Australian Therapeutic Goods Administration Grants Provisional Registration for Moderna's COVID-19 Vaccine

August 9, 2021

Australia has secured 25 million doses of Moderna's COVID-19 vaccine

Delivery to begin in the second half of September

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 9, 2021-- Moderna, Inc. (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced that the Therapeutic Goods Administration (TGA) has granted provisional registration to the COVID-19 Vaccine Moderna in Australia for active immunization to prevent COVID-19 caused by SARS-CoV-2 virus in individuals 18 years of age and older. Delivery of Moderna's COVID-19 vaccine to Australia is expected to commence in the second half of September.

"I want to thank the government of Australia for their collaboration and for the confidence they have demonstrated in COVID-19 Vaccine Moderna with this decision," said Stéphane Bancel, Chief Executive Officer of Moderna. "As we seek to protect people around the world with our COVID-19 vaccine, we look forward to continuing discussions with the Australian Government about potentially establishing local mRNA manufacturing capabilities."

The Australian government has previously secured 10 million doses of COVID-19 Vaccine Moderna for delivery in 2021, through a supply agreement announced on May 12, 2021, as well as an option to procure 15 million doses in 2022. Moderna has also received emergency (or other conditional, interim or provisional) authorization for use of its COVID-19 vaccine from health agencies in more than 50 countries and an Emergency Use Listing (EUL) from the World Health Organization (WHO). The TGA continues to evaluate an application for provisional registration of Moderna's COVID-19 vaccine for use in adolescents aged 12 to 18 years.

Authorized Use

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IMPORTANT SAFETY INFORMATION

- Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine.
- Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine. Monitor Moderna COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).
- Reports of adverse events following use of the Moderna COVID-19 Vaccine under EUA suggest increased risks of myocarditis and pericarditis, particularly following the second dose. Typically, onset of symptoms has been within a few days following receipt of the Moderna COVID-19 Vaccine. Available data from short-term follow-up suggest that most individuals have had resolution of symptoms, but information is not yet available about potential long-term sequelae. The decision to administer the Moderna COVID-19 Vaccine to an individual with a history of myocarditis or pericarditis should take into account the individual's clinical circumstances. The CDC has published clinical considerations relevant to myocarditis and pericarditis associated with administration of the Moderna COVID-19 Vaccine (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).
- Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to the Moderna COVID-19 Vaccine.
- The Moderna COVID-19 Vaccine may not protect all vaccine recipients.
- Adverse reactions reported in a clinical trial following administration of the Moderna COVID-19 Vaccine include pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, swelling at the injection site, and erythema at the injection site.
- The following adverse reactions have been reported following administration of the Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials:
    - Severe allergic reactions, including anaphylaxis
    - Myocarditis
    - Pericarditis
- Available data on Moderna COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy. Data are not available to assess the effects of Moderna COVID-19 Vaccine on the breastfed infant or on milk production/excretion.
- There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Moderna COVID-19 Vaccine should receive a second dose of Moderna COVID-19 Vaccine to complete the vaccination series.

- Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 Vaccine.
- Vaccination providers must complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS, call 1-800-822-7967. The reports should include the words “Moderna COVID-19 Vaccine EUA” in the description section of the report.

Click for Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Full EUA Prescribing Information for more information.

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, 23 development programs are underway across these therapeutic areas, with 15 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 efforts to develop a vaccine against COVID-19 and the supply of the vaccine to the Australian government, the timing of that delivery, the potential establishment of mRNA manufacturing capabilities in Australia, the potential for the Australian government to exercise its option to purchase additional doses for delivery in 2022, and the potential extension of the TGA’s authorization for use of the vaccine to adolescent populations. 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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