



June 30, 2023

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Code Number: 2269, Prime Market, Tokyo Stock Exchange

## Additional Application for Booster Dose of ARCT-154, Self-Amplifying mRNA Vaccine against COVID-19, Submitted in Japan

Meiji Holdings Co., Ltd. announces that its subsidiary, Meiji Seika Pharma Co., Ltd., submitted an additional Application for a Booster Dose of ARCT-154 in adults in Japan. ARCT-154, a self-amplifying mRNA vaccine candidate against COVID-19, was developed by Arcturus Therapeutics Inc.<sup>\*1</sup>, and on April 11, 2023, Meiji Seika Pharma obtained exclusive rights to distribute ARCT-154 in Japan from CSL Seqirus.<sup>\*2</sup>

ARCT-154 uses next-generation self-amplifying mRNA technology which generates a strong immune response, a favorable tolerability profile and the potential for extended duration of protection while using lower doses of mRNA compared to existing mRNA vaccines.

Meiji Seika Pharma submitted an additional Application for a booster dose of ARCT-154 based on results of a Phase III clinical trial ([jRCT2071220080](#)) conducted in Japan involving subjects aged 18 years and older, who had received 3 complete doses of mRNA vaccine and the last dose received with COMIRNATY<sup>®</sup> occurred 3 months and more prior to screening. The trial evaluated the geometric mean titers and seroconversion rates of neutralizing antibodies against SARS-CoV-2(Wuhan strain) on day 29 after a booster shot of ARCT-154 or COMIRNATY<sup>®</sup>, and the results met its primary endpoint. No clinically significant concerns were identified in safety.

In the meantime, an NDA for primary immunization of ARCT-154 was submitted on April 28, 2023. This is the first application for a next generation mRNA vaccine in a developed country.

Under the terms of an agreement with CSL Seqirus, Meiji Seika Pharma will be responsible for obtaining regulatory approval, and for distribution, sales and marketing of ARCT-154 in Japan.

Meiji Seika Pharma is collaborating with ARCALIS, Inc.<sup>\*3</sup> to establish integrated mRNA vaccine manufacturing capabilities from drug substance to drug product in Japan. ARCALIS is building a manufacturing facility in Minami-soma City, Fukushima Prefecture.

Meiji Seika Pharma is working to supply ARCT-154 in Japan as soon as possible following approval. If approved, ARCT-154 will become a new vaccination option against COVID-19. 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.

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Disclaimer: This English translation is prepared for the readers' convenience. When there are any discrepancies between the original Japanese version and English translation version, the original Japanese version always prevails.

- \*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 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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