Arcturus Therapeutics Announces Preclinical Publication of its COVID-19 Vaccine Candidate

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Encouraging preclinical results demonstrate a strong antibody and cellular immune response and 100% protection against SARS-CoV-2 infection following a single vaccination

Clinical study remains on track, initial data readout expected Q4 2020

SAN DIEGO, Sept. 04, 2020 (GLOBE NEWSWIRE) -- Arcturus Therapeutics Holdings Inc. (the "Company", "Arcturus", Nasdaq: ARCT), a leading clinical-stage messenger RNA medicines company focused on the development of infectious disease vaccines and significant opportunities within liver and respiratory rare diseases, today announced that its *manuscript is now available on an online preprint server at Bioarchive and is concurrently undergoing scientific peer review.* The manuscript provides an in-depth assessment of humoral- and cell-mediated immune activation following a single shot vaccination in mice and shows that LUNAR®-COV19 (ARCT-021) produced robust antibody responses, with neutralizing antibody titers increasing up to day 60. In addition, single doses of LUNAR®-COV19 at both the 2 µg and 10 µg levels completely protected human ACE2 transgenic mice from both mortality and even measurable infection following wild-type SARS-CoV-2 challenge. The Company believes that the findings from this study, which was conducted in collaboration with Duke-NUS Medical School, collectively suggest the potential of LUNAR®-COV19 as a single dose vaccine. The Company is currently evaluating LUNAR®-COV19 in a Phase 1/2 clinical study.

The publication: de Alwis et al., *A Single Prime Self-Transcribing and Replicating RNA Based SARS-CoV-2 Vaccination Produces Protective Adaptive Immunity* is available on the *Bioarchive* website https://www.biorxiv.org/content/10.1101/2020.09.03.280446v1

"The data we have in preprint at Bioarchive continues to provide strong support for the potent immunogenicity of LUNAR®-COV19. Results demonstrate that a single vaccination in mice led to robust antibody responses, with neutralizing antibody titers increasing up to day 60. Furthermore, activation of cell mediated immunity produced a strong viral antigen specific CD8+ T lymphocyte response and a desirable Th1 dominant immune response. Importantly, a single LUNAR®-COV19 vaccination at very low microgram doses resulted in complete protection from infection and death from SARS-CoV-2 in a transgenic human ACE2 mouse challenge model, with no detectable virus present in LUNAR®-COV19 vaccinated mice," said Professor Ooi Eng Eong, Deputy Director, Emerging Infectious Diseases Programme, Duke-NUS Medical School and a member of Arcturus' Vaccine Platform Scientific Advisory Board.

"Our findings highlight the potential of LUNAR®-COV19 to be a highly potent, low dose, single shot vaccine. These favorable attributes may provide a substantial benefit compared to the multiple vaccine dosing regimens that are more commonly being developed. We believe that this advantageous profile could greatly facilitate the mass vaccination campaigns necessary to control the global COVID-19 pandemic," said Pad Chivukula, Ph.D., CSO & COO of Arcturus.

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 enables it 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 prophylactic 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 enabling to produce vaccines more quickly and simply.

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 and vaccine candidates includes self-replicating mRNA vaccine programs for SARS-CoV-2 (COVID-19) and Influenza, and other programs to potentially treat Ornithine Transcarbamylase (OTC) Deficiency, Cystic Fibrosis, Cardiovascular Disease along with partnered programs including Glycogen Storage Disease Type 3, Hepatitis B Virus, and non-alcoholic steatohepatitis (NASH). 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 (192 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

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 efforts to develop a vaccine against COVID-19, and therapeutic potential thereof, based on the Company's mRNA therapeutics, the Company's ongoing Phase 1/2 and availability of expected results, the potential of the vaccine against COVID-19 as a single dose vaccine 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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