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Daiichi-Sankyo

Press Release

# Daiichi Sankyo Announces Initiation of Phase 3 Trial of mRNA COVID-19 Vaccine (DS-5670) in Unvaccinated Individuals in Japan

**Tokyo - (September 1, 2022)** – Daiichi Sankyo (TSE: 4568) today announced that it has initiated a phase 3 trial of DS-5670, an mRNA vaccine against the novel coronavirus infectious disease (COVID-19), in healthy unvaccinated adults.

The trial is an active-controlled, trial to investigate the non-inferiority of DS-5670 to an already-approved mRNA vaccine (Comirnaty®) in terms of immunogenicity and seroconversion rate[1] in 322 healthy adults in Japan who have not yet received a COVID-19 vaccine or been infected with the novel coronavirus.

As a Japanese pharmaceutical company with specialty in developing vaccines, Daiichi Sankyo is proceeding with the development of DS-5670 and will continue consultation with regulatory authorities to deliver a domestically produced mRNA vaccine to people in Japan as soon as possible.

**About DS-5670**

DS-5670 is an mRNA vaccine against COVID-19 using a cationic lipid 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 efficacy and safety. In addition, DS-5670 in animal models induced neutralizing activities against the omicron variant to a certain extent following the initial vaccination.

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 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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References

[1] Seroconversion rate is defined as the percentage of subjects who have achieved a certain level of increase in neutralizing antibody titer after vaccination. In this trial, it is defined as the percentage of those who have achieved at least a 4-fold increase in neutralizing antibody titer after vaccination.