

## Press Release

# Daiichi Sankyo Announces Development Progress of mRNA COVID-19 Vaccine (DS-5670) in Japan

**Tokyo - (May 26, 2022)** – Daiichi Sankyo (TSE: 4568) today announced the current progress of development of DS-5670, an mRNA vaccine, being evaluated in Japan against the novel coronavirus infectious disease (COVID-19) in a phase 1/2/3 trial to determine the booster effect of an additional dose (booster vaccination trial) and a phase 2 trial in unvaccinated subjects.

### 1. Booster vaccination trial

The trial is being conducted as a phase 1/2/3 trial in healthy adult and elderly subjects who received two doses of an mRNA vaccine approved in Japan at least six months before receiving the additional dose of DS-5670 (third vaccination) in order to evaluate the booster effect of DS-5670. In January 2022, the dose-finding part of the trial was initiated, including approximately 500 healthy adult and elderly subjects.

In this trial, an mRNA vaccine approved in Japan or DS-5670 at one of three dose levels (10µg, 30µg, 60µg) was administered. Data on neutralizing activities four weeks after receiving the vaccination show that the efficacy of DS-5670 is comparable to or higher than an approved mRNA vaccine. Evaluation of safety during a period of seven days after the vaccination presented no serious adverse reactions at the injection site or systemic ones such as pyrexia, malaise, headache, rash, and myalgia. At all dose levels of DS-5670, tolerability, safety, and increased neutralizing antibody titers have been demonstrated.

In response to these results, Daiichi Sankyo today initiated an active-controlled non-inferiority trial to compare DS-5670 to an approved mRNA vaccine in order to further evaluate the booster effect and evaluate the safety of DS-5670 in approximately 4,500 healthy adult and elderly subjects.

### 2. Phase 2 trial in unvaccinated subjects

The trial was initiated in November 2021 as a phase 2 trial to investigate the immunogenicity, safety, and recommended dose of DS-5670 in 80 unvaccinated healthy adults.

Results from the trial presented no significant safety concerns. The neutralizing antibody titers 14 days after the second vaccination of DS-5670 have demonstrated acquirement of adequate immunity.

Daiichi Sankyo will proceed with preparation to initiate a phase 3 trial of DS-5670 in the first half of fiscal 2022.

As a Japanese pharmaceutical company with a specialty in developing vaccines, Daiichi Sankyo will continue consultation with the regulatory authorities to deliver the vaccine to people in Japan, aiming at commercialization of DS-5670 during 2022.

### **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 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, and the additional dose further increased neutralizing activities, demonstrating a potential booster effect.

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](http://www.daiichisankyo.com).

### **Media Contacts:**

#### **Japan:**

Masashi Kawase  
Daiichi Sankyo Co., Ltd.  
[kawase.masashi.a2@daiichisankyo.co.jp](mailto:kawase.masashi.a2@daiichisankyo.co.jp)  
+81 3 6225 1126 (office)

#### **Investor Relations Contact:**

[DaiichiSankyoIR@daiichisankyo.co.jp](mailto:DaiichiSankyoIR@daiichisankyo.co.jp)