News Release

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Johnson & Johnson Single-Shot COVID-19 Vaccine Granted Conditional Marketing Authorization by European Commission

Data have demonstrated vaccine protects against COVID-19 related hospitalisation in broad geographic regions, including those with emerging variants [1]

Decision follows the European Medicines Agency recommendation of the J&J COVID-19 vaccine[2]

The Company aims to begin delivery of its vaccine to the EU in the second half of April and is committed to supply 200 million doses in 2021[3]

NEW BRUNSWICK, N.J., March 11, 2021 – Johnson & Johnson (NYSE: JNJ) (the Company) today announced that the European Commission (EC) has granted a Conditional Marketing Authorization (CMA) for its single-dose COVID-19 vaccine, developed by the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen), to prevent COVID-19 in individuals 18 years of age and older.

The CMA follows a Positive Opinion from the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP).[2] The CMA is valid in all 27 member states of the European Union (EU), plus Norway, Iceland and Liechtenstein.

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Data from the Phase 3 ENSEMBLE study showed that the Johnson & Johnson COVID-19 vaccine was well tolerated and demonstrated a 67 percent reduction in symptomatic COVID-19 disease in participants who received the vaccine in comparison to participants given the placebo.[2] The onset of protection was observed from day 14 and was maintained 28 days post-vaccination.[1] The data also demonstrated the vaccine was 85 percent effective in preventing severe disease across all regions studied, and showed protection against COVID-19 related hospitalisation and death, beginning 28 days after vaccination.[1]

"For more than a year, we have been working around the clock – leveraging the scientific minds, scale and resources of our global organisation to bring forward a COVID-19 vaccine," said Alex Gorsky, Chairman and Chief Executive Officer at Johnson & Johnson. "We are thrilled with today's Conditional Marketing Authorization by the European Commission, which enables our single-dose vaccine to reach many more communities in need, as we continue to do everything we can to help bring an end to this pandemic."

Johnson & Johnson is committed to making its COVID-19 vaccine available on a not-for-profit basis for emergency pandemic use. The Company aims to begin delivery of its single dose COVID-19 vaccine to the EU in the second half of April and to supply 200 million doses to the EU,[3] plus Norway and Iceland in 2021.

"This vaccine is the result of more than a decade of investment in research and development and deep commitment by our scientists. We appreciate the collaboration and the support of the European Commission in this monumental effort," said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer at Johnson & Johnson. "With this Conditional Marketing Authorization, we are proud to bring our single-shot vaccine to help protect millions of people across EU member states."

In December 2020, the Company announced that Janssen initiated a rolling submission with the EMA for its single-dose COVID-19 vaccine candidate, enabling an expedited CHMP review process.[4] The COVID-19 vaccine candidate has also been filed for an Emergency Use Listing (EUL) with the World Health Organization.[5] Rolling submissions for our vaccine candidate have also been initiated in several countries worldwide.

"This latest major regulatory milestone would not have been possible without the hard work and dedication of everyone involved in our COVID-19 vaccine clinical trial programme, including our J&J team, our partners and study participants," said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, Johnson & Johnson. "We are delighted by today's announcement and remain fully committed to continuing our COVID-19 vaccine clinical programme as we strive to provide our single-dose COVID-19 vaccine to people all over the world."

The Company received Emergency Use Authorization (EUA) in the United States on February 27,[6] following a unanimous vote by the U.S. Food and Drug Administration's Vaccines and Related Biological Products Advisory Committee on February 26, 2021.[7] The Johnson & Johnson single-dose COVID-19 vaccine has also been granted Interim Order authorisation in Canada.[8]

Manufacturing and Supply Chain Information

The Johnson & Johnson COVID-19 single-dose vaccine is compatible with standard vaccine storage and distribution channels enabling delivery to remote areas.[6] The vaccine is estimated to remain stable for two years at -25 to -15°C, and a maximum of three months of which can be at routine refrigeration at temperatures of 2°-8°C.[9] The Company will ship

the vaccine using the same cold chain technologies it uses today to transport other medicines.[6]

Johnson & Johnson's COVID-19 Vaccine
The Johnson & Johnson 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.[10]

Phase 3 ENSEMBLE Study Design
The Phase 3 ENSEMBLE study is a randomised, double-blind, placebo-controlled clinical trial in individuals 18 years of age and older.[11] 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.[12] The study enrolled a total of 43,783 participants.[6]

The trial, conducted in eight countries across three continents,[11] includes a diverse and broad population including 34 percent of participants over age 60.[1] Forty-one percent of participants in the study had comorbidities associated with an increased risk for progression to severe COVID-19.[1]

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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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 https://www.janssen.com/emea/. 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 https://www.janssen.com/emea/. 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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REFERENCES

[1] Janssen. Johnson & Johnson Announces Single-Shot Janssen COVID-19 Vaccine Candidate Met Primary Endpoints in Interim Analysis of its Phase 3 ENSEMBLE Trial. Available at: https://www.janssen.com/emea/sites/www_janssen_com_emea/files/johnson_johnson_announces_single-shot_janssen_covid-19_vaccine_candidate_met_primary_endpoints_in_interim_analysis_of_its_phase_3_ensemble_trial.pdf. Last accessed: March 2021.

[2] European Medicines Agency. EMA recommends COVID-19 Vaccine Janssen for authorisation in the EU. Available at: https://www.ema.europa.eu/en/news/ema-recommends-covid-19-vaccine-janssen-authorisation-eu. Last accessed: March 2021.

[3] Janssen. Johnson & Johnson Announces European Commission Approval of Agreement to Supply 200 Million Doses of Janssen's COVID-19 Vaccine Candidate. Available at: https://www.janssen.com/emea/sites/www_janssen_com_emea/files/johnson_johnson_announces_european_commission_approval_of_agreement_to_supply_200_million_doses_of_janssens_covid-19_vaccine_candidate.pdf. Last accessed: March 2021.

[4] Janssen. Johnson & Johnson Announces Initiation of Rolling Submission for its Single-dose Janssen COVID-19 Vaccine Candidate with the European Medicines. Available at: http://www.janssen.com/sites/www_janssen_com_emea/files/jj_announces_initiation_of_rolling_submission_for_its_single_dose_janssen_covid19_vaccine_candidate_with_the_ema.pdf. Last accessed: March 2021.

[5] Janssen. Johnson & Johnson Announces Submission to World Health Organization for Emergency Use Listing of Investigational Single-Shot Janssen COVID-19 Vaccine Candidate. Available at: https://www.janssen.com/emea/sites/www_janssen_com_emea/files/jj_announces_submission_to_who_for_eul_of_investigational_single-shot_janssen_covid-19_vaccine_candidate_.pdf. Last accessed: March 2021.

[6] Johnson & Johnson. Johnson & Johnson COVID-19 Vaccine Authorized by U.S. FDA For Emergency Use - First Single-Shot Vaccine in Fight Against Global Pandemic. Available at: https://www.jnj.com/johnson-johnson-covid-19-vaccine-authorized-by-u-s-fda-for-emergency-usefirst-single-shot-vaccine-in-fight-against-global-pandemic. Last accessed: March 2021.

[7] Johnson & Johnson. Johnson & Johnson Single-Shot COVID-19 Vaccine Candidate Unanimously Recommended for Emergency Use Authorization by U.S. FDA Advisory Committee. Available at: https://www.jnj.com/johnson-johnson-single-shot-covid-19-vaccine-candidate-unanimously-recommended-for-emergency-use-authorization-by-u-s-fda-advisory-committee. Last accessed: March 2021.

[8] Johnson & Johnson. Johnson & Johnson COVID-19 Vaccine Granted Authorization under Interim Order by Health Canada For Emergency Use. Available at: https://www.jnj.com/johnson-johnson-covid-19-vaccine-granted-authorization-under-interim-order-by-health-canada-for-emergency-use. Last accessed: March 2021.

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[9] Summary of Product Characteristics. COVID-19 Vaccine Janssen suspension for injection. March 2021.
[10] Custers, J., Kim, D., et al. Vaccines based on replication incompetent Ad26 viral vectors: Standardized template with key considerations for a risk/benefit assessment. Vaccine. 2020.
[11] ClinicalTrials.gov. A study of Ad26.COV2.S for the Prevention of SARS-CoV-2-Mediated COVID-19 in Adult Participants (ENSEMBLE). Available at: https://clinicaltrials.gov/ct2/show/NCT04505722. Last accessed: March 2021.
[12] Johnson & Johnson. COVID-19 Phase 3 study clinical protocol. Available at: https://www.jnj.com/coronavirus/covid-19-phase-3-study-clinical-protocol. Last accessed: March 2021.