Moderna Receives Full U.S. FDA Approval for COVID-19 Vaccine Spikevax

1/31/2022

Approval based on a comprehensive submission package including efficacy and safety data approximately six months after second dose

SPIKEVAX has received approval by regulators in more than 70 countries, including Canada, Japan, the European Union, the UK, Israel

807 million doses of Moderna's COVID-19 vaccine shipped globally in 2021; approximately 25% of those doses shipped to low- and middle-income countries

CAMBRIDGE, MA / ACCESSWIRE / January 31, 2022 / Moderna, Inc. (Nasdaq:MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced the U.S. Food and Drug Administration (FDA) has approved the Biologics License Application (BLA) for SPIKEVAX (COVID-19 Vaccine, mRNA) to prevent COVID-19 in individuals 18 years of age and older.

"Our COVID-19 vaccine has been administered to hundreds of millions of people around the world, protecting people from COVID-19 infection, hospitalization and death. The totality of real-world data and the full BLA for Spikevax in the United States reaffirms the importance of vaccination against this virus. This is a momentous milestone in Moderna's history as it is our first product to achieve licensure in the U.S.," said Stéphane Bancel, Chief Executive Officer of Moderna. "The full licensure of Spikevax in the U.S. now joins that in Canada, Japan, the European Union, the UK, Israel, and other countries, where the adolescent indication is also approved. We are grateful to the U.S. FDA for their thorough review of our application. We are humbled by the role that Spikevax is
playing to help end this pandemic."

The FDA based its decision on the totality of scientific evidence shared by the Company in its submission package, which included follow-up data from the Phase 3 COVE study showing high efficacy and favorable safety approximately six months after the second dose. Moderna also submitted manufacturing and facilities data required by the FDA for licensure. SPIKEVAX has received approval by regulators in more than 70 countries.

Moderna’s COVID-19 vaccine was available under Emergency Use Authorization (EUA) in the U.S. from December 18, 2020. Under an EUA, the FDA has the authority to allow medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions during a declared public health emergency when there are no adequate, approved, and available alternatives. A booster dose of the Moderna COVID-19 vaccine at the 50 µg dose level is authorized for emergency use in the U.S. under EUA for adults 18 years and older. A third dose of the Moderna COVID-19 vaccine at the 100 µg dose level is authorized for emergency use in immunocompromised individuals 18 years of age or older in the United States who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

INDICATION (U.S.)

SPIKEVAX (COVID-19 Vaccine, mRNA) is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

IMPORTANT SAFETY INFORMATION

- Do not administer to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine.
- Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine.
- Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 18 through 24 years of age.
- 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 the vaccine.
- The vaccine may not protect all vaccine recipients.
- Adverse reactions reported in clinical trials following administration of the vaccine 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.
- The vaccination provider is responsible for mandatory reporting of certain adverse events to the Vaccine Adverse Event Reporting System (VAERS) online at https://vaers.hhs.gov/reportevent.html or by calling 1-800-822-7967.

About Moderna

In 10 years since its inception, Moderna has transformed from a 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 seven 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 approval 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.

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, or Spikevax); the ability of Spikevax to protect against COVID-19 and prevent infection, hospitalization and death; and the safety profile for 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. 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.

Moderna Contacts

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

SOURCE: Moderna, Inc.

View source version on accesswire.com: