Arcturus Therapeutics Announces Approval from Vietnam Ministry of Health to Proceed into Phase 3b Study for ARCT-154, a Next Generation STARR™ mRNA Vaccine Targeting SARS-CoV-2 Delta Variant and Other Variants of Concern

October 12, 2021

- *Phase 3b dosing of ARCT-154 initiated; study designed to enroll approximately 20,000 participants*

- *Initiation of Phase 3b study follows review of safety data from initial 1,000 Phase 1/2/3a participants*

- *ARCT-154 remains on track for Emergency Use Authorization (EUA) filing in December 2021*

SAN DIEGO--(BUSINESS WIRE)--Oct. 12, 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, today announced that the Vietnam Ministry of Health has approved initiation of the Phase 3b part of the placebo-controlled, observer-blind Phase 1/2/3 clinical trial of ARCT-154 self-replicating RNA vaccine targeting the SARS-CoV-2 delta variant and other variants of concern. Arcturus Therapeutics and Vinbiocare remain on track to potentially file an Emergency Use Authorization (EUA) for ARCT-154 in Vietnam in December 2021.

ARCT-154 Phase 3b study dosing has been initiated and the trial is expected to enroll approximately 20,000 participants with half of the participants receiving ARCT-154 under a two-dose regimen with injections 28 days apart, while the other half will receive placebo. The Phase 1 part of the trial has completed the priming vaccination series with two administrations in 100 participants (75 in ARCT-154 arm). The Phase 2 and Phase 3a parts of the trial are ongoing with 300 (225 in ARCT-154 arm) and 600 (450 in ARCT-154 arm) participants, respectively.

The approval to proceed with the Phase 3b portion of the study follows the review of safety data from the initial 1,000 participants included in the Phase 1/2/3a cohorts of the ARCT-154 study.

“I am very pleased with the progress, including the rapid enrollment and dosing in the ARCT-154 trial. Initiation of dosing in the Phase 3b portion of the study brings us one step closer to our goal of filing for EUA and making it available as quickly as possible,” said Joseph Payne, President and CEO of Arcturus Therapeutics. “As a low dose vaccine targeting variants of concern, ARCT-154 has a differentiated profile compared to currently available vaccines and we believe that our program has the potential to become a best-in-class option for Vietnam and many other countries around the world.”

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 (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-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 preclinical or clinical data will be predictive of future clinical results (including with respect to safety, immunogenicity and efficacy), the ability to enroll, and timing for enrollment of, participants in clinical trials, the timing and nature of any study results, 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 likelihood or timing of any regulatory approval, 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 participants 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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