

June 11, 2021

### **Phase III Study Result of FOIPAN<sup>®</sup> Tablets, a Protease Enzyme Inhibitor, in Japan in Patients with Novel Coronavirus Infection (COVID-19)**

Ono Pharmaceutical Co., Ltd. (Osaka, Japan; President, Representative Director, Gyo Sagara; “ONO”) announced that Foipan<sup>®</sup> (generic name: camostat mesilate) Tablets (“Foipan”), a protease enzyme inhibitor, did not meet the time to SARS-CoV-2 negative test, the primary endpoint, in the placebo-controlled Phase III study conducted in Japan in patients with asymptomatic to moderate novel coronavirus infection (COVID-19).

Taking into account the basic research literature suggesting the efficacy of Foipan and the blood concentrations in humans, ONO had conducted a Phase I study to investigate the safety of Foipan in healthy adults using higher doses than the currently approved dosage. Based on the result, ONO conducted a Phase III study with Foipan in patients with asymptomatic to moderate COVID-19, but did not show the efficacy of Foipan in the study.

ONO has been working on the development of Foipan for the treatment of COVID-19 as the responsibility of the pharmaceutical company, but decided to discontinue the development of Foipan in patients with COVID-19, based on the result from this study.

#### **About Phase III study in Japan**

The study is a multi-center, randomized, double-blind, placebo-controlled, parallel-group Phase III study in patients with asymptomatic to moderate COVID-19. Patients received Foipan 600 mg (77 patients) or placebo (76 patients) orally 4 times daily for up to 14 days. The primary endpoint was the time to SARS-CoV-2 negative test.

#### **About Foipan<sup>®</sup> Tablets**

Foipan<sup>®</sup> Tablets is an oral protease enzyme inhibitor created at ONO, and obtained a manufacturing and marketing approval in 1985 for the alleviation of acute symptoms associated with chronic pancreatitis. Foipan was also approved in 1994 for the treatment of postoperative reflux esophagitis. The substance patent for the product expired in January 1996.

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