NEWS RELEASE

EMA Committee for Medicinal Products for Human Use Issues Positive Opinion Recommending Authorization for the Use of Spikevax (mRNA-1273) in Children 6 Months - 5 Years in the European Union

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Announcement follows CHMP's previous decision to issue a positive opinion recommending marketing authorization for Moderna's COVID-19 vaccine to include children 6 years of age and older

Two-dose series takes one month to complete, with similar vaccine efficacy estimates against Omicron to those seen in adults

CAMBRIDGE, MA / ACCESSWIRE / October 19, 2022 / **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 issued a positive opinion recommending a variation to the conditional marketing authorization (CMA) to include a 25 µg two-dose series of Spikevax (mRNA-1273) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 in children 6 months to 5 years. Following the CHMP's positive opinion, the European Commission will make an authorization decision on the use of Spikevax in children ages 6 months to 5 years.

"This recommendation by the CHMP reaffirms the effectiveness and safety of mRNA-1273 and provides parents across Europe with another option to protect their young children against COVID-19, a group at high risk of infection and where additional health prevention measures may not always be feasible," said Stéphane Bancel, Moderna's Chief Executive Officer. "We are grateful to the CHMP for their review and look forward to an

authorization decision from the European Commission."

Positive interim results from the **Phase 2/3 KidCOVE study** showed a robust neutralizing antibody response in the 6-month to 5 years of age group after a two-dose primary series of mRNA-1273 and a favorable safety profile. The antibody titers in the pre-specified 6 months to 23 months and 2 years to 5 years of age sub-groups met the statistical criteria for similarity to the adults in the COVE study, which satisfied the primary objective of the study. Preliminary efficacy analysis on PCR-confirmed cases collected during the Omicron wave showed similar efficacy estimates against Omicron in the 6-month to 5 years of age group to those in adults after two doses of mRNA-1273.

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.

mRNA-1273 has been authorized for active immunization to prevent COVID-19 caused by SARS-CoV-2 in children aged 6 months to 5 years in a number of countries worldwide, including Australia, Canada, and the US. In addition, Spikevax bivalent Original/Omicron BA.1 (mRNA-1273.214), a bivalent vaccine candidate that contains mRNA-1273 and a vaccine candidate targeting the Omicron variant of concern (BA.1), is approved as a booster dose for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older, who have previously received at least a primary vaccination course against COVID- 19.

Authorized Use

Spikevax (elasomeran mRNA vaccine) has been granted Conditional Marketing Authorization by the European Commission, based upon the recommendation of the European Medicines Agency, and is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 in individuals 6 months of age and older. A booster dose may be given at least three months after the second dose for people aged 12 years and older.

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**.

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: development of the Company's COVID-19 Vaccine (mRNA-1273, or Spikevax); the potential approval of the vaccine in children ages 6 months - 5 years by the European Commission following the positive recommendation from the European Medicines Agency's Committee for Medicinal Products for Human Use; and the safety, efficacy, and tolerability of the vaccine in children ages 6 months to 5 years. 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2022, each 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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