Japan's Ministry of Health, Labour and Welfare Approves CSL and Arcturus Therapeutics' ARCT-154, the First Self-Amplifying mRNA Vaccine Approved for COVID in Adults

November 28, 2023

Exclusive Partner in Japan, Meiji Seika Pharma advances regulatory approval

- This historic approval of the world's first Self-Amplifying messenger RNA (sa-mRNA) COVID-19 Vaccine underscores CSL's promise to develop and deliver innovations when there is a public health need
- First marketing approval milestone for CSL and Arcturus Therapeutics since closing the Global Collaboration and Licensing agreement in 2022
- With the approval of ARCT-154, CSL now offers an even more comprehensive portfolio of innovative vaccines that combat respiratory viral diseases.

KING OF PRUSSIA, Pa. & SAN DIEGO--(BUSINESS WIRE)--Nov. 28, 2023-- Global biotechnology leader CSL (ASX:CSL; USOTC:CSLLY) and Arcturus Therapeutics today announced that Japan's Ministry of Health, Labor and Welfare (MHLW) granted approval for ARCT-154, a self-amplifying mRNA (sa-mRNA) COVID-19 vaccine for initial vaccination and booster for adults 18 years and older.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20231128722319/en/

"Self-amplifying mRNA technology has the potential to be an enduring vaccine option," said Nobel laureate Dr. Drew Weissman, "I look forward to seeing this next generation mRNA technology protect many from COVID-19 and possibly other harmful infectious diseases."

"Today's approval marks a historic and exciting milestone as the first sa-mRNA vaccine in the world to be registered, and supports CSL's promise to protect global public health," said Jonathan Edelman, M.D., Senior Vice President, Vaccines Innovation Unit, CSL. "We are committed to working with health authorities around the world to ensure this important vaccine technology will be available to people at risk for COVID-19."

The approval is based on positive clinical data from several ARCT-154 studies, including an ongoing 16,000 subject efficacy study performed in Vietnam as well as a Phase 3 COVID-19 booster trial, which achieved higher immunogenicity results and a favorable safety profile compared to a standard mRNA COVID-19 vaccine comparator. Initial study results have been published in MedRxiv and are expected to be published in a peer-reviewed journal by the end of the year.

"We are proud of the role that Arcturus has played in this collaboration to develop and validate the first approved sa-mRNA product in the world," said Joseph Payne, Chief Executive Officer of Arcturus Therapeutics. "This approval for the sa-mRNA COVID-19 vaccine is a major achievement, and we are excited to embark on future endeavors that utilize our innovative sa-mRNA vaccine platform alongside our global exclusive partner, CSL."

CSL's vaccine business, CSL Seqirus, one of the largest influenza vaccine providers in the world, partnered exclusively with Meiji Seika Pharma for distribution of the sa-mRNA COVID vaccine, ARCT 154, in Japan.

"Our expertise in seasonal and pandemic influenza positions us well to help the global community reduce the burden of COVID-19 and we look forward to playing a key role in helping protect the people of Japan," said Stephen Marlow, Senior Vice President and General Manager of CSL Seqirus.

About sa-mRNA

Messenger RNA (mRNA) vaccine technology protects against infectious diseases by instructing cells in the body to make a specific protein, stimulating the immune response, and leaving a blueprint to recognize and fight future infection. However, sa-mRNA makes copies of the mRNA which generates the production of more protein compared to an equivalent amount of mRNA in a vaccine. The technology has the potential to create more potent cellular immune responses and increase duration of protection, while using considerably lower doses of mRNA.

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 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 (sa-mRNA) and (iii) mRNA drug substance along with drug product manufacturing expertise. The Company 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 (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.

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Source: Arcturus Therapeutics Holdings Inc.