



NEWS RELEASE

EMA Committee for Medicinal Products for Human Use (CHMP) Recommends the Use of Moderna's BA.1 Targeting Bivalent COVID-19 Booster in Children (6-11 Years) In the European Union

12/16/2022

The recommendation is based on clinical data for Moderna's bivalent Omicron-targeting COVID-19 vaccine, mRNA.1273.214

Moderna's bivalent Omicron-targeting COVID-19 vaccines (mRNA.1273.214 (BA.1) & mRNA.1273.222 (BA.4-5)) are approved for use in individuals 12 years of age and older in the European Union

Both bivalents have been shown to trigger a superior antibody response compared to a booster dose of mRNA-1273, the Company's prototype vaccine, against Omicron (BA.4-5) in Phase 2/3 clinical trials

CAMBRIDGE, MA / ACCESSWIRE / December 16, 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 adopted a positive opinion recommending a variation to the marketing authorization (MA) to include a booster dose of Spikevax bivalent Original/Omicron BA.1 (mRNA-1273.214), at the dose level for children (6-11 years) of 12.5mcg/12.5mcg (0.25 mL) at least three months after the last prior dose of a COVID-19 vaccine.

"The recommendation to authorize the use of a booster dose of mRNA-1273.214 in children ages 6-11 is crucial to providing protection against Omicron and the emergence of new variants of concern, which is especially important

during the winter period in Europe when respiratory diseases are on the rise," said Stéphane Bancel, Chief Executive Officer of Moderna. "We are grateful to the CHMP for their review of our submission and look forward to an authorization decision from the European Commission."

The pediatric application is based on clinical trial booster data for Moderna's original vaccine, Spikevax, which was administered to over a thousand participants. The application described data from a 25 µg booster dose administered to children ages 6 to 11 years old following a completed primary series of the Moderna COVID-19 vaccine. In addition, the application included **clinical trial data from a Phase 2/3 studying mRNA-1273.214**.

In **November 2022**, Moderna announced that its bivalent Omicron-targeting booster candidates (mRNA-1273.214 and mRNA-1273.222) trigger a superior antibody response compared to a booster dose of mRNA-1273, the Company's prototype vaccine, against Omicron (BA.4-BA.5) in Phase 2/3 clinical trials. Both bivalent vaccines also met non-inferiority immunogenicity criteria to the original strain.

A Phase 2/3 trial evaluating mRNA-1273.214 as booster and primary series in children 6 months through 5 years of age is currently underway, with initial results expected in early 2023.

About Moderna

In 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 autoimmune diseases. Moderna has been named a top biopharmaceutical employer by Science for the past eight 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: the Company's development of bivalent vaccine candidates

against COVID-19 (mRNA-1273.222 and mRNA-1273.214); the ability of mRNA-1273.214 to protect children against COVID-19; the ability of mRNA-1273.214 and mRNA-1273.222 to induce higher neutralizing antibody titers against Omicron variants in adults than the Company's vaccine candidate against the ancestral strain of SARS-CoV-2 (mRNA-1273); and the pending authorization of mRNA-1273.214 in the European Union for administration in children ages 6-11 following the CHMP's positive opinion. 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 and the Quarterly Report on Form 10-Q for the quarter 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 of this press release.

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SOURCE: Moderna, Inc.

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