



NEWS RELEASE

Health Canada Authorizes Moderna's COVID-19 Vaccine in Young Children (6 Months-5 Years)

7/14/2022

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

CAMBRIDGE, MA / ACCESSWIRE / July 14, 2022 / Moderna, Inc. (NASDAQ:MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced that Health Canada has approved the use of Moderna's mRNA COVID-19 vaccine, SPIKEVAX™, in a two-dose series of 25 µg per dose for active immunization to prevent COVID-19 caused by SARS-CoV-2 in children aged 6 months to 5 years. Until now, children under 5 were the only age group not yet eligible in Canada for vaccination against COVID-19. The two-dose primary series of SPIKEVAX for children in this age group is completed in one month, the same primary dosing schedule as adults, adolescents, and children over 5 years of age.

"Since the pandemic began, we have worked with a deep sense of responsibility to deliver on the promise of mRNA science for Canadians," said Patricia Gauthier, President and General Manager, Moderna Canada. "This decision from Health Canada confirms the effectiveness and safety of Moderna's vaccine in this final and important age group. With this announcement, parents and caregivers now have an option to protect these very young children, a group at high risk of infection and where additional health prevention measures like wearing masks may not always be feasible."

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 5 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 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. The KidCOVE study included eight trial sites across Canada. A total of 414 Canadian children under the age of 5 were included in the KidCOVE trials.

Health Canada previously approved the use of Moderna's mRNA COVID-19 vaccine, SPIKEVAX (elasomeron mRNA vaccine), for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals six years of age and older in March 2022.

Authorized Use

Health Canada has approved the use of Moderna's mRNA COVID-19 vaccine, SPIKEVAX (elasomeron mRNA vaccine), for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 6 months of age and older.

About Moderna

In 10 years since its inception, Moderna has transformed from a science 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 ground-breaking 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 post contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including regarding: the development of the Company's COVID-19 Vaccine (mRNA-1273, or SPIKEVAX); the approval of the vaccine in children ages 6 months to 5 years by Health Canada; and the safety, efficacy, and tolerability of the vaccine in children ages 6 months to 5 years of age. 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 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.

Moderna Contacts

Media:

Luke Mircea-Willats

Director, Media Relations & Communications

Luke.MirceaWillats@modernatx.com

Investors:

Lavina Talukdar

Senior Vice President & Head of Investor Relations

617-209-5834

Lavina.Talukdar@modernatx.com

SOURCE: Moderna, Inc.

View source version on accesswire.com:

<https://www.accesswire.com/708579/Health-Canada-Authorizes-Modernas-COVID-19-Vaccine-in-Young-Children-6-Months-5-Years>

