



## Swissmedic Authorizes COVID-19 Vaccine Moderna for Use in Switzerland

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*Swiss Federal Government has secured 7.5 million doses and first deliveries expected to begin in January*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 12, 2021-- [Moderna, Inc.](#) (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced that Swissmedic, the Swiss Agency for Therapeutic Products, has authorized the COVID-19 Moderna Vaccine in Switzerland.

The authorization is given according to the ordinary approvals procedure and is based on a rolling submission of data and the totality of scientific evidence shared by the Company, including a data analysis from the pivotal Phase 3 clinical study announced on November 30.

"Having our COVID-19 Vaccine Moderna authorized in Switzerland is an important milestone for us," said Stéphane Bancel, Chief Executive Officer of Moderna. "Switzerland has played a critical role in Moderna's history since our early days and it means a lot to us that we can now provide a highly effective vaccine to help protect the citizens of Switzerland."

The Swiss Federal Government has secured 7.5 million doses of the COVID-19 Vaccine Moderna. Following today's authorization, the first deliveries are expected to begin in Switzerland in the next week.

Moderna has also received authorization for its COVID-19 vaccine from regulatory authorities in the United States, Canada, Israel, the European Union and the United Kingdom. Additional authorizations are currently under review in other countries and by the World Health Organization.

To learn more about Moderna's work on COVID-19 Vaccine Moderna, visit [www.modernatx.com/COVID19](http://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 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 granted temporary approval by Swissmedic, the Swiss Agency for Therapeutic Products, based upon the recommendation of the Human Medicines Expert Committee (HMEC), 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

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](http://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 Switzerland, and the timing of deliveries of the 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 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](http://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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