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Code Number: 2269, Prime Market, Tokyo Stock Exchange

Kostaive™, Self-Amplifying mRNA Vaccine against COVID-19, Approved for Manufacturing and Marketing from MHLW in Japan

Meiji Holdings Co., Ltd. announces that its subsidiary, Meiji Seika Pharma Co., Ltd., has received approval for the manufacturing and marketing of “Kostaive™ for Intramuscular Injection” (ARCT-154), a self-amplifying mRNA vaccine against COVID-19, from the Ministry of Health, Labour and Welfare (MHLW) in Japan. Kostaive™ is indicated for prevention of COVID-19 by primary immunization (2 doses) and booster immunization in adults. This is the world’s first approved replicon vaccine applying self-amplifying mRNA technology.

Kostaive™ is a vaccine against COVID-19 applying self-amplifying mRNA technology developed by Arcturus Therapeutics Inc.^{*1}, which is designed to self-amplify once delivered into cells, so that 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. Since its self-amplification is limited to over time, no safety issues have been identified.

In the Phase III clinical trials for booster vaccination conducted in Japan, Kostaive™ elicited higher ($p < 0.05$) and longer-lasting neutralizing antibody titers against the original strain, as well as the Omicron BA 4-5 subvariant, compared to the existing mRNA vaccine. Most adverse events were mild or moderate and transient, and no ARCT-154 related serious adverse events were observed, which suggests favorable safety and tolerability profile.

Meiji Seika Pharma obtained exclusive rights to distribute Kostaive™ in Japan from CSL Seqirus^{*2} on April 11, 2023, and is collaborating with ARCALIS, Inc.^{*3} to establish integrated mRNA vaccine manufacturing capabilities from drug substance to drug product in Minami-soma City, Fukushima Prefecture, Japan. Meiji Seika Pharma is currently preparing for and conducting clinical trials of replicon mRNA vaccines against novel variants of COVID-19 virus and intends to commercialize them in 2024.

The impact on the consolidated financial results forecast for the fiscal year ending March 31, 2024, has not been determined at this time. We will closely examine the situation and disclose the impact as soon as it is recognized.

- *1: Arcturus Therapeutics Holdings Inc. founded in 2013, is a global late-stage clinical messenger RNA Medicines Company focused on the development of infectious disease vaccines and therapeutic opportunities within liver and respiratory rare diseases. (<https://arcturusrx.com/>)
- *2: CSL Seqirus, a subsidiary of CSL Limited, is one of the world's largest suppliers of influenza vaccines. The company has state-of-the-art manufacturing facilities in the U.S., U.K., and Australia, and leading research and development capabilities. (<https://www.cslseqirus.com/>)
- *3: ARCALIS, Inc. is a joint venture company between Axcelead Inc. and Arcturus Therapeutics Inc., which owns a group of world-class drug-discovery and healthcare platform companies. The company provides drug discovery support, as well as a contract development and manufacturing business (CDMO business), for mRNA medicines and vaccines. (<https://corp.arcalis.co.jp/en>)

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