



Moderna Announces Supply Agreement with Gavi for up to 500 Million Doses of COVID-19 Vaccine Moderna for COVAX To Help End COVID-19 Pandemic in Lowest Income Countries

May 3, 2021

34 million doses to begin delivery in the fourth quarter of 2021

Option granted to COVAX Facility for up to 466 million additional doses in 2022

Doses provided at lowest tiered price, in keeping with Moderna's global access principles commitment

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 3, 2021-- [Moderna, Inc.](#) (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced an agreement with Gavi, the Vaccine Alliance to supply 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. Through this agreement, on behalf of the COVAX Facility, Gavi also retains the option to procure 466 million additional doses in 2022. All doses are offered at Moderna's lowest tiered price, in line with the Company's [global access commitments](#).

This agreement covers the 92 Gavi COVAX Advance Market Commitment (AMC) low- and middle-income countries. The Company is in discussions to allocate and supply to self-financing participants in the future. COVAX is a global initiative co-led by Gavi, the Vaccine Alliance (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.

On April 30, the World Health Organization (WHO) issued an [Emergency Use Listing](#) (EUL) for Moderna's COVID-19 vaccine to prevent COVID-19 in individuals 18 years of age and older.

"I am grateful to our Gavi and COVAX partners for their tireless work and to the entire Moderna team for their collaboration to reach this agreement. This is an important milestone as we work to ensure that people around the world have access to our COVID-19 vaccine," said Stéphane Bancel, Chief Executive Officer of Moderna. "We recognize that many countries have limited resources to access COVID-19 vaccines. We support COVAX's mission to ensure broad, affordable and equitable access to COVID-19 vaccines and we remain committed to doing everything that we can to ending this ongoing pandemic with our mRNA COVID-19 vaccine."

"We are very pleased to sign this new agreement with Moderna, giving COVAX Facility participants access to yet another highly efficacious vaccine," said Dr. Seth Berkley, CEO of Gavi. "Expanding and having a diverse portfolio has always been a core goal for COVAX, and to remain adaptable in the face of this continually evolving pandemic – including the rising threat posed by new variants. This agreement is a further step in that direction."

"We must find ways to help world-changing breakthroughs – especially in the form of life-saving medicines like mRNA – reach the entire world," said Noubar Afeyan, Ph.D., Co-Founder and Chairman of Moderna, and CEO of Flagship Pioneering. "I am delighted that the Moderna team has been able to bring this agreement with COVAX to completion, and with it the opportunity to bring up to half a billion doses of our vaccine to populations in 92 of the lowest income countries in the world. Having experienced the impact such agreements can have on reaching global development goals, I could not be more excited."

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 authorization for its COVID-19 vaccine from health agencies in Canada, Israel, the European Union, the United Kingdom, Switzerland, Singapore, Qatar and Taiwan. Additional authorizations are currently under review in other countries.

Preclinical data on the Company's variant-specific booster vaccine candidates have been submitted as a preprint to [bioRxiv](#) and will be submitted for peer-reviewed publication. These variant-specific vaccine candidates include mRNA-1273.351, which is more specifically targeted against the SARS-CoV-2 variant known as B.1.351 first identified in the Republic of South Africa, and a multivalent booster candidate, mRNA-1273.211, which combines mRNA-1273 (Moderna's authorized vaccine against ancestral strains) and mRNA-1273.351 in a single vaccine. The Company's Phase 2 study to evaluate three [approaches to boosting](#) is ongoing.

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 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 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), which causes COVID-19; the Company's agreement to supply the COVID-19 Vaccine Moderna to Gavi, the Vaccine Alliance, the number of doses to be supplied and timing for delivery of those doses and the pricing under the agreement; the potential to supply the COVID-19 Vaccine Moderna to low- and middle-income countries directly; and the COVID-19 Vaccine Moderna's ability to contribute to ending the COVID-19 pandemic. 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.

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