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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 Positive Results of Phase III Study of Bivalent Version of Kostaive<sup>®</sup>, Self-Amplifying mRNA Vaccine Against COVID-19 (Ancestral Strain and Omicron BA.4/5), for Booster Vaccination Conducted in Japan**

Meiji Holdings Co., Ltd. announces that a bivalent version of Kostaive<sup>®</sup> (ARCT-2301: ancestral strain with the D614G mutation and omicron BA.4-5 subvariant), self-amplifying mRNA vaccine against COVID-19, met the primary endpoint in Phase III clinical study (jRCT2031230340) for booster vaccination which its subsidiary, Meiji Seika Pharma Co., Ltd. conducted in Japan.

In the Phase III clinical study, immunogenicity and safety of a bivalent version of Kostaive<sup>®</sup> (ARCT-2301) was compared with COMIRNATY<sup>®</sup> RTU (Bivalent: Ancestral strain and Omicron BA.4-5 subvariant) in healthy Japanese adults aged 18 years or older previously immunized with three to five doses of mRNA COVID-19 vaccine. Since non-inferiority of ARCT-2301 to COMIRNATY (BA.4/5) was confirmed both in the geometric mean titer (GMT) ratio and seroresponse rate (SRR) difference of neutralizing antibodies against SARS-CoV-2 (Omicron strain BA.4/5), the primary endpoint of the study was achieved. In addition, the superiority of ARCT-2301 to COMIRNATY (BA.4/5) was confirmed for both SARS-CoV-2 (Omicron strain BA.4/5 and Wuhan strain). There were no causally-associated severe or serious adverse events with ARCT-2301.

These results support immunogenicity and safety of Kostaive<sup>®</sup>'s self-amplifying mRNA platform enable Meiji Seika Pharma's timely release of update version of Kostaive<sup>®</sup> against novel variants of concern in 2024 in Japan.

Meiji Seika Pharma conducted the study in collaboration with Arcturus Therapeutics and under its exclusive partnership with CSL Seqirus for the distribution of Kostaive<sup>®</sup> in Japan.

### **About sa-mRNA**

In contrast to standard messenger RNA vaccine technology, self-amplifying messenger RNA (sa-mRNA) vaccine technology helps protect against infectious diseases by not only instructing cells in the body to make a specific protein, but also by making copies of these instructions. The produced protein antigen stimulates the immune response and leaves a blueprint to recognize and fight future infection. Because of the self-amplifying element of the vaccine, more protein is produced compared to an equivalent amount of standard mRNA, allowing for lower doses of sa-mRNA to be used. sa-mRNA also has the potential to prompt a potent and durable cellular immune response in addition to producing effective antibodies against the targeted virus.

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Disclaimer: This English version is a translation of the original version in Japanese for the readers' convenience. In case of any discrepancies, the original Japanese version prevails.

**About CSL Seqirus**

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>)

**About Arcturus Therapeutics**

Arcturus Therapeutics Holdings Inc. founded in 2013, is a global messenger RNA Medicines Company focused on the development of infectious disease vaccines and therapeutic opportunities within liver and respiratory rare diseases. (<https://arcturusrx.com/>)

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