

Meiji Seika Pharma Co., Ltd.

February 28, 2025

Meiji Seika Pharma Submits Application for Two-Dose Vial of KOSTAIVE®, a Self-Amplifying mRNA COVID-19 Vaccine, in Japan

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, Japan; President and Representative Director: Daikichiro Kobayashi) announced today that it has submitted a manufacturing and marketing application for a new vial presentation of KOSTAIVE®, a self-amplifying mRNA vaccine against COVID-19, provided in a vial containing two doses, to the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan.

KOSTAIVE® is a vaccine against COVID-19 applying self-amplifying mRNA technology. It is designed to produce extra copies of mRNA once delivered into cells, so that it generates enhanced expression of the spike protein antigen leading to a strong immune response and for extended duration of protection while using a lower quantity of mRNA compared to conventional mRNA vaccines. Having received approval to add domestic manufacturing sites in January 2025, the product, including its active pharmaceutical ingredients and formulations, can be manufactured and shipped within Japan for commercial use.

Meiji Seika Pharma aims to receive approval for a two-dose vial (currently available in a sixteen-dose vial) designed for ease of vaccination in an individualized setting, such as medical clinics. Meiji expects the new vial presentation to enhance convenience in daily practice and contribute to the prevention of COVID-19 in time for the autumn to winter season of 2025.

KOSTAIVE® is approved in 31 countries including Japan and in the European Union.

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