News Release

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:
Jessica Moore
+1 732 524 2955

Johnson & Johnson Announces Positive CHMP Opinion for a Booster Shot of its COVID-19 Vaccine

CHMP recommendation based on data showing a booster (second shot) of the Johnson & Johnson COVID-19 vaccine increased protection to 75 percent against symptomatic COVID-19 infection globally

Data also demonstrated 100 percent protection against severe COVID-19, at least 14 days post-booster vaccination

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

NEW BRUNSWICK, N.J., December 15, 2021 – Johnson & Johnson (NYSE: JNJ) (the Company) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a Positive Opinion for use of the Company's COVID-19 vaccine as a booster for adults aged 18 and older at least two months after primary vaccination with a single-shot of the Johnson & Johnson COVID-19 vaccine, and as a 'mix and match' booster following primary vaccination with an approved two-shot mRNA COVID-19 vaccine regimen (known as heterologous boosting).

"We are pleased with today's Positive Opinion from the CHMP supporting the use of our COVID-19 vaccine as a booster for eligible individuals in Europe," said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, Johnson & Johnson. "There is a growing body of data showing that the Johnson & Johnson COVID-19 vaccine induces broad and durable humoral and cellular immune responses, whether administered as a single shot for an efficient response to the pandemic, or as a booster shot after at least two months to

strengthen protection against symptomatic COVID-19. Cellular immune responses are showing potential to be important for both breadth of protection and durability."

The CHMP Opinion was based on a comprehensive data package that included results from the Phase 3 ENSEMBLE 2 study, which found a booster of the Johnson & Johnson COVID-19 vaccine given two months after the primary shot provided 75 percent protection against symptomatic (moderate to severe) COVID-19 globally (CI, 55%-87%) and 94 percent protection against symptomatic (moderate to severe) COVID-19 in the U.S. (CI, 59%-100%). It also demonstrated 100 percent protection against severe COVID-19, at least 14 days post-booster vaccination (CI, 33%-100%). The vaccine, when given as a booster or primary shot, was generally well-tolerated, with no new safety signals observed in the two-shot ENSEMBLE 2 trial compared with single-shot studies.

Also included in the data package reviewed by the CHMP were results from multiple real-world evidence (RWE) studies, including the Company's previously announced RWE study that demonstrated similar estimates of single-shot vaccine effectiveness as observed in our randomized clinical trials. The effectiveness estimates remained stable with no evidence of reduced effectiveness over time before the Delta variant emerged and after it became the dominant strain in the U.S. from March through August (sequencing data were not available for analysis).

The CHMP recommendation is supported by latest data for heterologous boosting with the Johnson & Johnson COVID-19 vaccine. Interim data from the National Institute of Allergy and Infectious Disease (NIAID) "MixNMatch" study demonstrated that a booster of the Johnson & Johnson COVID-19 vaccine increases immune response regardless of a person's primary vaccination. A second study by the Beth Israel Deaconess Medical Center (BIDMC), including a subset of participants from the Janssen-sponsored COV2008 study, demonstrated the potential benefits of heterologous boosting: a booster shot of the Johnson & Johnson vaccine administered at six months after a two-shot primary regimen of the Pfizer/BioNTech vaccine, increased both antibody and T-cell responses. In these participants, antibodies continued to increase for at least four weeks whereas in individuals who received a homologous boost with the BNT162b2 vaccine, antibodies declined from week two to week four post-boost, resulting in similar antibody levels in both groups.

The Company's single-shot COVID-19 vaccine, developed by its Janssen Pharmaceutical Companies of Johnson & Johnson, received an Emergency Use Authorization in the United States on 27 February 2021 and Conditional Marketing Authorisation (CMA) by the European Commission on 11 March. On 21 October 2021, the U.S. Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) authorized for emergency use a booster shot of the Johnson & Johnson COVID-19 vaccine for adults aged 18 and older. On 9 December 2021, the Strategic Advisory Group of Experts (SAGE) on Immunization for the World Health Organization (WHO) supported the use of the Johnson & Johnson COVID-19 vaccine as a heterologous booster shot in persons aged 18 years and above.

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

###

AUTHORIZATION OF 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).

- Primary vaccination regimen for the Janssen COVID-19 Vaccine is a single-dose (0.5 mL) administered to individuals 18 years of age and older.
- A single Janssen COVID-19 Vaccine booster dose (0.5 mL) may be administered at least 2 months after the primary vaccination to individuals 18 years of age and older.
- A single booster dose of the Janssen COVID-19 Vaccine (0.5 mL) may be administered to individuals 18 years of age and older as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.

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 <u>NOT</u> GET THE JANSSEN COVID-19 VACCINE?

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

- had a severe allergic reaction after a previous dose of this vaccine.
- had a severe allergic reaction to any ingredient of this vaccine.
- had a blood clot along with a low level of platelets (blood cells that help your body stop bleeding) following Janssen COVID-19 Vaccine or following AstraZeneca's COVID-19 vaccine (not authorized or approved in the United States).

HOW IS THE JANSSEN COVID-19 VACCINE GIVEN?

The Janssen COVID-19 Vaccine will be given to you as an injection into the muscle.

<u>Primary Vaccination:</u> The Janssen COVID-19 Vaccine is administered as a single dose.

Booster Dose:

- A single booster dose of the Janssen COVID-19 Vaccine may be administered at least two months after primary vaccination with the Janssen COVID-19 Vaccine.
- A single booster dose of the Janssen COVID-19 Vaccine may be administered to individuals 18 years of age and older who have completed primary vaccination with a different authorized or approved COVID-19 vaccine. Please check with your health care provider regarding timing of the booster 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.
- Blood clots.
- 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 after vaccination. Blood clots with low levels of platelets following the Janssen COVID-19 Vaccine have been reported in males and females, across a wide age range of individuals 18 years and older; reporting has been highest in females ages 30 through 49 years (about 1 case for every 100,000 vaccine doses administered), and about 1 out of every 7 cases has been fatal. You should seek medical attention right away if you have any of the following symptoms after receiving the 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.

CAN I RECEIVE THE JANSSEN COVID-19 VACCINE AT THE SAME TIME AS OTHER VACCINES?

Data have not yet been submitted to FDA on administration of the Janssen COVID-19 Vaccine at the same time as other vaccines. If you are considering receiving the Janssen COVID-19 Vaccine with other vaccines, discuss your options with your healthcare provider.

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, manufacture and distribution of the Johnson & Johnson COVID-19 vaccine. 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.

###