Arcturus Therapeutics Receives FDA Allowance to Proceed with Phase 2 Study of ARCT-021 (LUNAR-COV19) Vaccine Candidate in the United States

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Phase 2 study to be conducted in the U.S. and Singapore, and will evaluate both single dose and two dose priming regimens of ARCT-021 in up to 600 participants

Anticipate interim Phase 2 data in early 2021; targeting global Phase 3 study start in Q2 2021 which could allow application for emergency use authorization/conditional approval in H2 2021

SAN DIEGO--(BUSINESS WIRE)--Jan. 4, 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 Company has received allowance of the Investigational New Drug (IND) application from the U.S. Food and Drug Administration (FDA) for the Phase 2 clinical study of its vaccine candidate ARCT-021 following review of data from the Phase 1/2 study.

Arcturus previously announced that the ARCT-021 Phase 2 study had been approved to proceed by the Singapore Health Sciences Authority (HSA), who reviewed the same data as reviewed by the FDA. These Phase 1/2 study results demonstrated favorable tolerability and both humoral and cellular immunogenicity following administration of ARCT-021.

The Phase 2 study will enroll 600 participants, with 450 receiving ARCT-021 and 150 receiving placebo. Both older and younger adult participants will be included. Early interim analyses of safety and immunogenicity will be performed to inform dose selection for a Phase 3 study, which is targeted to start in Q2 2021, if the Phase 2 study is successful.

“Allowance of the IND for our ARCT-021 Phase 2 clinical study represents an important milestone for the program and we look forward to starting to screen study participants at U.S. and Singapore clinical sites very soon," said Steve Hughes, M.D., Chief Medical Officer of Arcturus. “We have advanced ARCT-021 to Phase 2 based on promising interim results from our Phase 1/2 study and extensive preclinical data. Our prior clinical results show that ARCT-021 administration results in humoral and cellular immunogenicity, and we are encouraged by an increasing body of evidence highlighting the potential importance of T cells in providing protection against SARS-CoV-2 infection and COVID-19. We believe that ARCT-021 holds promise to be a highly effective vaccine with a differentiated clinical profile, including the potential to only require a single dose for protection.”

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, and 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 (205 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 the Company’s development strategy, the likelihood that preclinical or clinical results will be predictive of future clinical results or sufficient for regulatory approval, the likelihood of the Company to obtain clearance from regulatory authorities to proceed with planned clinical trials, the planned initiation, design or completion of clinical trials, the likelihood of success, or of the efficacy or safety, of the Company’s COVID-19 vaccine candidate or other product candidates, potential treatment regimens of the Company’s COVID-19 vaccine candidate, future operations, the Company’s efforts to develop a vaccine against COVID-19 and therapeutic potential thereof based on the Company’s mRNA therapeutics, the continuation or success of collaborations with the Company’s strategic partners, 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, 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, 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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