



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

September 22, 2021

Phase 1 (100 participants): both doses completed

Phase 2 (300 participants) has initiated

Phase 3a (600 participants) on track to initiate by end of September

Phase 3b (20,000 participants) dosing planned for first week of October

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

SAN DIEGO--(BUSINESS WIRE)--Sep. 22, 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 it has completed dosing of 100 subjects for the Phase 1 portion of the ARCT-154 Phase 1/2/3 clinical trial, which consisted of a two-dose regimen with injections 28 days apart. The Vietnam Ministry of Health has reviewed the safety data following both injections in the Phase 1 part of the study and has given permission to proceed with enrollment of Phase 2 and Phase 3a. Recruitment of these cohorts is now progressing. Emergency Use Authorization filing in Vietnam could be as soon as December 2021.

The tolerability profile of ARCT-154 in the Phase 1 study was favorable. The Phase 2 and Phase 3a studies will evaluate safety and immunogenicity in an additional 900 subjects in total, and the subsequent Phase 3b will evaluate safety and efficacy in approximately 20,000 subjects.

"We are very pleased, together with our partner Vinbiocare, to have rapidly completed enrollment and dosing of the ARCT-154 Phase 1 study, and to receive approval to proceed into Phase 2/3a. Our goal is to make ARCT-154 available as quickly as possible in Vietnam, as well as many other countries where there remains a high unmet need for effective vaccines 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 (231 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 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 ability to enroll, and timing for enrollment of, subjects 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 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.