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Taiho Pharmaceutical Submits New Drug Application for NK₁ Receptor Antagonist Fosnetupitant for Prevention of Gastrointestinal Symptoms (Nausea and Vomiting) Associated with Cancer Chemotherapy

Lugano, Switzerland, March 23, 2021 – Helsinn Group (Lugano, Switzerland; CEO: Riccardo Braglia, “Helsinn”) is pleased to announce that its Japanese partner Taiho Pharmaceutical Co., Ltd. (hereinafter “Taiho”) announced today that it has submitted to the Japanese Ministry of Health, Labour and Welfare a new drug application for an NK₁ receptor antagonist antiemetic drug (development code: Pro-NETU; generic name: fosnetupitant chloride hydrochloride; hereinafter “fosnetupitant”) for gastrointestinal symptoms (nausea and vomiting) associated with cancer chemotherapy.

Fosnetupitant is an NK₁ receptor antagonist antiemetic drug developed for the prevention of chemotherapy-induced nausea and vomiting. It is a phosphorylated pro-drug preparation (injection) of netupitant, the active component. The prevention of chemotherapy-induced nausea and vomiting is considered important in clinical practice. Taiho acquired exclusive development and marketing rights for fosnetupitant in Japan under a license agreement signed in April 2011 with Helsinn Healthcare SA and has conducted clinical trials in Japan since then.

The new drug application is based on the results of a Phase III clinical trial comparing the efficacy and safety of fosnetupitant and fosaprepitant (NK₁ receptor antagonist) in patients receiving highly emetogenic chemotherapy. In the trial, either fosnetupitant (235 mg) or fosaprepitant (150 mg) was administered in a single I.V. dose prior to administration of the chemotherapeutic agent, in combination with palonosetron (5-HT₃ receptor antagonist) and dexamethasone. Details of the trial results will be presented at a future medical conference.

Within Taiho’s mainstay field of oncology, the company is also focusing on cancer supportive care. Under a former distribution and license agreement effective as of January 2004 with Helsinn Healthcare SA, Taiho has been marketing the 5-HT₃ receptor antagonist Aloxi® (generic name: palonosetron hydrochloride) in Japan since April 2010.

Taiho will work to secure approval of fosnetupitant, aiming to deliver the agent as soon as possible as a new treatment which can contribute to improving quality of life for patients, thereby contributing to comprehensive care in cancer.

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

About Taiho Pharmaceutical Co., Ltd. (Japan)

Taiho Pharmaceutical, a subsidiary of Otsuka Holdings Co., Ltd., is an R&D-driven specialty pharma company with a focus on oncology. Taiho Pharmaceutical also has development programs in allergy and immunology, urology and consumer healthcare products. Our corporate philosophy is simple: “We strive to improve human health and contribute to a society enriched by smiles.”

For more information about, please visit: <https://www.taiho.co.jp/en/>

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 long-standing partners in 190 countries, who share our values.

For more information, please visit: <https://www.helsinn.com/about-the-helsinn-group>

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