Moderna Provides U.S. COVID-19 Vaccine Supply Update

February 16, 2021

Company has supplied 45.4 million doses of Moderna COVID-19 Vaccine to U.S. Government to date

The CDC communicated that approximately 25.5 million doses of the Moderna COVID-19 Vaccine have been administered in the U.S.

Additional 33.2 million doses have been produced and are filled in vials and in the final stages of final production and testing before release

Moderna expects to deliver 100 million doses to the U.S. Government by end of March 2021

Moderna expects to deliver 100 million additional doses by end of May 2021 followed by another 100 million additional doses by end of July 2021

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Feb. 16, 2021-- Moderna, Inc. (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today provided a supply update for the Moderna COVID-19 Vaccine in the United States, reporting that 45.4 million doses have been supplied to the U.S. Government to date. The Company continues to work closely with the U.S. Government to provide regular updates on supply and production. An additional 33.2 million doses of Moderna COVID-19 Vaccine have been filled in vials and are at various stages of final production and testing before release to the U.S. Government. Approximately 25.5 million doses of the Moderna COVID-19 Vaccine have been administered in the U.S., according to the U.S. Centers for Disease Control and Prevention[1].

Short term delays in the final stages of production and release of filled vials at Moderna's fill and finish contractor Catalent have recently delayed the release of some doses, but these delays are expected to be resolved in the near term and are not expected to impact monthly delivery targets.

The Company expects to meet commitment dates to the U.S. Government for all currently ordered doses of the Moderna COVID-19 Vaccine, including targeting delivery of the first 100 million doses by the end of the first quarter 2021. The Company has moved forward delivery of its second 100 million doses by one month, from end of June 2021 to end of May 2021. It has moved forward delivery of its third 100 million doses by two months, from end of September 2021 to end of July 2021.

These commitments reflect a ramping up of production over the last few months and an expectation of further ramp up over the coming months. Between October and the end of December, the Company produced 17.8 million doses that were released at the end of December 2020, and 19.1 million doses were produced and released in January 2021, representing roughly a tripling of monthly production. Looking forward, the monthly doses released to the US Government are expected to double again by April, with an expected average of 30-35 million doses per month for February and March, and 40-50 million doses a month from April through the end of July.

The Company does not intend to stockpile significant quantities to smooth shipments, choosing instead to ship doses to the U.S. Government as released. Accordingly, weekly totals of released doses are expected to be volatile and may not reflect the underlying trajectory of manufacturing scale-up. The Company is in active and frequent communication with the U.S. Government to provide transparency on expected timing of deliveries in order to aid the U.S. Government's vaccine deployment efforts.

All U.S. supply comes from Moderna's dedicated supply chain in the U.S. Supply to locations outside of the U.S. comes from dedicated supply points based outside of the U.S.

The Moderna COVID-19 Vaccine received Emergency Use Authorization from the U.S. Food and Drug Administration (FDA) on December 18, 2020 and Moderna began supplying to the government shortly thereafter. The U.S. Government has agreed to purchase a total of 300 million doses of the Moderna COVID-19 Vaccine.

About the Moderna COVID-19 Vaccine

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 Disease's (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 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). 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 and Qatar. Additional authorizations are currently under review in other countries and by the World Health Organization.

The Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and

Response (ASPR) within the U.S. Department of Health and Human Services (HHS) is supporting the continued research and development of mRNA-1273 with $955 million in federal funding under contract no. 75A50120C00034. BARDA is reimbursing Moderna for 100 percent of the allowable costs incurred by the Company for conducting the program described in the BARDA contract. The U.S. government has agreed to purchase supply of mRNA-1273 under U.S. Department of Defense contract no. W911QY-20-C-0100.

Authorized Use

Moderna COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older. Moderna COVID-19 Vaccine is investigational and not approved by FDA.

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/).
- 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. Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 Vaccine.
- Available data on the 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 the 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 the Moderna COVID-19 Vaccine should receive a second dose of the 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.

About Moderna

In 10 years since its inception, Moderna has transformed from a science research-stage company advancing programs in the promising-but-still-unproven field of messenger RNA (mRNA), to an enterprise with its first medicine having treated millions of people, 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 13 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 the purchase by the U.S. government of additional doses of the Moderna COVID-19 Vaccine from the Company, the timing of delivery of vaccine doses for the U.S. government, and efforts to speed production and manufacturing of the Moderna COVID-19 Vaccine. 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 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 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.

[1] https://covid.cdc.gov/covid-data-tracker/#vaccinations

View source version on businesswire.com: https://www.businesswire.com/news/home/20210216005775/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.