



December 1, 2020

Johnson & Johnson Announces the Initiation of a Rolling Submission for its Single-dose Janssen COVID-19 Vaccine Candidate with Health Canada

Janssen Inc. the pharmaceutical companies of Johnson & Johnson, has initiated a rolling submission with Health Canada for its investigational single-dose vaccine candidate for the prevention of COVID-19.

Health Canada announced 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 neutralizing antibodies. Janssen will continue to work with Health Canada to complete the rolling review process and to facilitate an approval when appropriate.

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

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

THE COMPANY'S INVESTIGATIONAL COVID-19 VACCINE CANDIDATE

The investigational Janssen COVID-19 vaccine candidate leverages Janssen'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. Janssen's AdVac® technology has been used to vaccinate more than 114,000 people to date across Janssen's investigational vaccine programs.

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. Immune responses are similar across the age groups studied, including older adults. Based on these initial findings, the Janssen COVID-19 vaccine candidate is being further evaluated in the [Phase 3 ENSEMBLE](#) and [Phase 3 ENSEMBLE 2](#) clinical trials.

For more information on Johnson & Johnson's multi-pronged approach to helping combat the pandemic, visit: www.jnj.com/coronavirus.

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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.