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Meiji Seika Pharma Co., Ltd.

September 29, 2023

# Initiation of Phase III Clinical Trial of Self-Amplifying mRNA COVID-19 Vaccine, ARCT-2301 (Bivalent: Original Strain and Omicron Strain) in Japan

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, Japan, President and Representative Director: Daikichiro Kobayashi) announced the initiation of Phase III clinical trial in Japan (jRCT2031230340) for booster vaccination of ARCT-2301 (bivalent, ancestral strain with the D614G mutation and omicron BA.4-5 subvariant), a self-amplifying mRNA vaccine candidate against COVID-19.

In June, Meiji completed dosing in a Phase 3 clinical study of ARCT-154 administered as a booster vaccination, with data demonstrating non-inferiority of immune response against the ancestral strain of COVID-19 as compared to COMIRNATY. Through this latest clinical trial with ARCT-2301, Meiji Seika Pharma will confirm that variant updates to the self-amplifying mRNA vaccine platform generate comparable immune responses, in this case against an Omicron subvariant, and simultaneously work toward commercialization of self-amplifying mRNA vaccines against novel variants of COVID-19 virus, including XBB.1 subvariant.

Summary of the Phase III clinical trial of ARCT-2301*

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| Objective | To verify the non-inferiority of immunogenicity of one booster dose of ARCT-2301 [bivalent: ancestral strain with D614G mutation/Omicron BA.4-5 subvariant] to COMIRNATY RTU [bivalent: origin strain/Omicron BA.4-5 subvariant] in subjects 18 years of age or older who have received 3 to 5 doses of an approved mRNA COVID-19 vaccine and more than 3 months have passed since the last dose. The safety of a booster dose of ARCT2301 will also be evaluated. |
| Target number of subjects | A total of 850 subjects<br>ARCT-2301 group: 425 subjects, COMIRNATY group: 425 subjects |
| Study design | Multicenter, randomized, double-blind, active-controlled comparative study |

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| Intervention summary | ARCT-2301: Administer 0.5 mL (5 microgram) as a single intramuscular injection.<br>COMIRNATY (BA.4-5): Administer 0.3 mL (30 microgram) as a single intramuscular injection. |
| Trial period | September 2023 to June 2024 |

*: ARCT-2301 is a bivalent vaccine candidate against the ancestral strain with the D614G mutation and Omicron BA.4-5 subvariant of the SARS-CoV-2 virus, applying the same technology platform as ARCT-154.

**: This bivalent booster trial (jRCT2031230340) will not impact the timing of PMDA approval for the monovalent ARCT-154, which is expected later this year.

About ARCT-154

ARCT-154 is a monovalent vaccine candidate against the ancestral strain (D614G) of the SARS-CoV-2 virus. By applying self-amplifying mRNA technology developed by Arcturus Therapeutics Inc., ARCT-154 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 obtained exclusive rights to distribute ARCT-154 in Japan from CSL Seqirus on April 11, 2023. A New Drug Application for primary immunization to prevent COVID-19 in adults (two doses of ARCT-154) was submitted in April, and an additional Application for a Booster Dose of ARCT-154 in adults was submitted in June, 2023, respectively in Japan.

About Arcturus Therapeutics

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/)

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)