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Development of Therapeutic Drugs for Novel Coronavirus Infection (COVID-19)

Ono Pharmaceutical Co., Ltd. (Osaka, Japan; President, Representative Director, Gyo Sagara; “ONO”) announced today that it has decided not to enter into the development of ONO-5334, as a therapeutic drug for novel coronavirus infection (COVID-19), which was reported as one of the promising compounds that suppresses the growth of novel coronavirus in human iPSC-derived pneumocyte-like cells in the English scientific journal "Nature" on July 24. In addition, ONO will further promote the development of a proteinase inhibitor, Foipan[®] (generic name: camostat mesilate) Tablets (“Foipan”) under the clinical development for the treatment of COVID-19.

While ONO-5334 had been developed by ONO as a drug candidate for the treatment of osteoporosis based on its inhibitory effect on cathepsin K, its development in the osteoporosis area was discontinued in 2012 comprehensively taking into consideration the competitive situation in the osteoporosis area and changes in the environment.

ONO-5334 has an inhibitory effect on cathepsins including cathepsin L, which is known as a potential enzyme involved in coronavirus infection. According to the report in Nature, ONO-5334 was identified as a potent compound to inhibit viral replication in several cells suggesting its possibility as a therapeutic drug for COVID-19.

Also, it is known that the proteolytic enzyme TMPRSS2 is greatly involved in major infections of the COVID-19 causative virus SARS-CoV-2 in the lungs or airways.

Under such circumstances, ONO has provided domestic and international research facilities with samples of our protease inhibitors including ONO-5334 and camostat mesilate for the investigation of inhibition of viral infections. As a result, we have confirmed a similar effect of ONO-5334 reported in Nature, while the effect is markedly attenuated in some assay systems, namely the one using a human lung epithelial cell line in which TMPRSS2 is highly expressed.

Meanwhile, camostat mesilate, which is being developed by ONO for the treatment of COVID-19, has various findings, such as (1) inhibitory effect on infection in the cellular system expressing TMPRSS2, (2) relationship between its blood concentration in human and in vitro antiviral effect, and (3) a certain level of safety based on the extensive experience in humans.

Given this situation, ONO decided not to develop ONO-5334, but continue to promote the development of Foipan[®] Tablets, which is currently undergoing Phase I clinical study.

About Foipan[®] Tablets

Foipan[®] Tablets is an oral protease enzyme inhibitor created internally 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.

About ONO-5334

ONO 5334 is a cathepsin K inhibitor that was discovered and developed by ONO for the treatment of osteoporosis as an oral formulation. It was in Phase II clinical study in Japan, but ONO discontinued the development of the compound in the osteoporosis area, taking into consideration competitiveness as well as marketing conditions in osteoporosis area.

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