



## Moderna Announces Initiation of Rolling Submission to Health Canada for mRNA Vaccine Against COVID-19 (mRNA-1273)

October 13, 2020

*Confirmation underscores Moderna's commitment to make its vaccine available in Canada*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 13, 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 the initiation of a rolling submission to Health Canada for mRNA-1273, the Company's vaccine candidate against COVID-19. This initiation follows [positive results](#) from a preclinical viral challenge study of mRNA-1273 and the positive interim analysis of the Phase 1 study of mRNA-1273 in [healthy adults](#) (ages 18-55 years) and [older adults](#) (ages 56-70 and 71+) published in the *New England Journal of Medicine*.

The rolling submission has been accepted under the Canadian Minister of Health's [Interim Order](#), which permits companies to submit safety and efficacy data and information as they become available. This rolling review process allows Health Canada to begin its assessment using the information submitted by the applicant and accept new evidence as it becomes available until the application is deemed complete. This process can reduce time to authorization for these important new drugs while maintaining appropriate standards of safety, efficacy, and quality. Health Canada will not make a decision to authorize any vaccine being considered under rolling review until it has received all necessary evidence to support its safety and efficacy. Following the authorization of any vaccine submission, Health Canada will publish the evidence used in making its decision for transparency.

On September 22, the Canadian Government [increased its confirmed order commitment](#) to 20 million doses of mRNA-1273. Moderna remains on track to be able to deliver up to 56 million doses of its COVID-19 vaccine to help protect Canadians beginning in 2021. The Canadian vaccine supply will be sourced from Moderna's European production capacity with its strategic manufacturing partner Lonza of Switzerland, and ROVI of Spain for fill-finish services.

"We are pleased with the interactions with the Canadian regulatory authorities and we appreciate their guidance and confidence in Moderna to pursue a rolling submission in Canada for our COVID-19 vaccine candidate, mRNA-1273," said Stéphane Bancel, Moderna's Chief Executive Officer. "We are committed to developing a safe and effective vaccine following the guidance of regulatory agencies around the world and we will continue working closely with Health Canada."

The Phase 1 interim analysis showed that mRNA-1273 was generally well-tolerated across all age groups and induced rapid and strong immune responses against SARS-CoV-2. In the [18-55 age group](#), neutralizing antibody titers were observed in 100% of evaluated participants and at the 100 µg dose level selected for Phase 3, the geometric mean titers were above those seen in convalescent sera. Similarly, mRNA-1273 induced consistently high levels of pseudovirus neutralization antibody titers in all participants in the [56-70 and 71+ age groups](#). In addition, vaccination with mRNA-1273 elicited Th1-biased CD4 T cell responses in all age groups.

mRNA-1273 is currently being studied in a Phase 3 randomized, 1:1 placebo-controlled trial of 30,000 participants at the 100 µg dose level in the U.S. As of Friday, October 9, the Phase 3 COVE study has enrolled approximately 28,618 participants with 22,194 having received their second vaccination. The [clinicaltrials.gov](#) identifier is NCT04470427. For more information about the Phase 3 COVE study, [click here](#).

### 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 [seven development candidates](#) in its prophylactic vaccines modality, including:

#### *Vaccines against respiratory infections*

- 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](http://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: the Company's plans to submit safety and efficacy data for mRNA-1273 to Health Canada; the potential authorization of mRNA-1273 for distribution in Canada; the potential for mRNA-1273 to induce rapid and strong immune responses against SARS-CoV-2 in individuals of different ages; plans for the manufacture of mRNA-1273 and the scale of anticipated production, particularly for the Canadian market; and the potential advantages of mRNA-based prophylactic vaccines and the ability to combine multiple mRNAs into a single 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: 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, Health Canada or other regulatory agencies, the FDA, Health Canada 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](http://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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