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