Moderna to Present Data From Two of Its Prophylactic mRNA Vaccines at IDWeek 2019

October 2, 2019

hMPV+PIV3: Phase 1 data show first combination vaccine against respiratory viruses hMPV and PIV3 (mRNA-1653) boosted hMPV and PIV3 neutralizing antibody titers above baseline through seven months; safety analysis at two months shows mRNA-1653 generally well-tolerated at all dose levels

Zika: Preclinical data show Zika vaccine (mRNA-1893) protective against Zika virus transmission during pregnancy in mice; mRNA-1893 is currently being evaluated in a Phase 1 study

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 2, 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 data presentations regarding two of its wholly owned prophylactic mRNA vaccines at IDWeek in Washington, D.C. The presentations include interim Phase 1 data from its combination vaccine against the respiratory viruses human metapneumovirus (hMPV) and parainfluenza type 3 (PIV3) (mRNA-1653) and preclinical data from its Zika vaccine (mRNA-1893).

Presentation Details

Abstract 2754: Phase 1 Trial of an mRNA-based Combination Vaccine Against hMPV and PIV3
Presented by: Christine Shaw, Ph.D., Senior Director of Translational Research, Infectious Diseases, Moderna
(Poster Presentation, Saturday, October 5, 12:15 p.m. – 1:30 p.m. ET)

Abstract 2904: Protective Efficacy of Nucleic Acid Vaccines Against Transmission of Zika Virus During Pregnancy in Mice
Presented by: Brett W. Jagger, M.D., Ph.D., Infectious Diseases Fellow, Washington University
(Oral Presentation, Saturday, October 5, 4:00 p.m. – 4:15 p.m. ET)

The IDWeek presentations will be available on the "Events and Presentations" section of our website.

hMPV+PIV3 Vaccine (mRNA-1653) Phase 1 Data

Results from the second pre-planned interim analysis of the Phase 1 study of mRNA-1653 in healthy seropositive adults show that vaccination with mRNA-1653 led to hMPV and PIV3 antibody levels above baseline that persisted through seven months. The study is one of the six positive Phase 1 readouts Moderna has announced from its prophylactic vaccines portfolio to date.

"These promising data demonstrate the potential of mRNA-1653 to provide protection against both hMPV and PIV3, two viruses that can cause severe respiratory diseases in infants and children and currently have no approved vaccines," said Tal Zaks, M.D., Ph.D., chief medical officer at Moderna. "Our hMPV+PIV3 program is one of several in development focused on preventing respiratory illnesses and addressing unmet needs. We look forward to evaluating mRNA-1653 in a Phase 1b study in toddlers who have previously been exposed to these viruses."

In the study, all participants had neutralizing antibodies against both viruses at baseline (seropositive), consistent with prior exposure. The first interim analysis showed a single dose of mRNA-1653 boosted hMPV and PIV3 neutralization titers, and the magnitude of this boost was similar at all dose levels tested. There was an inverse relationship between baseline neutralizing antibody titer and the response to the first mRNA-1653 vaccination (Day 28 / Day 1 titer ratio), particularly for PIV3, regardless of dose. A second dose of mRNA-1653 was not associated with further increase of hMPV and PIV3 neutralization titers.

Safety data from the first interim analysis showed mRNA-1653 was generally well-tolerated at all dose levels. The most common solicited local adverse event (AE) was injection site pain. More severe (Grade 3) injection site pain events occurred after the first vaccination overall and at the 300 µg dose. The most common solicited systemic AEs were headache, fatigue and myalgia, and appeared to increase with dose level. No serious AEs (SAEs), AEs of special interest or AEs leading to withdrawal were reported.

In August 2019, the Company announced that a potential path forward to evaluate protection against both hMPV and PIV3 in a single Phase 3 study was discussed in a recent type C meeting with the U.S. Food and Drug Administration (FDA). Consistent with this development path, Moderna is planning to initiate a Phase 1b study of mRNA-1653 in seropositive toddler participants as the next step.

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 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.

Zika Vaccine (mRNA-1893) Preclinical Data

Moderna will also present a preclinical study of its investigational Zika vaccine (mRNA-1893) at IDWeek. The study shows that intramuscular administration of mRNA-1893 induced a robust neutralizing antibody response and provided complete protection against transmission of the virus during pregnancy in mice. These data have also been published in *The Journal of Infectious Diseases*.

"There is a great need to prevent Zika around the world, and we are committed to developing an effective vaccine designed to prevent the spread of

this infection, especially in women during pregnancy," said Zaks. "We look forward to sharing Phase 1 data when available and continuing our work to improve public health through the development of mRNA vaccines."

Moderna's investigational Zika vaccine (mRNA-1893), currently in a Phase 1 study, was recently granted FDA Fast Track Designation. More information about the study is available on clinicaltrials.gov.

Zika virus has rapidly emerged in recent years as a pandemic with potential long-term public health implications. Zika is primarily transmitted by mosquitos, but can also be transmitted sexually. Children born to mothers infected with Zika can develop microcephaly, a severe disease characterized by small, not fully developed heads and severe disabilities. In adults, outbreaks in Latin American and Caribbean countries have been associated with Guillain-Barré syndrome, a rare but serious autoimmune disorder in which the immune system attacks part of the nervous system. There is no approved vaccine for Zika.

About Moderna's Development Candidates

mRNA-1653

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

mRNA-1893

mRNA-1893 contains an mRNA sequence encoding for the structural proteins of Zika virus, designed to cause cells to secrete virus-like particles, mimicking the response of the cell after natural infection. mRNA-1893 is currently in a Phase 1 study evaluating safety and immunogenicity in healthy volunteers and was recently granted FDA Fast Track Designation. mRNA-1893 is wholly owned by Moderna.

mRNA-1893 development is funded in whole or in part with Federal funds from the U.S. Department of Health and Human Services (HHS); the Office of the Assistant Secretary for Preparedness and Response; and the Biomedical Advanced Research and Development Authority (BARDA), under Contract No. HHSO100201600029C.

About Moderna's Prophylactic Vaccines Modality

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. The potential advantages of an mRNA approach to prophylactic vaccines include the ability to mimic natural infection to stimulate a more potent immune response, combining multiple mRNAs into a single vaccine, rapid discovery to respond to emerging pandemic threats and manufacturing agility derived from the platform nature of mRNA vaccine design and production.

Four of the programs within this modality are aimed at preventing respiratory illnesses and include respiratory syncytial virus (RSV) vaccine (mRNA-1777 and mRNA-1172 or V172 with Merck), human metapneumovirus and parainfluenza virus type 3 (hMPV+PIV3) vaccine (mRNA-1653), influenza H10N8 vaccine (mRNA-1440) and influenza H7N9 vaccine (mRNA-1851).

Other mRNA vaccine candidates include cytomegalovirus (CMV) vaccine (mRNA-1647), 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).

To date, Moderna has demonstrated positive Phase 1 data readouts for six prophylactic vaccines (H10N8, H7N9, RSV [mRNA-1777], chikungunya virus, hMPV+PIV3 and CMV).

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 and mRNA-1893, including data from the ongoing Phase 1 study of mRNA-1893 evaluating safety and immunogenicity in healthy volunteers; Moderna's plans to advance mRNA-1653 into a Phase 1b study; the potential path forward to evaluate protection against both hMPV and PIV3 in a single Phase 3 study; and Moderna's commitment to developing an effective Zika vaccine designed to prevent the spread of Zika infection and to improve public health through the development of mRNA vaccines. 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 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 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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