Moderna Announces First Participant Dosed in Phase 1/2 Study of Moderna COVID-19 Vaccine in Japan Led by Takeda

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Phase 1/2 study expected to enroll 200 adult participants in Japan

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 21, 2021-- Moderna Inc. (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced that the first participant has been dosed in the Phase 1/2 study of Moderna's vaccine candidate against COVID-19 (mRNA-1273 or TAK-919) in Japan, led by Takeda Pharmaceutical Co., Ltd (NYSE: TAK). TAK-919 is Takeda's development code for Moderna's COVID-19 vaccine candidate.

"We are pleased that this Phase 1/2 study of our COVID-19 vaccine in healthy adults in Japan has begun. This is the first clinical trial of a Moderna product in Japan and we thank Takeda for partnering with us to potentially protect the Japanese population from COVID-19 with a vaccine," said Stéphane Bancel, Chief Executive Officer of Moderna.

This placebo-controlled Phase 1/2 study will evaluate the safety and immunogenicity of two vaccinations of mRNA-1273 given 28 days apart. Takeda intends to enroll 200 participants aged 20 years and above in Japan. Each participant will be assigned to receive a placebo or a 100 µg dose at both vaccinations. Participants will be followed through 12 months after the second vaccination. The ClinicalTrials.gov identifier is NCT04677660.

Takeda and Moderna previously announced that Takeda will import and distribute 50 million doses of Moderna's COVID-19 vaccine candidate starting in the first half of 2021, pending licensure in Japan.

About Moderna

In 10 years since its inception, Moderna has transformed from a science research-stage company advancing programs in the promising-but-still-unproven field of messenger RNA (mRNA), to an enterprise with its first medicine having treated millions of people, a diverse clinical portfolio of vaccines and therapeutics across six modalities, a broad intellectual property portfolio in areas including mRNA and lipid nanoparticle formulation, and an integrated manufacturing plant that allows for both clinical and commercial production at scale and at unprecedented speed. Moderna maintains alliances with a broad range of domestic and overseas government and commercial collaborators, which has allowed for the pursuit of both groundbreaking science and rapid scaling of manufacturing. Most recently, Moderna's capabilities have come together to allow the authorized use of one of the earliest and most-effective vaccines against the COVID-19 pandemic.

Moderna's mRNA platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, and has allowed the development of therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases, cardiovascular diseases and auto-immune diseases. Today, 24 development programs are underway across these therapeutic areas, with 13 programs having entered the clinic. Moderna has been named a top biopharmaceutical employer by Science for the past six 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 conduct for clinical studies of Moderna's COVID-19 vaccine candidate in Japan and the sale and distribution of the vaccine in Japan. 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: 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; the safety, tolerability and efficacy profile of the Moderna COVID-19 Vaccine observed to date may change adversely in ongoing analyses of trial data or subsequent to commercialization; 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; Moderna may encounter delays in meeting manufacturing or supply timelines or disruptions in its distribution plans for the Moderna COVID-19 Vaccine; whether and when any biologics license applications and/or emergency use authorization applications may be filed and ultimately approved by regulatory authorities; potential adverse impacts due to the global COVID-19 pandemic such as delays in regulatory review, manufacturing and clinical trials, 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 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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