April 20, 2022

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

# Notice concerning Submission of Clinical Trial Notifications for KD-414, Inactivated COVID-19 Vaccine

Meiji Holdings Co., Ltd. submitted two clinical trial notifications for clinical trials of KD-414, inactivated COVID-19 vaccine, to Pharmaceuticals and Medical Devices Agency (PMDA). One is for international Phase III clinical trial submitted on April 8, 2022 and the other is for Phase II/III pediatric clinical trial in Japan submitted on April 12, 2022. KD-414 has been developed by its subsidiaries, KM Biologics Co., Ltd. and Meiji Seika Pharma Co., Ltd.

After the examination of the clinical trial notifications and review at the trial sites by the PMDA, both companies will start enrolling subjects and vaccine administration at the end of April.

## Details

1. Summary of the Phase III Clinical Trial

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| Objective | Comparative study on the immunogenicity, efficacy, and safety of KD-414 against Vaxzevria™ intramuscular injection in adults between 18 and 40 years of age. |
| Target number of subjects | A total of 1,500 subjects (KD-414 group: 750 subjects, Vaxzevria™ group: 750 subjects) |
| Trial design | Multicenter, double-blind, randomized, parallel-group comparative study |
| Intervention summary | Investigational drug: KD-414<br>A dose of 0.5 mL administered twice via intramuscular injection with an interval of 28 days between doses.<br>A dose of 0.5 mL administered via intramuscular injection 13 weeks after the second dose.<br><br>Control drug: Vaxzevria™ intramuscular injection<br>A dose of 0.5 mL administered twice via intramuscular injection with an interval of 28 days between doses.<br>A dose of 0.5 mL of placebo (saline) administered via intramuscular injection 13 weeks after the second dose. |
| Countries to carry out clinical trial | Japan and Philippines |
| Trial period | April 2022 to November 2023 (planned) |

2. Summary of the Phase II/III Pediatric Clinical Trial

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| Objective | Comparative study on immunogenicity and safety of KD-414 when it is administered to children between six months and 17 years of age.<br>Evaluate the dosage (0.25 mL or 0.5 mL) and the number of doses (2 doses or 3 doses) in each age group (12 to 17 years of age, 5 to 11 years of age, 6 months to 4 years of age) |
| Target number of subjects | A total of 600 subjects (12 to 17 years of age group: 200 subjects, 5 to 11 years of age group: 200 subjects, 6 months to 4 years of age group: 200 subjects) |
| Trial design | Multi-center, single-blind randomized study |
| Intervention summary | Vaccinate a dose of 0.25 mL or 0.5 mL twice via intramuscular injection with an interval of 28 days between doses.<br>Vaccinate a dose of 0.25 mL or 0.5 mL via intramuscular injection 13 weeks after the second dose. |
| Trial period | April 2022 to March 2024 (planned) |

Currently, the number of COVID-19 patients in children and young adults is increasing. Nevertheless, only about 10%* of children aged 5-11 years have completed a single dose, and in addition, there is no vaccine available for children under 5 years of age. Inactivated vaccines have been used as pediatric routine vaccines and influenza vaccines for many years, and are reported to have relatively few adverse events. Thus, KD-414 might be a new option for those who cannot be vaccinated due to safety concerns or allergies. When KD-414 becomes available, it will be possible to vaccinate all age groups older than 6 months.

* Officially published document by Prime Minister of Japan and His Cabinet, dated April 18, 2022.

The Meiji Group will continue to work on developing safe and effective inactivated vaccines that can be delivered to the public as early as possible.

The development of KD-414 and the construction of production facilities for KD-414, including the abovementioned clinical trials, are partially funded by the Ministry of Health, Labour and Welfare of Japan 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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