News Release

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Real World Evidence Shows Johnson & Johnson COVID-19 Vaccine Demonstrates Durable Protection Against Breakthrough Infection, Hospitalization, and Intensive Care Unit Admission in the United States

NEW BRUNSWICK, N.J., January 6, 2022 – Johnson & Johnson (NYSE: JNJ) (the Company) today announced new results from the largest study to date on the durability of COVID-19 vaccines in the United States (U.S.), showing that a single shot of the Johnson & Johnson COVID-19 vaccine resulted in long-lasting protection for up to six months against COVID-19 breakthrough infections, hospitalizations, and intensive care unit (ICU) admissions. The study was sponsored by the Janssen Pharmaceutical Companies of Johnson & Johnson and conducted in partnership with the Department of Science-Aetion, Inc, and the Division of Pharmacoepidemiology, Department of Medicine at Brigham and Women's Hospital and Harvard Medical School.

"We continue to undertake extensive efforts to study the durability of protection offered by the Johnson & Johnson vaccine amidst the ever-changing COVID-19 pandemic," said Mathai Mammen, M.D., Ph.D., Executive Vice President, Pharmaceuticals, Janssen Research & Development LLC, Johnson & Johnson. "While these are rapidly evolving data, we are seeing vaccine effectiveness against COVID-19-related hospitalization of approximately 80 percent from a single shot of the Johnson & Johnson vaccine, and this level of protection holds steady across the length of time studied thus far – up to six months. The robust and sustained durability of our COVID-19 vaccine reflects its unique underlying immunology. We previously reported that our vaccine induces a strong antibody response as well as an especially strong increase in T-cells that is consistent across variants, including Omicron."

The new study posted on *medRxiv* comprehensively looked at the durability profiles for all three vaccines authorized or approved in the U.S. using the same methodology across three outcomes of interest: COVID-19 breakthrough infections, hospitalizations, and ICU admissions.

The study showed that the effectiveness of the Johnson & Johnson COVID-19 vaccine against breakthrough infections and hospitalizations remained durable. The mRNA vaccines (two-doses) showed waning effectiveness for hospitalizations and breakthrough infections. All three vaccines showed no evidence of waning protection against COVID-19-related ICU admissions at any point, showing strong sustained protection against critically severe disease. The study was not designed to compare the durability of vaccines.

New Real World Evidence Study Details
Comprehensive studies to date on the durability of all vaccines authorized or approved for use in the U.S. have been limited, with many focusing on high-risk populations[1,2,3,4,5,6,7] or specific geographic regions or states.[8,9,10] This is the largest COVID-19 real-world effectiveness durability study to date in the U.S., and the first to analyze the durability of baseline protection up to six months for all three U.S. authorized or approved vaccines, and for three COVID-19 outcomes of interest (breakthrough infections, hospitalizations, and ICU admissions). Researchers utilized national claims, laboratory, and hospital data covering 168 million individuals to conduct a matched case-control study between January 1 and September 7, 2021 for 17 million fully vaccinated individuals matched on calendar time, 3-digit zip code, age, sex, and comorbidity scores.

The study assessed durability by measuring the Odds Ratio (OR), which represents the odds of a fully vaccinated individual having an outcome (breakthrough infection, hospitalization, or ICU admission) in each month relative to the odds of having an outcome in the first month after full vaccination. An OR greater than one indicates waning of the vaccine protection over time for that outcome. The study authors acknowledged that direct comparisons of OR between vaccines should not be made as there may remain baseline differences including initial effectiveness between the three vaccine cohorts.

Johnson & Johnson COVID-19 vaccine (single-shot)
The Johnson & Johnson COVID-19 vaccine demonstrated a profile that showed durability of effectiveness up to 6 months for hospitalizations and ICU admissions across the study period, with a modest increase in breakthrough infections starting in month 4.

- The initial level of effectiveness at month 1 after full vaccination was found to be 81% (95% CI: 76%-82%) for hospitalizations and 74% (95% CI: 72%-75%) for breakthrough infections.
- Durability:
    - There was no evidence of waning protection against COVID-19-related hospitalization during the study period (OR = 1.25, 95% CI [0.86, 1.80] in month 5+).
    - There was no evidence of waning protection against breakthrough infection in the first three months of follow-up, with modest waning of protection against breakthrough infection observed in month 4 (OR = 1.16, 95% CI [1.04, 1.29]) and in month 5+ (OR = 1.31, 95% CI [1.18, 1.47]).
    - There was no evidence of waning protection against COVID-19-related ICU admissions at any point (OR = 1.40, 95% CI [0.43, 4.55] in month 4).
    - There was not sufficient follow-up to include a category for 6+ months for breakthrough infections and hospitalizations.

BNT162b2 vaccine effectiveness (two doses 21-42 days apart)
BNT162b2 demonstrated a profile that showed an increase in hospitalizations and breakthrough infections starting in month 2, with no waning of effectiveness for ICU admissions over the study period.

- The initial level of effectiveness at month 1 after full vaccination was found to be 89% (95% CI: 88%-90%) for hospitalizations and 88% (95% CI: 87%-88%) for breakthrough infections.
- Durability:
    - There was evidence that protection waned against COVID-19-related hospitalization over time as compared to the first month of follow-up from vaccination (OR = 3.97, 95% CI [3.26, 4.83] in month 6+).
    - There was evidence that protection waned against breakthrough infection, where the waning was successively higher for each month of follow-up (OR = 2.93, 95% CI [2.72, 3.15] for BNT162b2 in month 6+).
    - There was no evidence of waning protection against COVID-19-related ICU admissions at any point (OR = 1.36, 95% CI [0.80, 2.30] in month 4).

mRNA-1273 vaccine effectiveness (two doses 28-42 days apart)
mRNA-1273 demonstrated a profile that showed an increase in hospitalizations in month 3 and breakthrough infections in month 2, with no waning of effectiveness for ICU admissions over the study period.

- The initial level of effectiveness at month 1 after full vaccination was found to be 94% (95% CI: 93%-95%) for hospitalizations and 92% (95% CI: 91%-92%) for breakthrough infections.
- Durability:
    - There was evidence of modest waning in protection against COVID-19-related hospitalization over time as compared to the first month of follow-up from vaccination (OR = 1.66, 95% CI [1.26, 2.19] in month 6+).
    - There was evidence that protection waned against breakthrough infection, where the waning was successively higher for each month of follow-up (OR = 2.76, 95% CI [2.51, 3.04] in month 6+).
    - There was no evidence of waning protection against COVID-19-related ICU admissions at any point (OR = 1.17, 95% CI [0.64, 2.13] in month 4).

Other Recent Data for the Johnson & Johnson COVID-19 Vaccine
These results add to the body of evidence showing that the Johnson & Johnson COVID-19 vaccine elicits protection against variants of concern. Recently, preliminary data from the Phase 3b Sisonke study, conducted in November and December of 2021, demonstrated 85 percent effectiveness for the homologous (same vaccine) booster shot of the Johnson & Johnson vaccine, against COVID-19-related hospitalization in South Africa when Omicron was dominant.[11]

The Company also recently announced that a heterologous booster (different vaccine) of the Johnson & Johnson 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.[12] 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.

Additional Information
The Johnson & Johnson COVID-19 vaccine has been authorized as a booster by multiple regulators and healthcare bodies around the world. Johnson & Johnson continues to submit relevant data to healthcare 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 & Johnson COVID-19 vaccine. 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 in the U.S. 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 WHO's 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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Authorized Use
The Janssen COVID-19 Vaccine also known as the Johnson & Johnson 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 NOT 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.

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 and 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. 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.

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.

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