Arcturus Therapeutics Receives U.S. FDA Fast Track Designation for the STARR® mRNA Vaccine Candidate ARCT-2304 for Pandemic Influenza A Virus H5N1

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SAN DIEGO--(BUSINESS WIRE)--Apr. 10, 2025-- Arcturus Therapeutics Holdings Inc. (the “Company”, “Arcturus”, Nasdaq: ARCT), a commercial messenger RNA medicine company focused on the development of infectious disease vaccines and opportunities within liver and respiratory rare diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for the self-amplifying mRNA (sa-mRNA) vaccine candidate, ARCT-2304, designed for active immunization to protect against disease caused by influenza A H5N1 subtype contained in the vaccine. This designation recognizes the potential of ARCT-2304 as an innovative approach to address unmet medical needs for the prevention of disease caused by pandemic influenza A virus H5N1, a significant global health risk. The Phase 1 clinical study initiated in November 2024.

Fast Track Designation from the FDA is granted to vaccines intended to prevent serious conditions caused by infectious disease. The designation is designed to expedite the development and review process, providing several benefits, including enhanced communication with the FDA and eligibility for priority review, and the possibility of a rolling review.

“We are pleased to receive Fast Track Designation from the FDA for ARCT-2304,” said Joseph Payne, President and CEO of Arcturus Therapeutics. “We remain steadfast in our commitment to the U.S. government to develop safe and effective STARR® next-generation mRNA vaccines to protect U.S. citizens from future pandemic threats. This designation from the FDA is an important step forward in our mission to provide protective solutions for global health crises.”

This project has been supported in whole with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), under contract number 75A50122C0007.

About ARCT-2304 (LUNAR-H5N1)

ARCT-2304, also known as LUNAR-H5N1, is a STARR® sa-mRNA vaccine candidate formulated with Arcturus proprietary LUNAR® delivery technology. The sa-mRNA vaccine candidate is designed to make many copies of mRNA within the host cell after intramuscular injection to achieve enhanced expression of haemagglutinin (HA) and neuraminidase (NA) antigens, thereby enabling lower doses than conventional mRNA vaccines. Utilizing a sa-mRNA-based platform for pandemic influenza vaccine development offers further options for meeting domestic vaccine manufacturing surge capacity goals. The technology may make vaccines available much sooner than egg- and cell-based technologies. The lyophilized vaccine formulation is stable in refrigerators, thereby simplifying cold-chain storage and reducing distribution risks.

About Arcturus

Founded in 2013 and based in San Diego, California, Arcturus Therapeutics Holdings Inc. (Nasdaq: ARCT) is a commercial 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 KOSTAIVE®, the first self-amplifying messenger RNA (sa-mRNA) COVID vaccine 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 (OTC) deficiency and cystic fibrosis (CF), 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 500 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 the likelihood of success (including safety and efficacy) of ARCT-2304, the likelihood of ARCT-2304 attaining approval or addressing unmet medical needs, the continued development of ARCT-2304, the continued involvement and support of BARDA, 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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Arcturus Therapeutics
Public Relations & Investor Relations
Neda Safarzadeh
VP, Head of IR/PR/Marketing
(858) 900-2682
IR@ArcturusRx.com

Source: Arcturus Therapeutics Holdings Inc.