

Shionogi Announces Commitment to Fight COVID-19 (6)

Osaka, Japan, December 18, 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 in infectious disease, 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 products¹⁻¹¹. The progress of each of these efforts can be summarized as follows:

1. Commitment to the discovery of novel therapeutic drugs

Shionogi have been conducting nonclinical assessment to identify the best candidate compound against SARS-CoV-2 through collaborative research with the Hokkaido University Research Center for Zoonosis Control and the National Institutes of Biomedical Innovation, Health and Nutrition. However, as we announced on October 30, 2020¹⁰, we decided to revise our original plan (to start clinical trials in FY2020) because further efficacy and safety studies are required to assess the compound’s potential. Now we are assessing the efficacy and safety of this compound in detail to determine whether it is an optimal candidate for development. Furthermore, we are continuing our discovery efforts, not only for SARS-CoV-2, but also for other coronaviruses, to prepare for potential future coronavirus pandemics, using various modalities, including small molecules, peptides, and antibodies.

2. Commitment to vaccine development

Shionogi is pursuing the discovery and development of a recombinant protein vaccine for COVID-19, in collaboration with the National Institute of Infectious Diseases and Kyoto University. This month, we initiated a Phase 1/2 clinical trial in Japan¹¹. For details, please refer to our [press release](#) dated December 16, 2020 and the Japan Registry of Clinical Trials website (jRCT2051200092). In addition, with the goal of producing sufficient vaccine for more than 30 million people by the end of 2021, we are optimizing our manufacturing methods for large-scale production as well as equipping and expanding production facilities.

3. Commitment to the development of diagnostic products

Based on our license agreement for a new rapid diagnostic method for viral infections, including SARS-CoV-2, with Nihon University, Gunma University, and Tokyo Medical University⁷, Shionogi is pursuing the development of a new rapid diagnostic method for COVID-19, using an innovative nucleic acid amplification technique, the SATIC (signal amplification by ternary initiation complexes) method. We are seeking to commercialize, as soon as possible, an *in-vitro* diagnostic test for SARS-CoV-2 utilizing the unique approach and superior properties of the SATIC method. After internal testing, we decided that some of the component reagents need to be improved to achieve higher sensitivity and stability of the response to SARS-CoV-2 viruses. As reagent reformulation requires several steps to confirm reaction performance and scalability, we have recently reassessed our projected initial launch timings. In parallel, we are accelerating the development of a new kit form that would be easier and quicker to use, particularly for multiple

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samples, and which could be efficiently deployed by general medical institutions, etc.

We have marketed the IgG/IgM Antibody-test Kit for COVID-19 (20 test/kit) as a research reagent in Japan since June 3, 2020 for epidemiological surveillance and assessment of the number of individuals previously infected with SARS-CoV-2.^{4,9}

Shionogi is committed to “Protecting people worldwide from the threat of infectious diseases” as our key focus. In addition to our continued efforts for the research and development of therapeutics, we are also pursuing total care for infectious diseases, through awareness building, prevention, diagnosis, and treatment of exacerbations, as well as addressing the infection itself. We will continue to strive to fulfill our social responsibility and seek to contribute to re-establishing the safety and security of society by bringing forward new tools and technologies for the prevention, diagnosis, and 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 our progress.

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

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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)
9. [Press release on September 24, 2020](#)
Shionogi Announces Commitment to Fight COVID-19 (5)
10. [Presentation material on October 30, 2020](#)
1st Half of Fiscal 2020 Financial Results (Press Conference)
11. [Press release on December 16, 2020](#)
Notice Regarding an Initiation of Phase 1/2 Clinical Trial for COVID-19 Recombinant Protein-based Vaccine

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