Meiji Seika Pharma Receives Approval for Adding Domestic Manufacturing Sites in Japan for KOSTAIVE®, a Self-amplifying mRNA Vaccine Against COVID-19

January 31, 2025

TOKYO--(BUSINESS WIRE)--Jan. 31, 2025-- Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, Japan, President and Representative Director: Daikichiro Kobayashi) announced today that it has received approval for a partial amendment to the manufacturing and marketing approval of "KOSTAIVE ® for Intramuscular Injection," a self-amplifying mRNA vaccine for protection against COVID-19, to include domestic manufacturing sites in Japan.

Meiji Seika Pharma and ARCALIS Co., Ltd. (Headquarters: Minami-soma City, Fukushima Prefecture; President: Satoshi Takamatsu) have been working together to establish an infrastructure that enables the integrated production of pharmaceuticals, from active ingredients to final products, within Japan. With this approval, ARCALIS's Minami-soma facilities and Meiji Seika Pharmatech Co., Ltd., a subsidiary of Meiji Seika Pharma, have been added as manufacturing sites. The technology transfer was managed and implemented by CSL Seqirus, the global licensor of KOSTAIVE®. As a result, domestically produced products, with active pharmaceutical ingredients manufactured at ARCALIS's Minami-soma facilities and formulated at Meiji Seika Pharmatech, are now able to be shipped for commercial use in Japan.

"We are pleased with the approval of domestic manufacturing sites in Japan for KOSTAIVE®," said Dr. Pad Chivukula, COO of Arcturus Therapeutics. "As a joint venture partner with ARCALIS, Arcturus is delighted to support this effort through the continued transfer of our next-generation technologies, including LUNAR® lipid nanoparticle formulation processes and STARR® sa-mRNA drug substance manufacturing."

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 Meiji Seika Pharma

Meiji Seika Pharma, since it launched penicillin in 1946, has been providing efficacious and high-quality pharmaceutical products including therapeutics and vaccines for infectious diseases, therapeutics for central nervous system diseases and generic drugs, to meet various medical needs. (https://www.meiji.com/global/pharmaceuticals/)

About Arcturus Therapeutics

Arcturus Therapeutics Holdings Inc., founded in 2013, is a commercial mRNA Medicines and vaccines Company focused on the development of infectious disease vaccines and 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)

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