



December 13, 2022

Name of Company: Meiji Holdings Co., Ltd.

Name of Representative: Kazuo Kawamura, CEO, President and Representative Director

Code Number: 2269, Prime Market, Tokyo Stock Exchange

Notice concerning Start of Phase III Trial of “ARCT-154,”  
A Potential New Class of mRNA Vaccine for COVID-19, in Japan

Meiji Holdings Co., Ltd. announces that its subsidiary, Meiji Seika Pharma Co., Ltd., started Phase III clinical trial of potential new class of mRNA vaccine, "ARCT-154" (development code) in Japan. ARCT-154 was developed by Arcturus Therapeutics Inc. The abovementioned clinical trial is partially funded by the Ministry of Health, Labour and Welfare of Japan.

ARCT-154 is a new class of mRNA vaccine and is potentially effective against SARS-CoV-2 variants including the Omicron variant. It is also expected that the dose of inoculation is small and the effect of the vaccine is long-lasting. Also, we are going to establish a domestic production system with a subsidy from the Ministry of Economy, Trade and Industry.

COVID-19 may spread due to new mutant strains repeatedly or may move from pandemic to endemic. In either case, we believe ARCT-154 could be a new option of vaccine for COVID-19.

Summary of the Phase III Clinical Trial for Adults

Objective	Comparative study on immunogenicity and safety of ARCT-154 when it is administered to healthy adults over 18 years of age, who have received three doses of approved mRNA COVID-19 vaccine, at least 3 months prior.
Target number of subjects	A total of 780 subjects ARCT-154 group: 390 subjects, COMIRNATY® group: 390 subjects
Study design	Multicenter, observer-blind, randomized, active-controlled comparative study
Intervention summary	ARCT-154: A dose of 5 µg (0.5 mL) administered via intramuscular injection. COMIRNATY®: A dose of 30 µg (0.3 mL) administered via intramuscular injection.
Trial period	November 2022 to April 2024

The impact of this matter on consolidated earnings forecasts for the fiscal year ending March 31, 2023 is expected to be minor.

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