

**Social Issues** ★ Countermeasures against Emerging and Re-emerging Infectious Diseases

With more than one year having passed since the emergence of COVID-19, we have renewed our recognition that countermeasures against emerging and re-emerging infectious diseases is a significant social issue. Meiji Seika Pharma and KM Biologics are actively working on the development, production, and distribution of vaccines and therapeutic drugs. They are also proactively providing patients and medical institutions with information that promotes the appropriate use of antibiotics.

Initiatives for Development and Provision of a COVID-19 Vaccine

**Promoting Development of a Domestically Produced Inactivated Vaccine**

KM Biologics is developing an inactivated vaccine (KD-414)<sup>\*1</sup> against the COVID-19, leveraging the expertise acquired over the years of developing vaccines. The development is being conducted in collaboration with the National Institute of Infectious Diseases, the Institute of Medical Science, the University of Tokyo, and the National Institutes of Biomedical Innovation, Health and Nutrition.

In March 2021, the company started clinical studies in healthy adults and elderly people, investigating the safety and immunogenicity of the vaccine (Phase I and II clinical studies). KM Biologics is the first company conducting clinical studies for an inactivated COVID-19 vaccine in Japan.

KM Biologics has already obtained approval for production and sale of a prototype vaccine<sup>\*2</sup> against novel influenza, which may cause a pandemic like COVID-19. We have thus developed a system that enables the vaccine to be produced expeditiously and provided at the time of emergence of pandemic influenza. A new virus could cause a pandemic in the future. Therefore, we will scientifically investigate whether it is also possible to apply for approval for production and sale of the inactivated vaccine being currently developed as a prototype vaccine.

Vaccines developed earlier overseas have been provided in Japan. However, the development of domestically produced vaccines is vital for early containment of COVID-19. We will accelerate our development so that we can provide a vaccine produced in Japan as soon as possible. In doing so, we will strive to realize a society where people can live with peace of mind.

<sup>\*1</sup> A vaccine produced from pathogens or their components obtained by collecting virus particles or bacterial cells from a virus or bacterium cultured in large quantities, refining them, and removing their infectivity and toxicity using chemicals, etc.  
<sup>\*2</sup> A mock-up vaccine produced and developed using the model virus for vaccine production before the occurrence of a pandemic on the premise that the vaccine strain produced at the time of a pandemic is changed as needed



Japan's first clinical study for an inactivated vaccine started in March 2021



Inactivated vaccine against COVID-19 being developed by KM Biologics



Developing a domestically produced vaccine is an urgent issue. Development is underway, aiming for the fastest possible completion

**Business Agreement on Supply of the AstraZeneca Vaccine in Japan**

Meiji Seika Pharma and KM Biologics respectively concluded an agreement with AstraZeneca to supply VAXZEVRIA™ Intramuscular Injection<sup>\*3</sup>, a COVID-19 vaccine, in Japan. AstraZeneca was granted a Special Approval by MHLW in May 2021 for manufacturing and marketing this vaccine in Japan. In accordance with the agreements, KM Biologics receive the vaccine bulk in March 2021 and undertook the formulation and packaging. Meiji Seika Pharma takes over storage, shipping and collection of safety information of the AstraZeneca vaccine, by using its own vaccine distribution and supply system. It started domestic operations for distribution of the vaccine in August 2021.

<sup>\*3</sup> The vaccine jointly developed by AstraZeneca and Oxford University

Initiative to Develop Therapeutic Drugs for COVID-19

To control COVID-19, it is necessary to expand the testing system and develop effective therapeutic drugs as well as development of vaccines. Meiji Seika Pharma has already launched Check MR-COV19, an antigen test kit as a tool for expanding the testing system, in June 2021. As for therapeutic drugs, the company is developing a low molecular weight therapeutic agent and therapeutic antibodies.

**Creating Ground-breaking Therapeutics by Using Next-generation Ivermectin Derivatives and Building a Foundation for Antiviral Drugs<sup>\*1</sup>**

Preventing severe cases of COVID-19 has also become a major challenge. This has increased demand for the development of safe and highly effective therapeutic drugs. In May 2021, Meiji Seika Pharma started joint research and development with the Kitasato Institute, which is known its history and track records of research on infectious disease. The joint work is aimed at creating therapeutic drugs using next-generation derivatives of ivermectin and building a foundation for antiviral drugs. Ivermectin derivatives may be used for treatment of COVID-19 and prevention of the after effects (of the disease), as they have both anti-inflammatory and immune-regulatory effects in addition to antiviral effects. Through this research and development, we aim to create ground-breaking therapeutic drugs for various infectious diseases.



Meiji Seika Pharma President Daikichiro Kobayashi (left) and Distinguished Emeritus Professor of Kitasato University Satoshi Omura (right) at a press conference on joint research and development

<sup>\*1</sup> Selected as a project under the Cyclic Innovation for Clinical Empowerment (CiCLE) program of the Japan Agency for Medical Research and Development (AMED)  
<sup>\*2</sup> Selected as a project under the Research Program on Emerging and Re-emerging Infectious Diseases of AMED  
<sup>\*3</sup> Antibodies with a single amino acid sequence that react with only one type of antigenic determinant (epitope)

**Research and Development of Therapeutic Antibodies for COVID-19<sup>\*2</sup>**

Meiji Seika Pharma is also working on research and development of therapeutic antibodies for COVID-19. Antibody therapy is considered to be highly effective for COVID-19. We plan to analyze human monoclonal antibodies<sup>\*3</sup>, select ones that are effective for COVID-19, determine therapeutic antibodies, and consider production methods for the investigational drug used in non-clinical and clinical studies.

KM Biologics' Factory Tours and Activities to Increase Awareness of Prevention of Infectious Disease

**Conducting Factory Tours for Students to Learn About Influenza Vaccine Production Process**

KM Biologics conducts factory tours for students to help them learn about the production process for influenza vaccines. Due to the spread of COVID-19, the number of tours decreased in FY2020. We plan to gradually resume tours when the current pandemic settles down.

As we were unable to provide plant tours, we started offering fun interactive classes for elementary and junior high schools to increase awareness of preventing infectious disease.

**Providing Fun Interactive Classes for Elementary and Junior High Schools to Communicate the Importance of Health**

With the spread of COVID-19, health awareness is growing. KM Biologics provides fun interactive classes that communicate the importance of health. The classes are aimed at increasing knowledge and consciousness of infectious disease and raising awareness of prevention of infectious disease by teaching basic knowledge of immunity and methods to prevent infectious disease in an easy-to-understand manner. The company conducted the classes at five elementary schools and one junior high school in Kumamoto prefecture in FY2020 (a total of 2,232 students participated). After participating in the classes, students gave us comments, such as "I realized that I need to take thorough prevention measures, such as hand washing and getting vaccinated, in order avoid being infected with COVID-19." Teachers also gave feedback, stating, "The program was so great, offering something that teachers alone would not have been able to provide. Thank you very much."

Infectious disease is not limited to COVID-19. We do not know what type of new infectious diseases will appear and when such diseases will cause a pandemic. For this reason, it is necessary for each and every one of us to acquire knowledge on infectious disease and take preventive measures. We will further expand this activity and contribute to realizing a healthy, fulfilling future.



Fun interactive class provided by a KM Biologics employee. It is conducted online during the COVID-19 pandemic.