

## **Notice Regarding the Initiation of a Phase 1 Clinical Trial for a COVID-19 Therapeutic Agent in Japan**

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**OSAKA, Japan, July, 26, 2021** - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; President and CEO: Isao Teshirogi, Ph.D.; hereafter "Shionogi") today announced that Shionogi has initiated a Japanese Phase 1 clinical trial of the therapeutic agent S-217622 as an orally administered antiviral drug for COVID-19, caused by the novel coronavirus (SARS-CoV-2) infection, and the first dose was administered successfully on July 22. No safety concerns have been identified after the first dose.

S-217622 is a 3CL protease inhibitor discovered by Shionogi. SARS-CoV-2 has an enzyme called 3CL protease, which is essential for the duplication of the virus. S-217622 suppresses the duplication of SARS-CoV-2 by selectively inhibiting 3CL protease. In non-clinical trials using SARS-CoV-2 infected animals, it has been confirmed that the viral load is rapidly and significantly reduced. In the Japanese phase 1 clinical trial that just started, we will confirm the pharmacokinetics, safety and tolerability of this drug in healthy adults.

COVID-19 is still widespread, and vaccinations are underway in various countries to combat this pandemic. On the other hand, even after vaccinations, a risk of infection and disease onset remains. Furthermore, if a new variant virus becomes widespread, it is unclear whether the existing vaccine will be effective, or, if not, whether an effective vaccine can be rapidly developed and supplied. Therefore, not only vaccines but also antiviral drugs, similar to those used to treat influenza virus infections, which can quickly reduce the amount of virus in the body and, if administered early in the infectious process, can prevent development of clinical symptoms such as fever or respiratory symptoms and also avoid severe exacerbations, are needed as a treatment for infected individuals. This is particularly true because COVID-19 can rapidly become more severe even if it is asymptomatic or mild in the early stages of infection. Therefore, there is a need for safe and convenient antiviral drugs that can be administered to many infected patients. Since this compound is a small molecule oral antiviral drug, it is expected to meet the needs of society and healthcare practitioners.

Shionogi is committed to "Protect people worldwide from the threat of infectious diseases" as our key focus. We are not only pursuing the research and development of therapeutics, but are also working towards total care for infectious diseases, through awareness building, prevention, diagnosis, and addressing exacerbations, as well as the treating the infection itself. As SARS-CoV-2 continues to have a major impact on people's lives and to represent a global threat, we will seek to contribute to re-establishing the safety and security of society by developing this compound and keeping 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 outcome 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,*

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*but are not limited to, inability to build production capacity to meet demand, lack of availability 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:**

SHIONOGI Website Inquiry Form : <https://www.shionogi.com/global/en/contact.html>