



Moderna Announces Agreement to Supply the Republic of Botswana with its COVID-19 Vaccine

June 3, 2021

Supply agreement reflects Moderna's commitment to make its vaccine available in Africa

Botswana Medicines Regulatory Authority issues emergency use authorization (EUA) for COVID-19 Vaccine Moderna

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jun. 3, 2021-- [Moderna, Inc.](#), (Nasdaq: MRNA) a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced a supply agreement with the Government of the Republic of Botswana for Moderna's vaccine against COVID-19, to support the government's ongoing efforts to secure access to a COVID-19 vaccines for the people of Botswana. The Company also announced that the Botswana Medicines Regulatory Authority (BMRA) has issued an emergency use authorization for the COVID-19 Vaccine Moderna.

"We appreciate the collaboration with the Government of the Republic of Botswana for this supply agreement and with the Botswana Medicines Regulatory Authority for this EUA," said Stéphane Bancel, Moderna's Chief Executive Officer. "We are committed to ensuring that people on every continent have access to our mRNA vaccine so that we can defeat the COVID-19 pandemic."

This agreement with Botswana is separate from the supply agreement with Gavi, the Vaccine Alliance, which Moderna [announced](#) in May. The agreement with Gavi, on behalf of the COVAX Facility, is for the supply of up to 500 million doses of the COVID-19 Vaccine Moderna, including an initial 34 million doses to be delivered in the fourth quarter of 2021. COVAX is a global initiative co-led by Gavi, the Coalition for Epidemic Preparedness Innovations (CEPI) and the World Health Organization (WHO), to ensure equitable access to COVID-19 vaccines for all countries, regardless of income levels.

Authorized Use

The COVID-19 Vaccine Moderna has been granted emergency use authorization by the Botswana Medicines Regulatory Authority 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 and an Emergency Use Listing (EUL) from the World Health Organization (WHO).

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 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 to protect against the SARS-CoV-2 virus (mRNA-1273, also referred to as COVID-19 Vaccine Moderna and the Moderna COVID-19 Vaccine); and the Company's agreement to supply the COVID-19 Vaccine Moderna to the Republic of Botswana and the COVAX facility. 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 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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