



Moderna and ROVI Announce Collaboration for OUS Fill-Finish Manufacturing of Moderna's COVID-19 Vaccine Candidate

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CAMBRIDGE, Mass. & MADRID--(BUSINESS WIRE)--Jul. 9, 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, and Laboratorios Farmacéuticos Rovi, S.A. (BME: ROVI), a pan-European pharmaceutical company specializing and engaging in the research, development, contract manufacturing and marketing of small molecules and biological specialties, today announced a collaboration for large-scale, commercial fill-finish manufacturing of Moderna's mRNA vaccine candidate against COVID-19 (mRNA-1273) at ROVI's facility in Madrid, Spain.

As part of the agreement, ROVI will provide vial filling and packaging capacity by procuring a new production line and equipment for compounding, filling, automatic visual inspection and labeling to support production of hundreds of millions of doses of the vaccine candidate intended in principle to supply markets outside of the U.S. starting in early 2021. ROVI will also hire additional staffing required to support manufacturing operations and production.

"Moderna is committed to helping address the COVID-19 crisis. We are pleased to partner with ROVI to potentially supply hundreds of millions of doses of finished mRNA-1273, once approved, and help address the need for a vaccine against COVID-19 around the world," said Juan Andres, Moderna's Chief Technology Operations and Quality Officer. "ROVI's experience as a global manufacturer of drug product and expertise in fill-finish will be an important partnership for us to establish dedicated supply chains that can meet the needs of different countries and regions. I am delighted to be working with ROVI again."

"We are very happy about the collaboration with Moderna, whose vaccine against COVID-19 is one of the frontrunners in the race to solve this health crisis. We would be thrilled for ROVI to form part of the solution to this pandemic that is affecting all of us and to support Moderna in supplying it on a wide scale. Our proven experience and capabilities as a toll manufacturer of injectables has allowed us to reach this agreement, which would help strengthen our manufacturing area and would, in all probability, provide us with a significant growth opportunity in the area. Likewise, I would like to thank the Ministry of Health and the Spanish Medicines Agency for making themselves available and providing their support, which has been of fundamental importance, during this entire process," said Juan López-Belmonte, Chief Executive Officer of ROVI.

About mRNA-1273, Moderna's Vaccine Candidate Against COVID-19

mRNA-1273 is an mRNA vaccine candidate against COVID-19 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 National Institutes of Health (NIH). On July 8, the Company's Phase 2 study of mRNA-1273 [completed enrollment](#). Moderna's Phase 3 study of approximately 30,000 participants, is expected to begin in July 2020.

About Moderna

Moderna is advancing messenger RNA (mRNA) science to create a new class of transformative medicines for patients and to protect populations from vaccines preventable diseases. 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, cardiovascular diseases, and autoimmune and inflammatory 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 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 ROVI

ROVI is a pan-European pharmaceutical company specializing and engaging in the research, development, contract manufacturing and marketing of small molecules and biological specialties. The company, in a continuous international expansion process, has subsidiaries in Portugal, Germany, the United Kingdom, Italy France and Poland, and has a diversified marketing portfolio of more than 40 products, among which its flagship product, Bemiparin, which is already marketed in 56 countries all over the world, should be highlighted. Likewise, in 2017, ROVI commenced the marketing of its in-house developed enoxaparin biosimilar in Europe. ROVI continues to develop the ISM® Platform technology, a leading-edge line of research in the field of prolonged drug release with proven advantages. For more information, please visit www.rovi.es.

Moderna's 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 scope of the Company's manufacturing collaboration with ROVI, the potential number of doses to be provided under the collaboration, the timing of supply of mRNA-1273 outside of the U.S., and the timing of the planned Phase 3 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 manufacturing infrastructure required to manufacture mRNA-1273 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 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.

ROVI's Forward-Looking Statements

This news release contains forward-looking statements. Such forward looking statements involve known and unknown risks, uncertainties and other factors which might cause the actual results, financial condition, performance, or achievements of ROVI or industry results, to be materially different from any future results, performance, or achievements expressed or implied by such 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 manufacturing infrastructure required to manufacture mRNA-1273 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. The statements in this press release represent ROVI's expectations and beliefs as of the date of this press release. ROVI anticipates that subsequent events and developments may cause these expectations and beliefs to change. However, while ROVI may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing ROVI's expectations or beliefs as of any date subsequent to the date of this press release.

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