



Moderna Announces Positive Interim Phase 1 Data for First Combination Vaccine Against the Respiratory Viruses hMPV and PIV3

February 12, 2019

Interim data show vaccination with mRNA-1653 boosted serum neutralization titers against hMPV and PIV3 at all dose levels tested and was generally well tolerated

Company plans to advance mRNA-1653 into a Phase 1b study in seropositive pediatric subjects

Conference call to be held at 5:00 p.m. ET today

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Feb. 12, 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 topline data from the first planned interim analysis of safety and immunogenicity from its Phase 1 study of mRNA-1653 in healthy adults. mRNA-1653 is a wholly-owned program in Moderna's prophylactic vaccine modality.

mRNA-1653 is designed to protect against human metapneumovirus (hMPV) and parainfluenza type 3 (PIV3), two viruses that cause respiratory infections. It is a combination vaccine that consists of two distinct mRNA sequences encoding the fusion (F) proteins of hMPV and PIV3 formulated in Moderna's proprietary lipid nanoparticle (LNP) technology.

"There are no approved vaccines to prevent hMPV or PIV3 infections, which are significant causes of severe respiratory diseases and hospitalizations for infants and children," said Tal Zaks, M.D., Ph.D., chief medical officer at Moderna. "Based on these positive interim Phase 1 data, we are excited to further advance mRNA-1653 into pediatrics as the first combination vaccine to focus on both hMPV and PIV3."

These Phase 1 interim data show that a single vaccination with mRNA-1653 boosted serum neutralization titers against hMPV and PIV3, and that the magnitude of the boost was similar at all dose levels tested. Consistent with prior exposure to hMPV and PIV3, all study participants had neutralizing antibodies against both viruses at baseline. One month after a single mRNA-1653 vaccination, the hMPV neutralization titers were approximately six-fold baseline and PIV3 neutralization titers were approximately three-fold baseline (based on geometric mean ratios). A second mRNA-1653 vaccination one month after the first vaccination did not further boost antibody titers, suggesting a single vaccination was sufficient to achieve a plateau in neutralizing antibodies in this pre-exposed population.

mRNA-1653 was found to be generally well tolerated. No serious adverse events (SAEs), adverse events of special interest, or adverse events leading to withdrawal were reported. Injection site pain was the most commonly reported adverse event and the most common Grade 3 adverse event.

Much of Moderna's commercial vaccine development efforts are focused on addressing major causes of respiratory infections, including hMPV+PIV3 and respiratory syncytial virus (RSV). These infections share many of the same features, often causing upper and lower respiratory tract illness, characterized by wheezing, bronchiolitis and pneumonia and are associated with a substantial burden of hospitalizations and outpatient visits among children throughout the first five years of life. There are currently no approved vaccines for hMPV, PIV3 or RSV.

Conference Call

Moderna will host a conference call and webcast today at 5:00 p.m. ET to discuss these interim data and the Company's broader efforts to develop respiratory vaccines. Participants are invited to listen by dialing (866) 922-5184 (domestic) or (409) 937-8950 (international) and providing conference ID 3580988 or join the live webcast by going to the "[Events and Presentations](#)" area on the Investors page of the Company's website, www.modernatx.com. An archived webcast of the conference call can also be accessed through the Company's website and a replay of the call will be available there for four weeks after the call.

About the Study

mRNA-1653-P101 is a Phase 1, first-in-human, randomized, observer-blind, placebo-controlled, dose-ranging study in healthy adults. The trial's key objectives include evaluating the safety and tolerability, reactogenicity and humoral immunogenicity of mRNA-1653, and selecting the optimal dose and vaccination schedule for further clinical development. This study is being conducted in the United States, and enrolled 124 subjects across four dose levels of mRNA-1653 (25, 75, 150, and 300 µg) and placebo. Subjects were randomized to a one-dose or two-dose vaccination schedule, with the second vaccination of mRNA-1653 administered one month after the first vaccination.

About Moderna's Prophylactic Vaccines Modality

Moderna has 21 mRNA development candidates in its pipeline, with 12 programs now in clinical development. 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 nine programs, all of which are vaccines against viruses. Some of these programs are designed for commercial use and others for 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: RSV (mRNA-1777 with Merck), cytomegalovirus (CMV) vaccine (mRNA-1647), hMPV+PIV3 vaccine (mRNA-1653) and varicella zoster virus (VZV) vaccine (mRNA-1278 with Merck).

Five 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-1325 and mRNA-1893 with BARDA) and chikungunya vaccine (mRNA-1388 with DARPA).

About hMPV and PIV3

hMPV was discovered in 2001 as the cause of acute respiratory infections in up to 15 percent of patients. The virus primarily affects young children but can also infect adults, the elderly and those who are immunocompromised. Symptoms range from a mild upper respiratory tract infection to life-threatening severe bronchiolitis and pneumonia. Despite the need, there is currently no approved vaccine for hMPV.

Infections from PIV account for up to seven percent of acute respiratory infections among children younger than five years of age. Of the four PIV types identified, PIV3 most frequently results in infections and leads to the more serious lower respiratory tract infections. Though PIV3-related infections were identified in the past, their burden to patients and hospitals has been elevated over the past few years. There is currently no approved vaccine for PIV3.

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 have a therapeutic or preventive benefit with 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 and 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 design, safety profile, tolerability and future expectations regarding mRNA-1653; the Company's plans to advance mRNA-1653 into a Phase 1b study; and the final and expected outcomes of Moderna's other clinical trials. 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 the interim results for mRNA-1653 will be predictive of the final results for the ongoing study or any future clinical studies; whether mRNA-1653 will be unsafe or intolerable during further clinical studies, particularly studies involving pediatric subjects; the fact that 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 described in Moderna's Prospectus filed with the U.S. Securities and Exchange Commission (SEC) on December 7, 2018 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.

View source version on businesswire.com: <https://www.businesswire.com/news/home/20190212005810/en/>

Source: Moderna, Inc.

Moderna Contacts:

Investors:

Lorence Kim

Chief Financial Officer

617-209-5849

Lorence.kim@modernatx.com

Media:

Jason Glashow

Head, Corporate Communications

617-674-5648

Jason.glashow@modernatx.com