United Kingdom Medicines and Healthcare products Regulatory Agency Authorizes Use of COVID-19 Vaccine Moderna

January 8, 2021

UK MHRA authorization is based on a rolling review of COVID-19 Vaccine Moderna data, including data from the Phase 3 COVE study

UK government secured an additional 10 million doses for a total of 17 million doses of the vaccine with supply beginning in early 2021

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 8, 2021-- Moderna, Inc. (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced that the UK's Medicines and Healthcare products Regulatory Agency (MHRA) has approved its mRNA vaccine against COVID-19 (COVID-19 Vaccine Moderna) for use under Regulation 174. The temporary authorization permits the supply of COVID-19 Vaccine Moderna in Great Britain and is based upon the advice of the UK Commission on Human Medicines.

"We appreciate the confidence shown by the UK MHRA in COVID-19 Vaccine Moderna with this decision, which marks an important step forward in the global fight against COVID-19," said Stéphane Bancel, Chief Executive Officer of Moderna. "I want to thank the MHRA and the Commission on Human Medicines' reviewers for their tireless efforts. The authorization of a product developed by Moderna is a significant milestone on the Company's 10-year journey, and I would like to thank all our colleagues that have helped us get to this point."

The United Kingdom government has also exercised its option to purchase an additional 10 million doses of the COVID-19 Vaccine Moderna, bringing its confirmed order commitment to 17 million doses. The first deliveries of the COVID-19 Vaccine Moderna to the UK from Moderna's dedicated non-U.S. supply chain are expected to commence early in 2021.

The UK is the fifth jurisdiction to authorize COVID-19 Vaccine Moderna, following the United States on December 18, 2020, Canada on December 23, 2020, Israel on January 4, 2021 and the European Union on January 6, 2021. Additional authorizations are currently under review in a number of countries including Singapore and Switzerland.

The decision from the MHRA is based on a rolling submission of data that was announced on October 27, 2020. The MHRA based its authorization on the totality of scientific evidence shared by the Company, including a data analysis from the pivotal Phase 3 clinical study announced on November 30.

To learn more about Moderna's work on the COVID-19 Vaccine Moderna, visit www.modernatx.com/COVID19.

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 NIAID's 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 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 July 28, results from a non-human primate preclinical viral challenge study evaluating the vaccine were published in The New England Journal of Medicine. On July 14, an interim analysis of the original cohorts in the NIH-led Phase 1 study of the vaccine was published in The New England Journal of Medicine. On November 30, Moderna announced the primary efficacy analysis of the Phase 3 study of the vaccine conducted on 196 cases. On November 30, 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 3, a letter to the editor was published in The New England Journal of Medicine reporting that participants in the Phase 1 study of the Moderna COVID-19 Vaccine retained high levels of neutralizing antibodies through 119 days following first vaccination (90 days following second vaccination).

Authorized Use

The COVID-19 Vaccine Moderna has been authorized by the Medicines and Healthcare products Regulatory Agency (MHRA), based upon the recommendation of the Commission on Human Medicines, which authorizes the COVID-19 Vaccine Moderna for active immunization to prevent COVID-19 caused by SARS-CoV-2 virus in individuals 18 years of age and older.

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, cardiovascular diseases, and autoimmune and inflammatory 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 BARDA. 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 against the novel coronavirus, and plans for the supply and distribution of the Moderna COVID-19 Vaccine to the United Kingdom. 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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