# Moderna and Catalent Announce Long-Term Strategic Collaboration for Dedicated Vial Filling of Moderna's COVID-19 Vaccine and Clinical Portfolio

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CAMBRIDGE, Mass. & SOMERSET, N.J.--(BUSINESS WIRE)--Apr. 6, 2021-- Moderna, Inc. (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, 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 the expansion of their strategic collaboration to dedicate a new high-speed vial filling line for the manufacture of the Moderna COVID-19 Vaccine and potentially other investigational programs in Moderna's pipeline, at Catalent's biologics facility in Bloomington, Indiana.

In June 2020, Catalent and Moderna announced that Catalent would provide aseptic vial filling and packaging from its Bloomington site, including additional staffing required for 24x7 manufacturing to support production of an initial 100 million doses of Moderna's vaccine. On March 29, Moderna announced that this significant milestone was achieved.

As part of this expanded agreement, Catalent will now dedicate to Moderna's use a new high-speed filling line at the site through June 2023, which can be used to manufacture the COVID-19 vaccine and potentially additional investigational programs in Moderna's large clinical pipeline. Catalent will also provide inspection, labeling, cartoning, and final packaging for these programs.

"We appreciate this expanded collaboration with Catalent and the dedication of their team," said Juan Andres, Moderna's Chief Technical Operations and Quality Officer. "This additional fill-finish capacity will be important for not only our COVID-19 vaccine, but also potentially for other programs in our clinical development pipeline."

"Catalent's partnership with Moderna began in 2016, when we had only glimpsed the potential applications of mRNA and could not have guessed how pivotal mRNA would become in the fight against COVID-19," commented Alessandro Maselli, Catalent's President and Chief Operating Officer. "We are proud to announce this extension of our companies' strategic collaboration, and we look forward to further demonstrating our commercial manufacturing expertise as we help supply more vaccine doses."

Catalent announced in September 2020 its $50 million investment into this third high-speed vial filling line at Bloomington. Due to the company's considerable experience in facility and capacity expansion, it was able to accelerate the overall project from a typical 18-month timeframe to approximately 10 months, including construction, procurement, installation, and CGMP qualification of the line, which will be completed in April 2021. Furthermore, the ability to dedicate this new line to Moderna will enable the site to free-up capacity on existing lines for other important customer programs.

**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.

**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 approximately 15,000 people, including over 2,400 scientists and technicians, at more than 45 facilities, and in fiscal year 2020 generated over $3 billion in annual revenue. Catalent is headquartered in Somerset, New Jersey. For more information, visit www.catalent.com

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**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 statements regarding: Moderna's development of a vaccine (mRNA-1273) to protect against the SARS-CoV-2 virus, which causes COVID-19; the strategic collaboration between Moderna and Catalent for the filling and finishing of Moderna's COVID-19 Vaccine and other investigational products; and the terms of that collaboration and implications for production of the Moderna COVID-19 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; the Moderna COVID-19 Vaccine may prove less effective against variants of the SARS-CoV-2 virus, or Moderna 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 Moderna'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.

**Catalent's Forward-Looking Statements**

Statements concerning the finalization and future manufacturing capacity of Catalent's production lines 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 vaccine, any competing vaccine, or any treatment for COVID-19, competitor responses to potential future expansion of vaccine production, 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 production on this line, fluctuations in currency exchange rates that affect Catalent's ability to source the materials needed for production, 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, 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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