



January 31, 2023

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Name of Representative: Kazuo Kawamura, CEO, President and Representative Director
Code Number: 2269, Prime Market, Tokyo Stock Exchange

Notice concerning the Initiation of Pediatric Phase III Clinical Trial of KD-414,
an Inactivated COVID-19 Vaccine

Meiji Holdings Co., Ltd. has initiated a pediatric Phase III clinical trial in Japan for KD-414, an inactivated vaccine* against novel coronavirus infections (COVID-19), and today the first dose of KD-414 was administered to the first subject. KD-414 is being developed by the Company's operating subsidiaries, Meiji Seika Pharma Co., Ltd. and KM Biologics Co., Ltd.

Details

Summary of the Pediatric Phase III Clinical Trial

Objective	Placebo-controlled comparative study to evaluate the immunogenicity and safety of two intramuscular injections of KD-414 in children 6 months to less than 12 years of age
Target number of subjects	A total of 540 subjects Cohort 1 210 subjects aged 5 to less than 12 years old (KD-414: 180 subjects, Placebo: 30 subjects) Cohort 2 330 subjects aged 6 months to less than 5 years old (KD-414: 300 subjects, Placebo: 30 subjects)
Trial design	Multicenter, double-blind, randomized, placebo-controlled parallel-group comparative study
Intervention summary	Two doses of 0.5 mL administered intramuscularly with an interval of 28 days between doses.
Trial period	January 2023 to September 2024 (planned)

The Meiji Group will continue to work to develop safe and effective inactivated vaccines that can be made available to the public as soon as possible.

The development of KD-414, including various ongoing clinical trials, and the construction of manufacturing facilities for KD-414 are partially funded by the Ministry of Health, Labour and Welfare of Japan and by research grants from the Japan Agency for Medical Research and Development (AMED).

We will closely examine the impact of the clinical trial progress on the Group's consolidated earnings forecasts.

- * An inactivated vaccine is a vaccine produced from pathogens or their components obtained by collecting virus particles or bacterial cells from a virus or bacterium cultured in large quantities, refining them, and removing their infectivity and toxicity using chemicals etc. Inactivated vaccines currently used in Japan include influenza vaccines and Japanese encephalitis vaccines, which are conventional vaccines that have been used for many years.

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