

Press Release

Daiichi Sankyo Reaches Agreement with MHLW to Supply Omicron XBB.1.5-adapted COVID-19 Vaccine (DS-5670) in Japan

Tokyo - (November 17, 2023) - Daiichi Sankyo (TSE: 4568) today announced that it had reached an agreement with Japan’s Ministry of Health, Labour and Welfare (MHLW) to supply the omicron XBB.1.5-adapted monovalent mRNA vaccine (DS-5670) against the novel coronavirus infectious disease (COVID-19). DS-5670 will be used in the current special temporary vaccination program against COVID-19 in Japan that began in Autumn 2023.

This agreement was concluded to supply 1.4 million doses in FY2023 under the condition that regulatory approval for DS-5670 should be granted by MHLW. Daiichi Sankyo submitted a supplemental New Drug Application (sNDA) for DS-5670 to the MHLW in September 2023.

Daiichi Sankyo is now preparing its production facilities to supply DS-5670, the first Japan-made COVID-19 mRNA vaccine, within this year. Daiichi Sankyo will strive to further strengthen technologies for vaccine development and production, thereby contributing to the safety and security of society and people’s health in Japan.

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 manufacturing and 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 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 striving to establish mRNA-vaccine-related 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 the safety and security of society and people's health in Japan.

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

<http://www.daiichisankyo.com/>.

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