Moderna Announces New Supply Agreement with Australia for 25 Million Doses of its COVID-19 Vaccine

May 12, 2021

25 million doses includes 10 million doses of mRNA-1273 to begin delivery in 2021 and 15 million doses of updated variant booster candidate to begin delivery in 2022

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 12, 2021-- Moderna, Inc. (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced a new supply agreement with the government of Australia for 25 million doses. This includes 10 million doses of Moderna's COVID-19 vaccine against the ancestral strain (mRNA-1273) to be delivered in 2021 and 15 million doses of Moderna's updated variant booster vaccine candidate to be delivered in 2022.

Purchase under this agreement is subject to regulatory approval of mRNA-1273 and booster vaccine candidates by the Therapeutic Goods Administration (TGA) of Australia. The Company expects to submit an application to the TGA shortly. As Moderna has continued to scale its commercial network, the Company announced earlier this year that it also plans to open a commercial subsidiary in Australia in 2021.

"We appreciate the partnership and support from the government of Australia with this first supply agreement for doses of the Moderna COVID-19 vaccine and our variant booster candidates," said Stéphane Bancel, Chief Executive Officer of Moderna. "As we seek to protect people around the world with our COVID-19 vaccine and potentially our variant booster candidates, we look forward to continuing discussions with Australia about establishing potential local manufacturing opportunities."

Initial data from Moderna's Phase 2 study in the U.S. showed that a single 50 µg dose of mRNA-1273 or mRNA-1273.351 given as a booster to previously vaccinated individuals increased neutralizing antibody titer responses against SARS-CoV-2 and two variants of concern, B.1.351 (first identified in South Africa) and P.1 (first identified in Brazil). A booster dose of mRNA-1273.351, the Company's strain-matched booster, achieved higher neutralizing antibody titers against the B.1.351 variant of concern than a booster dose of mRNA-1273. Safety and tolerability profiles following third dose booster injections of 50 µg of mRNA-1273 or mRNA-1273.351 were generally comparable to those observed after the second dose of mRNA-1273 in the previously reported Phase 2 and Phase 3 studies. A manuscript describing these preliminary results was submitted as a preprint to *medRxiv* and will be submitted for peer-reviewed publication upon completion of the multivalent mRNA-1273.211 booster arm.

About the COVID-19 Vaccine Moderna

The COVID-19 Vaccine Moderna (referred to in the U.S. as the Moderna COVID-19 Vaccine) is an mRNA vaccine against COVID-19 encoding for a prefusion stabilized form of the Spike (S) protein, which was co-developed by Moderna and investigators from the National Institute of Allergy and Infectious Diseases' (NIAID) Vaccine Research Center. The first clinical batch, which was funded by the Coalition for Epidemic Preparedness Innovations, was completed on February 7, 2020 and underwent analytical testing; it was shipped to the National Institutes of Health (NIH) on February 24, 42 days from sequence selection. The first participant in the NIAID-led Phase 1 study of the Moderna COVID-19 Vaccine was dosed on March 16, 63 days from sequence selection to Phase 1 study dosing. On May 12, the U.S Food and Drug Administration granted the Moderna COVID-19 Vaccine Fast Track designation. On May 29, the first participants in each age cohort: adults ages 18-55 years (n=300) and older adults ages 55 years and above (n=300) were dosed in the Phase 2 study of the vaccine. On July 8, the Phase 2 study completed enrolment.

Results from the second interim analysis of the NIH-led Phase 1 study of the Moderna COVID-19 Vaccine in the 56-70 and 71+ age groups were published on September 29 in *The New England Journal of Medicine*. On November 30, 2020, Moderna announced the primary efficacy analysis of the Phase 3 study of the vaccine conducted on 196 cases. On November 30, 2020, the Company also announced that it filed for Emergency Use Authorization with the U.S. FDA and a Conditional Marketing Authorization (CMA) application with the European Medicines Agency. On December 18, 2020, the U.S. FDA authorized the emergency use of the Moderna COVID-19 Vaccine in individuals 18 years of age or older. Moderna has also received authorization for its COVID-19 vaccine from health agencies in Canada, Israel, the European Union, the United Kingdom, Switzerland, Singapore, Qatar, Taiwan, the Philippines, Brunei and from the World Health Organization. Additional authorizations are currently under review in other countries.

About Moderna

In 10 years since its inception, Moderna has transformed from a science research-stage company advancing programs in the field of messenger RNA (mRNA), to an enterprise with 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 14 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 Company's development of a vaccine, the COVID-19 Vaccine Moderna, against the SARS-CoV-2 virus; the Company's development of booster vaccines to protect against specific variants of the SARS-CoV-2 virus and the potential protection to be provided by those

boosters, and the safety and tolerability profile of those boosters; plans for the supply and distribution of the COVID-19 Vaccine Moderna to Australia and the timing for such supply; the potential regulatory approval for the distribution of the COVID-19 Vaccine Moderna in Australia; and the potential establishment by the Company of additional manufacturing capacity in Australia. 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 Annual Report on Form 10-K 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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