October 16, 2023

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 Submission of Clinical Trial Notification for Pediatric Phase III of KD-414, a COVID-19 Vaccine Effective against Mutant Strains

Meiji Holdings Co., Ltd. announced that its subsidiaries KM Biologics Co., Ltd. and Meiji Seika Pharma Co., Ltd. submitted a clinical trial notification to the Pharmaceuticals and Medical Devices Agency (PMDA) on October 13, 2023, for 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 variant.
After the examination of the clinical trial notification by PMDA and the review by the Institutional Review Board of the medical institution implementing the clinical trial, we will start enrolling subjects and vaccine administration from December 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 the abovementioned clinical trial, is partially funded by the Ministry of Health, Labour and Welfare of Japan (MHLW) and by the Japan Agency for Medical Research and Development (AMED).

We will duly examine the impact of developments in these clinical trials on consolidated earnings forecasts.

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