News Release

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Johnson & Johnson Announces Single-Shot Janssen COVID-19 Vaccine Candidate Met Primary Endpoints in Interim Analysis of its Phase 3 ENSEMBLE Trial

Vaccine Candidate 72% Effective in the US and 66% Effective Overall at Preventing Moderate to Severe COVID-19, 28 Days after Vaccination

85% Effective Overall in Preventing Severe Disease and Demonstrated Complete Protection Against COVID-19 related Hospitalization and Death as of Day 28

Protection Against Severe Disease Across Geographies, Ages, and Multiple Virus Variants, including the SARS-CoV-2 Variant from the B.1.351 Lineage[1] Observed in South Africa

Single-shot compatible with standard vaccine distribution channels provides important tool in pandemic setting

NEW BRUNSWICK, N.J., January 29, 2021 – Johnson & Johnson (NYSE: JNJ) (the Company) today announced topline efficacy and safety data from the Phase 3 ENSEMBLE clinical trial, demonstrating that the investigational single-dose COVID-19 vaccine in development at its Janssen Pharmaceutical Companies met all primary and key secondary endpoints. The topline safety and efficacy data are based on 43,783 participants accruing 468 symptomatic cases of COVID-19.

The Phase 3 ENSEMBLE study is designed to evaluate the efficacy and safety of the Janssen COVID-19 vaccine candidate in protecting moderate to severe COVID-19, with

[1] The B.1.351 lineage also known as 501Y.V2 variant and 20H/501Y.V2 (formerly 20C/501Y.V2) is a variant of SARS-CoV-2, the virus that causes COVID-19

co-primary endpoints of 14 days and 28 days following vaccination. Among all participants from different geographies and including those infected with an emerging viral variant, Janssen's COVID-19 vaccine candidate was 66% effective overall in preventing moderate to severe COVID-19, 28 days after vaccination. The onset of protection was observed as early as day 14. The level of protection against moderate to severe COVID-19 infection was 72% in the United States, 66% in Latin America and 57% in South Africa, 28 days post-vaccination.

"Johnson & Johnson embarked on the global effort to combat the COVID-19 pandemic a year ago, and has brought the full force of our capabilities, as well as tremendous public-private partnerships, to enable the development of a single-shot vaccine. Our goal all along has been to create a simple, effective solution for the largest number of people possible, and to have maximum impact to help end the pandemic," said Alex Gorsky, Chairman, Board of Directors and Chief Executive Officer, Johnson & Johnson. "We're proud to have reached this critical milestone and our commitment to address this global health crisis continues with urgency for everyone, everywhere."

Prevention of severe disease; protection against COVID-related hospitalization and death

The vaccine candidate was 85 percent effective in preventing severe disease across all regions studied,[i] 28 days after vaccination in all adults 18 years and older. Efficacy against severe disease increased over time with no cases in vaccinated participants reported after day 49.

The Janssen COVID-19 vaccine candidate demonstrated complete protection against COVID-related hospitalization and death, 28 days post-vaccination. There was a clear effect of the vaccine on COVID-19 cases requiring medical intervention (hospitalization, ICU admission, mechanical ventilation, extracorporeal membrane oxygenation (ECMO)), with no reported cases among participants who had received the Janssen COVID-19 vaccine, 28 days post-vaccination.

"These topline results with a single-shot COVID-19 vaccine candidate represent a promising moment. The potential to significantly reduce the burden of severe disease, by providing an effective and well-tolerated vaccine with just one immunization, is a critical component of the global public health response," said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer, Johnson & Johnson. "A one-shot vaccine is considered by the World Health Organization to be the best option in pandemic settings, enhancing access, distribution and compliance. Eighty-five percent efficacy in preventing severe COVID-19 disease and prevention of COVID-19-related medical interventions will potentially protect hundreds of millions of people from serious and fatal outcomes of COVID-19. It also offers the hope of helping ease the huge burden placed on healthcare systems and communities."

In the study, the definition of severe COVID-19 disease included laboratory-confirmed SARS-CoV-2 and one or more of the following: signs consistent with severe systemic illness, admission to an intensive care unit, respiratory failure, shock, organ failure or death, among other factors. Moderate COVID-19 disease was defined as laboratory-confirmed SARS-CoV-2 and one or more of the following: evidence of pneumonia, deep vein thrombosis, shortness of breath or abnormal blood oxygen saturation above 93%, abnormal respiratory rate (≥20); or two or more systemic symptoms suggestive of COVID-19.

Protection was generally consistent across race, age groups, including adults over 60 years of age (N= 13,610), and across all variants and regions studied, including South Africa where nearly all cases of COVID-19 (95%) were due to infection with a SARS-CoV-2 variant from the B.1.351 lineage[ii].

Multi-continent Study Provides Clinical Data on Multiple Emerging Viral Mutations

The ENSEMBLE study results include efficacy against newly emerging strains of coronavirus, including some highly infectious variants present in the US, Latin America and South Africa. The Phase 3 ENSEMBLE trial is being conducted at the height of the COVID-19 pandemic in eight countries and three regions, at a time when disease spread has accelerated throughout the world resulting in people having increased exposure to the virus.

“These results are a testament to the extraordinary efforts of everyone involved in our COVID-19 vaccine candidate clinical program, and we are extremely grateful to the clinical trial staff and trial participants for their invaluable contributions,” said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development. “Changing the trajectory of the pandemic will require mass vaccination to create herd immunity, and a single-dose regimen with fast onset of protection and ease of delivery and storage provides a potential solution to reaching as many people as possible. The ability to avoid hospitalizations and deaths would change the game in combating the pandemic.”

Trial participants of the phase 3 ENSEMBLE study continue to be followed for up to two years for assessments of safety and efficacy. Therefore, these data may be updated based on ongoing analysis. The comprehensive available data set will be submitted to a peer-reviewed journal in the coming weeks.

Phase 3 ENSEMBLE Study Safety Data

The analysis included a concurrent review of the available Phase 3 ENSEMBLE study safety data by the Data and Safety Monitoring Board (DSMB), an independent group of experts, that did not report any significant safety concerns relating to the vaccine. A review of adverse events indicated that a single-dose of Janssen’s COVID-19 vaccine candidate was generally well-tolerated.

The safety profile was consistent with other vaccine candidates using Janssen’s AdVac® technology among more than 200,000 people to date. Overall fever rates were 9% and Grade 3 fever 0.2%. Overall serious adverse events (SAEs) reported were higher in participants who received placebo as compared to the active vaccine candidate. No anaphylaxis was observed.

Janssen Vaccine Candidate Access and Distribution

The Company is committed to bringing an affordable COVID-19 vaccine on a not-for-profit basis for emergency pandemic use, pending regulatory authorizations.

In addition, the Janssen vaccine candidate is compatible with standard vaccine distribution channels. If authorized, Janssen’s single-dose vaccine candidate is estimated to remain stable for two years at -20°C (-4°F), at least three months of which can be at temperatures of 2-8°C (36°F–46°F). The Company will ship the vaccine using the same cold chain technologies it uses today to transport other innovative medicines.

The Company intends to file for U.S. Emergency Use Authorization (EUA) in early February and expects to have product available to ship immediately following authorization. It expects to share more information on specifics of deployment as authorizations are secured and contracts are finalized. The Company’s anticipated manufacturing timeline will enable it to meet its 2021 supply commitments, including those signed with governments and global organizations.

Phase 3 ENSEMBLE Study Design

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 Janssen vaccine candidate in protecting against both moderate and severe COVID-19 disease, with assessment of efficacy as of day 14 and as of day 28 as co-primary endpoints.

Phase 3 ENSEMBLE Study Demographics

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

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

Forty-five percent of participants are female, 55% male.

Among participants globally, 59% are White/Caucasian; 45% are Hispanic and/or Latinx; 19% are Black/African American; 9% are Native American and 3% are Asian. In the United States, 74% are White/Caucasian; (15% are Hispanic) and/or Latinx; 13% are Black/African American; 6% are Asian and 1% are Native American.

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

Janssen's Vaccine Technology
The investigational Janssen COVID-19 vaccine candidate leverages the Company's AdVac® vaccine platform, which was also used to develop and manufacture Janssen's European Commission-approved Ebola vaccine regimen and construct its Zika, RSV, and HIV investigational vaccine candidates.

The Janssen AdVac® viral vector technology can induce potent and long-lasting humoral and cellular immune responses, enabling the pursuit of vaccines for disease targets that are currently unpreventable or untreatable.

Johnson & Johnson continues to develop and test its COVID-19 vaccine candidate in accordance with ethical standards and sound scientific principles. The Company is committed to transparency and sharing information related to its ongoing clinical studies – including the ENSEMBLE study protocol.

ENSEMBLE has been funded in whole or in part with Federal funds from the 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).

Janssen has worked with BARDA since 2015 on innovative solutions for influenza, chemical, biological, radiation and nuclear threats and emerging infectious diseases such as Ebola. In February 2020, Janssen and BARDA began work on the development of a COVID-19 vaccine based on Janssen's AdVac® technology.

The Janssen Pharmaceutical Companies entered into a collaboration with the Beth Israel Deaconess Medical Center (BIDMC) to support the development of the preventive vaccine candidate for COVID-19.

Janssen's COVID-19 vaccine program has been designed to be thorough and driven by science. As such, the Company is also investigating immune responses for different doses and dosing regimens as well as studying a two-dose regimen of its COVID-19 vaccine candidate for efficacy in the Phase 3 ENSEMBLE 2 study.

For more information on the Company's multi-pronged approach to helping combat the pandemic, visit: www.jnj.com/coronavirus.

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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.

The company plans to hold an investor webcast to share the results and provide opportunity for Q&A today at 9:00am EST. The call will be hosted by Chris DelOrefice, Vice President of Investor Relations and Mathai Mammen, Global Head of Janssen Research and Development. The webcast is accessible at www.investor.jnj.com and telephone, for both "listen-only" participants and financial analysts who wish to take part in the question and answer portion of the call. Please dial (877) 869-3847 in the U.S. and (201) 689-8261 outside of the U.S.

Notice to Investors 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 its COVID-19 vaccine candidate. 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 December 29, 2019, 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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[i] https://www.jnj.com/coronavirus/covid-19-phase-3-study-clinical-protocol

[ii] The B.1.351 lineage also known as 501Y.V2 variant and 20H/501Y.V2 (formerly 20C/501Y.V2) is a variant of SARS-CoV-2, the virus that causes COVID-19