NEWS RELEASE

Moderna Files for Authorization of Its COVID-19 Vaccine in Young Children Six Months to Under Six Years of Age

4/28/2022

Submission to Regulators Globally Is Based on Phase 2/3 Studies of mRNA-1273 in Young Children

CAMBRIDGE, MA / ACCESSWIRE / April 28, 2022 / Moderna, Inc. (NASDAQ:MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced that it has submitted a request for emergency use authorization (EUA) for its COVID-19 vaccine (mRNA-1273) in children 6 months to under 2 years and 2 years to under 6 years of age to the U.S. Food and Drug Administration and that similar requests are underway with international regulatory authorities. The requests are based on a 25 µg two-dose primary series of mRNA-1273.

"We are proud to share that we have initiated our EUA submission for authorization for our COVID-19 vaccine for young children," said Stéphane Bancel, Chief Executive Officer of Moderna. "We believe mRNA-1273 will be able to safely protect these children against SARS-CoV-2, which is so important in our continued fight against COVID-19 and will be especially welcomed by parents and caregivers."

Positive interim results from the Phase 2/3 KidCOVE study, announced **on March 23, 2022**, showed a robust neutralizing antibody response in the 6 month to under 6 years of age group after a two-dose primary series of mRNA-1273, along with a favorable safety profile. The antibody titers in the pre-specified 6 month to 23 month and 2 years to under 6 years age sub-groups met the statistical criteria for similarity to the adults in the COVE study, which satisfied the primary objective of the study. The previously announced results included a supportive

preliminary efficacy analysis on cases mostly collected during the Omicron wave, including home testing for COVID-19. When the analysis is limited only to cases confirmed positive for SARS-CoV-2 by central lab RT-PCR vaccine efficacy remained significant at 51% (95% CI: 21-69) for 6 months to <2 years and 37% (95% CI: 13-54) for 2 to <6 years. These efficacy estimates are similar to vaccine efficacy estimates in adults against Omicron after two doses of mRNA-1273.

The EUA submission for children ages 6 months to under 6 years will be complete next week. Moderna is also currently studying booster doses for all pediatric cohorts.

The KidCOVE study is being conducted in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH) and the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services. The **ClinicalTrials.gov** identifier is NCT04796896.

BARDA, part of ASPR within the U.S. HHS is supporting the continued research and development of the Company's COVID-19 vaccine development efforts with federal funding under contract no. 75A50120C00034. BARDA is reimbursing Moderna for 100 percent of the allowable costs incurred by the Company for conducting the program described in the BARDA contract.

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 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.
- 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 for primary vaccination of children 6 months to under 6 years of age; the potential for mRNA-1273 to provide protection from COVID-19 and severe COVID-19 disease in vaccine recipients down to 6 months of age; the safety and tolerability of mRNA-1273 in pediatric populations; and Moderna's plans to evaluate the potential of a booster dose for pediatric populations. 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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