Arcturus Announces Approval of a Clinical Trial Application to Advance ARCT-154, a Next Generation STARR™ mRNA Vaccine Targeting the SARS-CoV-2 Delta Variant and Other Variants of Concern

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The Phase 1/2/3 trial to be funded and sponsored by Arcturus' manufacturing partner Vinbiocare

ARCT-154 to be developed in parallel with ARCT-021, Arcturus' lead investigational COVID-19 vaccine

SAN DIEGO--(BUSINESS WIRE)--Aug. 2, 2021-- 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, announced today that the company's partner Vinbiocare has received approval for a Clinical Trial Application (CTA) from the Vietnam Ministry of Health to advance ARCT-154, a next generation Arcturus vaccine targeting SARS-CoV-2 variants of concern, including the Delta variant.

The ARCT-154 Phase 1/2/3 clinical study is a randomized, observer-blind, placebo-controlled design, and is sponsored and completely funded by Arcturus' manufacturing partner Vinbiocare – a subsidiary of Vingroup, the largest private industry conglomerate in Vietnam. The study is to assess the safety, immunogenicity and efficacy of the SARS-CoV-2 self-amplifying mRNA vaccine in adults 18 years or older and will enroll up to 21,000 participants across the 3 phases, with 20,000 in Phase 3. Primary endpoints include safety and efficacy with immunogenicity being evaluated in a subgroup. Participants will receive two doses of study vaccine separated by 28 days. Placebo participants will receive active vaccine after 6 months. All participants will be followed up for 1 year. If the clinical trial proves successful at interim evaluations, Emergency Use Approval (EUA) by the Vietnam Ministry of Health is anticipated in December 2021.

Preclinical research demonstrates that non-human primate immunization with ARCT-154 elicits neutralizing antibodies to SARS-CoV-2 variants of concern, including to the widely circulating and highly infectious Delta variant (see table below).

Neutralizing Antibody Titers to Variants of Concern (Geometric Mean NT50)

	Alpha	Beta	Gamma	Delta
STARR™ Vaccine ARCT-154	9080	874	1297	6876

Non-Human primate (NHP) data collected one month after second dose; Analysis of NHP serum was performed using non-replicating vesicular stomatitis virus pseudo-typed with the spike protein of the SARS-CoV-2 VOCs indicated. Titers were determined by calculating the dilution that resulted in 50% inhibition of cells expressing GFP encoded by the pseudovirus, a surrogate of virus infection.

"We are very pleased to advance ARCT-154 into a significant, staged Phase 3 clinical development study with our partner to target SARS-CoV-2 variants of concern, including the Delta variant. ARCT-154 utilizes Arcturus' STARR™ mRNA technology, and our preclinical immunogenicity data demonstrates that our newly developed vaccine candidate elicits a strong neutralizing antibody immune response against the Delta variant and other variants of concern," said Joseph Payne, President and CEO of Arcturus.

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 mRNA vaccine programs for SARS-CoV-2 (COVID-19) and Influenza, and other programs to potentially treat Ornithine Transcarbamylase (OTC) Deficiency, and Cystic Fibrosis 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 (222 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 Medical School, and the Cystic Fibrosis Foundation. For more information visit www.ArcturusRx.com. In addition, please connect with us on Twitter and LinkedIn.

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, are forward-looking statements, including those regarding strategy, future operations, collaborations, the likelihood of success (including safety and efficacy) of the Company's pipeline (including ARCT-021 and ARCT-154), the Company's efforts to develop a vaccine against COVID-19 and therapeutic potential thereof based on the Company's mRNA therapeutics, the planned initiation, design or completion of clinical trials, the likelihood that the Company will

obtain clearance from regulatory authorities to proceed with future planned clinical trials, the likelihood that preclinical or clinical data will be predictive of future clinical results (including with respect to safety, immunogenicity and efficacy), the likelihood that clinical data will be sufficient for regulatory approval or completed in time to submit an application for regulatory approval within a particular timeframe, the potential administration regimen or dosage of any of Company's drug candidates, the ability to enroll, and timing for enrollment of, subjects in clinical trials, the timing and nature of any study results, the likelihood that a patent will issue from any patent application, its current cash position and expected cash burn and the impact of general business and economic conditions. Actual results and performance could differ materially from those projected in any forward-looking statements as a result of many factors including, without limitation, the ability to enroll subjects in clinical trials as a result of the COVID-19 pandemic, the impact of commercialization of third-party COVID-19 vaccines on the design, and ability to conduct, clinical trials, the availability of manufacturing capacity and raw materials, unexpected clinical results, government regulations impacting the regulatory environment or intellectual property landscape, and general market conditions that may prevent such achievements or performance. 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, 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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