This press release has been adapted for audiences in the EMEA region.

News Release

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

Single-dose vaccine prevented hospitalisation and death across all study participants, 28 days after vaccination[1]

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[1]

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[1]

NEW BRUNSWICK, N.J., April 21, 2021 – Johnson & Johnson (NYSE: JNJ) (the Company) today announced publication in the *New England Journal of Medicine*[1] of primary data from the Phase 3 ENSEMBLE clinical trial[2] 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 hospitalisation and death across all study participants 28 days after vaccination.[3]

The data published in the *New England Journal of Medicine* 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 hospitalisation and death as of 28 days after vaccination.[1]

"This comprehensive evidence demonstrates that Johnson & Johnson's single-shot COVID-19 vaccine offers protection and prevents hospitalisation 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 against severe/critical disease

The ENSEMBLE data demonstrated that Johnson & Johnson's single-dose COVID-19 vaccine was 85 percent effective against severe/critical disease at least 28 days after vaccination.[1] 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 hospitalisation and death at least 28 days after vaccination.[1] Protection was generally consistent across race, age groups and participants with and without comorbidities.[1]

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).[1,4] Additional data collected since the announcement of topline results[3] 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.[1]

Reactogenicity (reaction to vaccination) was higher with the Johnson & Johnson COVID-19 vaccine versus placebo, but reactions were generally mild-to-moderate and transient.[1]

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.[1] 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.[1] 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.[1]

"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."

Phase 3 ENSEMBLE study design
The Phase 3 ENSEMBLE study is a multi-national, randomised, double-blind, placebo-controlled clinical trial in individuals 18 years of age and older.[2]

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 study enrolled a total of 44,325 participants.[2,1] The cumulative incidence of severe/critical COVID-19 cases is being monitored throughout the study.

Topline results release in January found the ENSEMBLE trial met all primary and key secondary endpoints.[5,1]

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 authorisations 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.[5] 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.[1]

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.[1]

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.[1]

Forty-one percent of participants in the study had comorbidities associated with an increased risk for progression to severe/critical COVID-, obesity (28.5 percent), type 2 diabetes (7.3 percent) or hypertension (10.3 percent). Other immunocompromised participants also were in the study.[6]

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. [7] The vaccine is estimated to remain stable for two years at -20°C, and a maximum of three months at routine refrigeration temperatures of 2 to 8°C. [8] 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 2 to 8°C.[8]

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.[9]

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: https://www.janssen.com/emea/our-focus/infectious-diseases-vaccines/respiratory-infections/covid-19.

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Important safety information
Please refer to the full Summary of Product Characteristics for full prescribing information for COVID-19 Vaccine Janssen: https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-janssen-epar-product-information_en.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 @JanssenEMEA.

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 @JanssenEMEA.

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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