Arcturus Therapeutics and CSL Announce European Medicines Agency Validates Marketing Authorization Application for ARCT-154 Vaccine to Prevent COVID-19

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EMA application supported by Phase 3 primary vaccination study demonstrating primary efficacy endpoint was met

An additional Phase 3 booster study demonstrating non-inferiority of immune response compared to Comirnaty® and superiority of ARCT-154 in neutralizing antibody response against SARS-CoV-2 Omicron BA.4/5 variant was shown as a key secondary endpoint

SAN DIEGO--(BUSINESS WIRE)--Sep. 5, 2023-- 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 opportunities within liver and respiratory rare diseases, and CSL (ASX:CSL), and its vaccine business, CSL Seqirus, one of the largest influenza vaccine providers in the world, announced today that the European Medicines Agency (EMA) has validated the marketing authorization application (MAA) for ARCT-154, a next generation mRNA vaccine, for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older. The companies (Arcturus and CSL Seqirus) anticipate an approval decision by the European Commission in 2024.

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The EMA submission is based on successful Phase 3 clinical results of ARCT-154 against the ancestral D614G variant as a primary series and booster. In an analysis of 6-month data from the pivotal Phase 3 study, the primary efficacy endpoint was met and ARCT-154 as a primary series resulted in 56.6% efficacy for prevention of symptomatic COVID-19 overall, and 95.3% efficacy for prevention of severe COVID-19 including COVID-19 related deaths. The study was conducted when Delta variant was dominant in Vietnam. The booster data result was previously announced by CSL Seqirus’ partner, Meiji Seika Pharma, indicating that the primary endpoint was achieved in a Phase 3 booster vaccine study by demonstrating non-inferiority of immune response against SARS-CoV-2 ancestral strain compared to Comirnaty®. Superiority of ARCT-154 in neutralizing antibody response against SARS-CoV-2 Omicron BA.4/5 variant was a key secondary endpoint.

“EMA acceptance of the marketing application for ARCT-154 represents another major achievement in the development of this innovative mRNA vaccine platform. This is also an important milestone for Arcturus and our global exclusive partner, CSL Seqirus, as we work towards achieving approval in Europe,” said Joseph Payne, President & CEO of Arcturus Therapeutics. “ARCT-154 is expected to be efficiently updated as new variants of concern arise and has the potential to be a longer lasting vaccine against the pervasive and ever-changing COVID virus.”

“This pivotal regulatory milestone brings CSL one step closer to bringing innovative mRNA vaccines to Europe,” said Emmanuelle Lecomte Brisset, Head of Global Regulatory Affairs at CSL. “We look forward to working with regulatory authorities to continue to advance how we protect public health.”

About Arcturus Therapeutics

Founded in 2013 and based in San Diego, California, Arcturus Therapeutics Holdings Inc. (Nasdaq: ARCT) is a global late-stage clinical mRNA medicines and vaccines company with enabling technologies: (i) LUNAR® lipid-mediated delivery, (ii) STARR® mRNA Technology (samRNA) and (iii) mRNA drug substance along with drug product manufacturing expertise. The Company has an ongoing exclusive global collaborative partnership for innovative mRNA vaccines with CSL Seqirus. The Company also has a joint venture with the Japanese CMO, ARCALIS. Arcturus’ pipeline includes RNA therapeutic candidates to potentially treat ornithine transcarbamylase deficiency and cystic fibrosis, along with its partnered innovative mRNA vaccine programs for SARS-CoV-2 (COVID-19), influenza, pandemic preparedness and a range of other respiratory pathogens. 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 (patents and patent applications issued 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.

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.

Forward Looking Statements

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looking statements, including those regarding strategy, future operations, the likelihood of success of ARCT-154 and the partnered COVID-19 program, the timing for an approval decision by the European Commission for ARCT-154, the likelihood that any clinical data will be predictive of future clinical results, the likelihood that the interim study results of the ARCT-154 Phase 3 booster vaccine study will be predictive of, or consistent with, the complete study results, the potential for ARCT-154 to be a longer lasting vaccine, 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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