# Arcturus Therapeutics Announces that it has Initiated Dosing of its COVID-19 STARR™ mRNA Vaccine Candidate, LUNAR-COV19 (ARCT-021) in a Phase 1/2 study

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*Potential for highly differentiated COVID-19 vaccine profile with a single administration, at a low dose*

*Clinical study data expected in Q4 2020*

SAN DIEGO, Aug. 11, 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 all subjects in the first cohort have been dosed in the Phase 1/2 clinical study with its ARCT-021 investigational vaccine for COVID-19. The study is being conducted with CTI Clinical Trial and Consulting Services, a global CRO, and in collaboration with Duke-NUS Medical School in Singapore.

“We are very pleased to have initiated dosing in our ARCT-021 Phase 1/2 study, and in fact, we have already completed dosing of all subjects in the first cohort of the study. Based on preclinical immunogenicity data, our self-replicating mRNA-based investigational vaccine could have a highly differentiated safety and efficacy profile, and may potentially allow vaccination at very low doses, and with a single administration. These favorable attributes could greatly facilitate mass vaccination campaigns necessary to control this global pandemic,” said Joseph Payne, President & CEO of Arcturus. “We look forward to sharing initial clinical data from this Phase 1/2 study in Q4 which we expect to enable dose selection for late phase clinical trials.”

The ARCT-021 Phase 1/2 study includes two parts. In Phase 1, escalating doses will be administered as a single injection to younger adults aged 21 to 55 years old. Based upon the safety, immunogenicity and T-cell response data from this group, dose regimens will be selected for further evaluation in Phase 2 which includes cohorts in younger adults and older adults aged 56 to 80 years old. The study is listed with ClinicalTrials.gov Identifier: NCT04480957.

ARCT-021 preclinical data has shown highly promising results with 100% seroconversion for neutralizing antibodies after a single administration using a very low 2 µg dose. Neutralizing antibodies continued to increase for 60 days after dosing. Preclinical results also demonstrated robust CD8+ T-cell Induction and a Th1 biased T-helper cellular immune response. The ARCT-021 vaccine candidate is devoid of viruses and does not utilize viral vectors or adjuvants. ARCT-021 utilizes Arcturus’ self-transcribing and replicating (STARR™) mRNA technology and is delivered with Arcturus’s proprietary LUNAR® lipid-mediated delivery system.

**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 likelihood of success, efficacy or safety of ARCT-021 as a vaccine against COVID-19 and therapeutic potential thereof based on the Company’s mRNA therapeutics, the timing of the release of ARCT-021 clinical data for human trials of a vaccine against COVID-19, the likelihood that ARCT-021 preclinical data will be predictive of clinical data, the expected dose size and required number of doses of ARCT-021 that may be approved for use by any applicable regulatory authority 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. 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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