

Press Release

DAICHIRONA[®] FOR INTRAMUSCULAR INJECTION for Booster Vaccination Approved in Japan as Omicron XBB.1.5-adapted Monovalent mRNA Vaccine against COVID-19

Tokyo - (November 28, 2023) - Daiichi Sankyo (TSE:4568) today announced that DAICHIRONA[®] FOR INTRAMUSCULAR INJECTION (DS-5670) for booster vaccination has been approved in Japan as an Omicron XBB.1.5-adapted monovalent mRNA vaccine against COVID-19.

Daiichi Sankyo had submitted a supplemental New Drug Application (sNDA) to Japan's Ministry of Health, Labour and Welfare (MHLW) for manufacturing and marketing approval of the Omicron XBB.1.5-adapted monovalent mRNA vaccine in September 2023. Based on the supply agreement with the MHLW, Daiichi Sankyo will commence the distribution of this first-ever Japan-made mRNA vaccine in the coming days and is committed to supply a total of 1.4 million doses in FY2023 for the current special temporary vaccination program against COVID-19 in Japan. DAICHIRONA[®] FOR INTRAMUSCULAR INJECTION can be distributed and stored under refrigeration (2–8°C), offering improved convenience to healthcare professionals.

Daiichi Sankyo will strive to further strengthen the development and production technologies and supply system for mRNA vaccine, thereby contributing to the safety and security of society and people's health.

About DAICHIRONA[®] FOR INTRAMUSCULAR INJECTION

DAICHIRONA[®] FOR INTRAMUSCULAR INJECTION 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.

The research and development and establishment of production system of DAICHIRONA[®] FOR INTRAMUSCULAR INJECTION are 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 occurrence of emerging and reemerging infectious diseases and thereby will contribute to the safety and security of 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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