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), the final stage prior to approval. We also started domestic pediatric Phase 3 clinical trials (children between six months and 12 years of age) in January 2023.
- In October 2023, we submitted a clinical trial notification for domestic pediatric Phase III clinical trials (children 6 months to less than 13 years of age). We will start enrolling subjects and vaccine administration in December 2023.

* 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  
- Wellness Stories/ COVID-19: Hope for an Inactivated Vaccine  
- Pipeline  

**Development status of self-amplifying mRNA vaccine “ARCT-154” and “ARCT-2301”**

- In April 2023, Meiji Seika Pharma and CSL Seqirus®, a subsidiary of CSL Limited, entered into a distribution agreement for the distribution and sales of ARCT-154, a self-amplifying mRNA COVID-19 vaccine developed by Arcturus Therapeutics Inc.®, in Japan. CSL Seqirus has exclusively licensed worldwide rights to the vaccine, ARCT-154, from Arcturus Therapeutics Inc.
- In April 2023, Meiji Seika Pharma submitted a New Drug Application to manufacture and market ARCT-154 for primary immunization to prevent COVID-19 in adults (two doses of ARCT-154) in Japan.
- In June 2023, Meiji Seika Pharma submitted an additional Application for a Booster Dose of ARCT-154 in adults in Japan.
- In September 2023, Meiji Seika Pharma started domestic Phase III clinical trials for booster vaccination of ARCT-2301 (bivalent, original strain and Omicron BA.4-5 subvariant).

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*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.

*2: 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. It also has excellent research and development capabilities. ([https://www.csseqirus.com/](https://www.csseqirus.com/))

*3: Arcturus Therapeutics Inc. is a U.S.-based pharmaceutical company founded in 2013. The company develops a global late-stage clinical vaccines for infectious diseases, and mRNA therapeutics and vaccines for rare diseases of the liver and respiratory tract. ([https://arcturusrx.com](https://arcturusrx.com))