

Our initiatives for the development and supply of COVID-19 vaccines

The Meiji Group is engaged in the following initiatives for the development of inactivated vaccine and self-amplifying mRNA vaccine for COVID-19. We are working with public institutions, academia, and partner companies to fulfill our social responsibility as a leading company in infectious diseases.

Development status of inactivated vaccine* “KD-414”

- Group subsidiaries KM Biologics and Meiji Seika Pharma are developing an inactivated vaccine for COVID-19.
- In April 2022, we launched Phase 3 clinical trials (multi-regional, adults under 40 years of age). We also started domestic pediatric Phase 3 clinical trials (children between six months and 12 years of age) in January 2023.
- In December 2023, we started a domestic pediatric Phase 3 clinical trials (children 6 months to less than 13 years of age), the final stage prior to approval, to verify the efficacy of KD-414 against mutant strains (XBB.1.5).

*A vaccine created from a pathogen or pathogen component by collecting virus particles and bacterial cells from virus strains or bacterial cultivated in large amounts. These particles or cells are refined and then heat-treated or treated with formalin or another agent to eliminate infectiousness or toxicity.

For detailed information, please see the websites below:

- Vaccines
<https://www.meiji.com/global/pharmaceuticals/vaccines.html>
- Wellness Stories/ COVID-19: Hope for an Inactivated Vaccine
<https://www.meiji.com/global/wellness-stories/covid-19.html>
- Pipeline
<https://www.meiji.com/global/pharmaceuticals/pipeline.html>

Development status of self-amplifying mRNA vaccine*1 “Kostaive™ for Intramuscular Injection”

- In November 2023, Meiji Seika Pharma has received approval for the manufacturing and marketing of “Kostaive™ for Intramuscular Injection” (ARCT-154) from the Ministry of Health, Labour and Welfare (MHLW) in Japan. *Kostaive™*, a self-amplifying mRNA vaccine against COVID-19, is indicated for prevention of COVID-19 by primary immunization (2 doses) and booster immunization in adults.
- In September 2023, Meiji Seika Pharma started domestic Phase 3 clinical trials (adults) for booster vaccination of this self-amplifying mRNA vaccine. The development code for the trials is ARCT-2301 (bivalent, original strain and Omicron BA.4-5 subvariant). We aim for early commercialization of a vaccine adapted to the latest epidemic strains so that the vaccination will be available in the fall and winter of 2024.

*1: A self-amplifying mRNA vaccine is a vaccine in which mRNA encoding an antigen protein is replicated intracellularly after vaccination, resulting in sustained production of the antigen protein. It is expected that the dose of inoculation is small and the effect of the vaccine is long-lasting.

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