



## Moderna Announces Health Canada Approves its COVID-19 Vaccine

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Sep. 16, 2021--

[Moderna, Inc.](#) (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced Health Canada has approved the New Drug Submission (NDS-CV) for SPIKEVAX™ (elasomeran mRNA vaccine), which has been known as COVID-19 Vaccine Moderna, for active immunization to prevent COVID-19 in individuals 12 years of age and older.

“Health Canada’s approval of our COVID-19 vaccine is an important milestone as it is our first full approval for Spikevax. I would like to thank Health Canada for their hard work throughout the process,” said Stéphane Bancel, Chief Executive Officer of Moderna. “I would also like to thank the Government of Canada for the partnership they have built with us and for their confidence in our mRNA platform in addressing the COVID-19 pandemic.”

Health Canada approved the New Drug Submission for SPIKEVAX based on [clinical data](#) from the Phase 3 COVE study of the Moderna COVID-19 vaccine, which enrolled more than 30,000 participants in the U.S. In final analysis of Phase 3 COVE study data, SPIKEVAX showed 93% efficacy, with the efficacy remaining durable through six months after administration of the second dose. The safety profile based on extended safety follow-up was consistent with the Phase 3 COVE study primary results.

The Moderna COVID-19 vaccine was originally authorized in Canada under an Interim Order for individuals 18 years of age and older granted by Health Canada on December 23, 2020. On August 27, 2021, Health Canada expanded the Interim Order authorization for the Moderna COVID-19 vaccine to include adolescents 12 years of age and older.

### About SPIKEVAX

The Moderna COVID-19 vaccine, brand name SPIKEVAX, is an mRNA vaccine against COVID-19 encoding for a prefusion stabilized form of the Spike (S) protein. On December 18, 2020, the U.S. FDA authorized the emergency use of the Moderna COVID-19 Vaccine in individuals 18 years of age or older. Moderna has received emergency (or other conditional, interim or provisional) authorization for use of its COVID-19 vaccine in adults from health agencies in more than 50 countries and an Emergency Use Listing (EUL) from the World Health Organization (WHO).<sup>1</sup>

### About Moderna

In 10 years since its inception, Moderna has transformed from a science research-stage company advancing programs in the field of messenger RNA (mRNA), to an enterprise with a diverse clinical portfolio of vaccines and therapeutics across six modalities, a broad intellectual property portfolio in areas including mRNA and lipid nanoparticle formulation, and an integrated manufacturing plant that allows for both clinical and commercial production at scale and at unprecedented speed. Moderna maintains alliances with a broad range of domestic and overseas government and commercial collaborators, which has allowed for the pursuit of both groundbreaking science and rapid scaling of manufacturing. Most recently, Moderna’s capabilities have come together to allow the authorized use of one of the earliest and most-effective vaccines against the COVID-19 pandemic.

Moderna’s mRNA platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, and has allowed the development of therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases, cardiovascular diseases and auto-immune diseases. Moderna has been named a top biopharmaceutical employer by *Science* for the past six years. To learn more, visit [www.modernatx.com](http://www.modernatx.com).

### AUTHORIZED USE IN CANADA

SPIKEVAX (elasomeran mRNA vaccine) has been granted approval by Health Canada and is indicated for active immunization against coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus in individuals 12 years of age and older.

### IMPORTANT SAFETY INFORMATION

- Do not administer SPIKEVAX to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of SPIKEVAX
- Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of SPIKEVAX. Monitor SPIKEVAX recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>).
- Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose.
- Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.
- Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to SPIKEVAX.
- SPIKEVAX may not protect all vaccine recipients.
- Adverse reactions reported in clinical trials following administration of SPIKEVAX include pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, swelling at the injection site, and erythema at the injection site.
- The following adverse reactions have been reported following administration SPIKEVAX during mass vaccination outside of clinical trials:

- o Severe allergic reactions, including anaphylaxis
- o Myocarditis and pericarditis
- o Syncope

- Available data on SPIKEVAX administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy. Data are not available to assess the effects of SPIKEVAX on the breastfed infant or on milk production/excretion.
- There are no data available on the interchangeability of SPIKEVAX with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of SPIKEVAX should receive a second dose of SPIKEVAX to complete the vaccination series.
- Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of SPIKEVAX.
- If a patient experiences a side effect following immunization, healthcare professionals should complete the Adverse Events Following Immunization (AEFI) Form appropriate for the province/territory (<https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/form.html>) and send it to the local Health Unit.

### Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including regarding the effectiveness and safety of the Company's vaccine against COVID-19 (mRNA-1273), brand name SPIKEVAX. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond Moderna's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties, and other factors include those other risks and uncertainties described under the heading "Risk Factors" in Moderna's most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) and in subsequent filings made by Moderna with the SEC, which are available on the SEC's website at [www.sec.gov](http://www.sec.gov). Except as required by law, Moderna disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on Moderna's current expectations and speak only as of the date hereof.

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<sup>1</sup> BARDA, part of ASPR within the U.S. HHS is supporting the continued research and development of the Company's COVID-19 vaccine development efforts with federal funding under contract no. 75A50120C00034 BARDA is reimbursing Moderna for 100 percent of the allowable costs incurred by the Company for conducting the program described in the BARDA contract. The U.S. government has agreed to purchase supply of mRNA-1273 under U.S. Department of Defense contract no. W911QY-20-C-0100.

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