



News Release

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Johnson & Johnson Announces Submission of Emergency Use Authorization Amendment to the U.S. FDA to Support Booster of its Single-Shot COVID-19 Vaccine

Submission includes data showing a booster increased protection to 94 percent against moderate to severe/critical COVID-19 in the U.S.

Substantial increase in immune response when booster was given at six months

The Company's single-shot vaccine has demonstrated strong and long-lasting protection and durable immune responses in clinical studies

NEW BRUNSWICK, N.J., October 5, 2021 – Johnson & Johnson (NYSE: JNJ) announced it has submitted data to the U.S. Food and Drug Administration (FDA) to support use of a booster shot of the Johnson & Johnson COVID-19 vaccine in individuals 18 years of age and older.

The submission includes recent results from the [Phase 3 ENSEMBLE 2 study](#) that found a booster of the Johnson & Johnson COVID-19 vaccine given 56 days after the primary dose provided 94 percent protection against symptomatic (moderate to severe/critical) COVID-19 in the U.S. (CI, 58%-100%) and 100 percent protection (CI, 33%-100%) against severe/critical COVID-19, at least 14 days post-booster vaccination.

Also part of the submission is Phase 1/2a [data](#) showing that when a booster of the Johnson & Johnson COVID-19 vaccine was given six months after the single shot, antibody levels increased nine-fold one week after the booster and continued to climb to 12-fold higher four weeks after the booster. The vaccine, when given as a booster or primary dose, was generally well-tolerated.

“Our clinical program has found that a booster of our COVID-19 vaccine increases levels of protection for those who have received our single-shot vaccine to 94 percent. We look forward to our discussions with the FDA and other health authorities to support their decisions regarding boosters,” said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, Johnson & Johnson. “At the same time, we continue to recognize that a single-shot COVID-19 vaccine that provides strong and long-lasting protection remains a crucial component to vaccinating the global population.”

Last month, the Company released [data](#) reinforcing the strong and long-lasting protection of its COVID-19 vaccine. The largest real-world evidence study for a COVID-19 vaccine reported to date in the U.S. demonstrated stable vaccine effectiveness of 79 percent (CI, 77%-80%) for COVID-19-related infections and 81 percent (CI, 79%-84%) for COVID-19-related hospitalizations. There was no evidence of reduced effectiveness over the study duration from March to July 31, 2021. Comparable vaccine effectiveness was demonstrated when the study was extended to August 31, 2021, for an overall study duration of six months, including when the Delta variant became dominant in the U.S. Sequencing data were not available for analysis.

These data were consistent with the Phase 3 ENSEMBLE trial, where strong protection against severe/critical disease and death was observed at least 28 days post-final vaccination.

Interim results from a Phase 1/2a sub-study published in the [New England Journal of Medicine](#) in July demonstrated that both humoral (antibody) and cellular (T-cell) immune responses generated by the Johnson & Johnson single-shot COVID-19 vaccine were strong and stable through eight months after immunization, the length of time evaluated in the study. These peer-reviewed data provide further and deeper insights into the durable humoral and cellular immune responses elicited by the single-shot Johnson & Johnson COVID-19 vaccine, thus offering potentially a dual mechanism of protection against COVID-19 disease, including against disease caused by the Delta variant (B.1.617.2) and other SARS-CoV-2 [variants of concern](#). The cellular immune response induced by the Company’s AdVac® platform is strong and plays a role in both protection and durability.

The Company plans to submit the data to other regulators, the World Health Organization (WHO) and National Immunization Technical Advisory Groups (NITAGs) worldwide to inform decision-making on local vaccine administration strategies, as needed.

The Johnson & Johnson single-shot COVID-19 vaccine, developed by its Janssen Pharmaceutical Companies of Johnson & Johnson, received an [EUA in the United States](#) on February 27, 2021 and [Conditional Marketing Authorization](#) (CMA) by the European Commission on March 11. The World Health Organization (WHO) issued [Emergency Use Listing](#) on March 12, and the Company received an [interim recommendation](#) by the Strategic Advisory Group of Experts (SAGE) on Immunization for the WHO on March 17. Many more authorizations have been granted in countries worldwide, and regulatory submissions are ongoing.

For more information on the Company’s multi-pronged approach to helping combat the pandemic, visit: www.jnj.com/covid-19.

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Authorized Use

The Janssen COVID-19 vaccine is authorized for use in the U.S. 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
- have ever fainted in association with an injection

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
- Swollen lymph nodes
- Unusual feeling in the skin (such as tingling or a crawling feeling) (paresthesia), decreased feeling or sensitivity, especially in the skin (hypoesthesia)
- Persistent ringing in the ears (tinnitus)
- Diarrhea, vomiting

Severe Allergic Reactions

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

Blood Clots with Low Levels of Platelets

Blood clots involving blood vessels in the brain, lungs, abdomen, and legs along with low levels of platelets (blood cells that help your body stop bleeding), have occurred in some people who have received the Janssen COVID-19 Vaccine. In people who developed these blood clots and low levels of platelets, symptoms began approximately one to two weeks following vaccination. Reporting of these blood clots and low levels of platelets has been highest in females ages 18 through 49 years. The chance of having this occur is remote. You should seek medical attention right away if you have any of the following symptoms after receiving Janssen COVID-19 Vaccine:

- Shortness of breath
- Chest pain
- Leg swelling
- Persistent abdominal pain
- Severe or persistent headaches or blurred vision
- Easy bruising or tiny blood spots under the skin beyond the site of the injection

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.

Guillain Barré Syndrome

Guillain Barré syndrome (a neurological disorder in which the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis) has occurred in some people who have received the Janssen COVID-19 Vaccine. In most of these people, symptoms began within 42 days following receipt of the Janssen COVID-19 Vaccine. The chance of having this occur is very low. You should seek medical attention right away if you develop any of the following symptoms after receiving the Janssen COVID-19 Vaccine:

- Weakness or tingling sensations, especially in the legs or arms, that's worsening and spreading to other parts of the body
- Difficulty walking
- Difficulty with facial movements, including speaking, chewing, or swallowing
- Double vision or inability to move eyes
- Difficulty with bladder control or bowel function

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.

Please read Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including full EUA Prescribing Information available at www.JanssenCOVID19Vaccine.com/EUA-factsheet

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.

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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