Moderna Receives FDA Authorization for Emergency Use of Omicron-Targeting Bivalent COVID-19 Booster Vaccine for Adults 18 Years and Older

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Moderna’s Bivalent Booster Shots to be Available Nationwide In Coming Days

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

CAMBRIDGE, MA / ACCESSWIRE / August 31, 2022 / Moderna, Inc. (NASDAQ:MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced that it has received emergency use authorization (EUA) from the U.S. Food and Drug Administration (FDA) for its BA.4/.5 Omicron-targeting bivalent COVID-19 booster vaccine, mRNA-1273.222. Authorization has been given for a 50 µg booster dose for adults over 18 years of age who have received either a primary series or an initial booster of any of the authorized or approved COVID-19 vaccines. The 50 µg booster dose of mRNA-1273.222 includes 25 µg of mRNA encoding for the spike protein of BA.4/.5 and 25 µg encoding for the original strain of the SARS-CoV-2 virus.

"The FDA's authorization of our updated bivalent booster, mRNA-1273.222, provides Americans with access to broader protection against Omicron variants," said Stéphane Bancel, Chief Executive Officer of Moderna. "Receiving a booster that specifically targets the Omicron BA.4/.5 variant, currently the most prevalent strain of SARS-CoV-2, is an important public health measure that people can take to help protect themselves, especially as we head into a season filled with indoor gatherings. We are grateful to the FDA for their decisive leadership."

mRNA-1273.222, which targets the BA.4/.5 subvariants of Omicron, was developed under guidance from the U.S. FDA, which based today's authorization on pre-clinical data for mRNA-1273.222 as well as clinical trial data from a
Phase 2/3 studying mRNA-1273.214, another Omicron-targeting bivalent booster vaccine developed by Moderna. In addition, a vast and growing body of real-world evidence provides strong evidence for the effectiveness and safety of mRNA-1273, the original Moderna COVID-19 vaccine which is the basis for the company's updated, bivalent vaccines. A Phase 2/3 clinical trial for mRNA-1273.222 is fully enrolled and currently underway, with initial data expected later this year.

Moderna's updated, bivalent booster is expected to be available at vaccination sites nationwide in the coming days. Doses of mRNA-1273.222 have been purchased by the U.S. Government's Department of Defense Joint Program Executive Office for Chemical, Biological, Radiological Nuclear Defense (JPEO-CBRND) and the Army Contracting Command under contract number W58P05-22-C-0017.

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.
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). The Moderna COVID-19 Vaccine is authorized in individuals 6 months of age and older as a primary series. The Moderna COVID-19 Vaccine, Bivalent is authorized as a booster dose in individuals 18 years of age and older.

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 or Moderna COVID-19 Vaccine, Bivalent.
- Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccines.
- 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 vaccines.
- 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 Vaccine Fact Sheets for Healthcare Providers Administering Vaccine (Vaccine Providers) and Full Prescribing Information for:

- Bivalent Booster dose for 18+ years
- Primary series for 12+
- 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: development of the Company's COVID-19 Vaccine targeting the Omicron BA.4/BA.5 variants (mRNA-1273.222); the potential for higher, broader and more durable protection against Omicron variants for mRNA-1273.222 than mRNA-1273; the timing and availability of mRNA-1273.222 for distribution to the U.S. population; the safety, efficacy, and tolerability of mRNA-1273.222; and the ability of mRNA-1273.222 to protect against COVID-19. 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 for the 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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