



September 13, 2024

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 Approval for Partial Amendment to Manufacturing and Marketing Approval of KOSTAIVE[®], Self-Amplifying mRNA Vaccine against COVID-19, Targeting the Omicron Subvariant JN.1 in Japan

Meiji Holdings Co., Ltd. announces that its subsidiary, Meiji Seika Pharma Co., Ltd. has received approval for a partial amendment to the manufacturing and marketing approval of monovalent KOSTAIVE[®] for Intramuscular Injection, a self-amplifying mRNA vaccine against COVID-19, targeting the Omicron subvariant JN.1 of COVID-19 in Japan.

On May 29, 2024, the panel of the Ministry of Health, Labour and Welfare decided to use the Omicron subvariant JN.1 for the antigen composition of the COVID-19 vaccines for the 2024/2025 season in Japan. In response to this decision, Meiji Seika Pharma submitted an application on May 31, 2024, for a partial amendment to the approval of KOSTAIVE[®] targeting this subvariant.

KOSTAIVE[®] is a vaccine against COVID-19 applying self-amplifying mRNA technology. It generates a strong immune response and the potential for extended duration of protection while using lower doses of mRNA compared to existing mRNA vaccines. In the clinical trials in Japan and overseas, we confirmed a high level of tolerability, and the safety profile was generally similar to that of the existing mRNA vaccine, with most adverse events being mild to moderate. KOSTAIVE[®] has a profile suitable for routine annual vaccination and provides a new option to prevent COVID-19, especially for the elderly who have high risks.

Meiji Seika Pharma will soon start supplying KOSTAIVE[®] targeting the Omicron subvariant JN.1, in a vial containing 16 doses, for the 2024/2025 season.

There are no changes to the consolidated earnings forecasts for FYE March 2025 as a result of this approval.

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