



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

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CAMBRIDGE, Mass. & SOMERSET, N.J.--(BUSINESS WIRE)--Jun. 25, 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 Catalent, Inc. (NYSE: CTLT), the leading global provider of advanced delivery technologies, development, and manufacturing solutions for drugs, biologics, cell and gene therapies, and consumer health products, today announced a collaboration for large-scale, commercial fill-finish manufacturing of Moderna's mRNA-based COVID-19 vaccine candidate (mRNA-1273) at Catalent's biologics facility in Bloomington, Indiana.

As part of the agreement, Catalent will provide vial filling and packaging capacity, as well as additional staffing required for 24x7 manufacturing operations at the site to support production of an initial 100 million doses of the vaccine candidate intended to supply the U.S. market starting in the third quarter of 2020. The companies are in discussions to secure fill-finish capacity for continued production of hundreds of millions of additional doses.

Catalent will also provide clinical supply services from its facilities in Philadelphia, Pennsylvania, including packaging and labeling, as well as storage and distribution to support Moderna's Phase 3 clinical study for this candidate.

"We appreciate this collaboration with Catalent and the flexibility of their team to deliver critical fill-finish capacity for mRNA-1273 at unprecedented speed," said Juan Andres, Moderna's Chief Technical Operations and Quality Officer. "It has been wonderful to see both teams working together to support the common good."

"Catalent is proud to partner with Moderna in its work to address this critical public health need," commented John Chiminski, Chair and Chief Executive Officer of Catalent. "Catalent's proven expertise in manufacturing scale-up and commercial production are well suited to support Moderna's efforts to prepare for wide-scale supply of this vaccine candidate so that it is available if appropriate to address the pandemic."

Catalent's state-of-the-art 875,000 square-foot biologics facility in Bloomington will undertake this vial filling work under barrier isolator technology. Moderna will leverage the site's recent packaging expansion, which provides fully automated and high-speed packaging capabilities to accelerate manufacturing timelines. The facility has deep expertise in sterile formulation, with drug substance development and manufacturing and drug product fill-finish capacity across liquid and lyophilized vials, prefilled syringes, and cartridges, as well as primary and secondary packaging. In addition to its Bloomington location, the Catalent Biologics network has facilities in Brussels, Belgium and Anagni, Italy that perform sterile drug product manufacturing and packaging, and in the United States and Europe for manufacturing proteins, viral vectors for gene therapies and cell therapies, as well as providing pre-filled syringe manufacture and biologics analytical services.

### 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 June 11, 2020, Moderna announced that enrollment of younger adults (n=300) and the sentinel group of older adults (n=50) in its Phase 2 study of mRNA-1273 was complete, and that its 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. 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](http://www.modernatx.com).

### About Catalent

Catalent is the leading global provider of advanced delivery technologies, development, and manufacturing solutions for drugs, biologics, cell and gene therapies, and consumer health products. With over 85 years serving the industry, Catalent has proven expertise in bringing more customer products to market faster, enhancing product performance and ensuring reliable global clinical and commercial product supply. Catalent employs over 13,500 people, including over 2,400 scientists and technicians, at more than 40 facilities, and in fiscal year 2019 generated over \$2.5 billion in annual revenue. Catalent is headquartered in Somerset, New Jersey. For more information, visit [www.catalent.com](http://www.catalent.com).

### 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 number of doses per year targeted for

manufacturing under the agreement with Catalent, the Company's manufacturing efforts, the expected funding for clinical studies and manufacturing activities, and the parameters and 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 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](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.

### **Catalent's Forward-Looking Statements**

Statements concerning the development, success, and administration of clinical trials, ability to launch and future manufacturing contained in this release are forward-looking statements. They involve known and unknown risks, uncertainties, and other factors that may cause actual results or performance to be different from those expressed or implied in this release. Catalent has based its forward-looking statements on its current expectations, assumptions, estimates and projections, which it believes to be reasonable, but various factors, including factors beyond Catalent's control, may affect future results or performance. Among the factors that may affect these forward-looking statements are: the rapidly changing market for treatments and vaccines to address the COVID-19 pandemic, the current or future effects of the COVID-19 pandemic, including its effects on Catalent's and its clients' businesses, the outcome of the development of this or any competing vaccine or any treatment for COVID-19, the outcome of any and all reviews, inspections, or other approvals by the U.S. Food and Drug Administration (FDA) or similar regulatory health authority, customer and payor acceptance of the proposed vaccine, any competing vaccine, or any treatment for COVID-19, competitor responses to a potential future launch of this vaccine, changes to the overall economic climate in the United States or among potential purchasers of the product, changes to the healthcare reimbursement system in the United States or elsewhere, competing initiatives at Catalent or Moderna, supply chain risks relating to the vaccine, fluctuations in currency exchange rates that affect Catalent's ability to source the materials needed for the production of the product, or potential third-party claims or litigation related to the vaccine. These and other important factors, including those discussed under "Risk Factors" in the Catalent, Inc. Annual Report on Form 10-K for the year ended June 30, 2019 and its Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, may affect future results or performance. Catalent makes the statements in this release only as of the date of this release, and Catalent disclaims any duty, except as required by law, to update or revise any forward-looking statement, regardless of the circumstances.

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