Johnson & Johnson Single-Shot COVID-19 Vaccinations to Resume in the U.S. for All Adults Aged 18 and Older Following CDC and FDA Decision

April 23, 2021

Important information for healthcare providers and the public included in updated FDA Emergency Use Authorization Fact Sheets

NEW BRUNSWICK, N.J., April 23, 2021 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) (the Company) today announced that vaccinations with the Company's COVID-19 single-shot vaccine will resume for all adults aged 18 years and older in the U.S., under Emergency Use Authorization (EUA), following a decision from the United States Centers for Disease Control (CDC) and Food and Drug Administration (FDA).

The decision was based on a recommendation from the U.S. CDC Advisory Committee on Immunization Practices (ACIP), which followed a rigorous evaluation of data relating to a very rare adverse event involving blood clots in combination with low platelet counts (thrombosis with thrombocytopenia) observed within approximately one to two weeks following vaccination.

"As the global pandemic continues to devastate communities around the world, we believe a single-shot, easily transportable COVID-19 vaccine with demonstrated protection against multiple variants can help protect the health and safety of people everywhere. We will collaborate with health authorities around the world to educate healthcare professionals and the public to ensure this very rare event can be identified early and treated effectively," said Paul Stoffels, Chief Scientific Officer of Johnson & Johnson.

Johnson & Johnson has updated the EUA Fact Sheets for Healthcare Providers Administering Vaccine (Vaccination Providers), and Recipients and Caregivers for the Company's COVID-19 vaccine, to include information about the diagnosis and treatment of thrombosis with thrombocytopenia. The revised EUA fact sheets is available at: www.janssencovid19vaccine.com.

The CDC, FDA and American Society of Hematology have made information available about the proper recognition and management of this medical condition, and the unique treatment required for this type of blood clot. The health authorities advise that people who have received our COVID-19 vaccine and develop severe headache, chest pain, swelling in the leg, abdominal pain, tiny blood spots under the skin or excessive bruising within two weeks after vaccination should immediately contact their health care provider.

The Company continues to work with other healthcare authorities and regulators around the world to ensure this information is included in product labels for the Company's COVID-19 vaccine. On April 20, the European Medicines Agency's (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) also issued a recommendation, confirming the overall benefit-risk profile of the Company's COVID-19 vaccine remains positive.

Johnson & Johnson's COVID-19 Vaccine
The Johnson & Johnson COVID-19 Vaccine, developed by the Janssen Pharmaceutical Companies of Johnson & Johnson, received EUA from the FDA on February 27, 2021, to prevent COVID-19 in individuals 18 years of age and older.

This decision was based in part on the totality of scientific evidence, including data from the Phase 3 ENSEMBLE study that demonstrated the vaccine was 66.1 percent effective in preventing moderate to severe/critical disease and 85 percent effective in preventing severe/critical disease across all regions studied, 28 days post-vaccination. The vaccine 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.

On April 21, 2021, Johnson & Johnson announced the publication of primary data from the Phase 3 ENSEMBLE clinical trial in the *New England Journal of Medicine*. The primary analysis of the Company's single-dose COVID-19 vaccine follows the topline efficacy and safety data announced in January, showing the trial met all primary and key secondary endpoints and prevented COVID-19 related hospitalization and death across all study participants 28 days after vaccination. The data also show the vaccine to be consistently effective against symptomatic infection, including in South Africa and Brazil where there was a high prevalence of rapidly emerging SARS-CoV-2 variants.

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

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

Blood clots involving blood vessels in the brain, 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. Most people who developed these blood clots and low levels of platelets were 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.

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.

The FDA EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and full EUA Prescribing Information are 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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Media Contacts: Jake Sargent, +1 732-524-1090, JSargen3@its.jnj.com; Seema Kumar, +1 908-405-1144, SKumar10@its.jnj.com; Katie Buckley, +44 7900-655-261, KBuckle8@its.jnj.com; Investor Relations: Chris DelOrefice, +1 732-524-2955; Jennifer McIntyre, +1 732-524-3922