Moderna Provides Business Update and Announces Three New Development Programs in Infectious Disease Vaccines

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Seasonal flu vaccine program will cover four seasonal viruses recommended by the World Health Organization (WHO)

HIV vaccine program to accelerate human validation of novel vaccination strategies

Nipah vaccine program established against a virus of public health concern

Moderna now has one commercial medicine and 24 development programs

Multiple therapeutic programs anticipated to see clinical proof of concept data in 2021

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 11, 2021-- Moderna, Inc. (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced that it is expanding its pipeline of innovative vaccines with three new development programs based on the clinical success of its infectious disease vaccine portfolio to date. This announcement reflects the Company's commitment to accelerating its infectious disease portfolio based on Moderna's experience with its COVID-19 vaccine. The development programs announced today are mRNA vaccine candidates against seasonal flu, HIV and the Nipah virus. Moderna also announced an expansion of its respiratory syncytial virus (RSV) vaccine program into older adults.

"The uniquely challenging year of 2020 for all of society proved to be an extraordinary proof-of-concept period for Moderna," said Stéphane Bancel, Moderna's chief executive officer. "Even as we have shown that our mRNA-based vaccine can prevent COVID-19, this has encouraged us to pursue more-ambitious development programs within our prophylactic vaccines modality. Today we are announcing three new vaccine programs addressing seasonal flu, HIV and the Nipah virus, some of which have eluded traditional vaccine efforts, and all of which we believe can be addressed with our mRNA technology. Beyond vaccines, we are extending our mRNA development work to a total of 24 programs across five therapeutic areas."

Mr. Bancel will present an update on the Company and its pipeline of mRNA development programs on Monday, January 11, 2021 at 4:30 p.m. ET at the 39th Annual J.P. Morgan Healthcare Conference. The presentation will be followed by a question-and-answer session. A live webcast of both the presentation and question and answer session will be available under "Events & Presentations" in the investors section of Moderna's website at investors.modernatx.com. A replay of the webcast will be archived on Moderna's website for 30 days following the presentation.

Moderna currently has 24 mRNA development programs in its portfolio with 13 having entered the clinic. The Company's updated pipeline can be found at www.modernatx.com/pipeline.

About Moderna's New Infectious Disease Vaccine Development Programs

- **Flu vaccine (mRNA-1010, mRNA-1020, mRNA-1030):** Seasonal flu (type A and type B) epidemics occur seasonally and vary in severity each year, causing respiratory illnesses and placing substantial burden on healthcare systems. The WHO estimates globally about 3,000,000-5,000,000 severe cases of flu each year, and 290,000-650,000 flu-related respiratory deaths. Approximately 8% of the U.S. population experiences symptoms from flu each year in the US, with 140,000-810,000 hospitalizations and 12,000-61,000 deaths per year. Peak flu activity is seen in temperate climates from fall to winter and is reflected in increases in outpatient visits, urgent care visits, and hospitalizations. In the U.S., the estimated average economic burden of flu is approximately $11 billion per year. The Company plans to explore potential combination vaccines against flu, SARS-CoV-2, RSV and human metapneumovirus (hMPV). The Company's first-generation flu program will evaluate multiple candidates comprising multiple antigen combinations against the four seasonal viruses recommended by the WHO. The Company expects to begin phase 1 clinical trials for the program in 2021.

- **HIV vaccine (mRNA-1644 & mRNA-1574):** HIV is the virus responsible for acquired immunodeficiency syndrome (AIDS), a lifelong, progressive illness with no effective cure. Approximately 38 million people worldwide are currently living with HIV with 1.2 million in the U.S. Approximately 2 million new infections of HIV are acquired worldwide every year and approximately 690,000 people die annually due to complications from HIV/AIDS. The primary routes of transmission are sexual intercourse and IV drug use, putting young adults at the highest risk of infection. From 2000 to 2015, a total of $562.6 billion globally was spent on care, treatment and prevention of HIV, representing a significant economic burden. mRNA-1644, a collaboration with the International AIDS Vaccine Initiative (IAVI) and the Bill and Melinda Gates Foundation (BMGF), is a novel approach to HIV vaccine strategy in humans designed to elicit broadly Neutralizing HIV-1 Antibodies (bNAbs). A Phase 1 study for mRNA-1644 will use iterative human testing to validate the approach and antigens and multiple novel antigens will be used for germline-targeting and immuno-focusing. A second approach, mRNA-1574, is being evaluated in collaboration with the National Institutes of Health (NIH) and includes multiple native-like trimer antigens. The Company expects to begin phase 1 clinical trials for both mRNA-1644 and mRNA-1574 in 2021.

- **Nipah virus (NiV) Vaccine (mRNA-1215):** NiV is a zoonotic virus transmitted to humans from animals, contaminated food,

or through direct human-to-human transmission and causes a range of illnesses including fatal encephalitis. Severe respiratory and neurologic complications of NiV have no treatment other than intensive supportive care. The case fatality rate among those infected is estimated at 40-75%. NiV outbreaks cause significant economic burden to impacted regions due to loss of human life and interventions to prevent further spread, such as the slaughter of infected animals. NiV has been identified as the cause of isolated outbreaks in India, Bangladesh, Malaysia, and Singapore since 2000 and is included on the WHO R&D Blueprint list of epidemic threats needing urgent R&D action. mRNA-1215 was co-developed by Moderna and the NIH's Vaccine Research Center (VRC).

Moderna's pipeline is organized into six modalities based on similar mRNA technologies, delivery technologies and manufacturing processes. The Company's approach is to leverage early programs within a modality to generate clinical data and insights that reduce the technology risk of subsequent programs and accelerate the expansion of the pipeline in that modality. Positive phase 1, 2 and 3 data from Moderna's infectious disease vaccine portfolio and positive phase 1 data from its chikungunya antibody program have de-risked its prophylactic vaccines and systemic therapeutics & cell surface modalities respectively. Beyond these core modalities, the Company has four exploratory modalities in which it is actively pursuing clinical proof of concept.

Summary of Program Updates by Modality:

Core Modalities

Prophylactic Vaccines: *Moderna is developing vaccines against viral diseases where there is unmet medical need – including complex vaccines with multiple antigens for common diseases, as well as vaccines against threats to global public health. The Company's global public health portfolio is focused on epidemic and pandemic diseases and often developed in collaborations with governments and non-profit organizations.*

Vaccines requiring complex antigens and against highly prevalent infections

- **Cytomegalovirus (CMV) vaccine (mRNA-1647):** Positive interim data from the phase 2 study assessing the safety, reactogenicity, and immunogenicity of different dose levels of mRNA-1647 were presented at Moderna's annual R&D Day. Based on the interim analysis of the phase 2 study, the 100 µg dose has been chosen for the phase 3 pivotal study, which is expected to begin this year. Moderna owns worldwide commercial rights for mRNA-1647.

- **Epstein-Barr virus (EBV) vaccine (mRNA-1189):** mRNA-1189 is a vaccine against EBV containing five mRNAs that encode viral proteins (gp350, gB, gp42, gH and gL) in EBV. 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. Moderna owns worldwide commercial rights to mRNA-1189.

Vaccines against respiratory infections

- **Moderna COVID-19 Vaccine (mRNA-1273) authorization:** On December 18, the U.S. Food and Drug Administration (FDA) authorized the emergency use of mRNA-1273, Moderna's vaccine against COVID-19, in individuals 18 years of age or older. The Moderna COVID-19 Vaccine is also authorized by Canada, Israel, the United Kingdom and the European Union. Additional authorizations are currently under review in additional markets including Singapore, Switzerland and by the WHO. On December 30, interim safety and primary efficacy results from the Phase 3 trial of the Moderna COVID-19 Vaccine (mRNA-1273) were published in the *New England Journal of Medicine*. The primary endpoint of the Phase 3 COVE study was based on the analysis of COVID-19 cases confirmed and adjudicated starting two weeks following the second dose of vaccine. This final analysis was based on 196 cases, of which 185 cases of COVID-19 were observed in the placebo group versus 11 cases observed in the Moderna COVID-19 Vaccine group, corresponding to a 94% vaccine efficacy (95% CI 89.3-96.8%; p<0.0001). The most common solicited adverse reactions (ARs) after the two-dose series was injection site pain (86.0%). Solicited systemic adverse events occurred more often in the Moderna COVID-19 vaccine group (54.9% and 79.4%) than in the placebo (42.2% and 36.5%) group after both the first dose and the second dose respectively and were most commonly headache, fatigue and myalgia. While the majority of these ARs were mild (grade 1) or moderate (grade 2), there was a higher occurrence of severe (grade 3) reactions in the Moderna COVID-19 Vaccine group after the first (2.9%) and second (15.8%) injections. The majority of local solicited ARs occurred within the first one to two days after injection and generally persisted for a median of one to two days. Safety data continues to accrue, and the study continues to be monitored by an independent Data Safety Monitoring Board (DSMB) appointed by the NIH. All participants in the COVE study will be monitored for two years after their second dose to assess long-term protection and safety. Additional data to be collected will include longer term safety follow-up, duration of protection against COVID-19, and efficacy against asymptomatic SARS-CoV-2 infection. BARDA, part of the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS), partially supported the research and development of mRNA-1273 with federal funding under Contract no. 75A50120C00034. A summary of the Company's work to date on COVID-19 can be found here. Moderna retains worldwide rights to develop and commercialize mRNA-1273.

- **Moderna COVID-19 Vaccine (mRNA-1273) additional clinical studies:** Moderna is also conducting a phase 2/3 study of the Moderna COVID-19 Vaccine in adolescents 12 to under 18 years of age. Additional studies are planned to evaluate the

Moderna COVID-19 Vaccine in pregnant women, children younger than 12 years, and those in special risk groups, such as the immunocompromised.

- **Human metapneumovirus (hMPV) and parainfluenza type 3 (PIV3) vaccine (mRNA-1653):** Sites have resumed dosing seropositive pediatric participants (12-36 months of age) in the Phase 1 study of hMPV/PIV3 study (mRNA-1653) following the COVID-19 related study disruption. Moderna owns worldwide commercial rights to mRNA-1653.

- **Respiratory syncytial virus (RSV) vaccine (mRNA-1345):** mRNA-1345 is a vaccine against RSV encoding for a prefusion F glycoprotein, which elicits a superior neutralizing antibody response compared to the postfusion state. The first cohort of the phase 1 study of mRNA-1345 is fully enrolled. This phase 1 study includes initial dosing in younger adults, followed by age de-escalation into children. The Company today, announced its plan to amend the protocol to include evaluation of mRNA-1345 in older adults who are also at risk of significant RSV disease. Going forward, the Company intends to evaluate the potential of combinations of mRNA-1345 with its vaccines against other respiratory pathogens in children and separately in older adults. There is no approved vaccine for RSV. Moderna owns worldwide commercial rights to mRNA-1345.

Public Health Vaccines

- **Zika virus vaccine (mRNA-1893):** All dose cohorts (10, 30, 100 and 250 µg) in the phase 1 study of mRNA-1893 have completed enrollment. Moderna is preparing for a phase 2 study of mRNA-1893. mRNA-1893 is being developed in collaboration with the U.S. Biomedical Advanced Research and Development Authority (BARDA) within the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services. Moderna owns worldwide commercial rights to mRNA-1893.

- **Pandemic influenza/H7N9 vaccine (mRNA-1851)**: Discussions regarding funding the Company's pandemic influenza/H7N9 vaccine program through approval are ongoing.

Systemic Secreted & Cell Surface Therapeutics: *In this modality, mRNA is delivered systemically to create proteins that are either secreted or expressed on the cell surface.*

- **Antibody against the chikungunya virus (mRNA-1944):** Positive interim data from the Phase 1 study evaluating escalating doses of mRNA-1944 in the 0.6 mg/kg dose with steroid premedication cohort and two doses of 0.3 mg/kg (without steroid premedication) given one week apart cohort were presented at Moderna's annual R&D Day and demonstrated dose-dependent increases in levels of antibody against chikungunya. Safety and increased CHKV-IgG production in the two-dose regimen shows the platform's ability for repeat dosing.

Exploratory Modalities

Cancer Vaccines: *These programs focus on stimulating a patient's immune system with antigens derived from tumor-specific mutations to enable the immune system to elicit a more effective anti-tumor response.*

- **Personalized cancer vaccine (PCV) (mRNA-4157):** The randomized Phase 2 study investigating a 1 mg dose of mRNA-4157 in combination with Merck's pembrolizumab (KEYTRUDA®), compared to pembrolizumab alone, for the adjuvant treatment of high-risk resected melanoma is ongoing. The Phase 1 study is ongoing. Moderna shares worldwide commercial rights to mRNA-4157 with Merck.

    - **Presentation of Note:** Interim data from the phase 1 dose expansion cohort of mRNA-4157 in combination with pembrolizumab was shared at The Society for Immunotherapy of Cancer's Annual Meeting 2020 and supported the expansion of the Head and Neck Squamous Cell Carcinoma (HNSCC) cancer patient cohort.

- **Mutant KRAS vaccine (mRNA-5671 or V941):** The phase 1 open-label, multi-center study to evaluate the safety and tolerability of mRNA-5671 both as a monotherapy and in combination with pembrolizumab, led by Merck, is ongoing. Moderna shares worldwide commercial rights to mRNA-5671 with Merck.

Intratumoral Immuno-Oncology**:** *These programs aim to drive anti-cancer T cell responses by injecting mRNA therapies directly into tumors.*

- **OX40L (mRNA-2416):** The phase 1/2 study of mRNA-2416 alone and in combination with durvalumab (IMFINZI®) is ongoing. The phase 2 dose expansion study of mRNA-2416 in combination with durvalumab in ovarian cancer patients is enrolling and the first patients have been dosed. Moderna owns worldwide commercial rights to mRNA-2416.

- **OX40L/IL-23/IL-36γ (Triplet) (mRNA-2752):** The phase 1 trial evaluating mRNA-2752 as a single agent and in combination with durvalumab in patients with advanced solid tumor malignancies and lymphoma is ongoing. mRNA-2752 is an investigational mRNA immuno-oncology therapy that encodes a novel combination of three immunomodulators.

Moderna owns worldwide commercial rights to mRNA-2752.

- **IL-12 (MEDI1191):** The phase 1 open-label, multi-center study of intratumoral injections of MEDI1191 alone and in combination with durvalumab in patients with advanced solid tumors, led by AstraZeneca, is ongoing. MEDI1191 is an mRNA encoding for IL-12, a potent immunomodulatory cytokine. Moderna shares worldwide commercial rights to MEDI1191 with AstraZeneca.

Localized Regenerative Therapeutics: *Localized production of proteins has the potential to be used as a regenerative medicine for damaged tissues.*

- **VEGF-A (AZD8601):** The phase 2a study of AZD8601 VEGF-A, which is being developed for patients with ischemic heart disease undergoing coronary artery bypass grafting (CABG) surgery with moderately impaired systolic function, led by AstraZeneca, is ongoing. Moderna has licensed worldwide commercial rights to AZD8601 to AstraZeneca.

Systemic Intracellular Therapeutics: *These programs aim to deliver mRNA into cells within target organs as a therapeutic approach for diseases caused by a missing or defective protein.*

- **Propionic acidemia (PA) (mRNA-3927):** Sites are being initiated, with entry into the clinic expected in 2021. The Company will be looking for biomarkers as early indicators for therapeutic impact. Moderna owns worldwide commercial rights to mRNA-3927.

Information about each development candidate in Moderna's pipeline, including those discussed in this press release, can be found on the investor relations page of Moderna's website: https://investors.modernatx.com.

Corporate Updates

- **Continued growth across organization:** Moderna ended 2020 with approximately 1,300 full time employees, an increase from approximately 820 full time employees at the end of 2019. Moderna was named a top employer by Science for the sixth year in a row.
- Announced additions to the Moderna team:
  - **Corinne Le Goff**, Pharm.D., MBA, will join Moderna as Chief Commercial Officer effective Tuesday, January 19, 2021. Dr. Le Goff served as senior vice president and president of the U.S. Business Organization at Amgen (Nasdaq: AMGN). Prior to that, Dr. Le Goff held a number of senior international roles at Roche Group (SWX: RO), including President of Roche France and Global Product Strategy Head of Neuroscience & Rare Diseases, and leadership roles at Sanofi (Nasdaq: SNY) and Pfizer (NYSE: PFE) in the United States.
  - **Ruchira Glaser**, M.D., MSCE, joined Moderna as the Senior Vice President, Therapeutic Area Head for the Rare Disease, Autoimmune, and Cardiovascular Therapeutic Areas, where she will oversee development for our broad therapeutics portfolio outside of oncology. Dr. Glaser joins from GlaxoSmithKline (NYSE: GSK), where she was most recently Head of Clinical Sciences for the Respiratory and Specialty areas, including rare diseases, immunology and anemia. Prior to that, Dr. Glaser spent 10 years as an interventional cardiologist and clinical researcher at the University of Pennsylvania.
- **Continued strong cash position:** The Company expects cash, cash equivalents, and investments as of December 31, 2020 to be approximately $5.25 billion (unaudited), as compared to $1.26 billion as of December 31, 2019, including customer deposits of $2.81 billion for future supply of product.
- **Moderna has signed Advance Purchase Agreements (APAs) for the delivery of its COVID-19 Vaccine.** To date, the product revenue associated with these APAs for FY 2021 is $11.7 billion. These doses of Moderna COVID-19 Vaccine are expected to be delivered in 2021. The company is in active discussions to sign additional APAs for deliveries in 2021 and 2022. Moderna has also made a proposal to COVAX via a UNICEF tender to supply low-and-mid income countries.
- **Commitment to access:** The Company published seven principles as part of its Commitment to Vaccines and Therapeutics Access.
- **Shareholder Letter:** Moderna CEO Stéphane Bancel published a letter to shareholders on January 4, 2021.

Key 2021 Investor and Analyst Event Dates

- Vaccines Day– April 14
- Science Day – May 27
- R&D Day – September 9

About Moderna

In 10 years since its inception, Moderna has transformed from a science research-stage company advancing programs in the promising-but-still-unproven field of messenger RNA (mRNA), to an enterprise with its first medicine having treated millions of people, a diverse clinical portfolio of vaccines and therapeutics across six modalities, a broad intellectual property portfolio in areas including mRNA and lipid nanoparticle formulation, and an integrated manufacturing plant that allows for both clinical and commercial production at scale and at unprecedented speed. Moderna maintains alliances with a broad range of domestic and overseas government and commercial collaborators, which has allowed for the pursuit of both groundbreaking science and rapid scaling of manufacturing. Most recently, Moderna's capabilities have come together to allow the authorized use of

one of the earliest and most-effective vaccines against the COVID-19 pandemic.

Moderna's mRNA platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, and has allowed the development of therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases, cardiovascular diseases and auto-immune diseases. Today, 24 development programs are underway across these therapeutic areas, with 13 programs having entered the clinic. Moderna has been named a top biopharmaceutical employer by *Science* for the past six years. To learn more, visit www.modernatx.com.

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 statements regarding: development programs for vaccines against influenza, HIV and the Nipah virus and the specifics of those programs, including the timing of potential clinical trials; the timing for receipt of proof of concept clinical data from multiple therapeutics; the potential advantages of infectious disease vaccines; the development of combination vaccines against multiple diseases; the conduct of studies for the Company's vaccines against CMV, Zika virus, anti-cancer vaccines (i.e., OX40L, OX40L/IL-23/IL-36γ and IL-12), VEGF-A and PA; the potential for the Moderna COVID-19 Vaccine to prevent COVID-19 disease and slow the spread of SARS-CoV-2, the safety profile for the Moderna COVID-19 Vaccine; plans for further clinical trials for the Moderna COVID-19 Vaccine; the potential for repeat dosing of certain therapeutics; the Company's plans for research and development and timelines for any individual product or the platform as a whole; cash, cash equivalents and investment balances; and discussions related to further sales of the Moderna COVID-19 Vaccine. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "could," "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; the safety, tolerability and efficacy profile of the Moderna COVID-19 Vaccine observed to date may change adversely in ongoing analyses of trial data or subsequent to commercialization; despite having ongoing interactions with the FDA or other regulatory agencies, the FDA or such other regulatory agencies may not agree with the Company's regulatory approval strategies, components of our filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of data submitted; Moderna may encounter delays in meeting manufacturing or supply timelines or disruptions in its distribution plans for the Moderna COVID-19 Vaccine; whether and when any biologics license applications and/or emergency use authorization applications may be filed and ultimately approved by regulatory authorities; potential adverse impacts due to the global COVID-19 pandemic such as delays in regulatory review, manufacturing and clinical trials, supply chain interruptions, adverse effects on healthcare systems and disruption of the global economy; and those other risks and uncertainties described under the heading "Risk Factors" in Moderna's most recent Quarterly Report on Form 10-Q 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.

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