



Health Canada Authorizes Booster Dose of Moderna's COVID-19 Vaccine in Individuals 18 Years of Age and Older

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 15, 2021-- Moderna Inc., a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today confirmed that Health Canada authorized the use of a booster dose of the Moderna COVID-19 vaccine (SPIKEVAX™) at the 50 µg dose for individuals aged 18 and older administered at least six months after completion of the primary series.

"We would like to thank Health Canada for this authorization and the Government of Canada for its continued confidence in our mRNA platform," said Stéphane Bancel, Chief Executive Officer of Moderna. "We are grateful for the opportunity to provide Canadians with another layer of protection."

Health Canada based this authorization on the totality of scientific evidence shared by the company, including a data analysis from the Phase 2 clinical study of mRNA-1273, which was amended to offer a booster dose of mRNA-1273 at the 50 µg dose level to interested participants 6-8 months following their second dose. Neutralizing antibody titers had waned prior to boosting, particularly against variants of concern, at approximately 6 months. Notably, a booster dose of mRNA-1273 at the 50 µg dose level boosted neutralizing titers significantly above the Phase 3 benchmark. After a booster dose, a similar level of neutralizing titers was achieved across age groups including in older adults (ages 65 and above). The safety profile following the booster dose was similar to that observed previously for dose 2 of mRNA-1273.

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 ground-breaking 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 seven years. To learn more, visit www.modernatx.com.

AUTHORIZED USE IN CANADA

SPIKEVAX (elasmomeran 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 .
- Post-marketing 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 and send it to the local Health Unit.

The full product monograph is available at the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html> and <https://www.modernacovid19global.com/ca/>.

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 Company's development of a vaccine against COVID-19 (mRNA-1273); the authorization of mRNA-1273 for use as a booster dose by Health Canada; the ability of mRNA-1273 booster at the 50 µg dose to trigger an immune response, and the safety profile for that booster. 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. 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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