

Meiji Seika Pharma Co., Ltd.

November 28, 2023

Meiji Seika Pharma Receives Manufacturing and Marketing Approval of  
Kostaive™, Self-Amplifying mRNA Vaccine against COVID-19, from MHLW in Japan  
The World's First Approved Vaccine Applying Self-Amplifying mRNA Technology

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, Japan, President and Representative Director: Daikichiro Kobayashi) announced today that it has received approval for the manufacturing and marketing of “Kostaive™ for Intramuscular Injection” (ARCT-154), a self-amplifying mRNA vaccine against COVID-19, from the Ministry of Health, Labour and Welfare (MHLW) in Japan. Kostaive™ is indicated for prevention of COVID-19 by primary immunization (2 doses) and booster immunization in adults. This is the world's first approved product applying self-amplifying mRNA technology.

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

Kostaive™ is a vaccine against COVID-19 applying self-amplifying mRNA technology developed by Arcturus Therapeutics Inc. and exclusively licensed to CSL Seqirus. The mRNA in Kostaive is designed to self-amplify once delivered into cells, so that it generates a strong immune response and the potential for extended duration of protection while using lower doses of mRNA compared to existing mRNA vaccines. In the Phase III clinical trials for booster vaccination conducted in Japan, 5 µg Kostaive™ elicited higher ( $p < 0.05$ ) and longer-lasting neutralizing antibody titers against the original strain, as well as the Omicron BA 4-5 subvariant, compared to 30 µg COMIRNATY®, a licensed conventional mRNA vaccine targeting COVID-19. Most adverse events were mild or moderate and transient, and no ARCT-154 related serious adverse events were observed.

Meiji Seika Pharma obtained exclusive rights to distribute Kostaive™ (ARCT-154) in Japan from CSL Seqirus on April 11, 2023, and is collaborating with ARCALIS, Inc. to establish integrated mRNA vaccine manufacturing capabilities from drug substance to drug product in Minami-soma City, Fukushima Prefecture, Japan. Meiji Seika Pharma is working toward the goal of commercializing in 2024.

### 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. 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 Arcturus Therapeutics

Arcturus Therapeutics Holdings Inc. founded in 2013, is a global late-stage clinical messenger RNA Medicines Company focused on the development of infectious disease vaccines and therapeutic opportunities within liver and respiratory rare diseases. (<https://arcturusrx.com/>)

### About CSL Seqirus

CSL Seqirus, a subsidiary of CSL Limited, is one of the world's largest suppliers of influenza vaccines. The company has state-of-the-art manufacturing facilities in the U.S., U.K., and Australia, and leading research and development capabilities. (<https://www.cslseqirus.com>)

### About ARCALIS

ARCALIS, Inc. is a joint venture company between Axcelead Inc. and Arcturus Therapeutics Inc., which owns a group of world-class drug-discovery and healthcare platform companies. The company provides drug discovery support, as well as a contract development and manufacturing business (CDMO business), for mRNA medicines and vaccines. (<https://corp.arcalis.co.jp/en>)