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mRNA-1273.222 Targets BA.4/BA.5 Strains of Omicron Variant

 Pending Authorization, Moderna Ready to Ship Bivalent Booster mRNA-1273.222 in September

Clinical Data Available for Moderna's Bivalent COVID-19 Booster Vaccines Have Met All Primary Endpoints and Support Request for Emergency Use Authorization

CAMBRIDGE, MA / ACCESSWIRE / August 23, 2022 / Moderna, Inc. (NASDAQ:MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced that it has completed its submission to the U.S. Food and Drug Administration (FDA) for emergency use authorization for its BA.4/BA.5 Omicron-targeting bivalent COVID-19 booster vaccine, mRNA-1273.222. The application is for a 50 µg booster dose for adults 18 years of age and older, and is based on preclinical data as well as clinical trial data available for the company's BA.1 Omicron-targeting bivalent booster candidate, mRNA-1273.214.

"We have worked closely with the FDA to ensure that Americans will have access to Moderna's updated, bivalent booster, which, if authorized, may offer higher, broader, and more durable protection against COVID-19 compared to the currently authorized booster," said Stéphane Bancel, Chief Executive Officer of Moderna. "Moderna's mRNA platform has enabled us to develop, study, and deploy bivalent booster vaccine candidates that demonstrate
superior protection against all tested COVID variants, in record time. Our commitment to using cutting-edge science to protect the world against the ongoing COVID threat continues."

mRNA-1273.222 targets both the original strain of SARS-CoV-2 as well as the BA.4/BA.5 subvariants of the Omicron strain. Moderna’s application to the FDA is based on preclinical data for mRNA-1273.222 as well as clinical trial data from a Phase 2/3 studying mRNA-1273.214, a bivalent booster vaccine targeting the Omicron BA.1 subvariant. In the study, mRNA-1273.214 met all primary endpoints, including superior neutralizing antibody response against Omicron (BA.1) when compared to a 50 µg booster dose of mRNA-1273 in previously uninfected participants, as well as potent neutralizing antibody responses against the Omicron subvariants BA.4 and BA.5 compared to the currently authorized booster (mRNA-1273) regardless of prior infection status or age.

Moderna developed mRNA-1273.222 in accordance with U.S. FDA guidance to develop a BA.4/BA.5-targeting bivalent vaccine. A Phase 2/3 trial for mRNA-1273.222 is currently underway. Moderna has rapidly scaled manufacturing of mRNA-1273.222 in order to be ready, if authorized, to deliver doses in September.

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.

INDICATION (U.S.)

- SPIKEVAX (COVID-19 Vaccine, mRNA) is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older. Emergency uses of the vaccine have not been approved or licensed by the FDA, but have been authorized by the FDA, under an Emergency Use Authorization (EUA) to prevent
Coronavirus Disease 2019 (COVID-19) in either individuals 6 months of age and older or as a booster dose in individuals 18 years of age and older, as appropriate.

AUTHORIZED USE IN THE U.S.

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IMPORTANT SAFETY INFORMATION

- Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine.
- Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine.
- Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose.
- Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.
- Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to the Moderna COVID-19 Vaccine.
- The Moderna COVID-19 Vaccine may not protect all vaccine recipients.
- Adverse reactions reported in clinical trials for children 6 years of age and older following administration of the Moderna COVID-19 Vaccine include pain at the injection site, fatigue, headache, myalgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, erythema at the injection site, swelling at the injection site, and arthralgia.
- Adverse reactions in children 6 months through 5 years of age following administration of Moderna COVID-19 Vaccine include pain at the injection site, irritability/crying, fatigue, sleepiness, loss of appetite, headache, fever, myalgia, chills, nausea/vomiting, axillary (or groin) swelling/tenderness, arthralgia, erythema at the injection site, and swelling at the injection site.
- Anaphylaxis and other severe allergic reactions, myocarditis, pericarditis, and syncope have been reported following administration of the Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials.
- The vaccination provider is responsible for mandatory reporting of certain adverse events to the Vaccine Adverse Event Reporting System (VAERS) online at https://vaers.hhs.gov/reportevent.html or by calling 1-800-822-7967.

Please see the Moderna COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccine Fact Sheet) for additional information.
Providers) and Full Prescribing Information for:

- Booster dose for 18+ years
- Primary series for 12+ and Booster dose 18+ years
- Primary series for 6 - 11 years
- Primary series for 6 months - 5 years

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: Moderna's application to the FDA for emergency authorization of mRNA-1273.222, and the potential authorization of mRNA-1273.222 by the FDA; Moderna's anticipated shipment of mRNA-1273.222; the anticipated timing of the availability of mRNA-1273.222 nationwide, including in advance of predicted fall surges; the ability of mRNA-1273.222 to offer broad and durable protection against COVID-19; and real-world evidence supporting the effectiveness and safety profile of the Moderna COVID-19 vaccine. 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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