



March 5, 2021

Johnson & Johnson COVID-19 Vaccine Granted Authorization under Interim Order by Health Canada For Emergency Use

Data demonstrated protection against COVID-19 related hospitalization and death, and across different variants

Johnson & Johnson (the Company) announced today that Health Canada has granted an Interim Order (IO) authorization for its single-shot COVID-19 vaccine, developed by the Janssen Pharmaceutical Companies of Johnson & Johnson, to prevent COVID-19 in individuals 18 years of age and older.

This decision was based on scientific evidence, including data from the Phase 3 ENSEMBLE study that demonstrated the vaccine was 85 percent effective in preventing severe disease, and showed protection against COVID-19 related hospitalization and death, beginning 28 days after vaccination.

Johnson & Johnson anticipates fulfilling the 10 million doses included in the Advance Purchase Agreement with the Government of Canada by the end of Q3 2021.

We have been working around the clock to develop and broadly activate our manufacturing capabilities, which will enable us to meet our 2021 supply commitments.

The Company will share more information on anticipated delivery timing as it becomes available.

"A vaccine that prevents severe disease and protects against COVID-related hospitalization and death will help ease the burden on Canadians and the strain on our healthcare systems," said Dr. Ebele Ola, Vice President, Medical Affairs, Janssen Canada. "Our single-shot COVID-19 vaccine is a critical tool for fighting this global pandemic."

The terms of the IO allow use of the vaccine while more data are gathered. The Company plans to file for a Notice of Compliance with Health Canada later in 2021.

Manufacturing and Supply Chain Information

The Janssen COVID-19 single-dose vaccine is compatible with standard vaccine storage and distribution channels with ease of delivery to remote areas. The vaccine is estimated to remain stable for two years at -20°C, and a maximum of three months at routine refrigeration at temperatures of 2 to 8°C. The Company will ship the vaccine using the same cold chain technologies it uses today to transport treatments for cancer, immunological disorders and other medicines. The COVID-19 vaccine should not be re-frozen if distributed at temperatures of 2°-8°C.

Johnson & Johnson's COVID-19 Vaccine

The Company's 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.

The Janssen COVID-19 vaccine has not been approved or licensed but has been granted authorization under Interim Order for active immunization 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 a randomized, double-blind, placebo-controlled clinical trial in individuals 18 years of age and older. 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. The study enrolled a total of 43,783 participants.

The trial, conducted in eight countries across three continents, includes a diverse and broad population including 34 percent of participants over age 60.

Fifty-nine percent of participants in the study were White/Caucasian; 45 percent were Hispanic and/or Latinx; 19 percent were Black/African American; 3 percent were Asian and 9 percent were Native American.

Authorized Use

The Janssen COVID-19 Vaccine (SARS-CoV-2 Vaccine [Ad26.COVS.S, recombinant]) is indicated for active immunization for the prevention of coronavirus disease-2019 (COVID-19) caused by SARS-CoV-2 virus in individuals 18 years of age and older.

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/canada. Follow us at @JanssenCanada. Janssen Inc. is a member of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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Cautions Concerning Forward-Looking Statements

This statement contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding a potential preventative 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 [OPCO] [, 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.