moderna

Moderna Ships mRNA Vaccine Against Novel Coronavirus (mRNA-1273) for Phase 1 Study

February 24, 2020

mRNA-1273 delivered from Company's cGMP facility in 42 days from sequence selection

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Feb. 24, 2020-- 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 that it has released the first batch of mRNA-1273, the Company's vaccine against the novel coronavirus, for human use. Vials of mRNA-1273 have been shipped to the National Institute of Allergy and Infectious Diseases (NIAID), a part of the National Institutes of Health (NIH) to be used in the planned Phase 1 study in the U.S.

mRNA-1273 is an mRNA vaccine against the novel coronavirus encoding for a prefusion stabilized form of the Spike (S) protein, which was selected by Moderna in collaboration with investigators at the NIAID Vaccine Research Center (VRC). Manufacture of this batch was funded by the Coalition for Epidemic Preparedness Innovations (CEPI).

"I want to thank the entire Moderna team for their extraordinary effort in responding to this global health emergency with record speed. The collaboration across Moderna, with NIAID, and with CEPI has allowed us to deliver a clinical batch in 42 days from sequence identification," said Juan Andres, Chief Technical Operations and Quality Officer at Moderna. "This would not have been possible without our Norwood manufacturing site, which uses leading-edge technology to enable flexible operations and ensure high quality standards are met for clinical-grade material."

The Company's manufacturing plant in Norwood, MA manufactures Moderna's portfolio of mRNA development candidates, including vaccines and therapeutics. To date, the Company has produced and released more than 100 batches from its Norwood site for human clinical trials. mRNA-1273 is part of the Company's core prophylactic vaccines modality, which has had six positive Phase 1 clinical readouts across six different vaccines over the past four years.

About mRNA-1273

mRNA-1273 is an mRNA vaccine against the novel coronavirus encoding for a prefusion stabilized form of the Spike (S) protein, which was designed by Moderna in collaboration with NIAID. The S protein complex is necessary for membrane fusion and host cell infection and has been the target of vaccines against the coronaviruses responsible for Middle Eastern Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS).

About Coronavirus

Coronaviruses are a family of viruses that can lead to respiratory illness, including MERS and SARS. Coronaviruses are transmitted between animals and people and can evolve into strains not previously identified in humans. On January 7, 2020, a novel coronavirus was identified as the cause of pneumonia cases in Wuhan, Hubei Province of China.

About Moderna's Prophylactic Vaccines Modality

Moderna scientists designed the Company's prophylactic vaccines modality to prevent infectious diseases. More than 1,000 participants have been enrolled in Moderna's infectious disease vaccine clinical studies under health authorities in the U.S., Europe and Australia. Based on clinical experience across six Phase 1 studies, the Company has designated prophylactic vaccines a core modality and intends to accelerate development of its infectious disease vaccine candidates.

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. Moderna has built a fully integrated manufacturing plant in Norwood, MA which enables the promise of the technology platform.

Moderna currently has nine development candidates in its prophylactic vaccines modality, including:

Vaccines against serious respiratory infections

- Respiratory syncytial virus (RSV) vaccine for older adults (mRNA-1777 and mRNA-1172/V172 with Merck)
- RSV vaccine for young children (mRNA-1345)
- Human metapneumovirus and parainfluenza virus type 3 (hMPV/PIV3) vaccine (mRNA-1653)
- Novel coronavirus vaccine (mRNA-1273)
- Influenza H7N9 (mRNA-1851)

Vaccines against serious infections transmitted from mother to baby

- Cytomegalovirus (CMV) vaccine (mRNA-1647)
- Zika vaccine (mRNA-1893) with the Biomedical Advanced Research and Development Authority (BARDA)

Vaccines against common viral infections

- Epstein-Barr virus (EBV) vaccine (mRNA-1189)

To date, Moderna has demonstrated positive Phase 1 data readouts for six prophylactic vaccines (H10N8, H7N9, RSV, chikungunya virus, hMPV/PIV3 and CMV). Moderna's CMV vaccine is currently in a Phase 2 dose-selection study. Moderna's investigational Zika vaccine (mRNA-1893), currently in a Phase 1 study, was granted FDA Fast Track designation.

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, cardiovascular diseases, and autoimmune and inflammatory diseases, independently and with strategic collaborators. Moderna has 24 mRNA development candidates in its portfolio across all modalities, with 12 in clinical studies. Four of these programs are in or preparing for Phase 2 studies and the Company is preparing for its first Phase 3 study.

Headquartered in Cambridge, Mass., Moderna currently has strategic alliances for development programs with AstraZeneca, Plc. (Nasdaq: AZN) and Merck, Inc. (Nasdaq: MRK), 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 named a top biopharmaceutical employer by *Science* for the past five 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, the Company's development of a potential vaccine against the novel Coronavirus and the intention and belief that the clinical batch of such vaccine will be used to conduct 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: the fact that there has never been a commercial product utilizing mRNA technology approved for use; the fact that the rapid response technology in use by Moderna is still being developed and implemented; and those other 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 contained 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/20200224005955/en/

Media:
Colleen Hussey
Senior Manager, Corporate Communications
203-470-5620
Colleen.Hussey@modernatx.com

Investors:
Lavina Talukdar
Head of Investor Relations
617-209-5834
Lavina.Talukdar@modernatx.com

Source: Moderna, Inc.