

## Shionogi Announces Commitment to Fight COVID-19 (2)

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**Osaka, Japan, June 3, 2020** – The social disruption caused by the spread of the novel coronavirus (SARS-CoV-2) is showing signs of resolution, such as the resumption of economic activities in some countries and the release of the declaration of emergency in Japan. However, SARS-CoV-2 remains a global threat impacting the way people live, including the emergence of new outbreaks and concerns regarding a second wave of infections. In the face of the need to prevent the spread of infection, the pharmaceutical industry, among others, must diligently work toward prompt responses, such as the development of therapeutics and vaccines. Under these circumstances, 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 preparations for offering an antibody test kit. The progress of each of these efforts can be summarized as follows:

1. 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 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 also engaged in a collaborative research project with SyntheticGestalt KK and Hokkaido University Research Center, with the goal of identifying new drug candidates for COVID-19 using SyntheticGestalt's AI drug discovery technology. Identifying therapeutic compounds against SARS-CoV-2 is one of the top priority projects for Shionogi. We are accelerating our drug discovery efforts with the aim of starting clinical trials in FY2020.

2. 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. To accelerate this project with top-priority, alongside the discovery of COVID-19 therapeutic drugs, we are working in collaboration with the National Institute of Infectious Diseases (NIID) and Kyushu University in “Drug Discovery Support Project: Vaccine Development for New Coronavirus Infection (COVID-19)” which was publicly established by the Japan Agency for Medical Research and Development (AMED) in fiscal 2020. Since our application was accepted as an industrial research and development task, as a result we will receive approximately 1.3 billion yen (direct expenses, planned) in research funding for our research plans from late May 2020 to March 2021.

\* Baculovirus Expression Vector System

We have already confirmed expression of protein antigens with BEVS and are currently working to purify antigens and establish analytical methods for initiation of nonclinical studies. With the

# Press Release



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, Pharmaceuticals and Medical Devices Agency, and the NIID, as well as to develop a production system in Japan to enable early supply.

### 3. Commitment to offer antibody test kit

Regarding the IgG/IgM Antibody-test Kit for COVID-19<sup>1</sup> that was licensed from Micro Blood Sciences Inc., we launched it as a research reagent in Japan today. For details, please visit the following website: [IgG/IgM Antibody-test Kit for COVID-19 launched in Japan](#).

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-

# Press Release



- 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

In addition, there has been a considerable amount of valuable information on COVID-19 posted on other websites. The following official websites are recommended for your reference:

Information on the impact of the novel coronavirus on daily life:

- Prime Minister's Office of Japan: Useful Information on the Novel Coronavirus Disease (COVID-19)  
[http://japan.kantei.go.jp/ongoingtopics/coronavirus\\_info\\_e.html](http://japan.kantei.go.jp/ongoingtopics/coronavirus_info_e.html)

Information related to disease caused by the novel coronavirus:

- Cabinet Secretariat: The Novel Coronavirus Infection Control: (only in Japanese)  
<https://corona.go.jp/>
- MHLW: Ministry of Health, Labour and Welfare : About Coronavirus Disease 2019 (COVID-19)  
[https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/newpage\\_00032.html](https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/newpage_00032.html)
- CDC: Centers for Disease Control and Prevention: Coronavirus Disease 2019 (COVID-19)  
[https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/summary.html?CDC\\_AA\\_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fsummary.html](https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/summary.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fsummary.html)
- WHO: World Health Organization: Coronavirus  
[https://www.who.int/health-topics/coronavirus#tab=tab\\_1](https://www.who.int/health-topics/coronavirus#tab=tab_1)