Arcturus Therapeutics and Catalent Announce Partnership to Manufacture mRNA-Based COVID-19 Vaccine

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SAN DIEGO and SOMERSET, N.J., May 04, 2020 (GLOBE NEWSWIRE) -- Arcturus Therapeutics Holdings Inc. ("Arcturus", "the Company", Nasdaq: ARCT), a leading clinical-stage messenger RNA (mRNA) medicines and vaccines company, 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 partnership to support the expected manufacture of Arcturus' COVID-19 mRNA vaccine candidate (LUNAR-COV19), intended to protect against the SARS-CoV-2 coronavirus.

LUNAR-COV19 utilizes Arcturus' self-transcribing and replicating mRNA (STARR™) technology and the Company's LUNAR® lipid-mediated delivery to produce an extraordinarily low dose, potential single shot COVID-19 vaccine.

The manufacture of LUNAR-COV19 at Catalent's state-of-the-art drug substance biomanufacturing facility in Madison, Wisconsin will support human clinical studies and, if successful, commercialization of the vaccine. The COVID-19 vaccine program will take advantage of the facility's flex-suite, a cGMP manufacturing suite that can produce batches at multiple scales and support Arcturus' proprietary mRNA manufacturing process.

The partnership will combine Arcturus' low-dose STARR™ mRNA vaccine technology with Catalent's scalable cGMP manufacturing capabilities to produce millions of doses of LUNAR-COV19 mRNA in 2020 and potentially 100s of millions of doses annually for worldwide use. Preparations for this program have already begun at the Madison facility, and both organizations are committed to meeting the global demand on unprecedented manufacturing timelines. Technology transfer will be completed this month and manufacture of the first cGMP batches of LUNAR-COV19 mRNA are expected to be completed by June 2020.

"Catalent is proud to partner with Arcturus in the pursuit of a vaccine that could protect people against the coronavirus pandemic," said John Chiminski, Chair and Chief Executive Officer of Catalent. "Our unique experience and flex-suite cGMP capacity will enable rapid scale-up of Arcturus' proprietary manufacturing process to make the vaccine available as soon as possible."

Joseph Payne, President & CEO of Arcturus, stated, "Government agencies and foundations are securing rights and access to vaccines being developed to protect their respective populations. The Catalent Biologics team and their high-tech Madison facility is ideally suited to manufacture a substantial number of doses. Arcturus will be better positioned to supply these entities with our COVID-19 vaccine candidate on an accelerated basis with Catalent as our manufacturing partner."

STARR™ and LUNAR® are trademarks of Arcturus Therapeutics.

About Arcturus Therapeutics
Founded in 2013 and based in San Diego, California, Arcturus Therapeutics Holdings Inc. (Nasdaq: ARCT) is a clinical-stage mRNA medicines and vaccines company with enabling technologies: (i) LUNAR® lipid-mediated delivery, (ii) STARR™ mRNA Technology and (iii) mRNA drug substance along with drug product manufacturing expertise. Arcturus' diverse pipeline of RNA therapeutic candidates includes programs to potentially treat Ornithine Transcarbamylase (OTC) Deficiency, Cystic Fibrosis, Glycogen Storage Disease Type 3, Hepatitis B, non-alcoholic steatohepatitis (NASH) and a self-replicating mRNA vaccine for SARS-CoV-2. Arcturus' versatile RNA therapeutics platforms can be applied toward multiple types of nucleic acid medicines including messenger RNA, small interfering RNA, replicon RNA, antisense RNA, microRNA, DNA, and gene editing therapeutics. Arcturus' technologies are covered by its extensive patent portfolio (187 patents and patent applications, issued in the U.S., Europe, Japan, China and other countries). Arcturus' commitment to the development of novel RNA therapeutics has led to collaborations with Janssen Pharmaceuticals, Inc., part of the Janssen Pharmaceutical Companies of Johnson & Johnson, Ultragenyx Pharmaceutical, Inc., Takeda Pharmaceutical Company Limited, CureVac AG, Synthetic Genomics Inc., Duke-NUS, and the Cystic Fibrosis Foundation. For more information visit www.ArcturusRx.com

About Catalent Biologics
Catalent Biologics is a global leader in development, manufacturing and analytical services for new biological entities, cell and gene therapies, biosimilars, sterile injectables, and antibody-drug conjugates. With over 20 years of proven expertise, Catalent Biologics has worked with 600+ mAbs and 80+ proteins, produced 13 biopharmaceutical drugs using GPEx® cell line development technology, and 35+ commercially approved products. Catalent has recently acquired MaSTherCell, a technology-focused cell therapy development and manufacturing partner with expertise in autologous and allogeneic cell therapy that complements Catalent's industry-leading expertise and commercial success in gene therapy development, manufacturing and adeno-associated virus (AAV) vector production. Together, Paragon Gene Therapy and MaSTherCell have produced over 100 GMP batches across 60+ clinical and commercial programs. For more information on Catalent Biologics, visit www.catalent.com/biologics

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 https://www.catalent.com/

Arcturus Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact included in this press release, including those regarding the Company's expected performance, the Company's development of any specific novel mRNA therapeutics, the Company's efforts to develop a vaccine against COVID-19 based on the Company's mRNA therapeutics, the forecasted safety, efficacy or reliability of a vaccine against COVID-19,were one to be successfully developed based on the Company's mRNA therapeutics, the timing and availability of a vaccine against COVID-19 were one to be successfully developed based on the Company's mRNA therapeutics, the potential initiation of human trials of a vaccine against COVID-19 based on the Company's mRNA therapeutics, the timing of initiation of human trials of a vaccine against COVID-19 based on the Company's mRNA therapeutics, the ability of any product to receive regulatory approval in Singapore and whether or not any other countries will accept the trials conducted in that jurisdiction, the potential market impact of a vaccine against COVID-19 based on the Company's mRNA therapeutics, the potential manufacturing capabilities of the Company's partnership with Catalent, the timing of technology transfer related to the Company's partnership with Catalent, the manufacture of GMP batches of a vaccine against COVID-19, were one to be successfully developed based on the Company's mRNA therapeutics, any expected benefit from the Company's partnership with Catalent and timing of any benefits related thereto and the impact of general business and economic conditions are forward-looking statements. Arcturus may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in any forward-looking statements such as the foregoing and you should not place undue reliance on such forward-looking statements. Such statements are based on management's current expectations and involve risks and uncertainties, including those discussed under the heading "Risk Factors" in Arcturus' Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on March 16, 2020 and in subsequent filings with, or submissions to, the SEC. No assurances can be given that any results reported in pre-clinical studies can be replicated in further studies or in human beings, or that a vaccine can or will ever be developed or approved using the Company's technology. Except as otherwise required by law, Arcturus disclaims any intention or obligation to update or revise any forward-looking statements, which speak only as of the date they were made, whether as a result of new information, future events or circumstances or otherwise.

Catalent Forward-Looking Statement Notice
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 Arcturus, 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, 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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