

Shionogi Announces Commitment to Fight COVID-19 (5)

Osaka, Japan, September 24, 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 product¹⁻⁸. Shionogi today announces a progress in the development of prophylactic vaccines as well as current situations of other 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. The recombinant protein vaccine contains the target antigen protein manufactured based on the genetic information of the virus. Compared to novel technologies such as mRNA vaccines, by which the target antigen protein is synthesized in the body, the recombinant protein vaccine needs a certain development period for antigen expression and purification before initiating dosing trials. However, the recombinant protein vaccine is manufactured based on an established technology and several vaccines such as influenza prophylactic vaccine utilizing BEVS have been approved and put to practical use based on its efficacy and safety.

So far, Shionogi has continuously conducted immunogenicity tests in mice in collaboration with the National Institute of Infectious Diseases (NIID) to examine the multiple candidate antigen proteins produced by Shionogi and our collaborative research partner, Kyushu University (Dr. Hashiguchi who is in charge of this research has moved to Kyoto University) including candidate adjuvants**. In these tests, we have selected the combination of antigen protein and adjuvant that induces an increase of antigen-specific IgG antibody titer and virus neutralization activity. Currently, we are undertaking non-clinical safety studies and pharmacological studies to support the preventive effects which are required for starting clinical trials. We will promptly carry out these non-clinical studies toward the start of clinical trials within 2020, and will continue to discuss the clinical trials necessary for confirming enough safety and efficacy in humans with the Ministry of Health, Labor and Welfare and Pharmaceuticals and Medical Devices Agency (PMDA). In addition, with the goal of producing vaccines for more than 30 million people by the end of 2021, we will accelerate the institution of manufacturing and scale-up methods as well as the construction and expansion of production facilities.

* Baculovirus Expression Vector System

** Substance that fortifies vaccine efficacy by activating immunity

2. Commitment to the discovery of novel therapeutic drugs

Shionogi has identified the follow-up compounds synthesized based on the promising lead compounds against SARS-CoV-2 found through a collaborative research with the Hokkaido University Research Center for Zoonosis Control. We have been conducting exploratory

assessments, such as safety and drug efficacy, on the follow-up compounds sequentially and the manufacturing process of the most promising candidate had already been investigated at this time. Now we are preparing to start non-clinical studies immediately after the best candidate has been identified. We will continue to focus on 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 various assays, such as antigen kits, being released recently, we believe that it is necessary to ensure a supply count of more than a certain level in order to meet the needs of medical institutions by taking advantage of the characteristics of this technology. It is therefore we decided to revise our initial target for the launch of early-stage products from September 2020 to December 2020 and focus on establishing a supply system. Since it is necessary to mix and prepare multiple reagents at the time of use for the initial type of the product, Shionogi will accelerate product development and its scale-up studies for early provision of kits that enable easier and quicker diagnosis of multiple samples, so that they can be widely used by general medical institutions, etc.

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. In order to improve convenience, we have changed the product standards from the original 50 test/kit to the 20 test/kit.

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.

Press Release



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 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
8. [Press release on Augst 7, 2020](#)
Shionogi Announces Commitment to Fight COVID-19 (4)

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](#)