July 6, 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 the Summary Results of Phase II/III Clinical Trial of KD-414, Inactivated COVID-19 Vaccine

Meiji Holdings Co., Ltd. announces results from the domestic Phase II/III clinical trial (jRCT 2071210081) of an inactivated vaccine* for COVID-19 (KD-414) being developed by Meiji Holdings subsidiaries KM Biologics Co., Ltd. and Meiji Seika Pharma Co., Ltd.

The objective of this trial is to evaluate the immunogenicity and safety of KD-414. Initiated in Japan in October 2021, this study was conducted on 2,500 healthy adults aged 18 and over with no prior history of COVID-19 vaccination. A single 0.5 mL dose of KD-414 was administered via intramuscular injection twice with an interval of 28 days between the shots. Thirteen weeks following the second dose, a single dose of 0.5 mL was administered via intramuscular injection.

As an assessment of immunogenicity, a high neutralizing antibody titer was observed in subjects between the ages of 18 and 40 years old. These results are expected to provide sufficient superiority validation relative to Vaxzevria™ (intramuscular injection), which is being used the control drug in an international Phase III clinical trial (jRCT 2031210679) currently underway.

As an assessment of safety, we confirmed a high level of tolerability and safety typically seen in conventional inactivated vaccines. Adverse reaction incidence profiles were similar to those observed with influenza vaccines, indicating a difference compared to COVID-19 vaccines already approved in Japan. The study also indicated no increase in adverse reactions incidental to an increase in the number of vaccinations.

A preprint (preliminary version prior to peer review) of the Phase I/II clinical trial (jRCT 2071200106) we conducted ahead of the Phase II/III clinical trial was published to MedRxiv.
https://www.medrxiv.org/content/10.1101/2022.06.28.22276794v1

Our Phase II/III clinical trial (jRCT 2031220032) involving 600 children aged six months to 17 years old currently underway is also progressing smoothly, with first dose administration already completed.

As of June, public vaccination of children (aged 5 to 11 years) started in February of this year only has about 16.6% completion rate for the administration of second doses. In Japan, there is also the issue there being no vaccine available for administration to children under the age of 5 years old. We

are striving for the rapid development of a highly safe and reliable inactivated vaccine that will contribute to increased vaccination rates for all age groups, help control the spread of COVID-19 infections, and move the society towards a return to normal lifestyles.

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.

* 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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