Johnson & Johnson Single-Shot COVID-19 Vaccine Phase 3 Data Published in *New England Journal of Medicine*

Single-dose vaccine prevented hospitalization and death across all study participants, 28 days after vaccination

Vaccine shown to be effective against severe/critical COVID-19 disease as early as seven days after vaccination, with efficacy continuing to increase eight weeks post-vaccination

Vaccine also shown to be consistently effective against symptomatic infection, including in South Africa and Brazil where there was a high prevalence of rapidly emerging SARS-CoV-2 variants

NEW BRUNSWICK, N.J., April 21, 2021 – Johnson & Johnson (the Company) today announced publication in the *New England Journal of Medicine* of primary data from the Phase 3 ENSEMBLE clinical trial for its single-dose COVID-19 vaccine, developed by the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen). The publication of the primary analysis follows the topline efficacy and safety data announced in January, showing the trial met all primary and key secondary endpoints, and found that the Johnson & Johnson single-dose COVID-19 vaccine prevented hospitalization and death across all study participants 28 days after vaccination.

These data demonstrated that, despite the high prevalence of emerging SARS-CoV-2 variants among COVID-19 cases in the study, including the South African variant of the B.1.351 lineage and the P2 lineage variant found in Brazil, vaccine efficacy was consistent against symptomatic infection, and the vaccine showed protection against COVID-19-related hospitalization and death as of 28 days after vaccination.

"This comprehensive evidence demonstrates that Johnson & Johnson's single-shot COVID-19 vaccine offers protection and prevents hospitalization and death, including in countries where viral variants are highly prevalent," said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer at Johnson & Johnson. "Regardless of race and ethnicity, age, geographic location and comorbidities, these results remain consistent. A single-shot vaccine that provides this level of protection represents an important tool in the global fight against COVID-19, as we strive to help end this deadly pandemic. The safety and well-being of every individual who receives a Johnson & Johnson product remains our top priority, and these data reaffirm our confidence in the protective benefits of our COVID-19 vaccine."

Trial Data Reflect 7-Day Onset of Efficacy, Prevention of Hospitalization and Death

The ENSEMBLE data demonstrated that Johnson & Johnson's single-dose COVID-19 vaccine was 85 percent effective against severe/critical disease. Additionally, the trial met its co-primary endpoints of protecting against moderate to severe COVID-19 at 14 and 28 days after vaccination, achieving 67 percent efficacy at 14 days after vaccination; and 66 percent efficacy at 28 days after vaccination, with prevention against COVID-19-related hospitalization and death across all participants (N=44,325). Protection was generally consistent across race, age groups, including adults over 60 years of age (N=14,672), and those with and without comorbidities.

Onset of efficacy was evident seven days post-vaccination for severe/critical disease and 14 days post-vaccination for moderate to severe/critical disease. Importantly, vaccine efficacy continued to increase approximately eight weeks post-vaccination, which is the median duration for follow-up required by the U.S. Food and Drug Administration (FDA). Additional data collected since the announcement of topline results found no evidence of a decline in protection over time, after following approximately 3,000 participants for 11 weeks and 1,000 participants for 15 weeks.

Reactogenicity (reaction to vaccination) was higher with the Johnson & Johnson COVID-19 vaccine versus placebo, but reactions were generally mild-to-moderate and transient.

Vaccine Observed to be Effective against Emerging Variants of Concern
Variants observed in an ongoing analysis in the ENSEMBLE study included the B.1.351 (20H/501Y.V2) variant, which was identified in 95 percent of the COVID-19 cases in South Africa, and the variant from the P2 lineage, which was identified in 69 percent of COVID-19 cases in Brazil. In South Africa, vaccine efficacy was maintained with 64 percent efficacy against moderate to severe/critical disease, and 81.7 percent against severe/critical disease as of Day 28 post-vaccination. Efficacy was also maintained in participants in Brazil, with 68.1 percent efficacy against moderate to severe/critical disease, and 87.6 percent against severe/critical disease.

"Our COVID-19 ENSEMBLE data, published in the *New England Journal of Medicine*, demonstrate that, with a single shot, our vaccine offers a high level of activity across all variants and regions studied," said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, Johnson & Johnson. "We believe these data support the important role our COVID-19 vaccine can play in helping to address the global pandemic that continues to threaten people and healthcare systems around the world."

Review and Authorizations of COVID-19 Vaccine
The U.S. Centers for Disease Control and Prevention (CDC) and FDA currently are reviewing data involving at least six reported U.S. cases of blood clots in combination with low platelets in individuals who have received the Johnson & Johnson COVID-19 vaccine, out of more than 7.9 million doses administered. Out of an abundance of caution, the CDC and FDA have recommended a pause in the use of the Company's vaccine, pending further guidance at an April 23 meeting of the CDC's Advisory Committee on Immunization Practices (ACIP). Johnson & Johnson strongly supports raising awareness of the signs and symptoms of this extremely rare event to ensure the correct diagnosis, appropriate treatment and expedited reporting by health care professionals. The Company remains confident in the positive benefit-risk profile of the Johnson & Johnson COVID-19 vaccine.

On April 20, the European Medicines Agency's (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) provided updated guidance for use of the Company's COVID-19 vaccine and confirmed the overall benefit-risk profile remains positive. As a result, Johnson & Johnson will update its COVID-19 vaccine Summary of Product Characteristics and Package Leaflet to include important information on the diagnosis and management of this very rare adverse event. Following the PRAC recommendation, the Company will resume shipment of the Janssen COVID-19 vaccine in the European Union (EU), Norway and Iceland.

Johnson & Johnson's single-dose COVID-19 vaccine received Emergency Use Authorization (EUA) in the United States on February 27 and Conditional Marketing Authorization (CMA) by the European Commission on March 11, 2021. The World Health Organization (WHO) issued Emergency Use Listing on March 12, 2021 and the Company received an interim

recommendation by the Strategic Advisory Group of Experts (SAGE) on Immunization for the WHO on March 17, 2021. Additional authorizations have been granted in several countries worldwide and submissions are ongoing.

Phase 3 ENSEMBLE Study Design
The Phase 3 ENSEMBLE study is a multi-national, randomized, double-blind, placebo-controlled clinical trial in individuals 18 years of age and older.

The study was designed to evaluate the safety and efficacy of the Company's vaccine in protecting against both moderate and severe/critical COVID-19 disease, with assessment of efficacy as of day 14 and as of day 28 as co-primary endpoints. The cumulative incidence of severe/critical COVID-19 cases is being monitored throughout the study and began to differ across the vaccine and placebo arms at approximately seven days post-vaccination. The study enrolled a total of 43,783 participants.

Topline results release in January found the ENSEMBLE trial met all primary and key secondary endpoints.

The Company is committed to ensuring that everyone who participates in its COVID-19 vaccine clinical trials can receive access to its COVID-19 vaccine, pending the trials resuming and once local authorizations are in place. Trial participants of the Phase 3 ENSEMBLE study continue to be followed for up to two years for assessments of safety and efficacy. The data may be updated based on ongoing analysis to determine the vaccine's long-term safety profile and the full duration of protection from COVID-19.

Phase 3 ENSEMBLE Study Demographics
The trial, conducted in eight countries across three continents, includes a diverse and broad population including 34 percent (N= 14,672) of participants over age 60.

The study enrolled 44 percent (N=19,302) of participants in the United States, 41 percent (N=17,905) in Central and South America (Argentina, Brazil, Chile, Colombia, Mexico, Peru) and 15 percent (N=6,576) in South Africa.

Among participants globally, 59 percent are White/Caucasian; 45 percent are Hispanic and/or Latinx; 19 percent are Black/African American; 9 percent are Indigenous South American/American Indian/Alaskan Native, and 3 percent are Asian. In the United States, 74 percent are White/Caucasian; 14 percent are Hispanic and/or Latinx; 12 percent are Black/African American; 6 percent are Asian and 1 percent are Native American.

Forty-one percent of participants in the study had comorbidities associated with an increased risk for progression to severe/critical COVID-19 (overall 41 percent), obesity (28.5 percent), type 2 diabetes (7.3 percent), hypertension (10.3 percent) or HIV (2.8 percent). Other immunocompromised participants also were in the study.

Vaccine Access and Supply Chain Information
The Company is committed to ensuring global access to its single-shot COVID-19 vaccine on a not-for-profit basis for emergency pandemic use.

The Johnson & Johnson COVID-19 single-dose vaccine is compatible with standard vaccine storage and distribution channels with ease of delivery to remote areas. The vaccine is estimated to remain stable for two years at -4°F (-20°C), and a maximum of three months at routine refrigeration temperatures of 36-46°F (2 to 8°C). The Company will ship the vaccine using the same cold chain technologies it uses today to transport other medicines.

The COVID-19 vaccine should not be re-frozen if distributed at temperatures of 36–46°F (2 to 8°C).

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.

Research and development activities for the Company's COVID-19 vaccine, including the ENSEMBLE clinical trial and the delivery of doses for the U.S., 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 Contract No. HHSO100201700018C, and in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH) at the U.S. Department of Health and Human Services (HHS).

Johnson & Johnson has worked with BARDA since 2015 on innovative solutions for influenza, chemical, biological, radiation and nuclear threats and emerging infectious diseases such as Ebola.

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 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

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.
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
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.

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.

The FDA EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and full EUA Prescribing Information are available at: www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-HCP-fact-sheet.pdf.

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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