# Arcturus Therapeutics Announces Positive Development for Cystic Fibrosis Program

May 28, 2024

*Arcturus to present new Phase 1b interim data for ARCT-032 at European Cystic Fibrosis Conference on June 7, 2024*

*First four CF patients demonstrated an average improvement of 4% FEV1 after two administrations*

SAN DIEGO--(BUSINESS WIRE)--May 28, 2024-- Arcturus Therapeutics Holdings Inc. (the “Company”, “Arcturus”, Nasdaq: ARCT), a global late-stage clinical messenger RNA medicines company focused on the development of infectious disease vaccines and medicines to treat unmet medical needs within liver and respiratory rare diseases, today announced Arcturus will be presenting Phase 1 results in healthy volunteers and new Phase 1b interim data in CF patients for ARCT-032, an inhaled investigational mRNA therapeutic to treat CF, at the 47$^{th}$ European Cystic Fibrosis Conference on June 7, 2024.

“We were pleased to observe ARCT-032 treatments for the first four patients were generally safe and well tolerated with no serious adverse events,” said Joseph Payne, President & CEO of Arcturus Therapeutics. “Furthermore, we observed an encouraging trend towards lung function improvements in the first four CF participants after only two inhaled administrations.”

“The absolute change in percent predicted FEV1 (Forced Expiratory Volume in 1 second) in the first four CF participants was observed to be an average of 4.0% at day 8,” said Dr. Juergen Froehlich, Chief Medical Officer of Arcturus Therapeutics. “I am pleased to announce our team will present this new Phase 1b interim data at the upcoming European CF conference in Scotland, supplementing the favorable results from our Phase 1 single ascending dose study in healthy volunteers.”

**About Cystic Fibrosis**

Cystic fibrosis is a life-shortening disease with a worldwide distribution. Mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene result in a reduction or absence of CFTR protein and/or function in the airways, causing insufficient chloride transport to maintain airway surface homeostasis. CF mucus is more difficult to clear, thus clogging the airways and leading to infection, inflammation, respiratory failure, or other life-threatening complications. Currently approved CFTR modulator therapies are designed to increase function of the CFTR channel to help reduce symptoms yet are ineffective in some people with CF because of their underlying mutations.

**About ARCT-032**

ARCT-032 has received Orphan Medicinal Product Designation from the European Medicines Agency (EMA) and Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) to treat Cystic Fibrosis. ARCT-032 utilizes Arcturus' LUNAR® lipid-mediated aerosolized platform to deliver CFTR messenger RNA to the lungs. Expression of a functional copy of the CFTR mRNA in the lungs of people with CF has the potential to restore CFTR activity and mitigate the downstream effects that cause progressive lung disease. The ARCT-032 program is supported by preclinical data in rodents, ferrets and primates, as well as demonstrating restoration of CFTR expression and function in human bronchial epithelial cells.

**About Arcturus Therapeutics**

Founded in 2013 and based in San Diego, California, Arcturus Therapeutics Holdings Inc. (Nasdaq: ARCT) is a global mRNA medicines and vaccines company with enabling technologies: (i) LUNAR® lipid-mediated delivery, (ii) STARR® mRNA Technology (sa-mRNA) and (iii) mRNA drug substance along with drug product manufacturing expertise. Arcturus developed the first self-amplifying messenger RNA (sa-mRNA) COVID vaccine (Kostaive®) in the world to be approved. Arcturus has an ongoing global collaboration for innovative mRNA vaccines with CSL Seqirus, and a joint venture in Japan, ARCALIS, focused on the manufacture of mRNA vaccines and therapeutics. Arcturus’ pipeline includes RNA therapeutic candidates to potentially treat ornithine transcarbamylase deficiency and cystic fibrosis, along with its partnered mRNA vaccine programs for SARS-CoV-2 (COVID-19) and influenza. Arcturus’ versatile RNA therapeutics platforms can be applied toward multiple types of nucleic acid medicines including messenger RNA, small interfering RNA, circular RNA, antisense RNA, self-amplifying RNA, DNA, and gene editing therapeutics. Arcturus’ technologies are covered by its extensive patent portfolio (over 400 patents and patent applications in the U.S., Europe, Japan, China, and other countries). 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, the expectations for or likelihood of success of any collaborations, the continued clinical development of ARCT-032 including the ability to complete and timing for completion of the CF Phase 1b study, likelihood of success (including safety and efficacy) of ARCT-032, the likelihood that the interim results will be predictive of future clinical results, the likelihood of sharing and timing for sharing interim and final Phase 1b data, and the impact of general business and economic conditions. 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. These statements are only current predictions or expectations, and are subject to known and unknown risks, uncertainties, and other factors that may cause our or our industry’s actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements, including those discussed under the heading "Risk

Factors" in Arcturus' most recent Annual Report on Form 10-K, and in subsequent filings with, or submissions to, the SEC, which are available on the SEC's website at www.sec.gov. 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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