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ONO Receives a Manufacturing and Marketing Approval of Adlumiz® (Anamorelin), a Ghrelin Receptor Agonist for the Treatment of Cancer Cachexia in Japan

Lugano, Switzerland, and Osaka, Japan, January 22, 2021 - Helsinn Group (Lugano, Switzerland; CEO: Riccardo Braglia, “Helsinn”) and Ono Pharmaceutical Co., Ltd. (Osaka, Japan; President and Representative Director: Gyo Sagara; “ONO”) announced today that ONO received the manufacturing and marketing approval of Adlumiz® (generic name: anamorelin hydrochloride) Tablet 50mg (“Adlumiz”), a ghrelin receptor agonist, for the treatment of cancer cachexia in malignant tumors of non-small cell lung cancer, gastric cancer, pancreatic cancer or colorectal cancer in Japan.

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

1. Phase II multi-center, randomized, double-blind, placebo-controlled, parallel group study in cancer cachexia patients with non-small cell lung cancer (ONO-7643-04)
2. Phase III multi-center, open-label, uncontrolled study in cancer cachexia patients with gastric, pancreatic or colorectal cancer (ONO-7643-05)

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 well documented that cancer cachexia causes a significant impact on patients’ quality of life and prognosis. To date, an effective treatment method for cancer cachexia 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.

Riccardo Braglia, Helsinn Group Vice Chairman and CEO commented: “We are delighted that Ono’s application has been successful for the treatment of cancer cachexia in Japan. This is an important milestone towards the improvement of the quality of life for all cancer cachexia patients, a condition that is still largely untreatable.”

Kiyoaki Idemitsu, Corporate Executive Officer and Executive Director, Clinical Development of ONO commented: “We are extremely pleased that Adlumiz has been approved for the indication of cancer cachexia in Japan. We believe that today’s approval can provide a promising new treatment option for the patients suffering from cancer cachexia for which there previously were no other approved treatment methods”.

Overview of Adlumiz® Tablet 50 mg

Product Name	Adlumiz® Tablet 50mg
Generic name (JAN)	Anamorelin hydrochloride
Indication	Cancer cachexia in the following malignant tumors: Non-small cell lung cancer, gastric cancer, pancreatic cancer and colorectal cancer
Dosage and administration	Usually, for adults, administer 100 mg of anamorelin hydrochloride at fasting state orally once a day
Manufacturer/distributor	Ono Pharmaceutical Co., Ltd.
Approval date	January 22, 2021
Conditions for approval	<ol style="list-style-type: none">1. Risk Management Plan should be designed and appropriately implemented.2. A post-marketing use-results survey covering all cases should be performed until data on a certain number of patients have been accumulated after the launch of the product in order to collect safety and efficacy data as early as possible and take measures necessary for the proper use of the product.

About the ONO and Helsinn Collaboration

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. Helsinn retains full rights in the rest of the world.

About Ono Pharmaceutical Co., Ltd.

Ono Pharmaceutical Co., Ltd., headquartered in Osaka, is an R&D-oriented pharmaceutical company committed to creating innovative medicines in specific areas. ONO focuses on the oncology, immunology, neurology and specialty research with high medical needs as priority areas toward discovery and development of innovative new drugs. For further information, please visit the company’s website at www.ono.co.jp/eng.

About the Helsinn Group

Helsinn is a privately-owned Swiss Pharma Company which, since 1976, has been improving the lives of patients, guided by core family values of respect, integrity and quality. The Group has an extensive portfolio of marketed innovative cancer and rare disease therapies, a robust drug development pipeline and ambitions to further accelerate its growth through in-licensing and acquisition to address unmet medical needs. Helsinn operates a unique integrated licensing business model, achieving success with over 80 long-standing partners in 190 countries, who share our values. The Group's pharmaceutical business (Helsinn Healthcare) is headquartered in Lugano, Switzerland with operating subsidiaries in the U.S. (Helsinn Therapeutics US) and China (Helsinn Pharmaceuticals China) which market the Group's products directly in these countries. The Group has additional operating subsidiaries in Switzerland (Helsinn Advanced Synthesis, an active pharmaceutical ingredient manufacturer) and Ireland (Helsinn Birex Pharmaceuticals, a drug product manufacturer). Helsinn Investment Fund was created to enhance the future of healthcare by providing funding and strategic support to innovative companies.

Helsinn Group plays an active and central role in promoting social transformation in favor of people and the environment. Corporate social responsibility is at the heart of everything we do which is reinforced in the company's strategic plan by a commitment to sustainable growth.

To learn more about Helsinn Group please visit www.helsinn.com

The press release has been prepared in compliance with the Japanese regulations.

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