**News Release**

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# Johnson & Johnson Single-Shot COVID-19 Vaccine Candidate Unanimously Recommended for Emergency Use Authorization by U.S. FDA Advisory Committee

*Vote based on totality of scientific evidence provided by the Company including safety and efficacy data*

**NEW BRUNSWICK, N.J., February 26, 2021** – Johnson & Johnson (NYSE: JNJ) (the Company) today announced that the U.S. Food and Drug Administration's (FDA) Vaccines and Related Biological Products Advisory Committee (VRBPAC) unanimously voted to recommend Emergency Use Authorization (EUA) for the Company's single-shot COVID-19 vaccine candidate for adults 18 and older, developed by the Janssen Pharmaceutical Companies of Johnson & Johnson. The vote was based on a totality of scientific evidence provided by the Company, including efficacy and safety data from the Phase 3 ENSEMBLE trial.

"We are extremely grateful to the VRBPAC members for their extensive review of the data supporting emergency use of Johnson & Johnson's single-shot COVID-19 vaccine candidate," said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer, Johnson & Johnson. "We believe our COVID-19 vaccine candidate has the potential to help change the trajectory of the pandemic and stand ready to make it available to protect the public as soon as possible."

The next step in the process is for the FDA to decide whether to grant an EUA for Janssen's COVID-19 vaccine candidate. The recommendation of the FDA Advisory Committee is non-binding, and the final decision on authorization is made by the FDA. Under an EUA, the FDA has the authority to allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions during a declared public health emergency. If authorized by the FDA, the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization

Practices (ACIP) will then provide a recommendation on the use and roll-out of the Janssen COVID-19 vaccine candidate.

"We are grateful to everyone who has contributed to the wealth of data we presented today, including study participants, site investigators and teams, collaborators and everyone who has worked so hard to bring us to this moment. We are confident our COVID-19 vaccine candidate will have a significant impact in protecting people around the world," said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, Johnson & Johnson.

Johnson & Johnson is committed to making its COVID-19 vaccine candidate available on a not-for-profit basis for emergency pandemic use. The Company is prepared to supply its vaccine immediately upon EUA and expects to deliver enough single-dose vaccine candidate by the end of March to enable the full vaccination of more than 20 million people in the U.S. The Company plans to deliver 100 million single-dose vaccines to the U.S. during the first half of 2021.

Johnson & Johnson also recently announced its submission of a European Conditional Marketing Authorisation Application to the European Medicines Agency as well as an Emergency Use Listing (EUL) with the World Health Organization for its COVID-19 vaccine candidate. In addition, rolling submissions for the single-dose COVID-19 vaccine candidate have been initiated in several countries worldwide.

**Manufacturing and Supply Chain Information**
The Johnson & Johnson COVID-19 single-dose vaccine candidate 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 at 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 treatments for cancer, immunological disorders and other medicines. The COVID-19 vaccine should not be re-frozen if distributed at temperatures of 36°F–46°F (2°-8°C).

**Johnson & Johnson's COVID-19 Vaccine Candidate**
The Company's Janssen COVID-19 Vaccine leverages the AdVac® vaccine platform, a unique and 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.

**Phase 3 ENSEMBLE Study Design**
The Phase 3 ENSEMBLE study is a 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 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. The study enrolled a total of 43,783 participants.

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

The study enrolled 44% of participants in the United States. Seventy-four percent of participants in the U.S. 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.

Research and development activities for the Janssen COVID-19 vaccine candidate, including the ENSEMBLE clinical trial and the delivery of doses for the U.S., have been funded 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).

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.

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.

**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.