NEWS RELEASE

Moderna Receives FDA Authorization for Emergency Use of Omicron-Targeting Bivalent COVID-19 Booster Vaccine for Children and Adolescents 6 to 17 Years of Age

10/12/2022

mRNA-1273.222 Targets the BA.4/BA.5 Strains of Omicron Variant

Authorization Is Based Upon Clinical and Pre-Clinical Data for Moderna's Bivalent Vaccine Candidates

CAMBRIDGE, MA / ACCESSWIRE / October 12, 2022 / Moderna, Inc. (NASDAQ:MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced that it has received emergency use authorization (EUA) from the U.S. Food and Drug Administration (FDA) for its BA.4/BA.5 Omicron-targeting bivalent COVID-19 booster vaccine, mRNA-1273.222, in children and adolescents 6 to 17 years of age. The authorizations are based on a 25 µg booster dose for children ages 6 to 11 years old and a 50 µg booster dose for adolescents 12 to 17 years old, each following a completed primary series of any of the authorized COVID-19 vaccines or a previous booster. The booster doses of mRNA-1273.222 each contain mRNA encoding for the spike protein of BA.4/BA.5 as well as mRNA encoding for the original strain of the SARS-CoV-2 virus.

"We are proud to have received authorization for our updated, bivalent COVID-19 booster for children and adolescents 6 to 17 years of age," said Stéphane Bancel, Chief Executive Officer of Moderna. "With bivalent boosters available for most age groups, families have access to updated tools as they head into the winter months and holiday gatherings. We are grateful for the FDA for their thorough and timely review."

Last month, mRNA-1273.222, which targets the BA.4/BA.5 subvariants of Omicron, received FDA EUA for adults over the age of 18. The pediatric and adolescent EUA application is based upon clinical trial booster data for Moderna's original vaccine, Spikevax, which was administered to over a thousand participants in each cohort. In addition, the EUA application included pre-clinical data for mRNA-1273.222 as well as **clinical trial data from a Phase 2/3 studying mRNA-1273.214**, another Omicron-targeting bivalent booster vaccine developed by Moderna.

Moderna is currently working to finalize its EUA application for children ages 6 months to 5 years old. The application is expected to be completed later this year.

About Moderna

In over 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 rapid clinical and commercial production at scale. 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 and 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**.

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 6 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.
- Please see the **SPIKEVAX Full Prescribing Information**. For information regarding authorized emergency uses of the Moderna COVID-19 Vaccine, please see the **EUA Fact Sheet**.

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 potential authorization by the U.S. FDA of mRNA-1273.222 as a booster vaccination for children 6 months to 5 years of age and timing for submissions to the U.S. FDA for emergency use authorization; and the potential for mRNA-1273.222 to provide protection in pediatric and adolescent populations from COVID-19. 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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