Arcturus Therapeutics Receives Clearance from FDA to Begin H5N1 Pandemic Flu Vaccine Clinical Trial

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SAN DIEGO--(BUSINESS WIRE)--Nov. 11, 2024-- Arcturus Therapeutics Holdings Inc. (the “Company”, “Arcturus”, Nasdaq: ARCT), a commercial messenger RNA medicines 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 issued a “Study Can Proceed” notification for the Company’s Investigational New Drug (IND) application, ARCT-2304, a self-amplifying mRNA (sa-mRNA) vaccine candidate for active immunization to prevent pandemic influenza disease caused by H5N1 virus. The clinical study is funded by Biomedical Advanced Research and Development Authority (BARDA) and designed to enroll approximately 200 healthy adults in the United States.

“Arcturus is actively engaged with the U.S. government to prepare for the next pandemic, and clearance to proceed into the clinic with our STARR® self-amplifying mRNA technology is a key step in this important process,” said Joseph Payne, President & CEO of Arcturus Therapeutics. “The Phase 1 clinical trial is designed to evaluate the safety, reactogenicity, and immunogenicity of ARCT-2304 as a potential vaccine to protect against the highly pathogenic H5N1 avian influenza.”

About ARCT-2304

ARCT-2304 is a sa-mRNA vaccine candidate formulated within a lipid nanoparticle (LNP). 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 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 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 the initiation and enrollment of a Phase 1 clinical trial of ARCT-2304, the likelihood of success of the Company’s development and related efforts for an influenza vaccine candidate, the future activities under and fulfillment of the Company’s contract with BARDA, the ability of the Company’s influenza vaccine technologies to support U.S. government pandemic preparedness goals, 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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