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Ono files for approval of ONO-7643 in Japan

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ONO-7643 is a ghrelin receptor agonist, for improvement of body weight loss and anorexia in patients with cancer cachexia



Ono Pharmaceutical announced today that ONO has submitted in Japan an application for manufacturing and marketing approval of anamorelin hydrochloride (ONO-7643) ("Anamorelin"), a ghrelin receptor agonist, for improvement of body weight loss and anorexia in patients with cancer cachexia.

This application is mainly based on the results from the following two studies conducted in Japan in patients with cancer cachexia:

1) Phase II multi-center, placebo controlled, randomized, double-blind, parallel group study in patients with non-small cell lung cancer (ONO-7643-04 study)

2) Phase III multi-center, open-label, uncontrolled study in patients with colorectal, gastric or pancreatic cancer (ONO-7643-05 study)

Cancer cachexia is a complex metabolic disorder syndrome, characterized by decreased body weight (especially decreased muscle mass) and anorexia associated with cancer. It has been known that cancer cachexia causes large disadvantages in patients' quality of life and prognosis. To date, an effective treatment method has not yet been established.

Anamorelin is a selective, novel, orally active ghrelin receptor agonist. Ghrelin is an endogenous peptide primarily secreted by the stomach. Upon binding to its receptor, ghrelin stimulates multiple pathways in the positive regulation of body weight, muscle mass, appetite and metabolism. Anamorelin has shown effects in increasing body weight and muscle mass, as well as appetite in patients with cancer cachexia and is expected to be the first treatment drug for this patient population.

In accordance with a license agreement in force with Helsinn Healthcare SA (a company of the Helsinn Group), ONO has exclusive rights to develop and commercialize Anamorelin in Japan, South Korea and Taiwan.