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News Release

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Single-Dose COVID-19 Vaccine Janssen▼ Granted Conditional Marketing Authorisation by the Medicines and Healthcare Products Regulatory Agency (MHRA)

Data from a trial conducted in broad geographic regions, and including individuals exposed to emerging COVID-19 variants, have demonstrated COVID-19 Vaccine Janssen protects against severe disease[1]

HIGH WYCOMBE, UK, 28 May 2021 – Johnson & Johnson (NYSE: JNJ) (the Company) today announced that the Medicines and Healthcare Products Regulatory Agency (MHRA) has granted Conditional Marketing Authorisation for its single-dose vaccine, developed by the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen) in Great Britain. COVID-19 Vaccine Janssen is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.

Data from the Phase 3 ENSEMBLE study evaluated efficacy and safety of COVID-19 Vaccine Janssen in preventing moderate to severe (symptomatic) COVID-19 in individuals 18 years and older, with co-primary endpoints of 14 days and 28 days following vaccination. The data from the primary efficacy analysis showed that COVID-19 Vaccine Janssen was generally well tolerated and demonstrated 67 percent reduction (95 percent CI: 59–73 percent) in symptomatic COVID-19 disease 14 days after vaccination, and similar results were seen from 28 days after vaccination, in participants who received the vaccine in comparison to participants given the placebo. The data also demonstrated the vaccine was 85 percent effective (95 percent CI: 54–97 percent) in preventing severe disease across all regions studied and showed reduction of COVID-19 related hospitalisation from 14 days after vaccination.[1]

"The MHRA authorisation of our single-dose COVID-19 vaccine marks another important step forward in the global effort to end the COVID-19 pandemic," says Dr Mohamed Lockhat, Medical Director, Infectious Diseases & Vaccines at Janssen UK. *"This has only been made possible by the significant contributions from study participants, site investigators, and our research and development teams."*

Johnson & Johnson will make COVID-19 Vaccine Janssen available on a not-for-profit basis for emergency pandemic use. The Conditional Marketing Authorisation permits the supply and use of COVID-19 Vaccine Janssen in Great Britain while more data are gathered and while the Company files for a full license with the MHRA.

Manufacturing and supply chain information
The single-dose COVID-19 Vaccine Janssen is compatible with standard vaccine storage and distribution channels enabling delivery to remote areas. 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 to 8°C.[1] The Company will ship the vaccine using the same cold chain technologies it uses today to transport other medicines.

Under the terms of the initial advance purchase agreement, Janssen agreed to supply the UK Government with up to 30 million doses of its COVID-19 vaccine. Following the continued success of the UK's COVID-19 vaccination programme, the UK Government will now purchase 20 million doses of COVID-19 Vaccine Janssen, a reduction from its original order which could further support global equitable access.

The COVID-19 Vaccine Janssen
The COVID-19 Vaccine Janssen leverages the AdVac® vaccine platform, a unique and proprietary technology that was also used to develop and manufacture Janssen's European Union-authorised Ebola vaccine regimen and construct its investigational Zika, RSV, and HIV vaccines.[2]

The COVID-19 Vaccine Janssen has been granted conditional marketing authorisation for active immunisation to prevent Coronavirus Disease 2019 (COVID-19) in individuals 18 years of age and older.

Phase 3 ENSEMBLE study design
The Phase 3 ENSEMBLE study is an ongoing, multicentre, randomised, double-blind, placebo-controlled clinical trial in adults 18 years old and older.[3] 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.[4] The study enrolled a total of 44,325 participants.[1]

The trial, conducted in eight countries across three continents – North America, South America and Africa – includes a diverse and broad population including 20 percent of participants over age 65.[1,3] Forty 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/uk/covid-19.

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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/uk. Follow us at www.twitter.com/JanssenUK. Janssen Research & Development, LLC and Janssen-Cilag International NV are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Important safety information
Safety data from the ENSEMBLE study showed the most common local adverse reactions reported was injection site pain (48.6 percent). The most common systemic adverse

reactions were headache (38.9 percent), fatigue (38.2 percent), myalgia (33.2 percent) and nausea (14.2 percent). Pyrexia (defined as body temperature ≥38.0°C) was observed in nine percent of participants. Most adverse reactions occurred within 1–2 days following vaccination and were mild to moderate in severity and of short duration (1–2 days).[1]

Following more widespread use of the Company's COVID-19 vaccine, a combination of blood clots and low levels of 'platelets' (cells that help blood to clot) in the blood has been observed extremely rarely. These cases generally occurred within the first 3 weeks following vaccination. Fatal outcome has been reported.[5]

Please refer to the full Summary of Product Characteristics for full prescribing information for COVID-19 Vaccine Janssen: https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-janssen/summary-of-product-characteristics-for-covid-19-vaccine-janssen.

Adverse events should be reported. ▼ If you are concerned about a side-effect it can be reported directly via the Coronavirus Yellow Card reporting site https://coronavirus-yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. When completing a report please include the vaccine brand and batch/Lot number if available. Adverse events should also be reported to Janssen-Cilag Limited on 01494 567447 or at dsafety@its.jnj.com.

Cautions concerning forward-looking statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product authorisation for COVID-19 Vaccine Janssen. 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 Janssen Research & Development, LLC and Janssen-Cilag International NV, any of the other 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 COVID-19 Vaccine Janssen suspension for injection. Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-janssen-epar-product-information_en.pdf. Last accessed: May 2021.

2 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

3 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: May 2021.

4 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: May 2021.

5 European Medicines Agency. COVID-19 Vaccine Janssen: EMA finds possible link to very rare cases of unusual blood clots with low blood platelets. Available at: https://www.ema.europa.eu/en/news/covid-19-vaccine-janssen-ema-finds-possible-link-very-rare-cases-unusual-blood-clots-low-blood. Last accessed: May 2021.