



Arcturus Reports Positive Preclinical Data for its COVID-19 Vaccine Candidate

April 27, 2020

*100% of animals seroconverted by day 19 at a low dose (2 µg)
LUNAR-COV19 remains on track to initiate human clinical trials this Summer*

SAN DIEGO, April 27, 2020 (GLOBE NEWSWIRE) -- Arcturus Therapeutics Holdings Inc. (the "Company", "Arcturus", Nasdaq: ARCT), a leading clinical-stage messenger RNA medicines company focused on the discovery, development and commercialization of therapeutics for rare diseases and vaccines, today announced positive immunogenicity data from its preclinical study for the Company's COVID-19 Vaccine. These data for LUNAR-COV19 were measured by Duke-NUS Medical School in Singapore.

"These preclinical studies done in partnership with Arcturus establish a strong package of data to support initiation of human clinical trials this Summer," said Professor Ooi Eng Eong, Deputy Director of the Emerging Infectious Diseases Programme at Duke-NUS Medical School. "There is a tremendous urgency to develop an effective vaccine in this global fight against COVID-19."

Pad Chivukula, Ph.D., Chief Scientific Officer of Arcturus Therapeutics, stated "These data show that Arcturus' STARR™ mRNA is superior to conventional mRNA at all equivalent doses and timepoints. Self-replicating mRNA significantly increases spike protein expression, yielding many-fold higher seroconversion rates. The results at the 2 µg dose suggest LUNAR-COV19 has the potential to immunize millions more people."

Seroconversion, using a gold standard virus neutralization assay (Vero-E6 cells with a SARS-CoV-2 Singapore Clinical Isolate), and IgG/IgM antibody titers were assessed at day 10 and day 19. Rodents were immunized with a single dose (0.2, 2, and 10 µg, i.m.) of LUNAR-COV19 vaccine. The study results showed self-transcribing and replicating (STARR™) mRNA induced higher seroconversion relative to conventional mRNA at equivalent doses. In conjunction, anti-SARS-CoV-2 IgG and IgM antibody titers were also higher.

Seroconversion¹ Rate (% of Animals) – STARR™ mRNA vs. Conventional mRNA

Single Dose (µg) ²	LUNAR® Delivery			
	STARR™ mRNA (%)		Conventional mRNA (%)	
	Day 10	Day 19	Day 10	Day 19
0.2	40	60	20	20
2	80	100	20	0
10	100	100	40	80

¹ Seroconversion is the transition from a seronegative condition where no neutralizing antibodies are in the serum to a seropositive condition, in which neutralizing antibodies can be detected in serum following a 1/10 dilution. Definition set forth by the World Health Organization (WHO).

² One microgram (µg) is 1 millionth of a gram, 1 billionth of a kilogram (i.e. 1 kilogram contains 500 million doses at 2 µg/dose).

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 STARR™ Technology

The STARR™ Technology platform combines self-replicating RNA with LUNAR®, a leading nanoparticle delivery system, into a single solution to produce proteins inside the human body. The versatility of the STARR™ Technology affords its ability upon delivery into the cell to generate a protective immune response or drive therapeutic protein expression to potentially prevent against or treat a variety of diseases. The self-replicating RNA-based therapeutic vaccine triggers rapid and prolonged antigen expression within host cells resulting in protective immunity against infectious pathogens. This combination of the LUNAR® and STARR™ technology is expected to provide lower dose requirements due to superior immune response, sustained protein expression compared to non-self-replicating RNA-based vaccines and potentially enable us to produce vaccines more quickly and simply.

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 potential market impact of a vaccine against COVID-19 based on the Company's mRNA therapeutics 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.

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