

## Press Release

# **Daiichi Sankyo Submits Application for Marketing Approval of mRNA COVID-19 Vaccine (DS-5670) in Japan**

**Tokyo, Japan - (January 13, 2023)** – Daiichi Sankyo (TSE: 4568) today announced the submission of an application for marketing approval of DS-5670 to the regulatory authorities in Japan. DS-5670 is an mRNA vaccine, being developed against the novel coronavirus infectious disease (COVID-19) and is proposed to be used as a booster vaccine for the prevention of COVID-19.

The application is based on results of a phase 1/2/3 trial (original strain) in approximately 5,000 healthy adult and elderly subjects, who received the primary series (two doses) of an mRNA vaccine approved in Japan.

Daiichi Sankyo started prior assessment consultations for drugs with the Pharmaceuticals and Medical Devices Agency in September 2022 based on non-clinical, clinical, and quality data available up to now to obtain marketing approval at an earlier date.

In addition, Daiichi Sankyo plans to move forward with the development of DS-5670 for the Omicron strain in order to respond to new variants of the coronavirus, which continue to mutate, in parallel with the development for the original strain.

Daiichi Sankyo is striving to establish mRNA-vaccine-related technologies and the production and supply system in Japan to ensure a prompt provision of vaccines in the event of outbreaks of emerging and reemerging infectious diseases, thereby contributing to protect safety and security in society and people's health.

### **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 safety and desirable prevention against COVID-19. 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 the “Vaccine development project” promoted by the Japan Agency for Medical Research and Development and the “Urgent improvement

project for vaccine manufacturing systems” supported by the Japanese Ministry of Health, Labour and Welfare.

### **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).

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