



Moderna Announces Swissmedic Authorizes Booster Dose of Moderna's COVID-19 Vaccine

October 26, 2021

Authorization granted for particularly vulnerable individuals 12 years of age and older

Swissmedic also authorized a third dose for individuals 12 years of age and older with a weakened immune system

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 26, 2021-- [Moderna, Inc.](#) (Nasdaq:MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced Swissmedic has authorized a booster dose of Spikevax, the Company's vaccine against COVID-19, at the 50 µg dose level in particularly vulnerable individuals 12 years of age and older, at least six months after completion of the primary series.

Swissmedic also approved a third dose of Spikevax at the 100 µg dose level for people with a weakened immune system at least 28 days after the second dose.

"We thank Swissmedic for their review and decision. This approval is supported by clinical evidence that a 50 µg booster dose induces a strong immune response against COVID-19. We also appreciate their approval of a third dose of Spikevax for those with weakened immune systems," said Stéphane Bancel, Chief Executive Officer of Moderna. "We believe that mRNA vaccines are well positioned to adapt to the evolving epidemiology of SARS-CoV-2. We are grateful for the opportunity to provide individuals in Switzerland with another layer of protection."

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.

AUTHORIZED USE IN SWITZERLAND

Spikevax ▼ (COVID-19 Vaccine Moderna) has been granted temporary marketing authorisation by Swissmedic for active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 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, and rash.

- Anaphylaxis and other severe allergic reactions, myocarditis, pericarditis, and syncope have been reported following administration of Spikevax during mass vaccination outside of clinical trials.
- 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.
- Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of Spikevax.
- The black equilateral triangle denotes that additional monitoring is required to capture any adverse reactions. This will allow quick identification of new safety information. Individuals can help by reporting any side effects they may get. Side effects can be reported to EudraVigilance (<https://www.adrreports.eu/>) or directly to Moderna using email EMEAMedinfo@modernatx.com.

For complete information on the safety of Spikevax, always make reference to the approved Summary of Product Characteristics and Package Leaflet available in all the languages of the European Union on the EMA website.

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 approval of mRNA-1273 for use as a booster dose and as a third dose in immunocompromised persons by Swissmedic; the ability of mRNA-1273 boosters at the 50 µg dose to trigger an immune response, and the safety profile for those boosters. 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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Media:

Colleen Hussey
 Director, Corporate Communications
 617-335-1374
Colleen.Hussey@modernatx.com

Investors:

Lavina Talukdar
 Senior Vice President & Head of Investor Relations
 617-209-5834
Lavina.Talukdar@modernatx.com

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