Moderna Receives FDA Authorization for Emergency Use of Its COVID-19 Vaccine for Children 6 Months of Age and Older

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mRNA-1273 was authorized for children and adolescents aged 6 months through 17 years of age, administered as two doses given one month apart.

mRNA-1273 has been administered to millions of children and adolescents over the age of 6 worldwide, with safety and tolerability profiles consistent with other age groups.

CAMBRIDGE, MA / ACCESSWIRE / June 17, 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 COVID-19 vaccine (mRNA-1273) in young children ages 6 months through 5 years of age at a dose level of 25 µg. The company has also received emergency use authorization for a 50 µg two-dose regimen of mRNA-1273 for children ages 6 through 11 years old and a 100 µg two-dose regimen for adolescents aged 12 through 17 years old. The two-dose regimens, with doses tailored for each age group given one month apart, are well-timed to initiate protection for the start of the school year, as children return to higher-risk classroom and daycare settings.

"We are thrilled that the FDA has granted Emergency Use Authorization of Moderna’s COVID-19 vaccine for children and adolescents, particularly for our vulnerable, youngest children," said Stéphane Bancel, Chief Executive Officer of Moderna. "Children need to live highly social lives to develop and flourish. With this authorization, caregivers for young children ages 6 months through 5 years of age finally have a way to safeguard against COVID risks in
classroom and daycare settings. Our pediatric COVID-19 vaccine is a two-dose regimen for all children 6 months and older, providing protection against COVID-19 two weeks after the second dose.

mRNA-1273 for children and adolescents showed protection starting 14 days after the second dose. Protection was statistically significant, with data coming from large, well-controlled trials of more than 14,000 children and adolescents and a median follow-up of more than 2 months for 6 months through 5 years of age, 5.6 months for 6 through 11 years of age, and 11.1 months for adolescents.

Positive interim results from the Phase 2/3 KidCOVE study, announced on March 23, 2022, showed a robust neutralizing antibody response in the 6 months through 5 years of age group consistent with young adults, even at the lower 25 μg dose, along with a favorable safety profile consistent with other age groups. The antibody titers in the pre-specified 6 months to 23 months and 2 years to 5 years age sub-groups met the success criteria for similarity to the adults in the COVE study, which satisfied the primary objective of the study. The secondary endpoint of vaccine efficacy was observed to be 51% and 37% based on RT-PCR confirmed COVID-19 and CDC case definition in the 6 months through 23 months and 2 years through 5 years age groups, respectively, comparable to the vaccine efficacy observed in adults receiving mRNA-1273 during the same Omicron prevailing period.

Moderna shared interim results of its Phase 2/3 KidCOVE study in the 6 to 11 years of age group in October 2021, which showed non-inferior anti-SARS-CoV-2 neutralizing antibody responses at the 50 μg dose when compared to that in individuals 18 to 25 years old from the Phase 3 COVE study. The secondary endpoint of vaccine efficacy in the 6 to 11 years of age during the Delta wave was observed to be 88% based on CDC case definition. In May 2021, the company shared interim results of its Phase 2/3 TeenCOVE study of mRNA-1273 at the 100 μg dose. The non-inferior anti-SARS-CoV-2 neutralizing antibody responses at the 100 μg dose was demonstrated when compared to that in individuals 18 to 25 years old from the Phase 3 COVE study. The antibody response was also demonstrated to be non-inferior to adults and the vaccine efficacy in the nearly 2,500 adolescents who received the Moderna COVID-19 vaccine was observed to be 93% when using the CDC case definition.

Clinical trials have demonstrated the safety and tolerability of mRNA-1273 in all pediatric age groups, with no deaths or cases of myocarditis or pericarditis reported. The most commonly reported local symptom was injection site pain across all age groups. The most commonly reported systemic symptoms were headache and fatigue in older children and irritability in younger children.

Moderna's COVID-19 vaccine will be available for children and adolescents at select vaccination sites in the coming days. Children vaccinated early this summer with a two-dose regimen will initiate protection as they return to school and daycare settings in the fall. Millions of children and adolescents have been safely vaccinated with mRNA-1273 around the world.
On January 31, 2022, the U.S. FDA approved the Biologics License Application (BLA) for SPIKEVAX (COVID-19 Vaccine, mRNA) to prevent COVID-19 in individuals 18 years of age and older. Previously, Moderna's COVID-19 vaccine was available under EUA in the U.S. from December 18, 2020. 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 with certain kinds of immunocompromise. 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 second booster dose at 50 µg is authorized for emergency use in the U.S. under EUA for adults 50 and older and individuals 12 and over who are moderately or severely immunocompromised.

Moderna continues to collect and monitor real-world data on its COVID-19 vaccine. Real-world evidence continues to confirm the effectiveness and safety profile of the Moderna COVID-19 vaccine.

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 (HHS). The ClinicalTrials.gov identifier is NCT04796896.

BARDA, part of the Office of the Assistant Secretary for Preparedness Response 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.

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. Emergency uses of the vaccine have not been approved or licensed by the FDA, but have been authorized by the FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) in either individuals 6 months of age and older or as a booster dose in individuals 18 years of age and older, as appropriate.

AUTHORIZED USE IN THE U.S.

Emergency uses of the vaccine have not been approved or licensed by the FDA, but have been authorized by the FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) in either individuals 6 months of age and older or as a booster dose in individuals 18 years of age and older, as appropriate.

IMPORTANT SAFETY INFORMATION

- Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 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 Moderna COVID-19 Vaccine.
- 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 the Moderna COVID-19 Vaccine.
- The Moderna COVID-19 Vaccine may not protect all vaccine recipients.
- Adverse reactions reported in clinical trials for children 6 years of age and older following administration of the Moderna COVID-19 Vaccine include pain at the injection site, fatigue, headache, myalgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, erythema at the injection site, swelling at the injection site, and arthralgia.
- Adverse reactions in children 6 months through 5 years of age following administration of Moderna COVID-19 Vaccine include pain at the injection site, irritability/crying, fatigue, sleepiness, loss of appetite, headache, fever, myalgia, chills, nausea/vomiting, axillary (or groin) swelling/tenderness, arthralgia, erythema at the injection site, and swelling at the injection site.
- Anaphylaxis and other severe allergic reactions, myocarditis, pericarditis, and syncope have been reported...
following administration of the Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials.

- 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 Moderna COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccine Providers) and Full Prescribing Information for:

- Booster dose for 18+ years
- Primary series for 12+ and Booster dose 18+ years
- Primary series for 6 - 11 years
- Primary series for 6 months - 5 years

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 safety, tolerability and protection provided against SARS-CoV-2 by the Company's COVID-19 vaccine, mRNA-1273, in children ages 6 months through 17 years of age; the availability of mRNA-1273 for pediatric vaccinations in the United States; and the ongoing collection of data related to mRNA-1273 in clinical trials. 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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