Media Statement

December 1, 2020

Johnson & Johnson Announces Initiation of Rolling Submission for its Single-dose Janssen COVID-19 Vaccine Candidate with the European Medicines Agency

Janssen-Cilag International N.V., part of the Janssen Pharmaceutical Companies of Johnson & Johnson, has initiated a rolling submission with the European Medicines Agency (EMA) for its investigational single-dose vaccine candidate for the prevention of COVID-19.[1]

The EMA's Committee for Medicinal Products for Human Use (CHMP) enabled a rolling review of the investigational single-dose Janssen COVID-19 vaccine candidate based principally on positive non-clinical data showing that the vaccine candidate elicits a robust immune response, as demonstrated by neutralising antibodies.[2] Janssen will continue to work in close collaboration with the EMA's CHMP to complete the rolling review process and to facilitate a conditional Marketing Authorisation Application (MAA) when appropriate.

In addition to the EMA, Janssen is in discussions with other regulatory authorities worldwide, as it prepares to initiate regulatory review processes for use of its investigational single-dose COVID-19 vaccine candidate during the pandemic response period.

Janssen is committed to bringing an affordable COVID-19 vaccine to the public on a not-for-profit basis for emergency pandemic use.

WHAT IS A ROLLING REVIEW?

A rolling review is a regulatory tool used by regulatory authorities to speed-up the assessment of potentially promising investigational medicines or vaccines during a public health emergency.[3]

In normal circumstances, all data on an investigational vaccine's efficacy, safety, and quality, as well as all required documents, must be submitted together at the start of a license application procedure. However, in the case of a rolling review, a regulatory authority will review data as they become available from ongoing studies.[3]

By reviewing data as they become available, the regulatory authority can reach its decision sooner on whether the vaccine should be authorised.[3]

JANSSEN'S INVESTIGATIONAL COVID-19 VACCINE CANDIDATE

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.[4] Janssen's AdVac® technology has been used to

vaccinate more than 114,000 people to date across the Company's investigational vaccine programmes.[4]

The safety data profile from an interim analysis of the ongoing Phase 1/2a clinical trial of the investigational Janssen COVID-19 vaccine candidate – studying the safety profile and immunogenicity of both a single-dose and two-dose vaccination – is supportive of further development of the vaccine candidate.[5] Immune responses were shown to be similar across the age groups studied, including older adults.[5] Based on these initial findings, the investigational COVID-19 vaccine candidate is being further evaluated in the Phase 3 ENSEMBLE[1] and Phase 3 ENSEMBLE 2[6] clinical trials.

For more information on the Company's multi-pronged approach to helping combat the pandemic, visit: https://www.janssen.com/emea/covid19.

###

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 Mercado, N.B., Zahn, R., Wegmann, F. et al. Single-shot Ad26 vaccine protects against SARS-CoV-2 in rhesus macaques. Nature (2020). Available at: https://www.nature.com/articles/s41586-020-2607-z. Last accessed: December 2020.

3 European Medicines Agency. EMA starts first rolling review of a COVID-19 vaccine in the EU. Available at: https://www.ema.europa.eu/en/news/ema-starts-first-rolling-review-covid-19-vaccine-eu#:~:text=a%20rolling%20review%3F-,A%20rolling%20review%20is%20one%20of%20the%20regulatory%20tools%20that,during%20a%20public%20health%20emergency.&text=By%20reviewing%20the%20data%20as,or%20vaccine%20should%20be%20authorised. Last accessed: December 2020.
4 Custers, J., Kim, D., et al., 2020. Vaccines based on replication incompetent Ad26 viral vectors: Standardized template with key considerations for a risk/benefit assessment. Vaccine.
5 Sadoff J., Le Gras M., Shukarev G., et al. Safety and immunogenicity of the Ad26.COV2.S COVID-19 vaccine candidate: Interim results of a phase 1/2a, double blind, randomized, placebo-controlled trial. medRxiv. 2020. Available at: https://www.medrxiv.org/content/10.1101/2020.09.23.20199604v1.full.pdf. Last accessed: December 2020.
6 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.