



Paris, September 6<sup>th</sup> 2023

## PRESS RELEASE

### **MODERNA CLINICAL TRIAL DATA CONFIRM ITS UPDATED COVID-19 VACCINE GENERATES STRONG IMMUNE RESPONSE IN HUMANS AGAINST BA.2.86**

*CDC notes that the BA.2.86 (Pirola) variant may be more likely to break through existing immunity from previous vaccination or infection, highlighting the need for vaccination with an updated COVID-19 vaccine for the fall 2023 season*

*Clinical trial data from research assay confirmed Moderna's updated COVID-19 vaccine showed an 8.7 to 11-fold increase in neutralizing antibodies against circulating variants, including BA.2.86, EG.5, and FL.1.5.1 variants*

*With governments accelerating the timing of COVID-19 vaccination campaigns due to the potential risk of BA.2.86, Moderna has shared this data with regulators and is ready to supply its updated COVID-19 vaccine pending regulatory approval*

CAMBRIDGE, MA / ACCESSWIRE / September XX, 2023 / Moderna, Inc. (NASDAQ:MRNA) today announced that clinical trial data from its research assay confirm its updated COVID-19 vaccine, which is pending approval by the U.S. Food and Drug Administration for the fall 2023 vaccination season, generates an 8.7-fold increase in neutralizing antibodies in humans against BA.2.86 (Pirola), a variant under monitoring. The Centers for Disease Control (CDC) indicates that the highly mutated BA.2.86 variant may be more capable of causing infection in people who previously had COVID-19 or were vaccinated with previous vaccines, noting that updated COVID-19 vaccines may be effective in reducing severe disease and hospitalization.

"These results demonstrate that our updated COVID-19 vaccine generates a strong human immune response against the highly mutated BA.2.86 variant. Taken together with our previously communicated results showing a similarly effective response against EG.5 and FL.1.5.1 variants, these data confirm that our updated COVID-19 vaccine will continue to be an important tool for protection as we head into the fall vaccination season," said Stephen Hoge, M.D., President of Moderna. "Moderna will continue to rapidly assess global public health threats and is committed to leveraging our mRNA platform against COVID-19."

Public health authorities are vigilantly monitoring the BA.2.86 variant, a highly-mutated strain of COVID-19 with over 30 mutations as compared to prior Omicron strains, with some governments accelerating COVID-19 vaccination campaigns due to its potential to break through protective immunity generated

from previous COVID-19 vaccination or infection. The emergence of BA.2.86, in addition to the growing prevalence of the EG.5 and FL1.5.1 variants, underscores the need for vaccination with an updated COVID-19 vaccine, which can help reduce severe disease and hospitalizations caused by current circulating strains.

Moderna's clinical trial data around its updated COVID-19 vaccine's effectiveness against BA.2.86 have been shared with regulators and submitted for peer review publication.

### **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](http://www.modernatx.com).

### **AUTHORIZED USE IN THE U.S.**

mRNA-1273.815 has not yet 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> 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 pending regulatory application to the U.S. FDA for its updated COVID-19 vaccine; Moderna's ability to deliver its updated COVID-19 vaccine for the fall vaccination season, pending authorization; governments' acceleration of the timing of COVID-19 vaccination campaigns due to the potential risk of BA.2.86; the potential for BA.2.86 to be more likely to break through existing immunity from previous vaccination or infection; the ability of Moderna's updated vaccine to generate a strong immune response against circulating variants, including BA.2.86, EG.5 and FL.1.5.1; and the ability of Moderna's updated COVID-19 vaccine to effectively target circulating variants during the upcoming vaccination season and help reduce severe disease and hospitalizations. 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](http://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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