



Japan's Ministry of Health, Labor and Welfare Approves CSL and Arcturus Therapeutics' Updated Self-amplifying mRNA COVID-19 Vaccine for Protection against JN.1 Strain, to be Distributed in Japan by Meiji Seika Pharma

September 13, 2024

Approval underscores CSL and Arcturus Therapeutics' commitment to delivering disruptive technologies to combat COVID-19 and other respiratory viral diseases to protect public health

- KOSTAIVE[®], the world's first self-amplifying mRNA (sa-mRNA) COVID-19 vaccine, was [approved](#) for adults 18 years of age and older in November 2023
- The updated sa-mRNA COVID-19 vaccine is tailored to protect against the JN.1 lineage of Omicron subvariants
- Meiji Seika Pharma, CSL's exclusive partner in Japan, will begin vaccine distribution in time for the October COVID-19 vaccination campaign
- CSL and Arcturus Therapeutics' partnership delivers on the promise to advance innovative vaccine technology for viral respiratory diseases

KING OF PRUSSIA, PA & SAN DIEGO--(BUSINESS WIRE)--Sep. 13, 2024--

Global biotechnology leader CSL (ASX:CSL; USOTC:CSLLY) and sa-mRNA pioneer Arcturus Therapeutics today announced that Japan's Ministry of Health, Labor and Welfare (MHLW) granted approval and authorization for their updated self-amplifying mRNA (sa-mRNA) COVID-19 vaccine, KOSTAIVE[®]. The updated vaccine is targeted to protect against the JN.1 lineage of Omicron subvariants for adults 18 years of age and older.

CSL's exclusive partner in Japan, Meiji Seika Pharma, will begin distributing the updated vaccine in time for the October COVID-19 vaccination campaign, marking the world's first commercially available sa-mRNA COVID-19 vaccine for adults 18 and older.

In May 2024, a Japanese health ministry panel recommended that COVID-19 vaccines be updated to target the JN.1 lineage of Omicron subvariants for the 2024/2025 national immunization program. This aligns with recent recommendations from the World Health Organization.

"We are pleased to receive the updated approval from Japan's Ministry of Health, Labor and Welfare, and remain on track to distribute KOSTAIVE[®] in time for the October COVID-19 vaccination campaign," said Emmanuelle Lecomte-Brisset, Senior Vice President and Head of Global Regulatory Affairs, CSL. "We look forward to introducing KOSTAIVE[®] in Japan as a safe, tolerable and more durable option in protecting against COVID-19."

"We believe KOSTAIVE[®] has the potential to change the paradigm for COVID-19 vaccines in Japan," said Jonathan Edelman, M.D., Senior Vice President, Vaccines Innovation Unit, CSL. "Today's approval further demonstrates CSL's promise to pursue, develop and deliver new innovative treatment options to protect public health."

The approval is based on clinical evidence supporting the safety and effectiveness of CSL and Arcturus Therapeutics' sa-mRNA COVID-19 vaccine, including published data demonstrating superior immunogenicity to Omicron BA 4/5 compared to a conventional mRNA COVID-19 vaccine booster and follow-up data demonstrating duration of immunity lasting up to one year.

"We are pleased that our sa-mRNA technology will be available to vaccinate people in Japan against COVID-19, which remains an ongoing risk to public health around the world," said Joseph Payne, Chief Executive Officer of Arcturus Therapeutics. "We look forward to continuing to work with CSL and regulators to explore the development of KOSTAIVE[®] in additional countries."

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 conventional 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 [CSL Behring.com/Vita](https://www.CSL.com/Vita) and follow us on [Twitter.com/CSL](https://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 global 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](#).

About Meiji Seika Pharma Co., Ltd.

Meiji Seika Pharma, since it launched penicillin in 1946, has been providing efficacious and high-quality pharmaceutical products such as therapeutics and vaccines for infectious diseases, therapeutics for central nervous system diseases as well as generic drugs in response to various medical needs. As a leading company in the field of infectious diseases, we are strengthening our platform for infection control and prevention with vaccines and antimicrobial agents.

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 planned launch of KOSTAIVE® in Japan, the distribution of the updated vaccine by Meiji Seika Pharma and timing thereof, the timing and likelihood of availability of doses of the updated vaccine in Japan, the continued demonstration of KOSTAIVE® as a safe, tolerable and more durable option against COVID-19, that preclinical or clinical data will be predictive of future clinical results, 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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