

Helsinn Announces the Launch of Adlumiz[®] (anamorelin) for the Treatment of Cancer Cachexia in Japan

Lugano, Switzerland, April 21, 2021 – Helsinn, a Swiss pharmaceutical group focused on building quality cancer care and rare disease products, today announces the first launch of Adlumiz[®] (anamorelin) for the treatment of cancer cachexia in malignant non-small cell lung cancer, gastric cancer, pancreatic cancer and colorectal cancer in Japan, through its partner Ono Pharmaceutical.

Cancer cachexia is a complex metabolic disorder syndrome, characterized by decreased body weight (especially decreased muscle mass) and anorexia associated with cancer. This condition is a common complication of cancer, that can affect up to 80% of patients with advanced cancer. It has been well documented that cancer cachexia has a significant impact on patients' quality of life and prognosis. Adlumiz[®] (anamorelin), as approved by the Japanese Health Authorities, has shown efficacy in increasing body weight, muscle mass, as well as appetite in cancer cachexia patients. The risks identified in association with anamorelin are justified by the anticipated benefits that may be afforded to adult cancer patients.

Helsinn recently announced the approval of Adlumiz[®] (anamorelin) by the Japanese Minister of Health, Labour and Welfare based on results from two clinical studies conducted in Japan in patients with cancer cachexia in the following malignant tumors: non-small cell lung cancer, gastric cancer, pancreatic cancer, and colorectal cancer.

Ono Pharmaceutical, Helsinn's license partner, has exclusive rights to develop and commercialize the product in Japan, South Korea and Taiwan. Helsinn retains full rights in the rest of the world.

Development of anamorelin is ongoing internationally, through two phase III SCALA studies being conducted in the US, EU, Russia and Australia for adult patients with advanced non-small cell lung cancer for treatment of malignancy associated weight loss and anorexia. Further details on the two trials can be found on clinicaltrials.gov under:

- ANAM-17-20: <https://clinicaltrials.gov/ct2/show/NCT03743051>
- ANAM-17-21: <https://clinicaltrials.gov/ct2/show/NCT03743064>

Riccardo Braglia, Helsinn Group Vice Chairman and CEO commented: *“I am proud that we are able to announce the launch of Adlumiz[®] (anamorelin) in Japan, following the hard work and dedication of the Helsinn team around the world. We are pleased to be able to offer this important treatment to cancer patients in the region, in close collaboration with Ono Pharmaceutical.”*

Sergio Cantoreggi, Helsinn Group Chief Scientific Officer commented: *“We are thrilled to see the first commercial launch of Adlumiz[®] (anamorelin) in Japan and look forward to updating the market on the Phase III SCALA studies taking place in the US, EU, Russia and Australia which we hope will enable us to bring the treatment to more and more patients globally.”*

About Adlumiz[®] (anamorelin)

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.

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 acquisitions to address unmet medical needs. Helsinn operates a unique integrated licensing business model, achieving success with 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). 3B Future Health Fund (formerly known as 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

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 its research on the oncology, immunology, neurology and specialty research with high medical needs as priority areas for discovery and development of innovative medicines. For further information, please visit the company's website at www.ono-pharma.com/.

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