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Daiichi-Sankyo

Press Release

Daiichi Sankyo Announces Results of Booster Vaccination Trial of mRNA COVID-19 Vaccine DS-5670 (Bivalent: Original Strain and Omicron Strain) in Japan

Tokyo - (September 7, 2023) – Daiichi Sankyo (TSE: 4568) today announced that the primary endpoint was achieved in a phase 3 trial of a booster vaccination with DS-5670, an mRNA vaccine against the novel coronavirus infectious disease (COVID-19) being developed in Japan (in a booster vaccination trial) by Daiichi Sankyo.

The booster vaccination trial was conducted as a phase 3 clinical study to evaluate the immunogenicity and safety of a booster vaccination with DS-5670 (bivalent, the original strain and omicron BA.4-5 subvariant) in individuals who were aged 12 years or older and had completed the primary and booster series of SARS-CoV-2 vaccines. The primary endpoints of the booster vaccination trial were the geometric mean blood neutralizing antibody titer and immune response against SARS-CoV-2 (omicron BA.5 subvariant) four weeks after the investigational vaccination. Results on the endpoints in the DS-5670 group were higher than those in the control group (omicron-adapted bivalent vaccine approved in Japan), statistically demonstrating non-inferiority of DS-5670. For the safety, no clinical concerns were identified. Detailed results from the booster vaccination trial will be presented at academic conferences and in publications.

Based on the results of this trial, which confirmed the efficacy and safety of DS-5670 against the omicron strain, Daiichi Sankyo is advancing the development of its omicron-adapted vaccine and intends to begin supplying a monovalent vaccine containing omicron XBB.1 lineage by the end of this year for use in special temporary vaccinations that are scheduled to start in Japan from September 2023.

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 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 http://www.daiichisankyo.com/.

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