



Media Statement

December 18, 2020

Johnson & Johnson Announces Its First Phase 3 COVID-19 Vaccine Trial ENSEMBLE is Fully Enroled

The large-scale, pivotal, multi-country Phase 3 trial (ENSEMBLE) of the investigational Janssen COVID-19 single-dose vaccine candidate is now fully enroled with approximately 45,000 participants.¹ Given the high incidence of COVID-19 among the general population in the countries where the trial is being conducted,¹ this number of participants will be sufficient to generate the data needed to determine the efficacy and safety of the Company's investigational COVID-19 vaccine candidate.² Johnson & Johnson expresses its thanks to all participants, trial sites and health care professionals involved in the ENSEMBLE study.

Interim data from the ENSEMBLE trial is currently anticipated to be available by the end of January 2021. However as this trial is dependent on disease events, the timing is approximate. If the data indicate the vaccine is efficacious with a good safety profile, the Company expects to submit a conditional Marketing Authorisation Application (cMAA) to the European Medicines Agency (EMA) as soon as able. Should a cMAA be submitted to the EMA for the single dose Janssen COVID-19 vaccine candidate, an opinion on the cMAA could be issued within weeks. Such a short timeframe is only possible because the EMA has already reviewed data on the single-dose vaccine Janssen COVID-19 candidate during a '[rolling review](#)' process that started on December 1.³

A separate Phase 3 clinical trial of the investigational Janssen COVID-19 vaccine candidate to explore a two-dose regimen of Janssen's vaccine candidate (ENSEMBLE 2) is also ongoing. ENSEMBLE 2 is running in parallel to ENSEMBLE and is being conducted in collaboration with the UK National Institute for Health Research.⁴

Johnson & Johnson continues to develop and test its COVID-19 vaccine candidate in accordance with high scientific, ethical and regulatory standards. The Company is committed to safety and transparency and sharing information relating to the Phase 3 ENSEMBLE studies.⁵

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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 potential preventive and treatment regimens 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 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.

¹ 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: December 2020.

² Janssen Vaccines & Prevention B.V. Clinical Protocol. Available at: <https://www.jnj.com/coronavirus/covid-19-phase-3-study-clinical-protocol>. Last accessed: December 2020.

³ European Medicines Agency. EMA starts rolling review of Janssen's COVID-19 vaccine Ad26.COV2.S. Available at: <https://www.ema.europa.eu/en/news/ema-starts-rolling-review-janssens-covid-19-vaccine-ad26cov2>. Last accessed: December 2020.

⁴ ClinicalTrials.gov. A Study of Ad26.COV2.S for the Prevention of SARS-CoV-2-mediated COVID-19 in Adults (ENSEMBLE 2). Available at: <https://clinicaltrials.gov/ct2/show/NCT04614948>. Last accessed: December 2020.

⁵ Janssen EMEA Clinical Trial Transparency statement. Available at: <https://www.janssen.com/emea/health/research-and-development/clinical-development/transparency>. Last accessed: December 2020.