Arcturus Announces Approval of Singapore Clinical Trial Application to Advance ARCT-154 and ARCT-165, Next Generation STARR™ mRNA Vaccines Targeting SARS-CoV-2 Variants of Concern, in a Phase 1/2 Study

August 3, 2021

Singapore is the second country to approve the advancement of ARCT-154 into clinical development

ARCT-154 and ARCT-165 elicit high levels of neutralizing antibodies in non-human primates against multiple variants of concern

SAN DIEGO--(BUSINESS WIRE)--Aug. 3, 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 has received approval for a Clinical Trial Application (CTA) from the Singapore Health Sciences Authority (HSA) to enable the advancement of two STARR™ mRNA vaccine candidates into the clinic. The Phase 1/2 clinical trial will evaluate the vaccines both as a primary vaccination series and as a booster following initial vaccination with Comirnaty®. The Phase 1/2 trial costs are funded in part from a previously secured grant from Singapore.

ARCT-154 and ARCT-165 are next generation STARR™ mRNA vaccine candidates targeting current SARS-CoV-2 variants of concern. Preclinical data demonstrated that ARCT-154 and ARCT-165 induce strong neutralizing immunogenicity in non-human primates to SARS-CoV-2 Alpha, Beta, Gamma, and Delta variants. Arcturus also recently announced approval of a CTA for a Phase 1/2/3 clinical trial of ARCT-154 in Vietnam.

“SARS-CoV-2 variants are an increasing public health concern, and we believe that ARCT-154 and ARCT-165 may be well designed to elicit potent immunogenicity to a broad range of emerging variants, including the highly contagious Delta variant. We are pleased to have obtained approval from the Singapore Health Sciences Authority to proceed with the Phase 1/2 clinical trial of ARCT-154 and ARCT-165, and we look forward to the initiation of the trial in Singapore in the coming weeks,” 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, ARCT-154 and ARCT 165, the Company’s efforts to develop a vaccine against COVID-19 (including any existing or future variants) 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, 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 Company’s manufacturing methods and technologies (including lyophilization and fill finish), 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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Source: Arcturus Therapeutics Holdings Inc.