

Press Release

Daiichi Sankyo Announces Development Progress of mRNA COVID-19 Vaccine in Japan

Tokyo, Japan - (October 21, 2021) – Daiichi Sankyo Company, Limited (hereinafter, Daiichi Sankyo) announced the progress of development of DS-5670, an mRNA vaccine in Japan, being evaluated against the novel coronavirus infectious disease (COVID-19), including results from a phase 1/2 clinical trial.

The trial was initiated in March 2021 to evaluate the safety and immunogenicity¹ of DS-5670 and to estimate the recommended dose. No relevant safety concerns have been observed following four weeks of follow-up after administration of the second dose of the vaccine in 142 healthy adults, including elderly individuals. For the immunogenicity, both neutralizing activity² and IgG titer³ increased after the vaccination.

A non-clinical research project conducted in collaboration with the University of Tokyo's Institute of Medical Science showed that DS-5670 induced a neutralizing activity against previously designated Variant of Concerns, including the Delta variant.

Daiichi Sankyo plans to initiate a phase 2 clinical trial in November 2021 and a phase 3 clinical trial within FY2021, aiming for commercialization of DS-5670 in Japan within 2022. In addition, in order to initiate a clinical trial of a supplemental booster for the vaccine (booster vaccine) in January 2022, Daiichi Sankyo is continuing discussions with the Japanese Ministry of Health, Labour and Welfare (MHLW), Pharmaceuticals and Medical Devices Agency (PMDA), and Japan Agency for Medical Research and Development (AMED).

These R&D projects are being conducted through the “Development of vaccines for the novel coronavirus disease (COVID-19) (Second Round)” (company-initiated) promoted by AMED and “Emergent Initiative to Build Production Capacity for COVID-19 Vaccines (First Round)” supported by MHLW.

As a Japanese pharmaceutical company with a specialty in developing vaccines, Daiichi Sankyo is striving to ensure stable supply of an HA vaccine against seasonal influenza as well as help restore safety and security in society through the early eradication of COVID-19 by pursuing the development of DS-5670, a Japan-made vaccine against COVID-19, and manufacturing adequate supplies of DS-5670 as soon as possible.

About Daiichi Sankyo

Daiichi Sankyo is dedicated to creating new modalities and innovative medicines by leveraging our world-class science and technology for our purpose “to contribute to the enrichment of quality of life around the world.” In addition to our current portfolio of medicines for cancer and cardiovascular disease, Daiichi Sankyo is primarily focused on developing novel therapies for people with cancer as well as other diseases with high unmet medical need. With more than 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 16,000 employees around the world draw upon a rich legacy of innovation to realize our 2030 Vision to become an “Innovative Global Healthcare Company Contributing to the Sustainable Development of Society.” For more information, please visit www.daiichisankyo.com.

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Reference:

¹ Immunogenicity is defined as the ability of a vaccine to induce the antigen-specific immune response in a living human body.

² Neutralizing activity is defined as the activity to inhibit (neutralize) the infectivity of the virus.

³ IgG titer is defined as an amount of IgG, one of the antibodies, and serves as an indicator of the antigen-specific immune response.