Updated COVID-19 vaccine effectively targets EG.5, a dominant variant of concern, as well as the rapidly spreading FL.1.5.1 variant.

Updated vaccine expected to be available, pending approval, in coming weeks for fall vaccination season.

CAMBRIDGE, MA / ACCESSWIRE / August 17, 2023 / Moderna, Inc. (NASDAQ:MRNA) today announced that preliminary clinical trial data confirm its updated COVID-19 vaccine for the fall 2023 vaccination season showed a significant boost in neutralizing antibodies against EG.5 and FL.1.5.1 variants. These results suggest that Moderna’s updated COVID-19 vaccine may effectively target the expected circulating variants of COVID-19 during the upcoming vaccination season.

The World Health Organization (WHO) recently classified the EG.5, or "Eris," strain as a variant of interest. EG.5 is now the dominant variant in the U.S. according to the Centers for Disease Control and Prevention (CDC), while also accounting for a growing proportion of cases across the globe. The FL.1.5.1, or "Fornax," variant is also beginning to surge in parts of the U.S.

"These new results, which show that our updated COVID-19 vaccine generates a robust immune response against the rapidly spreading EG.5 and FL.1.5.1 strains and reflects our updated vaccine's ability to address emerging..."
COVID-19 threats," said Stephen Hoge, M.D., President of Moderna. "Moderna is committed to leveraging our mRNA technology to provide health security around the world."

In addition to demonstrating a human immune response against the EG.5 and FL 1.5.1 strains, Moderna previously presented the only clinical trial data confirming that its updated COVID-19 vaccine showed robust human immune responses across the key circulating XBB strains at the June 2023 FDA VRBPAC. With this new trial data, Moderna has now confirmed an antibody response against current strains of concern.

Moderna has submitted its updated COVID-19 vaccine to the U.S. Food and Drug Administration, the European Medicines Agency (EMA) and other regulators around the world. Pending authorization, it will be ready for fall vaccination with sufficient global supply.

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 and integrated manufacturing facilities that allow 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 eight years. To learn more, visit www.modernatx.com.

AUTHORIZED USE IN THE U.S.

mRNA-1273.815 has not been authorized or approved by the FDA.

Emergency uses of the Moderna COVID-19 Vaccine, Bivalent, 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).

IMPORTANT SAFETY INFORMATION
Do not administer the vaccines 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 primary series dose or first booster 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 vaccines may not protect all vaccine recipients.

Solicited adverse reactions included:

- 6 months through 36 months of age: Injection site erythema, pain and swelling; axillary (or groin) swelling/tenderness, fever, irritability/crying, loss of appetite and sleepiness
- 37 months of age and older: Injection site erythema, pain and swelling; arthralgia, axillary (or groin) swelling/tenderness, chills, fatigue, fever, headache, myalgia, nausea/vomiting, and rash
- 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](https://vaers.hhs.gov/reportevent.html) or by calling 1-800-822-7967.

Please see the Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) Fact Sheet for Healthcare Providers Administering Vaccine for more information.

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 regulatory application to the U.S. FDA, EMA and other regulators around the world for mRNA-1273.815; Moderna's ability to deliver its updated COVID-19 vaccine with ample and timely global supply for the fall vaccination season, pending authorization; the ability of Moderna's updated vaccine to generate an immune response against EB.5, FL.1.5.1 and XBB variants of concern; and the ability of mRNA-1273.815 to effectively target EG.5 and other circulating variants during the upcoming vaccination season. 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 year ended December 31, 2022, 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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1 https://covid.cdc.gov/covid-data-tracker/#variant-proportions

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