News Release

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Johnson & Johnson Announces Real-World Evidence and Phase 3 Data Confirming Strong and Long-Lasting Protection of Single-Shot COVID-19 Vaccine in the U.S.

Additional data show a booster increases protection

94 percent protection in the U.S. with booster given at two months
Four-fold increase in antibodies when given at two months
12-fold increase in antibodies when booster given at six months

NEW BRUNSWICK, N.J., September 21, 2021 – Johnson & Johnson (NYSE: JNJ) (the Company) today announced new data reinforcing the strong and long-lasting protection of its COVID-19 vaccine. New data also showed that protection against COVID-19 increases when a booster shot of the Johnson & Johnson vaccine is administered. The safety profile of the vaccine remained consistent and was generally well-tolerated when administered as a booster.

"Our large real-world evidence and Phase 3 studies confirm that the single-shot Johnson & Johnson vaccine provides strong and long-lasting protection against COVID-19-related hospitalizations. Additionally, our Phase 3 trial data further confirm protection against COVID-19-related death," said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, Johnson & Johnson. "Our single-shot vaccine generates strong immune responses and long-lasting immune memory. And, when a booster of the Johnson & Johnson COVID-19 vaccine is given, the strength of protection against COVID-19 further increases."

"It is critical to prioritize protecting as many people as possible against hospitalization and death given the continued spread of COVID-19. A single-shot COVID-19 vaccine that is easy to use, distribute and administer, and that provides strong and long-lasting protection is

crucial to vaccinating the global population," said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer at Johnson & Johnson. "At the same time, we now have generated evidence that a booster shot further increases protection against COVID-19 and is expected to extend the duration of protection significantly."

The Company has provided available data to the U.S. Food and Drug Administration (FDA) and plans to submit the 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 data are summarized below:

Johnson & Johnson single-shot vaccine showed strong and long-lasting protection in the real world

The largest real-world evidence study for a COVID-19 vaccine reported to date in the U.S. demonstrated stable vaccine effectiveness of 79 percent (CI, 77%-80%) for COVID-19-related infections and 81 percent (CI, 79%-84%) for COVID-19-related hospitalizations. There was no evidence of reduced effectiveness over the study duration, including when the Delta variant became dominant in the U.S. Sequencing data were not available for analysis. The study included 390,000 people who received the Johnson & Johnson COVID-19 vaccine versus approximately 1.52 million unvaccinated people matched on age, sex, time, three-digit zip code, and comorbidities and predictors for COVID-19 infection severity conducted from March to late July 2021.

These data were consistent with the Phase 3 ENSEMBLE trial, where strong protection against severe/critical disease and death was observed at least 28 days post-final vaccination:

- 75 percent overall efficacy (CI, 65%-82%) against severe/critical COVID-19, across all age cohorts and all countries included in the study.
- 74 percent efficacy in the U.S. against severe/critical COVID-19 (CI, 39%-91%); 89 percent against hospitalization (CI, 24%-100%); 83 percent against COVID-19-related death (CI, 41%-97%).

Booster shot at two months provided 94 percent protection against COVID-19 in the U.S.

The Phase 3 ENSEMBLE 2 study showed that another shot of the Johnson & Johnson COVID-19 vaccine given 56 days after the first provided:

- 100 percent protection (CI, 33%-100%) against severe/critical COVID-19 – at least 14 days post-final vaccination.
- 75 percent protection against symptomatic (moderate to severe/critical) COVID-19 globally (CI, 55%-87%).
- 94 percent protection against symptomatic (moderate to severe/critical) COVID-19 in the U.S. (CI, 58%-100%).

When a booster of the Johnson & Johnson COVID-19 vaccine was given two months after the first shot, antibody levels rose to four to six times higher than observed after the single shot.

Booster shot at six months provided 12-fold increase in antibodies

When a booster of the Johnson & Johnson COVID-19 vaccine was given six months after the single shot, antibody levels increased nine-fold one week after the booster and continued to climb to 12-fold higher four weeks after the booster. All rises were irrespective of age.

The Johnson & Johnson single-shot COVID-19 vaccine, developed by its Janssen Pharmaceutical Companies of Johnson & Johnson, received an Emergency Use Authorization (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.

- Additional Notes -

Real-World Evidence Study
In the largest real-world evidence Vaccine Effectiveness (VE) study of participants receiving the Johnson & Johnson single-shot COVID-19 vaccine in the U.S. to date, the Janssen R&D Data Science team, Harvard University and Aetion utilized the HealthVerity database, which consisted of longitudinal de-identified patient-level information representative of the U.S. population. This study compared approximately 390,000 people who received the Company's single-shot COVID-19 vaccine versus approximately 1.52 million unvaccinated people matched on age, sex, time, three-digit zip code, and comorbidities and predictors for COVID-19 infection severity.

This study is a longitudinal cohort design, using robust propensity matching methods to create a comparator cohort to assess real-world VE. All analyses were performed using the Aetion Evidence Platform, which is a scientifically validated software that is also used by regulators, payers, and health technology assessment bodies to assess the safety, effectiveness, and value of medical technologies. All transformations of the raw data are preserved for full reproducibility and audit trails are available, including a quality check of the data ingestion process.

In the real-world U.S. data, the Johnson & Johnson single-shot COVID-19 vaccine showed VE of 81 percent (CI, 79%-84%) for COVID-19-related hospitalizations and effectiveness of 79 percent (CI, 77%-80%) for COVID-19-related infections (VE was corrected to compensate for vaccination status misclassification due to under-recording of true vaccination status in health care claims data). Uncorrected VE was 69 percent (CI, 67%-71%) for COVID-19-related infections; VE of 73 percent (CI, 69%-76%) for COVID-19 hospitalizations.

The Johnson & Johnson single-shot COVID-19 vaccine showed VE against COVID-19-related hospitalizations at 86 percent (CI, 83%-89%) for participants younger than 60 years, and 78 percent (CI, 74%-81%) for those 60 years and older. VE against COVID-19 infections was 81 percent (CI, 79%-82%) for people younger than 60 years, and 75 percent (CI, 73%-78%) for those 60 years and older. These results are consistent with what was observed in the ENSEMBLE study.

ENSEMBLE 1 Study
The Phase 3 ENSEMBLE study is a randomized, double-blind, placebo-controlled clinical trial designed to evaluate the safety and efficacy of a single-dose vaccine versus placebo in adults 18 years old and older.

The ENSEMBLE study was designed to evaluate the safety and efficacy of the Johnson & Johnson vaccine candidate in protecting against moderate to severe/critical COVID-19 disease, with assessment of efficacy as of day 14 and as of day 28 as co-primary endpoints.

In the Phase 3 ENSEMBLE study, a single dose of the Johnson & Johnson COVID-19 vaccine offered strong and durable overall efficacy (75%; CI, 65%-82%; n=46 cases vaccine arm, n=176 cases placebo arm) against severe/critical COVID-19, across all age cohorts and all countries included in the study, after at least 28 days post-vaccination. While efficacy against severe/critical COVID-19 caused by the initial circulating SARS-COV-2 reference strain (Wuhan) remained high (93%; CI, 54%-99%; n=1 case vaccine arm, n=14 cases placebo arm), there was somewhat lower vaccine efficacy (72%; CI, 56%-82%; n=27 cases vaccine arm, n=93 cases placebo arm) against severe/critical disease caused by variants.

The single-dose regimen had 53 percent (CI, 47%-58%; n=433 cases vaccine arm, n=883 cases placebo arm) efficacy against moderate to severe/critical infection with 58 percent (CI, 35%-74%; n=30 cases vaccine arm, n=69 cases placebo arm) efficacy against the reference strain. Efficacy against hospitalizations related to COVID-19 in the ENSEMBLE trial was 76 percent (CI, 54%-88%; n=16 cases vaccine arm, n=64 cases placebo arm), and efficacy against COVID-19-related deaths was 83 percent (CI, 41%-97%; n=3 cases vaccine arm, n=17 cases placebo arm).

In the U.S., the ENSEMBLE trial demonstrated vaccine efficacy against moderate to severe/critical COVID-19 infection of 70 percent 28-days post-vaccination (CI, 61%-77%; n=77 cases vaccine arm, n=239 cases placebo arm), 74 percent against severe/critical infection (CI, 39%-91%; n=7 cases vaccine arm, n=26 cases placebo arm) and 89 percent against hospitalization (CI, 24%-100%; n=1 case vaccine arm, n=9 cases placebo arm).

Median follow-up time in the ENSEMBLE study was four months, with 23 percent of the participants with follow-up of greater than six months.

The vaccine was generally well-tolerated by all participants, with fewer local and systemic reactions as compared with Phase 1/2 data.

ENSEMBLE was initiated in collaboration with the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services (HHS) under Other Transaction Agreement HHSO100201700018C, and the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH) at HHS.

Full data will be submitted for publication in the coming months.

ENSEMBLE 2 Study

The Phase 3 ENSEMBLE 2 study is a randomized, double-blind, placebo-controlled clinical trial designed to evaluate the safety and efficacy of a two-dose vaccine regimen, given at a 56-day interval, versus placebo in adults 18 years old and older with and without comorbidities associated with an increased risk for severe COVID-19.

The study was designed to assess efficacy of the investigational vaccine after both the first and second dose to evaluate protection against the virus and potential incremental benefits for duration of protection with a second dose. In the ENSEMBLE 2 Phase 3 study solicited and unsolicited adverse events following this second dose are similar to those seen in single-dose studies.

Compared to the single-dose results, ENSEMBLE 2 also demonstrated increased efficacy of a two-dose schedule against moderate to severe/critical COVID-19 of 75 percent (CI, 55%-87%; n=14 cases vaccine arm, n=52 cases placebo arm) and severe/critical COVID-19 of 100 percent (CI, 33%-100%; n=0 cases vaccine arm, n=8 cases placebo arm) at least 14 days following the second vaccination prior to unblinding. In the U.S., efficacy against moderate to severe/critical COVID-19 was 94 percent (CI, 58%-100%; n=1 case vaccine arm, n=14 cases placebo arm).

Median follow-up time in the ENSEMBLE 2 study was 36 days since second vaccination, with 29 percent of participants having at least two months of follow-up after receipt of their second dose.

The vaccine, when given as a second dose or booster, remained generally well-tolerated.

Full data will be submitted for publication in the coming months.

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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