NEWS RELEASE

Therapeutic Goods Administration Grants Provisional Approval for Moderna’s COVID-19 Vaccine in Children Aged Six Months to Five Years

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Announcement follows recent authorization of the Company's mRNA COVID-19 vaccine in Argentina, Canada, Israel, the US, and Taiwan for active immunization to prevent COVID-19 caused by SARS-CoV-2 in children aged 6 months to five years

CAMBRIDGE, MA / ACCESSWIRE / July 18, 2022 / Moderna, Inc. (NASDAQ:MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced that the Therapeutic Goods Administration (TGA) in Australia has granted provisional registration for 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 six were the only age group not eligible for vaccination against COVID-19 in Australia.

"We are pleased that our vaccine for children under six years of age has received provisional approval by the TGA," said Michael Azrak, General Manager of Moderna for Australia and New Zealand. "The continued evolution of COVID-19 represents an emergent threat to global public health, including young children. Since the onset of the pandemic, we have worked with a deep sense of responsibility to deliver on the promise of mRNA science to all Australians. The approval from TGA helps extend an opportunity to all parents and caregivers in Australia to protect their young children against SARS-COV-2."

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.

Moderna is committed to supporting the Australian Government on the COVID-19 program implementation in children aged 6 months to five years upon receiving a recommendation from the Australian Technical Advisory Group on Immunisation (ATAGI).

The TGA previously **approved** the use of Moderna's mRNA COVID-19 vaccine, Spikevax (elasomeran mRNA vaccine), for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals aged six years or over.

Authorized Use

Therapeutic Goods Administration has provisionally approved the use of Moderna's mRNA COVID-19 vaccine, Spikevax (elasomeran 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 the Therapeutic Goods Administration; 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.

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