

Press Release

DAICHIRONA[®] for Intramuscular Injection (Monovalent: Original Strain), mRNA COVID-19 Vaccine, Approved for Manufacturing and Marketing as Booster Vaccination in Japan

Tokyo, Japan (August 2, 2023) - Daiichi Sankyo (TSE: 4568) today announced that it has received approval for the manufacturing and marketing of DAICHIRONA[®] for Intramuscular Injection (DS-5670), an original monovalent mRNA vaccine against the novel coronavirus infectious disease (hereafter, COVID-19), in Japan for the prevention of infectious disease caused by SARS-CoV-2 (booster vaccination).

The application for approval of DAICHIRONA[®] for its manufacturing and marketing in Japan was submitted in January 2023, and it is now approved as the first Japan-made mRNA vaccine against COVID-19. DAICHIRONA[®] can be distributed and stored under refrigeration (2°C–8°C), offering improved convenience to healthcare professionals.

In the current special temporary vaccination program against COVID-19, Omicron-adapted bivalent mRNA vaccines are used for the booster series campaign that began in May 2023. In addition, the Japanese government has shown an intention to use XBB.1 vaccines for the next booster series campaign that is scheduled to begin in September 2023.

Since DAICHIRONA[®] as approved now is an original monovalent mRNA vaccine for booster series, its supply for the campaign is not planned.

However, Daiichi Sankyo will immediately advance the development of an XBB.1-containing monovalent vaccine and strive to supply an XBB.1.5-containing monovalent vaccine before the end of this year at the earliest.

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 of DAICHIRONA[®], including the XBB.1.5 monovalent vaccine mentioned in this announcement, is being conducted through the “Vaccine development project” supported 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 is dedicated to enhancing the preventive healthcare environment in Japan and improving public health and hygiene, which is an essential part of national security, by ensuring a stable supply of vaccines, including the Influenza HA Vaccine and Live Attenuated Measles-Rubella Combined Vaccine. Additionally, 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 protection of the sense of 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/>.

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