

Press Release

Daiichi Sankyo Initiates Phase 3 Clinical Trial of Mutant Strain COVID-19 Vaccine (DS-5670) in Japan

Tokyo, Japan – (May 19, 2023) – Daiichi Sankyo (TSE: 4568) today announced that it has administered an mRNA vaccine (DS-5670) against the novel coronavirus infectious disease (COVID-19), which is being developed by Daiichi Sankyo in Japan, to the first subject in a phase 3 clinical trial of a booster vaccination with an Omicron-adapted bivalent vaccine (booster vaccination trial).

This booster vaccination trial is a phase 3 clinical trial that enrolls approximately 1,400 healthy individuals who have completed the primary and booster series of vaccination with a COVID-19 vaccine approved in Japan and evaluates the efficacy and safety of DS-5670 (Omicron-adapted bivalent vaccine) using a COVID-19 vaccine (Omicron-adapted bivalent vaccine) approved in Japan as the control.

Based on results from the booster vaccination trial, Daiichi Sankyo will pursue the approval of the Omicron-adapted bivalent vaccine. Furthermore, the company will continuously work toward supplying mRNA vaccines against new variants of coronavirus.

About DS-5670

DS-5670 is an mRNA vaccine against COVID-19 using a novel nucleic acid delivery technology discovered by Daiichi Sankyo. It is designed to produce antibodies against the receptor binding domain (RBD) of the spike protein of the novel coronavirus and thus expected to have desirable prevention against COVID-19 and safety. Daiichi Sankyo aims to make it possible to distribute the mRNA vaccine at refrigeration temperatures (2-8°C). The clinical development of DS-5670, including the mutant strain vaccine announced today, is being conducted through the “Vaccine development project” promoted by the Japan Agency for Medical Research and Development (AMED) and the “Urgent improvement project for vaccine manufacturing systems” supported by the Japanese Ministry of Health, Labour and Welfare (MHLW).

About Daiichi Sankyo

Daiichi Sankyo is dedicated to creating new modalities and innovative medicines by leveraging our world-class science and technology for our purpose “to contribute to the enrichment of quality of life around the world.” In addition to our current portfolio of medicines for cancer and cardiovascular disease, Daiichi Sankyo is primarily focused on developing novel therapies for people with cancer as well as other diseases

with high unmet medical need. With more than 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 16,000 employees around the world draw upon a rich legacy of innovation to realize our 2030 Vision to become an “Innovative Global Healthcare Company Contributing to the Sustainable Development of Society.” For more information, please visit www.daiichisankyo.com.

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