



April 28, 2023

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

Submitted New Drug Application to Manufacture and Market ARCT-154, Next Generation mRNA Vaccine against COVID-19, in Japan

Meiji Holdings Co., Ltd. announces that its subsidiary, Meiji Seika Pharma Co., Ltd., submitted a New Drug Application to manufacture and market ARCT-154 for primary immunization to prevent COVID-19 in adults (two doses of ARCT-154) in Japan. ARCT-154, a next generation mRNA vaccine against COVID-19, was developed by Arcturus Therapeutics Inc^{*1} and in April, Meiji Seika Pharma obtained exclusive rights to distribute ARCT-154 in Japan from CSL Seqirus^{*2}.

ARCT-154 uses next-generation mRNA technology which offers 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 NDA for primary immunization of ARCT-154 based on results of a Phase III clinical trial ([NCT05012943](#)) conducted in Vietnam involving more than 16,000 subjects. The trial evaluated safety, immunogenicity and efficacy of primary immunization of ARCT-154 and the results met its primary endpoint of prevention of COVID-19. Meiji Seika Pharma has been conducting a Phase III study in Japan since December 13, 2022, to evaluate the safety and immunogenicity of ARCT-154 as a booster against COVID-19, and completed enrollment in February 2023.

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.^{*3} to establish an integrated mRNA vaccine manufacturing 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.

*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. It also has excellent research and development capabilities. (<https://www.csseqirus.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>)

#####