Modern Moderna Partners with Takeda and the Government of Japan to Supply 50 Million Doses of mRNA Vaccine Against COVID-19 (mRNA-1273) to Japan

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MHLW and Takeda will import and distribute mRNA-1273 in Japan starting in the first half of 2021

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 29, 2020--Modern, Inc. (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of transformative medicines for patients, today confirmed that the Ministry of Health, Labour and Welfare of Japan (MHLW) and Takeda Pharmaceutical Co., Ltd (NYSE: TAK) have agreed to purchase and distribute 50 million doses of mRNA-1273, Moderna’s vaccine candidate against COVID-19, to support Japan’s aim of providing vaccines to the Japanese public as soon as possible, subject to necessary regulatory approvals. Moderna is responsible for the manufacture and supply of Moderna’s vaccine candidate, and Takeda, with the support of the MHLW, the Japan Agency for Medical Research and Development (AMED) and Moderna, is responsible for all import, local regulatory, development and distribution activities in Japan to ensure timely access starting during the first half of 2021.

“We thank the MHLW and Takeda for their support and for partnering with us to bring mRNA-1273, our vaccine candidate against COVID-19, to Japan. We appreciate the confidence of the MHLW in Moderna and mRNA-1273, which we hope will help address the pandemic, especially given the encouraging data we have recently published together with the NIH related to the clinical trial in the elderly and older adult population,” said Stéphane Bancel, Moderna’s Chief Executive Officer. “We look forward to our expected first review of our interim efficacy data, which is expected in November.”

About Moderna

Over the past nine years, Moderna has invested in creating and developing a novel platform for designing and manufacturing a new class of mRNA-based vaccines. The investments in this proprietary platform have enabled Moderna to expeditiously create, manufacture and clinically develop mRNA-1273 to potentially address the current COVID-19 pandemic. A summary of the company’s work to date on COVID-19 can be found here. mRNA-1273 currently is not approved for use by any regulatory body.

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. Moderna’s platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, providing the Company 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, cardiovascular diseases, and autoimmune and inflammatory diseases, independently and with strategic collaborators.

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, but not limited to, statements concerning: the Company’s development of a potential vaccine against the novel coronavirus (mRNA-1273), the potential for mRNA-1273 to prevent COVID-19 disease and slow the spread of SARS-CoV-2, including in elderly and older adult populations, the terms of the Company’s supply of mRNA-1273 to the MHLW, the distribution by Takeda of mRNA-1273 in Japan, and the timing for the manufacturing, supply and distribution of mRNA-1273. In some cases, forward-looking statements can be identified by terminology such as “will,” “may,” “should,” “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 ability to manufacture and deliver doses at the scale required by the agreement with the MHLW, Takeda and in separate agreements other customers; 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; the fact that the safety and efficacy of mRNA-1273 has not yet been established; 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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