



Moderna and Lonza Announce Worldwide Strategic Collaboration to Manufacture Moderna's Vaccine (mRNA-1273) Against Novel Coronavirus

May 1, 2020

Collaboration goal to enable manufacturing of up to 1 billion doses per year

Technology transfer expected to begin in June 2020

First batches of mRNA-1273 expected to be manufactured at Lonza U.S. in July 2020

Collaboration leverages Lonza's worldwide expertise in technology transfer and manufacturing

CAMBRIDGE, Mass. & BASEL, Switzerland--(BUSINESS WIRE)--May 1, 2020-- Moderna, Inc., (Nasdaq: MRNA) a clinical stage biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of transformative medicines for patients, and Lonza Ltd. (SIX: LONN) today announced a 10-year strategic collaboration agreement to enable larger scale manufacture of Moderna's mRNA vaccine (mRNA-1273) against the novel coronavirus (SARS-CoV-2) and additional Moderna products in the future.

Under the terms of the agreement, the companies plan to establish manufacturing suites at Lonza's facilities in the United States and Switzerland for the manufacture of mRNA-1273 at both sites. Technology transfer is expected to begin in June 2020, and the companies intend to manufacture the first batches of mRNA-1273 at Lonza U.S. in July 2020. Over time, the parties intend to establish additional production suites across Lonza's worldwide facilities, ultimately allowing for the manufacture of material equivalent to up to 1 billion doses of mRNA-1273 per year for use worldwide assuming the currently expected dose of 50 µg. The manufacturing facilities at Lonza complement Moderna's ongoing U.S. manufacturing efforts, which continue to ramp up to prepare for the further clinical development and commercialization of mRNA-1273.

A portion of the funding for the establishment of manufacturing operations at Lonza U.S. is covered by Moderna's contract with Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services, which was announced April 16, 2020. BARDA will support late-stage clinical development programs of mRNA-1273. Lonza's experience in scaling manufacturing of innovative medicines, including support for more than 50 commercial approvals across regulatory jurisdictions, will support Moderna for global supply.

"We are very pleased to partner with Lonza, which shares our commitment to rapidly addressing this pandemic which has created a global health crisis," said Stéphane Bancel, Moderna's Chief Executive Officer. "This long-term strategic collaboration agreement will enable Moderna to accelerate, by 10-times, our manufacturing capacity for mRNA-1273 and additional products in Moderna's large clinical portfolio. Lonza's global presence and expertise are critical as we scale at unprecedented speed. Our common goal is to potentially enable manufacturing of up to 1 billion doses of mRNA-1273."

"Moderna's technology represents a significant opportunity to change the way we protect people against disease," said Albert M. Baehny, Lonza's Chairman and CEO *ad interim*. "The current pandemic illustrates the need to combine the best science with resilient supply chains that can scale. We are fully committed to leveraging our global network and experience in manufacturing technologies to support Moderna's manufacture of mRNA-1273 as well as collaborating on future Moderna products."

On April 27, 2020, Moderna [announced](#) that it submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for Phase 2 and late stage studies of mRNA-1273 if supported by safety data from the Phase 1 study. Moderna has received initial feedback from the FDA on the design of the planned Phase 2 study, which is expected to begin in the second quarter of 2020. This study will evaluate the safety, reactogenicity and immunogenicity of two vaccinations of mRNA-1273 given 28 days apart. Each subject will be assigned to receive placebo, a 50 µg or a 250 µg dose at both vaccinations. The company intends to enroll 600 healthy participants across two cohorts of adults ages 18-55 years (n=300) and older adults ages 55 years and above (n=300). Participants will be followed through 12 months after the second vaccination.

About mRNA-1273

mRNA-1273 is an mRNA vaccine against SARS-CoV-2 encoding for a [prefusion stabilized](#) form of the Spike (S) protein, which was selected by Moderna in collaboration with investigators from Vaccine Research Center (VRC) at the National Institute of Allergy and Infectious Diseases (NIAID), a part of the NIH. 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 NIH on February 24, 42 days from sequence selection. The first participant in the NIAID-led Phase 1 study of mRNA-1273 was dosed on March 16, 63 days from sequence selection to Phase 1 study dosing. A summary of the company's work to date on SARS-CoV-2 can be found [here](#).

About the NIAID-led Phase 1 Study

An open-label Phase 1 study of mRNA-1273 is being conducted by the National Institute of Allergy and Infectious Diseases under its own Investigational New Drug (IND) application in the U.S. The Phase 1 study, which began on March 16, 2020, completed enrollment of 45 healthy adult volunteers ages 18 to 55 years in the original three dose cohorts (25 µg, 100 µg and 250 µg). The study is [enrolling](#) an additional six cohorts: three cohorts of older adults (ages 56-70) and three cohorts of elderly adults (ages 71 and above). Data from the original cohort of healthy adult volunteers ages 18 to 55 years will be reported once available.

About Moderna's Prophylactic Vaccines Modality

Moderna scientists designed the company's prophylactic vaccines modality to prevent infectious diseases. More than 1,400 participants have been enrolled in Moderna's infectious disease vaccine clinical studies under health authorities in the U.S., Europe and Australia. Clinical data demonstrate

that Moderna's proprietary vaccine technology has been generally well-tolerated and can elicit durable immune responses to viral antigens. Based on clinical experience across Phase 1 studies, the company designated prophylactic vaccines a core modality and is working to accelerate the development of its vaccine pipeline.

The potential advantages of an mRNA approach to prophylactic vaccines include the ability to combine multiple mRNAs into a single vaccine, rapid discovery to respond to emerging pandemic threats and manufacturing agility derived from the platform nature of mRNA vaccine design and production. Moderna has built a fully integrated manufacturing plant which enables the promise of the technology platform.

Moderna currently has [nine development candidates](#) in its prophylactic vaccines modality, including:

Vaccines against respiratory infections

- Respiratory syncytial virus (RSV) vaccine for older adults (mRNA-1777 and mRNA-1172 or V172 with Merck)
- RSV vaccine for young children (mRNA-1345)
- Human metapneumovirus (hMPV) and parainfluenza virus type 3 (PIV3) vaccine (mRNA-1653)
- Novel coronavirus (SARS-CoV-2) vaccine (mRNA-1273)
- Influenza H7N9 (mRNA-1851)

Vaccines against infections transmitted from mother to baby

- Cytomegalovirus (CMV) vaccine (mRNA-1647)
- Zika vaccine (mRNA-1893 with BARDA)

Vaccines against highly prevalent viral infections

- Epstein-Barr virus (EBV) vaccine (mRNA-1189)

To date, Moderna has demonstrated positive Phase 1 data readouts for seven prophylactic vaccines (H10N8, H7N9, RSV, chikungunya virus, hMPV/PIV3, CMV and Zika). Moderna's CMV vaccine is currently in a Phase 2 dose-confirmation study. Moderna's investigational Zika vaccine (mRNA-1893), currently in a Phase 1 study, was granted FDA Fast Track designation in August 2019.

About Moderna

Moderna is advancing messenger RNA (mRNA) science to create a new class of transformative medicines for patients. mRNA medicines are designed to direct the body's cells to produce intracellular, membrane or secreted proteins that can have a therapeutic or preventive benefit and have the potential to address a broad spectrum of diseases. The company's platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, providing Moderna the capability to pursue in parallel a robust pipeline of new development candidates. Moderna is developing therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases and cardiovascular diseases, independently and with strategic collaborators.

Headquartered in Cambridge, Mass., Moderna currently has strategic alliances for development programs with AstraZeneca PLC and Merck & Co., Inc., as well as the Defense Advanced Research Projects Agency (DARPA), an agency of the U.S. Department of Defense, and the Biomedical Advanced Research and Development Authority (BARDA), a division of the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS). Moderna has been named a top biopharmaceutical employer by Science for the past five years. To learn more, visit www.modernatx.com.

About Lonza

At Lonza, we combine technological innovation with world class manufacturing and process excellence. Together, these enable our customers to deliver their discoveries in the healthcare, preservation, and protection sectors. We are a preferred global partner to the pharmaceutical, biotech and specialty ingredients markets. We work to prevent illness and promote a healthier world by enabling our customers to deliver innovative medicines that help treat or even cure a wide range of diseases. We also offer a broad range of microbial control solutions, which help to create and maintain a healthy environment. Founded in 1897 in the Swiss Alps, Lonza today operates in 120 sites and offices in more than 35 countries. With approximately 15,500 full-time employees, we are built from high-performing teams and of individual employees who make a meaningful difference to our own business, as well as the communities in which we operate. The company generated sales of CHF 5.9 billion in 2019 with a CORE EBITDA of CHF 1.6 billion. Find out more at www.lonza.com and follow us on Twitter @LonzaGroup or Facebook @LonzaGroupAG.

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 potential vaccine against the novel coronavirus, the number of doses per year targeted for manufacturing under the Company's collaboration with Lonza, the assumed vaccine dose, the terms, scope, location and timing of technology transfer and manufacturing under the collaboration, the Company's manufacturing efforts, BARDA funding for clinical studies and manufacturing activities, the parameters and timing of the planned Phase 2 study of mRNA-1273, and timing of data from the Phase 1 study of mRNA-1273. 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 fact that the safety and efficacy of mRNA-1273 has not yet been established; potential adverse impacts due to the global COVID-19 pandemic such as delays in regulatory review, manufacturing and 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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