



## Moderna Announces Progress in Prophylactic Vaccines Modality with CMV Vaccine Phase 2 Study Data Now Expected in Third Quarter 2020 and Expands Investment in This Core Modality with Three New Development Candidates

February 10, 2020

*Phase 2 CMV vaccine dose-confirmation study more than sixty percent enrolled*

*mRNA-1189 to prevent infectious mononucleosis and Epstein-Barr virus (EBV) infection*

*mRNA-1345 to prevent respiratory syncytial virus (RSV) disease in young children, with the intent to combine with mRNA-1653 to create a pediatric respiratory vaccine against RSV, hMPV and PIV3*

*mRNA-1273 to prevent novel coronavirus (2019-nCoV) disease, in collaboration with the National Institutes of Health; physical manufacturing of first batch complete, awaiting analytical testing*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Feb. 10, 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 the Phase 2 dose-confirmation study of its mRNA vaccine against cytomegalovirus (CMV) is enrolling ahead of plan with data now expected in the third quarter of 2020. The Company also announced three new vaccine development candidates, which support the Company's strategy, announced January 12, to accelerate new development candidates in its core modalities, prophylactic vaccines and systemic secreted & cell surface therapeutics. The three new infectious disease vaccine candidates complement the January announcement of two autoimmune development candidates, PD-L1 (mRNA-6231) and IL-2 (mRNA-6981), in the Company's other core modality, systemic secreted & cell surface therapeutics.

Moderna's CMV vaccine (mRNA-1647), the first mRNA vaccine for an infectious disease to enter a Phase 2 study, is enrolling ahead of plan with the second cohort nearly completed. This Phase 2 study will investigate the safety and immunogenicity of mRNA-1647 in approximately 252 healthy adults in the U.S. at three dose levels (50, 100 and 150 µg) in both CMV-seronegative and CMV-seropositive participants administered in a three-dose vaccination schedule (0, 2 and 6 months). The first interim analysis, expected in the third quarter of 2020, will evaluate safety and immunogenicity at three months (one month after the second vaccination) and is intended to inform Phase 3 dose selection. The Company is actively preparing for a Phase 3 pivotal study, which will evaluate prevention of primary CMV infection in a population that includes women of childbearing age.

The development candidates announced today are mRNA vaccine candidates against Epstein-Barr virus (mRNA-1189), respiratory syncytial virus (mRNA-1345) in young children, and the novel coronavirus (mRNA-1273). mRNA-1345 will be evaluated in early clinical trials with the intention of combining the vaccine with mRNA-1653, Moderna's hMPV/PIV3 vaccine, to address RSV, hMPV and PIV3, viruses that cause significant respiratory diseases in young children, in one vaccine. Each of these new development candidates utilizes the Company's proprietary lipid nanoparticle (LNP) technology.

Today's announcement reflects the Company's belief that positive Phase 1 safety and immunogenicity data across nine studies with more than 1,000 participants have validated the Company's prophylactic vaccine modality. Clinical data demonstrate that Moderna's proprietary vaccine technology has been generally well-tolerated<sup>1</sup> and can elicit durable immune responses to viral antigens. The Company also believes that it has demonstrated the ability to leverage shared technology, digital systems and its flexible manufacturing infrastructure to advance a large portfolio quickly and efficiently.

"Our investments in science and manufacturing have resulted in six positive Phase 1 infectious disease vaccine readouts. These data validate the technology used in our prophylactic vaccines modality, which has allowed us to accelerate research and development timelines, and advance our mRNA vaccines into new areas of high unmet need. I am pleased with the continued progress of our late-stage CMV vaccine program as we prepare for a pivotal Phase 3 study and commercial readiness. The three new development candidates reflect the continued productivity of our platform and the potential of our mRNA technology. Moderna now owns global rights to three vaccines, which we believe have blockbuster potential – CMV, EBV and the potential combination RSV/hMPV/PIV3 vaccine for young children," said Stéphane Bancel, Moderna's Chief Executive Officer. "I am proud of the team's ability to rapidly respond to the ongoing public health crisis posed by the novel coronavirus and to be working with the National Institutes of Health and Coalition for Epidemic Preparedness Innovations."

Moderna currently has 24 mRNA development candidates in its portfolio with 12 in clinical studies. Across Moderna's pipeline, more than 1,500 participants have been enrolled in clinical studies.

### About Moderna's New Development Candidates

- **mRNA-1189** is an mRNA vaccine against Epstein-Barr virus (EBV) containing five mRNAs that encode viral proteins in EBV, gp350, gB, gp42, gH and gL. Similar to Moderna's CMV vaccine (mRNA-1647), the viral proteins in mRNA-1189 are expressed in their native membrane-bound form for recognition by the immune system. There is no approved vaccine for EBV.
- **mRNA-1345** is an mRNA vaccine against respiratory syncytial virus (RSV) in young children encoding for a prefusion F glycoprotein, which elicits a superior neutralizing antibody response compared to the postfusion state. The Company intends to combine mRNA-1345 with mRNA-1653, its vaccine against hMPV and PIV3, to create a combination vaccine against RSV, hMPV and PIV3. There is no approved vaccine for RSV.
- **mRNA-1273** is an mRNA vaccine against the novel coronavirus encoding for the viral Spike (S) protein, which was

selected by Moderna in collaboration with the National Institutes of Health, the manufacture of which was funded by the Center for Epidemic Preparedness and Innovations (CEPI). 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). On January 13, the NIH and Moderna's infectious disease research team finalized the sequence for the 2019-nCoV vaccine and Moderna mobilized toward clinical manufacture. The first clinical batch, including fill and finishing of vials, was completed on February 7. This mRNA vaccine was designed and manufactured in 25 days and is undergoing analytical testing prior to release to the NIH for use in their planned Phase 1 clinical trial in the U.S. Currently, there are no approved vaccines specific to 2019-nCoV.

#### **About Epstein-Barr Virus (EBV)**

EBV is a common herpesvirus that is spread through bodily fluids, most commonly saliva, and contracted primarily by young children and adolescents (approximately 50% and approximately 89% seropositivity, respectively). It is a major cause of infectious mononucleosis (IM) in the U.S., accounting for over 90% of the approximately 1-2 million cases annually. IM can debilitate patients for weeks to months and, in some cases, can lead to hospitalization and splenic rupture. EBV infection is associated with the development and progression of certain lymphoproliferative disorders, cancers, and an increased risk of autoimmune diseases including multiple sclerosis (MS), an autoimmune disease of the central nervous system. There is no approved vaccine for EBV.

#### **About Respiratory Syncytial Virus (RSV)**

RSV is the leading cause of unaddressed severe lower respiratory tract disease and hospitalization in infants and young children worldwide, with most children infected at least once by two years of age. The virus is transmitted primarily via contamination of environmental surfaces with infectious secretions, and symptoms typically begin within several days of exposure. The illness may manifest as wheezing, bronchiolitis, pneumonia, hospitalization or even death.

In the United States, it is estimated that over two million children younger than five years of age receive medical attention and more than 86,000 are hospitalized due to RSV infection annually. Globally, RSV is estimated to be responsible for over approximately 33 million episodes of acute lower-respiratory tract infection, 3.2 million hospitalizations and as many as 118,000 deaths per year in children younger than five years of age. Infections with RSV follow a seasonal pattern, occurring primarily in the Northern hemisphere between the months of November and April, and in the Southern hemisphere primarily between March and October. There is no approved vaccine for RSV.

#### **About Coronavirus (2019-nCoV)**

Coronaviruses are a family of viruses that can lead to respiratory illness, including Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (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. Estimates from the World Health Organization as of February 9, 2020 indicate that there are approximately 37,000 confirmed cases and over 800 deaths worldwide. The suspected number of infections is likely to be substantially higher. It is important to note that there is not yet a good understanding of the rate of asymptomatic infection. Currently, there are no approved vaccines specific to 2019-nCoV.

#### **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 deems 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 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 or V172 with Merck)
- RSV vaccine for young children (mRNA-1345)
- Human metapneumovirus and parainfluenza virus type 3 (hMPV/PIV3) vaccine (mRNA-1653)
- Novel coronavirus (2019-nCoV) 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 with high unmet need*

- 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-confirmation study. Moderna's investigational Zika vaccine (mRNA-1893), currently

in a Phase 1 study, was granted FDA Fast Track designation.

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

### **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.

### **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, without limitation, statements regarding plans for Moderna's development candidates, plans to create a pediatric respiratory vaccine against RSV, hMPV and PIV3, plans regarding regulatory submission and clinical testing for mRNA-1273, expected timing of data from the Phase 2 study of mRNA-1647, and Moderna's strategy, business plans and focus. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, uncertainties related to market conditions and the completion of the public offering on the anticipated terms or at all. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Moderna's most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) and other filings that Moderna has made or may make with the SEC in the future. Any forward-looking statements contained in this press release represent Moderna's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. Moderna explicitly disclaims any obligation to update any forward-looking statements.

Moderna has filed a registration statement (including a prospectus) with the SEC for the offering to which this communication relates. Before you invest, you should read the prospectus in that registration statement and other documents the issuer has filed with the SEC for more complete information about the issuer and this offering. You may get these documents for free by visiting EDGAR on the SEC Web site at [www.sec.gov](http://www.sec.gov). Alternatively, the issuer, any underwriter or any dealer participating in the offering will arrange to send you the prospectus if you request it by calling toll-free 1-866-471-2526.

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<sup>1</sup> The most common adverse reactions in Moderna's Phase 1 clinical trials in prophylactic vaccines include injection site pain, headache, myalgia, and fatigue.

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