

Shionogi Announces Commitment to Fight COVID-19 (4)

Osaka, Japan, August 7, 2020 – With continued social disruption caused by the worldwide spread of the novel coronavirus (SARS-CoV-2), Shionogi & Co., Ltd. (President & CEO: Isao Teshirogi, Ph.D., hereafter: “Shionogi”) continues our intensive efforts to deliver pharmaceutical products to patients in need in a reliable and stable manner. As a pharmaceutical company with a major focus on infectious diseases, Shionogi is also working with public institutions, academia, and partner companies to address COVID-19, by pursuing the discovery of novel therapeutics and the development of vaccine and diagnostic product¹⁻⁷. As a progress of the manufacturing of prophylactic vaccines, Shionogi today announces our project was adopted by the Ministry of Health, Labour and Welfare as a public recruitment project for “The Urgent Improvement of Vaccine Production Systems, etc.”. We also inform current situations of our efforts to fight COVID-19.

1. Commitment to the vaccine development

Shionogi is pursuing the discovery and development of a recombinant protein vaccine for COVID-19, using a unique technology, “BEVS*” of UMN Pharma Inc., a subsidiary of Shionogi. With the goal of initiating clinical trials within the year, an immunogenicity testing of protein antigens and adjuvant** candidates added to vaccine formulations has been currently conducting in the National Institute of Infectious Diseases (NIID), a research collaborator. Following the selection of antigens and adjuvants, we plan to promptly conduct non-clinical safety studies required for the initiation of clinical trials.

* Baculovirus Expression Vector System

** Substance that fortifies vaccine efficacy by activating immunity

In parallel with these development plans, Shionogi is establishing a production system for the early provision of vaccine in cooperation with Api Co., Ltd. (Headquarter: Gifu City, Gifu Prefecture) and its group company, UNIGEN Inc. (Headquarter: Ibi-gun, Gifu Prefecture), who was the only company in Japan to produce recombinant protein vaccines using BEVS technologies. Aiming for offering this vaccine to more than 30 million people by the end of 2021, we will accelerate the construction of production system and its augmentation in Japan with our own capital, “Grant to Promote the Domestic Investment Project to Combat the Supply Chain (15 billion-yen)” publicly established by the Ministry of Economy, Trade and Industry, which was adopted on July 17, 2020, and the grant from the Ministry of Health, Labour and Welfare (about 22 billion-yen) announced today.

2. Commitment to the discovery of novel therapeutic drugs

A number of promising lead compounds against SARS-CoV-2 have been identified through a collaborative research effort with the Hokkaido University Research Center for Zoonosis Control, and we have been conducting exploratory assessments, such as safety and drug efficacy, on these lead and follow-up compounds sequentially to select a candidate for development. We are accelerating our drug discovery efforts with the aim of starting clinical trials in FY2020.

3. Commitment to the development of diagnostic products

Based on a license agreement regarding a new rapid diagnostic method for viruses including SARS-CoV-2 with Nihon University, Gunma University, and Tokyo Medical University⁷, Shionogi is pursuing the practical development of a new rapid diagnostic method for COVID-19, using an innovative nucleic acid amplification technique, SATIC (signal amplification by ternary initiation complexes) method. The SATIC method enables a determination of presence or absence of SARS-CoV-2 infection visually without a detector. Virus determination can be made in about 25 minutes after sample collection. Furthermore, this method has competitive features which enable viral detection from saliva and sputum collected reliably and safely with high sensitivity equivalent to that of a PCR method. Shionogi is preparing an application for approval as in-vitro diagnostic drug and striving for commercialization with the goal of availability in September 2020. In parallel with these actions, Shionogi will accelerate development and production scale-up studies for early provision of kits that enable easier and quicker diagnosis of multiple samples.

We have marketed the IgG/IgM Antibody-test Kit for COVID-19 as a research reagent in Japan since June 3, 2020 to be useful for epidemiological surveillance and studies of SARS-CoV-2/COVID-19 aiming to determine the number of individuals previously infected with SARS-CoV-2⁴.

Shionogi is committed to “Protect people worldwide from the threat of infectious diseases” as our key focus. We are not limiting ourselves to the research and development of therapeutic medications, but are also focused on the total care of infectious disease, through awareness building, prevention, diagnosis, and treating exacerbations, as well as the infection itself. We will continue to strive to fulfill our social responsibility and to contribute to re-establishing the safety and security of society by bringing forward new tools and technologies for the diagnosis and subsequent treatment of COVID-19 to support early containment of the pandemic. Shionogi will work closely with government, industry, and academia to accelerate our efforts and will keep all stakeholders informed regarding the progress of our efforts.

Forward-Looking Statements

This announcement contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcomes of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials and entry of competitive products. The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events

Press Release



or otherwise.

For Further Information, Contact:

Corporate Communications Department
Shionogi & Co., Ltd.
Telephone: +81-6-6209-7885

References

1. [Press release on March 17, 2020](#)
Business Partnership with Micro Blood Science Inc. for an IgG/IgM Antibody-test Kit for COVID-19
2. [Press release on April 14, 2020](#)
Shionogi Announces Commitment to Fight COVID-19
3. [Press release on April 27, 2020](#)
Notice Regarding a Development Decision of Vaccine for COVID-19
4. [Press release on June 3, 2020](#)
IgG/IgM Antibody-test Kit for COVID-19 launched in Japan
5. [Press release on June 3, 2020](#)
Shionogi Announces Commitment to Fight COVID-19 (2)
6. [Press release on June 19, 2020](#)
Shionogi Announces Commitment to Fight COVID-19 (3)
7. [Press release on June 22, 2020](#)
Business Partnership with Nihon University, Gunma University, and Tokyo Medical University for a Rapid Diagnostic Methods for Viruses in the Field of Infectious Diseases, Including Novel Coronavirus

Our efforts against COVID-19 are updated on our website as needed. A considerable amount of valuable information on COVID-19 posted on other website is also summarized on this page, so please check it for your reference: [SHIONOGI website](#)