Newly Published Data Highlight Moderna’s mRNA Platform in Advancing Prophylactic Vaccine for Cytomegalovirus (CMV) Infections

**Paper in the Journal Vaccine Shows Versatility of Platform for Encoding and Delivering Complex CMV Antigens, including Six mRNAs for CMV Glycoprotein gB and Pentamer Protein**

CAMBRIDGE, Mass., February 20, 2018 — Moderna Therapeutics, a clinical stage biotechnology company that is pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of transformative medicines for high unmet medical needs in patients, today announced the publication of new data in the scientific journal *Vaccine* that demonstrate the versatility of its mRNA vaccine platform in developing novel prophylactic vaccines to potentially prevent human cytomegalovirus (CMV) infections and associated disease burdens, both for pregnant women and in transplant patients.

Human cytomegalovirus (CMV) is the leading cause of infection in newborns, and can lead to deafness, microcephaly (small, not fully developed heads) and severe disabilities, including vision loss and mental deficiencies, among other serious complications. It is also the most frequent viral disease in transplant recipients, often leading to transplant failure. At this time, there are no approved vaccines for CMV. Moderna currently is conducting a Phase 1 study in CMV in the U.S. with its clinical development candidate mRNA-1647.

The newly published data showed that Moderna’s mRNA encoding CMV glycoproteins gB and pentameric complex (PC), encapsulated in its delivery system, produced potent and durable neutralizing antibody titers in immunized mice and non-human primates. The mRNA delivered six mRNAs -- including the five subunits encoding the pentamer protein, which then correctly assembled within the cell to make the pentamer protein.

“We using mRNA, we have shown the ability to induce very precise copies of even complex antigens *in-vivo*, that in turn induce robust immune responses in mouse and non-human primate models. This gives us real hope that we will eventually see similar results in humans,” said Dr. Mike Watson, SVP Vaccine Partnerships & Health Impact. “These data highlight the ability of the platform to effectively, rapidly and precisely induce complex antigens that have proved so challenging to other vaccine approaches. For CMV, these platform characteristics give us the opportunity to potentially tailor the vaccine to target different CMV-related diseases, such as those associated with congenital CMV infections and transplant-associated CMV infections.”

The two dominant glycoproteins of CMV, gB and PC, play different roles in the infection of different cells. When brought together in a multi-valent vaccine, it may be possible to neutralize infection across a wide variety of cells, including fibroblasts, endothelial, epithelial and myeloid cells – with the majority of neutralizing antibodies in CMV seropositive individuals directed against PC. Moderna researchers also developed a pp65 mRNA/LNP that was used with gB and PC to broaden T cell responses. Neutralizing antibodies against envelope glycoproteins and cellular responses targeting a variety of viral proteins, particularly pp65, are believed to help control CMV infection and re-activation.
Moderna began dosing patients in November 2017 to assess the safety, tolerability and immunogenicity of mRNA-1647. Additional clinical trial information can be found here.

Notes for editors
“Multi-antigenic human cytomegalovirus mRNA vaccines that elicit potent humoral and cell-mediated immunity,” by Dr. Shinu John, Ph.D; Dr. Olga Yuzhakov, Ph.D; Angela Woods; Jessica Deterling; Dr. Kimberly Hassett, PhD; Dr. Christine A Shaw, Ph.D; Dr. Giuseppe Ciaramella, Ph.D. DOI: 10.1016/j.vaccine.2018.01.029.

Copies of this paper are available to credentialed journalists upon request; please contact Elsevier's Newsroom at newsroom@elsevier.com or +31 20 485 2492.

About Vaccine
Vaccine is the pre-eminent journal for those interested in vaccines and vaccination. It is the official journal of The Edward Jenner Society and The Japanese Society for Vaccinology, and is published by Elsevier. www.journals.elsevier.com/vaccine

About Moderna’s mRNA Prophylactic Vaccines
Messenger RNA (mRNA) plays a fundamental role in human biology, directing protein production in cells. When used as a drug, mRNA can direct cells to produce therapeutic proteins (mRNA therapeutics) to fight disease or antigenic proteins (mRNA vaccines) to prevent disease.

Moderna’s mRNA vaccines encode for viral antigenic proteins associated with viruses. The mRNA directs cells to produce and express the proteins, much like a native infection would do, but without the ability to cause disease.

As a result, the immune system recognizes the antigenic proteins as foreign to the body and produces antibodies that have the potential to neutralize the virus and to prevent infections in the event the vaccinated person is exposed to the actual virus in the future.

About Moderna Therapeutics
Moderna pioneers the discovery and development of messenger RNA (mRNA) therapeutics and vaccines, an entirely new class of medicines that directs the body’s cells to produce intracellular or secreted proteins that can have a therapeutic or preventive benefit for both patients and healthy individuals. With its breakthrough platform, Moderna is creating mRNA medicines for a wide range of diseases and conditions, in many cases by addressing currently undruggable targets or underserved areas of medical need. Moderna is developing its innovative mRNA medicines for infectious diseases, immuno-oncology, rare diseases, and cardiovascular diseases, through solely controlled programs and collaborations with strategic partners.

Headquartered in Cambridge, Mass., privately held Moderna currently has strategic relationships with AstraZeneca, Plc. (AZ), Merck, Inc (MRK) and Vertex Pharmaceuticals (VRTX), 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); and the Bill & Melinda Gates Foundation. In 2017, Moderna was ranked a top biopharma industry employer by Science Magazine and a Top Places to Work by the Boston Globe. To learn more, visit www.modernatx.com.
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