

Meiji Seika Pharma Co., Ltd.

February 18, 2025

## **European Commission Approves KOSTAIVE®, a Self-Amplifying mRNA Vaccine against COVID-19**

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, Japan, President and Representative Director: Daikichiro Kobayashi) announced today that the European Commission (EC) approved KOSTAIVE®, a self-amplifying mRNA (sa-mRNA) vaccine, on February 12, 2025 (European Central Time). It is indicated for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years and older. The centralized marketing authorization of KOSTAIVE® is valid in all EU Member States as well as in the European Economic Area (EEA) countries.

Meiji Seika Pharma has an exclusive partnership with CSL Seqirus for the distribution of KOSTAIVE® in Japan. Arcturus Therapeutics, Inc., the originator of KOSTAIVE®, submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA). On December 12, 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending approval of KOSTAIVE®.

The approval is based on positive clinical data from several studies, including an integrated Phase I/II/III study demonstrating KOSTAIVE®'s efficacy and tolerability, as well as Phase III booster clinical trials conducted by Meiji Seika Pharma in Japan.

### **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 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 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/>)