

## Press Release

# **Omicron XBB.1.5-adapted COVID-19 Vaccine (DS-5670) Supplemental New Drug Application Submitted in Japan**

**Tokyo - (September 7, 2023)** – Daiichi Sankyo (TSE: 4568) today announced that it has submitted a supplemental New Drug Application (sNDA) to Japan's Ministry of Health, Labour and Welfare (MHLW) for an omicron XBB.1.5-adapted mRNA vaccine (DS-5670) against the novel coronavirus infectious disease (COVID-19) for booster vaccination for individuals aged 12 years or older.

The monovalent vaccine containing omicron XBB.1 lineage will be used in the current special temporary vaccination program against COVID-19 in Japan that begins in September 2023, and Daiichi Sankyo is advancing production preparations to start the supply of DS-5670 within this year.

#### About DS-5670

DS-5670 is an mRNA vaccine against COVID-19 designed to produce antibodies against the receptor binding domain (RBD) of the spike protein of the novel coronavirus, utilizing a novel nucleic acid drug delivery system discovered by Daiichi Sankyo. In Japan, DS-5670, an original-strain-containing monovalent mRNA vaccine, was approved for marketing in August 2023 and is authorized to be used as a booster dose with an indication of "Prevention of disease caused by SARS-CoV-2 infection."

The research and development of DS-5670 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).

#### Vaccine business of Daiichi Sankyo

Daiichi Sankyo has been pushing on with the research and development to discover novel vaccines, aiming at ensuring stable supply of vaccines in Japan and, by leveraging our strong knowledge and experience in science and technology, enhancing the preventive healthcare environment in Japan through development of the COVID-19 vaccines, deliverables of our mRNA technology. Daiichi Sankyo has been developing the vaccine business in Japan in cooperation with Daiichi Sankyo Biotech Co., Ltd., a vaccine production functional subsidiary of the Daiichi Sankyo Group, and striving to establish mRNA-vaccine-related

technologies and the production and supply system to ensure prompt delivery of Japan-made vaccines in the event of outbreaks of emerging and reemerging infectious diseases and thereby will contribute to protect safety and security in society and people's health.

### About Daiichi Sankyo

Daiichi Sankyo is an innovative global healthcare company contributing to the sustainable development of society that discovers, develops, and delivers new standards of care to enrich the quality of life around the world. With more than 120 years of experience, Daiichi Sankyo leverages its world-class science and technology to create new modalities and innovative medicines for people with cancer, cardiovascular, and other diseases with high unmet medical need. For more information, please visit <a href="http://www.daiichisankyo.com/">http://www.daiichisankyo.com/</a>.

Media Contacts: Japan: Koji Ogiwara Daiichi Sankyo Co., Ltd. ogiwara.koji.ay@daiichisankyo.co.jp +81 3 6225 1126 (office)

Investor Relations Contact: DaiichiSankyoIR@daiichisankyo.co.jp