



Moderna Announces Publication of Preclinical Data for Chikungunya Antibody Program

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Published in Science Immunology, study shows mRNA encoding antibody against chikungunya virus is well tolerated, results in linear dose-dependent protein expression and provides 100 percent protection against infection in animals

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 17, 2019-- Moderna, Inc., (Nasdaq: MRNA) a clinical stage biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of transformative medicines for patients, today announced the publication of preclinical data in *Science Immunology*, showing that mRNA encoding a human monoclonal antibody against the chikungunya virus delivered in a proprietary lipid nanoparticle (LNP) can protect from infection by the virus *in vivo*. These data supported the initiation of a Phase 1 program of mRNA-1944 against chikungunya virus in January 2019 to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of escalating doses of mRNA-1944 via intravenous infusion in healthy adults.

"These preclinical data demonstrate three critical features of our therapeutic platform: first, that it was well-tolerated, with no dose-limiting toxicities; second, we showed linear dose-dependent pharmacology; and third, that the expressed protein was able to prevent disease," said Stephen Hoge, M.D., president at Moderna. "The mRNA and delivery technologies presented here underpin our expansion into systemic therapeutics in humans, first with mRNA-1944 against chikungunya virus this past January, and soon with our first metabolic rare disease program, mRNA-3704, for methylmalonic acidemia."

The preclinical data published today showed that treatment with mRNA was well tolerated at doses ranging from 0.3 mg/kg to 3.0 mg/kg in non-human primates, with linear dose-dependent pharmacology, meaning that increases in mRNA doses result in predictable and proportionate increases in expressed antibody in the blood. Finally, in a mouse viral challenge model for chikungunya virus infection, the mRNA-encoded protein provided protection from arthritis, musculoskeletal tissue infection and death. Extrapolating these findings from the preclinical models suggests that persistence of antibody levels of at least 1 microgram per milliliter could be protective against chikungunya virus infection in humans.

"Using the body's own machinery to produce antibodies against chikungunya by using mRNA may be a powerful way to combat the virus," said James Crowe Jr., MD, director of the Vanderbilt Vaccine Center. "We are pleased that our early work contributed to these preclinical findings and look forward to the results from the ongoing Phase 1 clinical study of the antibody against chikungunya virus."

mRNA-1944 encodes a fully human IgG antibody originally isolated from B cells of a patient with a prior history of potent immunity against chikungunya infection, a mosquito-borne virus. It is composed of two mRNAs that encode the heavy and light chains of this anti-chikungunya antibody within Moderna's proprietary lipid nanoparticle (LNP) technology. The research and development of mRNA-1944 was financially supported by the Defense Advanced Research Projects Agency (DARPA), an agency of the U.S. Department of Defense, and the antibody was initially identified by researchers at Vanderbilt University Medical Center.

A link to the publication, *A Lipid-encapsulated mRNA Encoding a Potently Neutralizing Human Monoclonal Antibody Protects Against Chikungunya Infection* (Kose, et al.), can be found [here](#).

Moderna currently has 21 mRNA development candidates in its portfolio spanning infectious diseases, immuno-oncology, rare diseases and cardiovascular disease, with 11 of these development candidates now in the clinic. The Company's pipeline can be found at www.modernatx.com/pipeline. In the past three years, Moderna and collaborators have published more than 26 peer-reviewed papers, with 13 in the last year alone.

About Chikungunya

Chikungunya is a mosquito-borne virus that poses a significant public health problem in tropical and subtropical regions. The disease is characterized by an acute onset of fever, rash, muscle pain, and sometimes debilitating pain in multiple joints. There are currently no effective therapies or approved vaccines to treat or prevent chikungunya infection or disease, and effective mosquito control is challenging. Currently, people infected with chikungunya are treated with non-steroidal anti-inflammatory drugs to relieve some symptoms. In addition to a systemic secreted antibody that could provide passive immunity, Moderna is also exploring using mRNA to encode viral antigens as a prophylactic vaccine against the chikungunya virus (mRNA-1388).

About Moderna

Moderna is advancing messenger RNA (mRNA) science to create a new class of transformative medicines for patients. mRNA medicines are designed to direct the body's cells to produce intracellular, membrane or secreted proteins that can have a therapeutic or preventive benefit and have the potential to address a broad spectrum of diseases. Moderna's platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, providing the Company the capability to pursue in parallel a robust pipeline of new development candidates. Moderna is developing therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases and cardiovascular diseases, independently and with strategic collaborators.

Headquartered in Cambridge, Mass., Moderna currently has strategic alliances for development programs with AstraZeneca, Plc. and Merck, Inc., as well as the Defense Advanced Research Projects Agency (DARPA), an agency of the U.S. Department of Defense; the Biomedical Advanced Research and Development Authority (BARDA), a division of the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS). Moderna has been ranked in the top ten of Science's list of top biopharma industry employers for the past four years. To learn more, visit www.modernatx.com.

Special Note Regarding 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, but not limited to, statements concerning: the suggestion that preclinical data for mRNA-1944 showing passive immunization may lead to the prevention of infectious diseases like chikungunya in humans and that mRNA-1944 may be well-tolerated and delivered in a dose-dependent manner in humans; and the potential for the human body to use its own machinery to produce antibodies against Chikungunya by using mRNA to combat the virus. In some cases, forward-looking statements can be identified by terminology such as “will,” “may,” “should,” “expects,” “intends,” “plans,” “aims,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue,” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. 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, among others: whether preclinical results of mRNA-1944 will be predictive of any future clinical studies, including the ongoing Phase 1 clinical study of mRNA-1944; whether mRNA-1944 will be shown to be unsafe or intolerable during future preclinical or clinical studies; clinical development is lengthy and uncertain, especially for a new class of medicines such as mRNA, and therefore our clinical programs or development candidates may be delayed, terminated, or may never advance; no mRNA drug has been approved in this new potential class of medicines, and may never be approved; mRNA drug development has substantial clinical development and regulatory risks due to the novel and unprecedented nature of this new class of medicines; and those risks and uncertainties described under the heading “Risk Factors” in Moderna’s most recent Annual Report on Form 10-K 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 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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Moderna Contacts:

Investors:

Lavina Talukdar
Head of Investor Relations
617-209-5834
lavina.talukdar@modernatx.com

Media:

Jason Glashow
Head of Corporate Communications
617-674-5648
Jason.glashow@modernatx.com