

November 27, 2018

**ONO Submits an Application for Manufacturing and Marketing Approval of Anamorelin (ONO-7643), a Ghrelin Receptor Agonist, for the Treatment of Cancer Cachexia in Japan**

Ono Pharmaceutical Co., Ltd. (Osaka, Japan, President and Representative Director: Gyo Sagara; “ONO”) 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.

**About the Helsinn Group**

Helsinn is a privately owned pharmaceutical group with an extensive portfolio of marketed cancer care products and a robust drug development pipeline. Since 1976, Helsinn has been improving the everyday lives of patients, guided by core family values of respect, integrity and quality. The Group works across pharmaceuticals, biotechnology, medical devices and nutritional supplements and has expertise in research, development, manufacture and the commercialization of therapeutic and supportive care products for cancer, pain and inflammation and gastroenterology. In 2016, Helsinn created the Helsinn Investment Fund to support early-stage investment opportunities in areas of unmet patient need. The company is headquartered in Lugano, Switzerland, with operating subsidiaries in Switzerland, Ireland, the U.S., Monaco, and China, as well as a product presence in approximately 190 countries globally. For more information, please visit [www.helsinn.com](http://www.helsinn.com).

Contact

ONO PHARMACEUTICAL CO., LTD.

Corporate Communications

[public\\_relations@ono.co.jp](mailto:public_relations@ono.co.jp)