

**News Release**

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**Johnson & Johnson COVID-19 Vaccine Fully Approved by Health Canada to Prevent COVID-19 in Individuals 18 years and Older**

*Vaccine demonstrates protection against COVID-19 related hospitalization and death, and across different variants*

**Toronto ON, 24 November 2021** – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that Health Canada has approved its single-shot COVID-19 vaccine to prevent COVID-19 in individuals 18 years of age and older.

This decision was based on scientific evidence, including initial 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.

“We are delighted by Health Canada’s decision to approve the Johnson & Johnson COVID-19 vaccine based on Phase 3 clinical data that proves the vaccine’s robust safety and efficacy,” said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, Johnson & Johnson. “As vaccination rates continue to climb, a vaccine that prevents severe disease and protects against COVID-related hospitalization and death will help ease the strain on healthcare systems and is an important option for people in Canada and around the world.”

“Today marks the first major regulatory approval for the Johnson & Johnson COVID-19 vaccine and an important moment to recognize the dedication of everyone involved in our COVID-19 vaccine development, our partners, the regulators and clinical study participants. We are proud to have a COVID-19 vaccine available to protect people around the world and will continue to work to ensure global access,” said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer and Johnson & Johnson.

### **Johnson & Johnson's COVID-19 Vaccine**

The Johnson & Johnson 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.

### **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 -25°C to -15°C, and a maximum of six 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 once thawed.

### **Phase 3 ENSEMBLE Study Design**

The Phase 3 ENSEMBLE study was 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, and included a diverse and broad population including 35 percent of participants over age 60. Forty percent of participants in the study had comorbidities associated with an increased risk for progression to severe COVID-19.

### **Authorized Use**

The Janssen COVID-19 Vaccine (Ad26.COV2.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](http://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 press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding development of a potential preventive 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 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 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](http://www.sec.gov), [www.jnj.com](http://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.