



UK Medicines and Healthcare products Regulatory Agency Begins Rolling Review of Moderna's mRNA Vaccine Against COVID-19 (mRNA-1273)

October 27, 2020

Moderna completed enrollment of its Phase 3 COVE study of mRNA-1273 on October 22

Rolling review based on preclinical, CMC, and clinical data available to date

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 27, 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 the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom has started the rolling review process of mRNA-1273, the Company's vaccine candidate against COVID-19. This announcement 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 [adults](#) (ages 18-55 years) and [older adults](#) (ages 56-70 and 71+) published in the *New England Journal of Medicine*.

Moderna has initiated the rolling submission of mRNA-1273 data for rolling review, in consideration of a potential authorization by the MHRA, provided the vaccine candidate meets the MHRAs rigorous standards of safety, effectiveness, and quality standards. This rolling review process allows the MHRA to begin its independent assessment using the information submitted by Moderna and accept new evidence as it becomes available until the application is deemed complete. This process can reduce time to authorization while maintaining usual high standards of safety, efficacy, and quality.

"We appreciate the collaboration we have had to date with regulatory authorities around the world, and the process established by the MHRA to address this ongoing public health emergency," said Stéphane Bancel, Chief Executive Officer of Moderna. "This is a great example of what's being done to support efforts to deliver a safe and effective vaccine to UK citizens as safely and efficiently as possible."

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. 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. On Thursday, October 22, Moderna [completed enrollment](#) of the Phase 3 COVE study. For more information about the Phase 3 COVE study, [click here](#).

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: the Company's plans to seek authorization for the use of mRNA-1273 in the United Kingdom; and the potential for mRNA-1273 to induce rapid and strong immune responses against SARS-CoV-2. 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, EMA, MHRA or other regulatory agencies, the FDA, EMA, MHRA 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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Moderna Contacts

Media:

Colleen Hussey

Director, Corporate Communications

617-335-1374

Colleen.Hussey@modernatx.com

Investors:

Lavina Talukdar

Senior Vice President & Head of Investor Relations

617-209-5834

Lavina.Talukdar@modernatx.com

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