News Release

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Johnson & Johnson COVID-19 Vaccine Booster Shot Unanimously Recommended for Emergency Use Authorization by U.S. FDA Advisory Committee

Recommendation informed by Phase 3 findings showing a booster increased protection to 94 percent against moderate to severe/critical COVID-19 in the U.S.

Johnson & Johnson COVID-19 vaccine, when given as a booster or primary dose, was generally well-tolerated

FDA to decide whether to authorize a booster dose in the coming days

NEW BRUNSWICK, N.J., October 15, 2021 – Johnson & Johnson (NYSE: JNJ) (the Company) today announced the U.S. Food and Drug Administration's (FDA) Vaccines and Related Biological Products Advisory Committee (VRBPAC) unanimously voted 19-0 to recommend Emergency Use Authorization (EUA) for a booster dose of the Johnson & Johnson COVID-19 vaccine for adults aged 18 and older at least two months following initial vaccination with the single-shot vaccine.

The vote was based on findings from two Company clinical trials, including the Phase 3 ENSEMBLE 2 study, which evaluated a booster dose of the Johnson & Johnson COVID-19 vaccine administered two months after the single-shot, as well as a large and robust real-world evidence study. The Company also presented data that support the increased potential of a booster when administered at six months. Phase 3 clinical data and real-world data both demonstrated the Johnson & Johnson single-shot COVID-19 vaccine was strong and long-lasting.

"Today's recommendation is based on the totality of evidence, with clinical and real-world data showing that while a single shot offers strong and long-lasting protection against

COVID-19, a booster given after the single-dose primary vaccination increases protection, in particular against symptomatic COVID-19," said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer, Johnson & Johnson.

"Johnson & Johnson is steadfast in its commitment to protect as many people globally as possible against the continued spread of COVID-19," said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, Johnson & Johnson. "Today's recommendation by the VRBPAC is another step toward ensuring that those who have received the single-shot Johnson & Johnson vaccine – or will receive it in the future – are provided the opportunity to increase their protection against COVID-19. We look forward to sharing these data with regulatory bodies and advisory groups around the world to address the continued threat of COVID-19."

The Company's EUA amendment submission included results from the Phase 3 ENSEMBLE 2 study, which found a booster dose at two months provided 94 percent protection against symptomatic (moderate to severe/critical) COVID-19 in the United States (CI, 58%-100%) and 100 percent protection (CI, 33%-100%) against severe/critical COVID-19, at least 14 days post-booster vaccination. Also submitted were findings from a Phase 1/2a study evaluating a booster dose given six months after the first shot, which show 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, with no new safety signals observed in the two-dose ENSEMBLE 2 trial compared with single-dose studies.

The submission also included data from a large and robust U.S. real-world evidence study, conducted from March to July 31, 2021, and recently extended to August 31, 2021. These real-world data demonstrated the single-dose Johnson & Johnson COVID-19 vaccine showed stable vaccine effectiveness of 76 percent (CI, 75%-77%) for COVID-19-related infections and 81 percent (CI, 79%-84%) for COVID-19-related hospitalizations, with no evidence of reduced effectiveness over the study duration of six months – including when the Delta variant became dominant in the U.S. (sequencing data were not available for analysis).

Johnson & Johnson remains committed to helping end this pandemic as quickly as possible and is committed to diligently generating and evaluating real-world evidence, as well as evidence from its ongoing clinical trial program.

The Company anticipates a decision from the FDA on the EUA amendment for a booster dose of the Johnson & Johnson COVID-19 vaccine in the coming days, and plans to submit relevant 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 Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) will discuss the use of boosters and provide a potential recommendation on October 21.

In the U.S., there is sufficient supply to support boosting to those who have received the more than 15.1 million doses of the Johnson & Johnson COVID-19 vaccine that have been administered as primary vaccinations.

The Johnson & Johnson single-shot COVID-19 vaccine, developed by its Janssen Pharmaceutical Companies of Johnson & Johnson, received initial 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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