News Release

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Johnson & Johnson COVID-19 Vaccine Demonstrates 85 Percent Effectiveness against Hospitalization in South Africa when Omicron was Dominant

Separate analysis showed Johnson & Johnson COVID-19 vaccine booster generated 41-fold increase in neutralizing antibodies and a 5-fold increase in T-cells against Omicron

NEW BRUNSWICK, N.J., December 30, 2021 – Johnson & Johnson (NYSE: JNJ) (the Company) today announced new preliminary results from the South African Phase 3b Sisonke study which showed that a homologous (same vaccine) booster shot of the Johnson & Johnson COVID-19 vaccine (Ad26.COV2.S) demonstrated 85 percent effectiveness against COVID-19-related hospitalization. The study, conducted by the South African Medical Research Council (SAMRC), showed that the Johnson & Johnson booster reduced the risk of hospitalization from COVID-19 among healthcare workers in South Africa after Omicron became the dominant variant. During the months studied (mid-November to mid-December) the frequency of Omicron increased from 82 to 98 percent of COVID-19 cases in South Africa as reported by GISAID, an initiative that provides COVID-19 data.

A second, separate analysis of the immune response to different vaccine regimens, conducted by Beth Israel Deaconess Medical Center (BIDMC), demonstrated that a heterologous booster (different vaccine) of the Johnson & Johnson COVID-19 vaccine in individuals who initially received the BNT162b2 mRNA vaccine generated a 41-fold increase in neutralizing antibody responses by four weeks following the boost and a 5-fold increase in CD8+ T-cells to Omicron by two weeks. A homologous boost with BNT162b2 generated a 17-fold increase in neutralizing antibodies by four weeks following the boost and a 1.4-fold increase in CD8+ T-cells by two weeks.

The increase in CD8+ T-cells generated by the Johnson & Johnson vaccine may be key to explaining the high levels of effectiveness against severe COVID-19 disease and

hospitalization in the Sisonke 2 study, as the Omicron variant has been shown to escape neutralizing antibodies.[1]

"Data from the Sisonke 2 study confirm that the Johnson & Johnson COVID-19 booster shot provides 85 percent effectiveness against hospitalization in areas where Omicron is dominant. This adds to our growing body of evidence which shows that the effectiveness of the Johnson & Johnson COVID-19 vaccine remains strong and stable over time, including against circulating variants such as Omicron and Delta," said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, LLC, Johnson & Johnson. "We believe that the protection could be due to the robust T-cell responses induced by the Johnson & Johnson COVID-19 vaccine. Furthermore, these data suggest that Omicron is not affecting the T-cell responses generated by our vaccine."

The data have been submitted to the pre-print server *medRxiv* by the studies' authors, with anticipation of publication in peer-reviewed journals.

Phase 3b Sisonke 2 Booster Shot Study in South African Healthcare Workers
Data from the Sisonke 2 trial (n=227,310), conducted among healthcare workers in South Africa who received the single-shot Johnson & Johnson COVID-19 vaccine as a primary dose, show that the Johnson & Johnson COVID-19 booster increased vaccine effectiveness (VE) against hospitalization to 85 percent. When a booster shot was administered six to nine months after a primary single dose, VE increased over time from 63 percent (95% CI, 31-81%) at 0-13 days, to 84 percent (95% CI, 67-92%) at 14-27 days and 85 percent (95% CI, 54-95%) at 1-2 months post-boost.

Sisonke 2 was conducted in approximately 350 vaccination centers across all nine provinces of South Africa. Utilizing data from Discovery Health, a South African managed care organization, trial investigators determined VE of the Johnson & Johnson COVID-19 booster shot (n=69,092) as compared to other individuals enrolled in the same managed care organization, during the period from November 15, 2021, through December 20, 2021.

Enrollment for the Sisonke 2 arm of the trial commenced just prior to the onset of the Omicron wave in South Africa, allowing researchers to evaluate the effectiveness of the Company's COVID-19 vaccine specifically as Omicron became the dominant variant in the country. Genomic characterization of isolates from COVID-19 cases was not conducted in this trial.

Healthcare workers have an increased risk of being infected with COVID-19, and in countries such as South Africa, which have a significant population living with comorbidities, the impacts of SARS-CoV-2 infections in healthcare workers are especially profound. The majority of South African healthcare workers who have died of COVID-19 had at least one comorbidity, and many had multiple comorbidities.

"Even before you factor in the increased infectiousness of Omicron, we have to remember that healthcare workers on the frontlines are at a greatly increased risk of being affected by COVID-19 in the first place," said Glenda E. Gray, MBBCH, FCPaed (SA), President and CEO of the SAMRC. "We are therefore encouraged to see that boosting with the Johnson & Johnson COVID-19 vaccine regimen provides strong protection in a challenging real-world setting where there is an elevated risk of exposure – not just to COVID-19, but to the highly transmissible Omicron variant."

Dr. Nicholas Crisp, the Deputy Director General of the South African National Department of Health said "The data showing the effectiveness of the Ad26.COV.2 vaccine booster against

Omicron in Sisonke is important, as this vaccine is part of our arsenal to combat COVID-19. This data should reassure healthcare workers who have not taken their booster to get vaccinated as soon as possible."

Antibody and T-Cell Responses After Heterologous Boosting Regimen Greater than After Homologous Regimen Against Omicron Variant

An analysis of 65 individuals who received primary vaccination with two doses of an mRNA COVID-19 vaccine (BNT162b2), followed by a homologous booster shot of BNT162b2 (n=24) or a heterologous booster with the Johnson & Johnson COVID-19 vaccine (n=41) after at least six months, found both regimens increased humoral and cellular responses against Omicron.

Antibody responses against Omicron were boosted by both the Johnson & Johnson COVID-19 vaccine and the BNT162b2 vaccine, with the Johnson & Johnson COVID-19 vaccine increasing neutralizing antibody titers by 41-fold at four weeks post-boost. The BNT162b2 vaccine was found to increase antibody titers to a higher level at week two post-boost, before declining to represent a 17-fold increase at week four post-boost. The progressive increase in antibodies the weeks following a vaccination of a Johnson & Johnson booster is similar to that seen following the first vaccine. The rapid immune response followed by waning of the antibody response after the BNT162b2 booster is also similar to that seen following the two-dose priming regimen.

The Johnson & Johnson COVID-19 vaccine boosted median Omicron-reactive CD8+ T-cells by 5.5-fold, and Omicron-reactive CD4+ T-cells by 3.1-fold, while the homologous (BNT162b2) regimen boosted both Omicron-reactive CD4+ and CD8+ T-cells by 1.4-fold.

T-cells can target and destroy cells infected by the virus that causes COVID-19 and are believed to contribute to protection against severe disease. Specifically, CD8+ T-cells can directly destroy infected cells and are aided by CD4+ T-cells.

These data suggest that heterologous boosting has the potential to induce strong cell-mediated immunity, which is important for immune memory and protection against severe lower respiratory tract disease. The durability of heterologous and homologous boost regimens for the SARS-CoV-2 Omicron variant remain to be determined.

"As the Omicron variant has mutated from the original SARS-CoV-2 strain, there is a need to understand how effective currently authorized COVID-19 vaccines remain at protecting against severe disease," said Dan Barouch, M.D., Ph.D., Director of the Center for Virology and Vaccine Research at BIDMC. "Our analysis shows that a booster shot of the Johnson & Johnson COVID-19 vaccine generated a robust increase in both neutralizing antibodies and T-cells to Omicron."

Additional Information

The Johnson & Johnson COVID-19 vaccine has been authorized as booster by multiple regulators and healthcare bodies around the world. Johnson & Johnson continues 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.

On December 16, 2021, the U.S. Centers for Disease Control and Prevention (CDC) endorsed updated recommendations made by the Advisory Committee on Immunization Practices (ACIP) for the prevention of COVID-19, expressing a clinical preference for individuals to receive an mRNA COVID-19 vaccine over the Johnson & Johnsons COVID-19

vaccine. In the U.S., individuals who are unable or unwilling to receive an mRNA vaccine will continue to have access to the Johnson & Johnson COVID-19 vaccine.

The Johnson & Johnson COVID-19 vaccine is an important choice for people who can't or won't return for multiple vaccinations or who would remain unvaccinated without an alternative to the mRNA vaccines. The Johnson & Johnson COVID-19 vaccine aligns with the World Health Organization's (WHO) recommendations for medical interventions in a pandemic setting, which emphasize ease of distribution, administration, and compliance.

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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Dr. Dan Barouch and Dr. Glenda E. Gray are independent study investigators who have collaborated with Janssen Research & Development, LLC on clinical trials of the Johnson & Johnson COVID-19 vaccine.

AUTHORIZATION OF USE
The Johnson & Johnson COVID-19 vaccine, also known as 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.
Primary Vaccination: 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 subsequently filed Quarterly Reports on Form 10-Q and other 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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[1] Planas D., et al. Nature. Considerable escape of SARS-CoV-2 Omicron to antibody neutralization. Available at: https://www.nature.com/articles/d41586-021-03827-2. Last accessed: December 2021.