Moderna and South Korea Explore Collaboration on mRNA Vaccines

May 22, 2021

Moderna and South Korea will explore potential areas of collaboration for research and development of mRNA vaccines and local manufacturing opportunities in South Korea

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 22, 2021-- Moderna, Inc. (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced two Memoranda of Understanding (MoU) with the government of South Korea: one MoU with the Korea National Institute of Health (KNIH), an agency of the Korea Centers for Disease Control and Prevention Agency (KDCA) for a new collaboration on mRNA vaccine research in South Korea; and an additional MoU with the Ministry of Trade, Industry and Energy of the Republic of Korea (MOTIE), the Ministry of Health and Welfare of the Republic of Korea (MOHW) to explore local manufacturing opportunities for mRNA vaccines in South Korea.

The MoUs were signed today by Kwon Junwook, Director, KNIH and Stéphane Bancel, Moderna's Chief Executive Officer at a signing ceremony in Washington, D.C. With these MoUs, Moderna and the KNIH will explore areas of collaboration for scientific research on mRNA vaccines. The teams will engage in discussions regarding collaboration opportunities such as pre-clinical or clinical development of mRNA vaccine candidates against viruses that create a high burden of disease in South Korea. These MoUs may also facilitate discussions between Moderna and South Korea for a potential manufacturing facility for mRNA vaccines in South Korea.

"We thank the South Korean government and we look forward to exploring this collaboration to bring mRNA vaccines that may help address areas of unmet need," said Stéphane Bancel, Chief Executive Officer of Moderna. "We will continue to explore options for establishing potential local manufacturing opportunities in South Korea."

Also announced at the signing ceremony, Moderna and Samsung Biologics have entered into a Manufacturing Services and Supply Agreement in which Samsung Biologics in South Korea will provide large scale, commercial fill-finish manufacturing for COVID-19 Vaccine Moderna intended for the supply of markets outside of the U.S. starting in the third quarter of 2021.

Earlier this year, Moderna announced that as it continues to scale its commercial network, the Company plans to open a commercial subsidiary in South Korea in 2021.

The Ministry of Food and Drug Safety of South Korea (MFDS) approved Moderna's application for Conditional Marketing Authorization for Moderna's COVID-19 vaccine on May 21. GC Pharma in South Korea is the Company's marketing authorization holder and distributor of Moderna's COVID-19 vaccine for South Korea. South Korea has secured access to 40 million doses of COVID-19 Vaccine Moderna.

Authorized Use

Moderna's COVID-19 vaccine is authorized pursuant to a Conditional Marketing Authorization in South Korea for use in adults aged 18 years and older.

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 emergency (or other conditional, interim or provisional) authorization for use of its COVID-19 vaccine from health agencies in Canada, Israel, the European Union, the United Kingdom, Switzerland, Singapore, Qatar, Taiwan, the Philippines, Thailand, Brunei, Paraguay, Japan, South Korea an Emergency Use Listing (EUL) from the World Health Organization (WHO).

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 statements regarding: collaborations between the Company and agencies of the South Korean government to collaborate on mRNA vaccine research in South Korea and to explore local manufacturing opportunities in the country; the provision of commercial fill-finish manufacturing services for the Company's COVID-19 vaccine by Samsung Biologics and the timing for such services; the establishment by the Company of a commercial subsidiary in South Korea in 2021; and the sale and delivery by the Company of its COVID-19 vaccines to South Korea.. 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; the Moderna COVID-19 Vaccine may prove less effective against variants of the SARS-CoV-2 virus, or the Company may be unsuccessful in developing future versions of its vaccine against these variants; 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 additional emergency use authorization applications may be filed in various jurisdictions 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20210522005009/en/

Moderna Contacts
Media:
Colleen Hussey
Director, Corporate Communications
617-335-1374
Colleen.Hussey@modernatx.com

Investors:
Lavina Talukdar
Head of Investor Relations
617-209-5834
Lavina.Talukdar@modernatx.com

Source: Moderna, Inc.