

Shionogi Announces Commitment to Fight COVID-19 (3)

Osaka, Japan, June 19, 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, vaccine development, and offering an antibody test kit¹⁻⁵. Shionogi today announces a progress of the manufacturing of prophylactic vaccines, along with current situations of these efforts.

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. We are currently investigating formulations of protein antigens and establishing analytical methods, while in parallel an immunogenicity testing of protein antigens and adjuvant** candidates added to vaccine formulations has been initiated in the National Institute of Infectious Diseases (NIID), a research collaborator.

* Baculovirus Expression Vector System

** Substance that fortifies vaccine efficacy by activating immunity

In the development of vaccines for SARS-CoV-2 infections, due to its urgency, we believe that it is necessary to investigate commercial production in parallel with development. To achieve offering this vaccine to 10 million people as early as possible, we have consulted with Api Co., Ltd. (Headquarter: Gifu City, Gifu Prefecture, president: Takahiko Nonogaki) 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, and applied for “Grant to Promote the Domestic Investment Project to Combat the Supply Chain” which was publicly established by the Ministry of Economy, Trade and Industry, jointly by three companies. We have begun preparing for the start-up of commercial production in advance while the Ministry is conducting a review for our application.

With the goal of initiating clinical trials within the year, we continue to coordinate our plans with relevant parties, such as the Ministry of Health, Labour and Welfare, the Ministry of Economy, Trade and Industry, Pharmaceuticals and Medical Devices Agency (PMDA), and the NIID, as well as to develop a production system in Japan to enable early supply.

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 conducted exploratory assessments, such as safety and pharmacokinetics, on these lead and follow-up compounds. We are currently preparing for definitive non-clinical studies to select a candidate for development, while in parallel investigating formulations suitable for subsequent non-clinical and clinical studies. We are accelerating our drug discovery efforts with

Press Release



the aim of starting clinical trials in FY2020.

3. Commitment to offer antibody test kit

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 or otherwise.

For Further Information, Contact:

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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

Press Release



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)

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](#)