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Public Relations

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Discontinuation of ONO-6818 Development for Chronic Obstructive Pulmonary Disease and Alpha 1 Antitrypsin Deficiency

Ono Pharmaceutical Co., Ltd., has announced that it decided to discontinue, due to a safety concern, the development of ONO-6818 for Chronic Obstructive Pulmonary Disease (COPD) and Alpha 1 Antitrypsin Deficiency (A1AT).

ONO-6818 is an oral elastase inhibitor generated from collaborative research with Cortech, Inc., USA. Ono had been developing the compound for COPD in Japan, and both for COPD and A1AT abroad. Elastase, one of proteases, is suggested to be involved in the development of COPD. A1AT is a disease resulting from a genetic defect of alpha 1 antitrypsin, an endogenous inhibitor of elastase, and is associated with COPD occurring at high rate with aging. It is reported that there are approximately 200,000 patients suffering from the disease in the Western countries, but it is very rare in Japan.

Ono had been conducting phase IIa double blind clinical study (low and high doses of ONO-6818 vs placebo) in patients with COPD in Japan since July, 2001, but it voluntarily suspended the study due to abnormal elevation of liver function test (LFT) values and deferred the commencement of the U.S. phase II study.

Ono has now decided to discontinue the development as the analysis of collected Japanese phase IIa clinical data revealed abnormal elevation in LFT values (mild to moderate) in ONO-6818 group, and their causal relationship with drug administration could not be denied.