European Commission Approves CSL and Arcturus Therapeutics' KOSTAIVE®, the First Self-amplifying mRNA COVID-19 Vaccine

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- KOSTAIVE represents a significant advancement in vaccine technology, demonstrating superior immunogenicity and antibody persistence for up to 12 months post-vaccination compared to conventional mRNA COVID-19 vaccines in clinical trials

WALTHAM, Mass. & SAN DIEGO--(BUSINESS WIRE)--Feb. 14, 2025-- Global biotechnology leader CSL (ASX: CSL; USOTC: CSLLY) and sa-mRNA pioneer Arcturus Therapeutics (Nasdaq: ARCT) today announced that the European Commission has granted marketing authorization for KOSTAIVE® (ARCT-154), a self-amplifying mRNA COVID-19 vaccine, for individuals 18 years and older. KOSTAIVE is the first sa-mRNA COVID-19 vaccine to receive approval from the European Commission (EC). KOSTAIVE is currently marketed in Japan against COVID-19.

The European Commission approval follows a positive opinion adopted by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) on December 12, 2024. The centralised marketing authorization of KOSTAIVE is valid in all EU member states and in the EEA countries.

"The European Commission's approval marks a significant milestone in our ongoing development program for KOSTAIVE," said Jonathan Edelman, MD, Senior Vice President of the Vaccines Innovation Unit, CSL. "We are actively working to optimize KOSTAIVE's formulation to better meet the needs of healthcare professionals and their patients. As COVID-19 remains an unpredictable global threat, CSL is dedicated to completing these technical enhancements and making this innovative vaccine available in Europe as soon as possible."

The approval is based on positive clinical data from several studies, including an integrated phase 1/2/3 study demonstrating KOSTAIVE's efficacy and tolerability, and Phase 3 COVID-19 booster trials, which achieved higher immunogenicity results compared to a conventional mRNA COVID-19 vaccine comparator. A follow-up analysis evaluating a booster dose of KOSTAIVE also showed that the vaccine elicited superior immunogenicity and antibody persistence for up to 12 months postvaccination against multiple SARS-CoV-2 strains in both younger and older adult age groups versus the same mRNA comparator.

"KOSTAIVE and sa-mRNA technology signify a major advancement in vaccine innovation, providing the potential for broader and more enduring protection," said Joseph Payne, CEO of Arcturus. "This approval highlights the clinical promise of KOSTAIVE and its ability to protect against the ever-changing COVID-19 virus."

About sa-mRNA

mRNA vaccines help protect against infectious diseases by providing a blueprint for cells in the body to make a protein to help our immune systems recognize and fight the disease. Unlike standard mRNA vaccines, self-amplifying mRNA vaccines instruct the body to make more mRNA and protein to boost the immune response.

About CSL

CSL (ASX: CSL; USOTC: CSLLY) is a global biotechnology company with a dynamic portfolio of lifesaving medicines, including those that treat haemophilia and immune deficiencies, vaccines to prevent influenza, and therapies in iron deficiency and nephrology. Since our start in 1916, we have been driven by our promise to save lives using the latest technologies. Today, CSL – including our three businesses: CSL Behring, CSL Seqirus and CSL Vifor – provides lifesaving products to patients in more than 100 countries and employs 32,000 people. Our unique combination of commercial strength, R&D focus and operational excellence enables us to identify, develop and deliver innovations so our patients can live life to the fullest. For inspiring stories about the promise of biotechnology, visit CSLBehring.com/Vita and follow us on Twitter.com/CSL.

For more information about CSL, visit www.CSL.com.

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 strategy, future operations, the likelihood of success (including safety, efficacy and commercialization) of KOSTAIVE, the likelihood that clinical results received to date will be predictive of future clinical results and of protection against changing virus variants, the likelihood of optimizing KOSTAIVE's formulation and completing technical enhancements, 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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