

Press Release

Daiichi Sankyo Announces Results of Booster Vaccination Trial of Its mRNA COVID-19 Vaccine (DS-5670) in Japan

Tokyo, Japan – (November 15, 2022) – Daiichi Sankyo (TSE: 4568) today announced that in a trial for evaluation of the efficacy and safety of booster vaccination with DS-5670, an mRNA vaccine against the novel coronavirus infectious disease (COVID-19) being developed by Daiichi Sankyo (hereafter, booster vaccination trial), the primary endpoint was achieved.

The booster vaccination trial included approximately 5,000 Japanese healthy adult and elderly subjects who had completed the primary series (two doses) of mRNA vaccines approved in Japan at least six months before enrolment. In January 2022, the trial was initiated as a phase 1/2/3 trial in order to evaluate the efficacy and safety of booster vaccination with DS-5670 using mRNA vaccines approved in Japan as the control.

GMFR of neutralizing antibody titer against SARS-CoV-2 (original strain) in blood four weeks after the booster vaccination, the primary endpoint of the booster vaccination trial, demonstrated a higher data and non-inferiority of DS-5670 to the mRNA vaccines (original strain) approved in Japan, achieving the intended purpose. No safety concerns were identified. Detailed results of the booster vaccination trial will be presented at academic conferences and in research papers.

Based on the trial results, Daiichi Sankyo will proceed with preparation for a new drug application of the mRNA vaccine in January 2023. In addition, Daiichi Sankyo is planning to conduct clinical trials of bivalent vaccines of the original strain and Omicron strains against new coronaviruses, which continue to mutate. Daiichi Sankyo will strive to strengthen the mRNA vaccine development and production system to ensure a stable supply in ordinary times as well as prompt provision of vaccines in the event of outbreaks of emerging and reemerging infectious diseases.

About DS-5670

DS-5670 is an mRNA vaccine against COVID-19 using a novel nucleic acid delivery technology discovered by Daiichi Sankyo, 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. Furthermore, Daiichi Sankyo is aiming for mRNA vaccines that can be distributed in the refrigerated temperature range (2-8°C).

The clinical development of DS-5670 is being conducted through “Vaccine development project” promoted by the Japan Agency for Medical Research and Development (AMED) and “Urgent improvement project for vaccine manufacturing systems” supported by the 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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