



Moderna Provides Update on the Impact of COVID-19 on Business Operations and Clinical Program Development

March 30, 2020

Conference call to be held on Monday, March 30 at 8:00 a.m. ET

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Mar. 29, 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 provided an update on the impact of the rapidly evolving COVID-19 pandemic on its business operations and clinical program development.

Moderna's paramount obligation is to ensure the safety of all participants in its clinical programs and the integrity of the studies in which they participate. Moderna is actively monitoring the situation and making adjustments where necessary, and is responding to regulatory, institutional, and government guidance and policies related to COVID-19. The Company is using a risk-based framework to evaluate new participant enrollment and new site initiation on a case-by-case basis. Moderna remains committed to its clinical development plans and is working closely with all stakeholders to try to mitigate the impact of the pandemic on the Company's ongoing clinical trials.

The safety and well-being of Moderna employees is also a top priority for the Company. On March 2, the Company created an internal, cross-functional COVID-19 Response Team to closely monitor the evolving situation and advise on the Company's response. In alignment with public health strategies designed to slow the spread of COVID-19, as of March 12 the Company transitioned to a remote work plan for many employees. Essential in-person laboratory, manufacturing and related functions continue on site, and the Company has restricted visitors and implemented heightened policies to ensure the safety of employees and business continuation. Other employees continue to perform business activities from remote locations.

"The COVID-19 pandemic has created unprecedented challenges and we are committed to ensuring the health and safety of all participants in our and our partners' clinical trials, our clinical trial site teams, vendors and our employees. Moderna's primary focus is on the safety of all involved and the continued conduct of our clinical programs as we navigate the pandemic together," said Stéphane Bancel, Moderna's Chief Executive Officer. "We are also focused on responding to the pandemic through our work on our vaccine candidate against COVID-19, mRNA-1273. We are grateful to everyone both inside and outside Moderna who is working to address this public health crisis. We will get through this together."

Summary of Clinical Trial Impact of COVID-19

Based on the special concerns for the safety and health of pediatric patients and their caregivers, and the risks of disruption to the integrity of trials from COVID-19, the Company has decided to pause new enrollment of its Phase 1 rare disease clinical trials (mRNA-3704 for MMA, mRNA-3927 for PA) and its age de-escalation trial for its pediatric respiratory vaccine (mRNA-1653 for hMPV/PIV3). These decisions will be re-evaluated on an ongoing basis as the COVID-19 situation evolves.

The Company plans to provide a detailed update on its clinical development programs during its first quarter 2020 conference call. Additional program-specific updates as of today follow.

Infectious Diseases

The Company is closely monitoring its ongoing Phase 2 CMV (mRNA-1647) and Phase 1 Zika (mRNA-1893) clinical trials. Both trials are fully enrolled, but some participants have not yet received all scheduled doses of the vaccines. The Company is aware that some participants will not be able to receive their next vaccine dose on time or at all due to the disruptions from COVID-19 and is evaluating the impact on the integrity of these trials.

Due to the pandemic, the Company has decided to suspend new enrollment of participants in the on-going hMPV/PIV3 study (mRNA-1653), which had been actively enrolling seropositive pediatric participants (12-36 months of age). The Company intends to work with appropriate medical and site personnel to determine when to resume new enrollment.

The Company's work on mRNA-1273, its vaccine candidate against the novel coronavirus continues to progress and updates can be found on the Company's [website](#).

Rare Diseases

Moderna has decided to pause new enrollment and new site initiation for its rare disease clinical trials with open Investigational New Drug (IND) applications, methylmalonic acidemia (MMA; mRNA-3704) and propionic acidemia (PA; mRNA-3927), to ensure the safety of these patients and their caregivers. No patients have been dosed to date.

Moderna has also been notified that the enrollment of further subjects in the Company's chikungunya virus antibody trial (mRNA-1944) has been paused by the site due to the impact of COVID-19.

Oncology

Moderna is continuing to treat current patients and enroll new patients in Company-sponsored oncology studies, including its Personalized Cancer Vaccine (mRNA-4157), Triplet (mRNA-2752) and OX40L (mRNA-2416) programs. Despite this, COVID-19 related challenges are leading to delays in enrollment. The Company is continuing to evaluate the initiation of new sites in oncology using a risk-based framework.

Financial and Operations Update

In February 2020, the Company raised \$550 million in net proceeds from a common stock offering. The Company has established a wide range of

strategic alliances with leading biopharmaceutical companies and has received grants from government-sponsored and private organizations focused on global health initiatives. As of February 29, 2020, Moderna had up to \$183 million (unaudited) in additional funding available from grants (including amounts not yet committed)¹. With cash and investments of approximately \$1.77 billion as of February 29, 2020 (unaudited), and access to additional grant funding, Moderna has access to up to \$1.95 billion in capital, which the Company expects will provide several years of cash to fund the business. Certain business disruptions related to COVID-19 are likely to lead to lower spending in 2020, while the Company is accelerating work on its vaccine candidate (mRNA-1273) against COVID-19 and is engaged in discussions for outside funding of such activities. The Company will provide an update to its 2020 financial guidance, if any, on its first quarter 2020 conference call.

Conference Call and Webcast Information

Moderna will host a live conference call and webcast at 8:00 a.m. ET on Monday, March 30, 2020. To access the live conference call, please dial 866-922-5184 (domestic) or 409-937-8950 (international) and refer to conference ID 3457566. A webcast of the call will also be available under "Events and Presentations" in the Investors section of the Moderna website at investors.modernatx.com. The archived webcast will be available on Moderna's website approximately two hours after the conference call and will be available for 30 days following the call.

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. The Company's platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, providing Moderna 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. 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. and Merck, Inc., 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) and the Coalition for Epidemic Preparedness Innovations (CEPI). Moderna has been named a top biopharmaceutical employer by Science for the past five 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 regarding the progression of the Company's clinical trials, enrollment, dosing and site-initiation decisions, potential clinical trial delays, the timing of updates on clinical trial progress and financial matters, the Company's cash to fund the business, and the anticipated impact of COVID-19 on 2020 spending. 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," "likely," 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; further potential delays in clinical trials due to the global COVID-19 pandemic, including with respect to site initiation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, study monitoring and data analysis; other potential adverse impacts due to the global COVID-19 pandemic such as delays in regulatory review, manufacturing and 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 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.

¹ Biomedical Advanced Research and Development Authority (BARDA), Defense Advanced Research Projects Agency (DARPA), The Bill and Melinda Gates Foundation (BMGF) and the Coalition for Epidemic Preparedness Innovations. Additional funding is subject to agreement on scope of additional projects.

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