

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 the Initiation of Pediatric Phase III Clinical Trial of KD-414,  
 a COVID-19 Vaccine Effective against Mutant Strains**

Meiji Holdings Co., Ltd. announces that its subsidiaries KM Biologics Co., Ltd. and Meiji Seika Pharma Co., Ltd. started a domestic pediatric phase III clinical trial to verify the efficacy of KD-414 (XBB.1.5), an inactivated vaccine under development against COVID-19 Omicron XBB.1.5 on December 5, 2023.

Summary of Phase III Pediatric Clinical Trial

Objective	Validation of the vaccine efficacy of KD-414 (XBB.1.5) in healthy children aged 6 months to less than 13 years
Target number of subjects	About 5,000 subjects · KD-414 (XBB.1.5) group: approx. 2,500 subjects · Placebo (physiological saline) group: approx. 2,500 subjects
Study Design	Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study
Intervention summary	KD-414 (XBB.1.5) or placebo injected intramuscularly twice, 0.5 mL per shot at 28-day interval.  Note 1: At the request of the subject, one shot of subcutaneous influenza vaccine of 0.5 mL (0.25 mL for children aged 6 months to 35 months) can be co-administered.  Note 2: The investigational drug (KD-414 XBB.1.5 vaccine or placebo) will be administered under double-blind conditions. Influenza vaccination will be performed under open-label conditions.
Study period	October 2023 to September 2025 (planned)

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).

The impact of this matter on consolidated earnings forecasts for the fiscal year ending March 31, 2024 is expected to be minor.

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