Moderna Announces European Medicines Agency’s Committee for Medicinal Products for Human Use Recommends Booster Dose of Moderna’s COVID-19 Vaccine in the European Union

October 25, 2021

Recommendation granted for individuals 18 years of age and older

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 25, 2021-- Moderna, Inc. (Nasdaq:MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced that the European Medicines Agency’s (EMA) Committee for Medicinal Products for Human Use (CHMP) has concluded that a booster dose of Spikevax, the Company’s vaccine against COVID-19, at the 50 µg dose level may be considered in people aged 18 years and older at least six months after completion of the primary series.

“This recommendation is supported by clinical evidence that a 50 µg booster dose induces a strong immune response against COVID-19. We thank the EMA and the CHMP for their review,” 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 the EU with another layer of protection.”

The EMA based this positive opinion on 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 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 THE EU

Spikevax ▼ (COVID-19 Vaccine Moderna) has been granted conditional marketing authorisation by the European Commission for active immunisation to prevent 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 by the European Medicines Agency; 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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