R&D Activities for COVID-19 Vaccines and Therapeutics

Tokyo, Japan (June 12, 2020) – Daiichi Sankyo Company, Limited (hereinafter, Daiichi Sankyo) established a company-wide task force in April 2020 to promote the R&D of vaccines and therapeutic agents targeting COVID-19. By leveraging the best use of our past and present research properties, technologies, and accumulated R&D knowledge and experience as an innovative pharmaceutical company, and also in collaboration with external institutions, we are proactively contributing to R&D to improve the medical infrastructure for COVID-19, which is currently an urgent, global social need.

1. R&D of genetic (mRNA) vaccines

For the prevention of COVID-19, Daiichi Sankyo is currently participating in "Fundamental Research on the Control of a Novel Coronavirus (2019-nCoV[*1])"[*2] (Principal investigator: Prof. Yoshiro Kawaoka, Institute of Medical Sciences, The University of Tokyo), which is an initiative supported by the Japan Agency for Medical Research and Development (AMED). In addition, using novel nucleic acid delivery technology[*3] developed by Daiichi Sankyo itself, we are taking part in a basic research project on a genetic (mRNA) vaccine with the title "Development of a Genetic Vaccine for 2019-nCoV".

Recently, in a pharmacological evaluation of a prototype mRNA vaccine using animal models, we achieved an increase in antibody titers to the novel coronavirus. Leveraging this result, we will position the development of a mRNA vaccine as a priority project and start to consider an increase in scale toward establishing a supply system. At the same time, we aim to proceed to clinical studies in Japan around March 2021.

In our role as a Japanese pharmaceutical company engaged in the vaccine business, Daiichi Sankyo will contribute to bringing the COVID-19 pandemic to an early end to restore people's peace of mind and safety in our society. Through collaboration with Japan's Ministry of Health Labour and Welfare, the Pharmaceutical and Medical Devices Agency (PMDA), our research partner the University of Tokyo, and other organizations, we will proceed with the research and development of this mRNA vaccine and make efforts to ensure that it can be supplied as soon as possible.

Daiichi Sankyo plans to use the facilities of the "New Influenza Vaccine Development and Production System Development Project" to develop the supply system. With the aim of starting supply of COVID-19 vaccines in Japan as soon as possible, we will prioritize efforts toward establishing a production platform and ensuring a stable supply.

*1 2019-nCoV is synonymous with SARS-CoV-2.

*2 A vaccine development initiative determined for support by AMED under urgent government-wide efforts against the worldwide spread of COVID-19.

*3 Technology focusing on forming lipid nanoparticle structures, stabilizing pharmaceutical active ingredients and delivering nucleic acids into immune cells. Compared to conventional vaccine technology, it has been demonstrated to induce a more optimal immune response.

2. Collaborative R&D of Nafamostat Inhalation Formulation

Daiichi Sankyo reached a basic agreement in June 2020 on collaborative R&D with the University of Tokyo, RIKEN, Nichi-Iko Pharmaceutical Co., Ltd on a Nafamostat inhalation formulation for the treatment of COVID-19.

In the first stage of infection by the causative virus of COVID-19, SARS-CoV-2, the outer envelope of the virus, fuses with the host cell surface membrane. Prof. Junichiro Inoue, Institute of Medical Science, The University of Tokyo (at the time of the study, currently Senior Professor at the University of Tokyo) and others discovered that by preventing this fusion, Nafamostat could efficiently inhibit the viral entry process. Nafamostat is an injectable that has been prescribed for many years in Japan mainly as a treatment for acute pancreatitis and disseminated intravascular coagulation, and adequate safety-related clinical data has been accumulated.

RIKEN has established the program for drug discovery and medical technology platforms in order to optimize the medical seeds generated from basic research at RIKEN and at universities for use in the drug discovery process at pharmaceutical companies, and in clinical practice, as a bridge to companies and medical institutions. In this case, RIKEN will also support this collaborative R&D using RIKEN's multidisciplinary advanced technologies.

Nichi-Iko, the marketing authorization holder of FUTHAN® (generic name: nafamostat mesilate), will provide data collected on the product over many years as well as supply the Active Pharmaceutical Product (API) for this collaborative R&D.

Daiichi Sankyo will carry out R&D on the Nafamostat inhalation formulation using technology gained in the development of its anti-influenza virus agent, Inavir®. Non-clinical studies are scheduled to begin in Japan in July 2020, and after consultation with authorities, aim to proceed to clinical studies by March 2021.

Through this partnership, Daiichi Sankyo hopes to provide patients with a new treatment option for COVID-19 as early as possible.

3. Drug Repositioning

In addition to the aforementioned activities, Daiichi Sankyo is also conducting a “drug repositioning” to search for COVID-19 treatments in which we, in collaboration with academia and others, are not only evaluating the potential applications of our existing products for COVID-19 treatment but are also focusing on selecting potential target molecules and chemical compounds for COVID-19 therapeutics using the knowledge and experience of our past and current R&D projects.

Through this drug repositioning, Daiichi Sankyo aims to provide patients with a new treatment option for COVID-19.