



Moderna Announces Updates on Respiratory Syncytial Virus (RSV) Vaccine Program

October 8, 2020

Moderna regains rights to adult RSV vaccine program from Merck

Start of Phase 1 dosing for mRNA-1345, Moderna's vaccine candidate against RSV

Moderna has consolidated all rights to its prophylactic vaccines portfolio

Conference call to be held on Thursday, October 8 at 8:00 a.m. ET

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 8, 2020-- [Moderna, Inc.](#), (Nasdaq: MRNA) a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of transformative medicines for patients, today announced that it has regained all rights to the respiratory syncytial virus (RSV) vaccine (mRNA-1172) from Merck, known as MSD outside the United States and Canada, including rights to develop RSV vaccines for adult populations. mRNA-1172, which uses a Merck lipid nanoparticle for delivery, entered Phase 1 development in 2019. Under the terms of the agreement, Merck will complete the Phase 1 study and transition the program to Moderna. Moderna has now consolidated all global commercial rights to all development candidates in its core prophylactic vaccines modality.

Among its RSV candidates, Merck decided to focus its efforts on RSV infections through its antibody program that is currently in Phase 2 development.

Separately, Moderna also announced the initiation of dosing in the Phase 1 study of its solely owned RSV vaccine candidate (mRNA-1345). This Phase 1 study includes initial dosing in adults, followed by age de-escalation into children. The company previously announced its intent to advance mRNA-1345 in children in combination with mRNA-1653, a vaccine against two other pediatric respiratory viruses (hMPV, PIV3) which is currently in its own age de-escalation study. With today's announcement, Moderna will have the right to also advance RSV vaccines in adults, either alone or in combination with other respiratory virus vaccines.

Moderna's mRNA-1345 vaccine uses the Company's proprietary lipid nanoparticle delivery technology also used in the Company's COVID-19 vaccine (mRNA-1273) and CMV vaccine (mRNA-1647).

Moderna and Merck will continue their ongoing collaboration in cancer vaccines. In 2016, Moderna and Merck entered into a collaboration for mRNA-4157, a personalized cancer vaccine candidate, which is currently being evaluated in a Phase 2 study. In 2018, the companies expanded the collaboration to include the development and commercialization of mRNA-5671 a mutant KRAS vaccine candidate currently in a Phase 1 study.

"We appreciate the collaboration with Merck to date and we are pleased to continue advancing our RSV vaccine (mRNA-1345), which uses our proprietary delivery technology," said Stéphane Bancel, Moderna's Chief Executive Officer. "With this portfolio consolidation, we will continue to pursue RSV vaccines to protect the most vulnerable populations – young children and older adults. With our investments in science and manufacturing, we have taken eleven infectious disease vaccines into human clinical trials. The technology used in our core prophylactic vaccines modality has allowed us to accelerate research and development timelines and advance our mRNA vaccines into new areas of high unmet need. We look forward to continuing our productive relationship with Merck to advance our novel mRNA-based cancer vaccines."

Conference Call and Webcast Information

Moderna will host a live conference call and webcast at 8:00 a.m. ET on Thursday, October 8, 2020. To access the live conference call, please dial 866-922-5184 (domestic) or 409-937-8950 (international) and refer to conference ID 5596196. 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.

About Moderna's Prophylactic Vaccines Modality

Moderna scientists designed the company's prophylactic vaccines modality to prevent infectious diseases. Across Moderna's pipeline, more than 30,000 healthy volunteers and patients have been enrolled in Moderna's clinical studies, including the Phase 3 study of mRNA-1273. Clinical data demonstrate that Moderna's proprietary vaccine technology has been generally well-tolerated and can elicit durable immune responses to viral antigens. Based on clinical experience across Phase 1 studies, the company designated prophylactic vaccines a core modality and is working to accelerate the development of its vaccine pipeline.

The potential advantages of an mRNA approach to prophylactic vaccines include the ability to combine 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 which enables the promise of the technology platform.

Moderna currently has [nine development candidates](#) in its prophylactic vaccines modality, including:

Vaccines against respiratory infections

- Respiratory syncytial virus (RSV) vaccine for older adults (mRNA-1777 and mRNA-1172)
- RSV vaccine for young children (mRNA-1345)
- Human metapneumovirus (hMPV) and parainfluenza virus type 3 (PIV3) vaccine (mRNA-1653)
- COVID-19 vaccine (mRNA-1273)
- Influenza H7N9 vaccine (mRNA-1851)

Vaccines against infections transmitted from mother to baby

- Cytomegalovirus (CMV) vaccine (mRNA-1647)
- Zika vaccine (mRNA-1893 with BARDA)

Vaccines against highly prevalent viral infections

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

To date, Moderna has demonstrated positive Phase 1 data readouts for eight prophylactic vaccines (H10N8, H7N9, RSV, chikungunya virus, hMPV/PIV3, CMV, Zika and COVID-19). 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 in August 2019.

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.

Headquartered in Cambridge, Mass., Moderna currently has strategic alliances for development programs with AstraZeneca PLC and Merck & Co., 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 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 statements regarding: plans for the completion of the Phase 1 study of mRNA-1172 and the transition of the program to Moderna; the Phase 1 de-escalation study for mRNA-1345 and Moderna's plans to produce a combination vaccine for RSV, HMPV and PIV3; plans for the expansion of Moderna's RSV program into the older adult population; and plans to continue collaborating with Merck on mRNA-based cancer vaccines. 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: preclinical and clinical development is lengthy and uncertain, especially for a new class of medicines such as mRNA, and therefore our preclinical programs or development candidates may be delayed, terminated, or may never advance to or in the clinic; no commercial product using mRNA technology has been approved 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; 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; the fact that the rapid response technology in use by Moderna is still being developed and implemented; potential adverse impacts due to the global COVID-19 pandemic such as delays in clinical trials, preclinical work, overall operations, regulatory review, manufacturing and supply chain interruptions, adverse effects on healthcare systems and disruption of the global economy; and those 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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