



Moderna Announces Publication of Phase 1 Data for mRNA Vaccines Against Two Potential Pandemic Influenza Strains

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Published in the journal Vaccine, data show vaccines targeting the H10N8 and H7N9 influenza viruses to be highly immunogenic and well-tolerated in healthy adults

Results are from Moderna's first human studies of mRNA vaccines; demonstrates a new technological approach to flu vaccine development and production

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 10, 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 results from two Phase 1 clinical studies showing that mRNA vaccines against H10N8 and H7N9 influenza viruses were well-tolerated and elicited robust immune responses. The results support the potential of mRNA-based vaccines to quickly and effectively address pandemic influenza strains.

Published in the scientific journal *Vaccine*, the findings include results from two randomized, placebo-controlled, double-blind Phase 1 studies. Both studies met their primary safety and secondary immunogenicity endpoints, and there were no vaccine-related serious adverse events (AEs) reported. In both studies, injection site pain was the most common solicited local AE.

Both H10N8 and H7N9 influenza infections have demonstrated high fatality rates, however neither have an approved vaccine.

"Both seasonal and pandemic influenzas are serious public health problems, and there is a clear need for effective vaccines that can be quickly developed and deployed. Production of current flu vaccines takes significant time and requires virus or antigen production in cell-culture or eggs in dedicated facilities," said Mike Watson, senior vice president of vaccine partnerships and health impact at Moderna and a study co-author. "These Phase 1 data highlight the potential of Moderna's mRNA platform to demonstrate similar or better immunogenicity than existing vaccines, which can be rapidly produced in a multi-use facility."

H10N8 Study Design and Results

In the H10N8 study, 201 healthy volunteers aged 18 to 64 years received two doses of vaccine or placebo three weeks apart, intramuscularly (IM) at dose levels from 25 µg to 400 µg, or intradermally (ID) at dose levels of 25 µg or 50 µg. The 100 µg IM dose induced seroprotective immunity of hemagglutination inhibition (HAI) $\geq 1:40$ in 100 percent of participants and microneutralization (MN) titers $\geq 1:20$ in 87 percent of participants. The 25 µg ID dose induced HAI titers $\geq 1:40$ in 64.7 percent of participants compared to 34.5 percent of participants receiving the IM dose. HAI titers of 1:40 and MN titers of 1:20 are expected to be protective in seasonal flu vaccines.

H7N9 Study Design and Results

In the H7N9 study, 156 healthy volunteers aged 18 to 49 years received two doses of vaccine or placebo three weeks apart (IM) at dose levels of 10 µg, 25 µg and 50 µg. A small subgroup also received two doses of 25 µg or 50 µg IM six months apart. IM doses of 10 µg, 25 µg and 50 µg achieved HAI titers $\geq 1:40$ in 36 percent, 96.3 percent and 89.7 percent of participants, respectively. MN titers $\geq 1:20$ were achieved by 100 percent in the 10 µg and 25 µg groups and by 96.6 percent in the 50 µg group.

Future development of Moderna's pandemic influenza program is contingent on government or other grant funding.

A link to the publication, *mRNA Vaccines Against H10N8 and H7N9 Influenza Viruses of Pandemic Potential are Immunogenic and Well Tolerated in Healthy Adults in Phase 1 Randomized Clinical Trials*, can be found [here](#).

This is the third peer-reviewed publication of human data using Moderna mRNA technology. In the past three years, Moderna and collaborators have published more than 25 peer-reviewed papers, with 12 in the last year alone.

About Moderna's Prophylactic Vaccines Modality

Moderna has 21 mRNA development candidates in its pipeline, with 11 programs now in the clinic. These investigational medicines are grouped together into six modalities based on similar mRNA technologies, delivery technologies and manufacturing processes. Typically, programs within a modality will also share similar pharmacology profiles, including the desired dose response, expected dosing regimen, target tissue for protein expression, safety and tolerability goals, as well as their pharmaceutical properties.

Moderna scientists designed the Company's prophylactic vaccines modality to prevent or control infectious diseases. This modality now includes eight development candidates, all of which are vaccines against viruses. Some of these programs are designed for commercial use and others for global public health. The goal of any vaccine is to safely pre-expose the immune system to a small quantity of a protein from a pathogen, called an antigen, so that the immune system is prepared to fight the pathogen if exposed in the future and prevent infection or disease.

Moderna currently has four development candidates for potential commercial uses in this modality, including: respiratory syncytial virus (RSV) vaccine (mRNA-1777 and mRNA-1172 with Merck), cytomegalovirus (CMV) vaccine (mRNA-1647) and human metapneumovirus and parainfluenza virus type 3 (hMPV+PIV3) vaccine (mRNA-1653). Four development candidates in this modality are being explored for potential global health uses including: influenza H10N8 vaccine (mRNA-1440), influenza H7N9 vaccine (mRNA-1851), Zika vaccine (mRNA-1893) with the Biomedical Advanced Research and Development Authority (BARDA) and chikungunya vaccine (mRNA-1388) with the Defense Advanced Research Projects Agency (DARPA).

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.

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.elsevier.com/locate/vaccine. Copies of this paper are available to credentialed journalists upon request; please contact Elsevier's Newsroom at newsroom@elsevier.com or +31 20 485 2719.

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 immunogenicity, tolerability, and future expectations regarding mRNA-1440 and mRNA-1851; the potential of mRNA-based vaccines to quickly and effectively address pandemic influenza strains; the potential of Moderna's mRNA platform to demonstrate similar or better immunogenicity than existing vaccines that can be rapidly produced; and Moderna's mRNA development candidates' ability to have a therapeutic or preventive benefit and their potential to address a broad spectrum of diseases. 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 Phase 1 results for mRNA-1440 and mRNA-1851 will be predictive of any future clinical studies; whether mRNA-1440 and mRNA-1851 will be unsafe or intolerable during future 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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