Media Statement

July 14, 2021

Johnson & Johnson Single-Shot COVID-19 Vaccine Demonstrated a Durable Immune Response and Elicited Dual Mechanisms of Protection Against Delta and Other SARS-CoV-2 Variants of Concern in Data Published in *New England Journal of Medicine*

Antibody and T-cell immune responses strong and stable at eight months after immunization

Demonstrated neutralizing antibody activity against the Delta variant (B.1.617.2) over time

NEW BRUNSWICK, N.J., July 14, 2021 – Interim results from a Phase 1/2a sub-study published in the *New England Journal of Medicine (NEJM)* 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 to date. Data showed that T-cell responses – including the important CD8+ T-cells that seek out and destroy infected cells – persisted over the eight-month timeframe examined. The Company announced topline preprint study results from this Phase 1/2a sub-study on July 1, 2021.

Data from the study conducted in collaboration with Dan Barouch, M.D., Ph.D., et al. of Beth Israel Deaconess Medical Center suggest maturation of B-cell response without further boosting. Mature B-cells produce antibodies, which can help fight the virus that causes COVID-19.

Findings indicate that a single dose of the Johnson & Johnson COVID-19 vaccine elicited dual mechanisms 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, including the Alpha (B.1.1.7), Beta (B.1.351), Gamma (P.1), Epsilon (B.1.429) and Kappa (B.1.617.1) variants, as well as the original SARS-CoV-2 strain (WA1/2020). These data suggest an expansion of neutralizing antibodies over eight months, along with the observations of durable T-cell responses and the suggestion of B-cell maturation.

"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 the Delta variant and other variants of concern," said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, Johnson & Johnson. "The study showed that variant specific neutralizing antibodies increased over the eight months examined after vaccination which suggests the maturation of B-cell responses. In addition, the T-cell responses are especially strong and stable over time, which is also potentially important for activity against these variants."

Sum total of recent data affirm ability to generate multiple components of immune responses
These data also extend and complement previously published results in *Nature*, which provided evidence of the vaccine's ability to elicit multiple components of the immune system in individuals, as well as preclinical data in *Nature* related to efficacy against SARS-CoV-2 infection due to the Beta variant in non-human primates. Collectively, these analyses indicate that the potential efficacy of vaccines against COVID-19, including disease caused by variants, should be considered in a broader immunological context regarding the role of non-neutralizing antibodies, B- and T-cells.

Additional data from a new analysis of blood samples obtained from a subset of participants (n=8) in the Phase 3 ENSEMBLE study posted on *bioRxiv* showed that the Johnson & Johnson single-shot COVID-19 vaccine elicited neutralizing antibody activity against the Delta variant at a higher level than what was recently observed for the Beta variant in South Africa.

Phase 1/2a Study Design (VAC31518COV1001)
This ongoing Phase 1/2a multi-center, randomized, double-blind, placebo-controlled trial aims to evaluate the safety, reactogenicity and immunogenicity of the Janssen COVID-19 Vaccine at two dose levels ($5x10^{10}$ or $1x10^{11}$ virus particles), administered intramuscularly as single-dose or two-dose schedules, eight weeks apart, in healthy adults. The study is ongoing at multiple clinical sites in Belgium and the United States.

The results from this sub-study are from cohort 1b of this ongoing Phase 1/2a study, which enrolled 25 adults who are 18-55 years of age at a single site at Beth Israel Deaconess Medical Center for detailed descriptive exploratory immunogenicity studies. Additional follow-up with trial participants is currently underway.

Johnson & Johnson's COVID-19 Vaccine
The Johnson & Johnson COVID-19 vaccine leverages the AdVac® vaccine platform 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.

This Phase 1/2a clinical trial has 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 other transaction authority ("OTA") agreement No. HHSO100201700018C.

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

###

What Is the Janssen COVID-19 Vaccine?
The Janssen COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of the Janssen COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

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 <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 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.

<u>Severe Allergic Reactions</u>
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

<u>Blood Clots with Low Levels of Platelets</u>
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**.

Cautions Concerning Forward-Looking Statements

This media statement 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.

###