

## **MODERNA FILES TO EXPAND CONDITIONAL MARKETING AUTHORIZATION FOR ITS COVID-19 VACCINE TO INCLUDE CHILDREN SIX MONTHS TO UNDER SIX YEARS IN THE EUROPEAN UNION**

*The filing follows the European Medicines Agency's Committee for Medicinal Products for Human Use recent decision to adopt a positive opinion recommending marketing authorization for Moderna's COVID-19 vaccine to include children six years of age and older.*

CAMBRIDGE, Mass. – April 29, 2022-- [Moderna, Inc.](#) (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced that it has submitted for a variation to the conditional marketing authorization (CMA) with the European Medicines Agency (EMA) for the evaluation of a 25 µg two-dose series of Spikevax, the Company's vaccine against COVID-19, in children six months to under six years of age. Similar requests are underway with international regulatory authorities and are based on a 25 µg two-dose primary series of mRNA-1273.

"We are proud to announce this filing for the use of our COVID-19 vaccine in children six months to under six years of age in the European Union, said Stéphane Bancel, Chief Executive Officer of Moderna. "We believe our vaccine will be able to safely protect this important age group against SARS-CoV-2, which is vital in our continued fight against COVID-19 and will be particularly welcomed by the parents and caregivers of these children."

Positive interim results from the Phase 2/3 KidCOVE study [showed](#) a robust neutralizing antibody response in the six months to under six 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 six months to 23 months and two years to under six 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 six 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. In addition, the tolerability profile was generally consistent with that observed in children aged six to under 12, in adolescents aged 12 to 17, and in adults.

The KidCOVE study is an ongoing randomized, observer-blind, placebo-controlled expansion study to evaluate the safety, tolerability, reactogenicity, and effectiveness of Spikevax given to healthy children 28 days apart. The study population is divided into three age groups (6 to <12 years, 2 to <6 years, and six months to <2 years).

The 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.

On February 24, 2022, the EMA's CHMP adopted a [positive opinion](#) recommending marketing authorization for Spikevax to include children six years of age and older. Moderna is currently studying booster doses for all pediatric cohorts.

### **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 six years of age and older. A booster dose may be given at least three months after the second dose for people aged 18 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](http://www.modernatx.com).

### **Forward Looking Statements**

This post contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including regarding: the potential authorization by European Union health officials of mRNA-1273 for primary vaccination of children six months to under six years of age; the potential for mRNA-1273 to provide protection from COVID-19 and severe COVID-19 disease in vaccine recipients down to six months of age; and the safety and tolerability of mRNA-1273 in 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](http://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 post 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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