

## **HELSINN GROUP GRANTS STENDHAL INTERNATIONAL EXCLUSIVE RIGHTS TO THE DISTRIBUTION AND MARKETING OF NETUPITANT-PALONOSETRON (NEPA) IN MULTIPLE COUNTRIES OF LATIN AMERICA**

*The exclusive agreement strengthens the existing alliance between the companies in the area of supportive cancer care.*

**Lugano, Switzerland and Mexico City, Mexico, February 2, 2015** – Helsinn, the Swiss Group focused on building quality cancer care, and Especificos Stendhal S.A. (“Stendhal”), today announced that exclusive rights to NEPA, an oral fixed combination of netupitant and palonosetron developed for the prevention of chemotherapy-induced nausea and vomiting (CINV), have been granted to Stendhal for Mexico, Venezuela, Colombia, Perú, Ecuador and most of Central American countries.

NEPA is an oral fixed combination of a novel NK<sub>1</sub> receptor antagonist (netupitant) and the best-in-class 5-HT<sub>3</sub> receptor antagonist palonosetron, already approved in the USA with the trade name AKYNZEO<sup>®</sup> for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. NEPA is currently in the registration phase in Europe and will be soon submitted to other regulatory authorities in the territories included in the agreement between Helsinn and Stendhal, for the prevention of CINV.

One of the components of NEPA is palonosetron, the market-leading treatment for CINV in patients with cancer. Palonosetron worldwide sales in 2014 were around USD 649 million (IMS data). The product is marketed and available in over 65 countries worldwide under the brand names of Aloxi<sup>®</sup>, Onicit<sup>®</sup> and Paloxi<sup>®</sup>.

Under the terms of the new agreement, Helsinn retains all international regulatory and clinical development activities and the supply of NEPA for commercial use. Stendhal will be responsible for all distribution and marketing activities in the designated territories.

This commercial agreement builds on the previously signed agreement in the same territories for anamorelin, a novel, once-daily, ghrelin receptor agonist under investigation for the treatment of unintended weight loss in non small cell lung cancer (NSCLC) patients which recently announced promising Phase III trials results.

**Riccardo Braglia, CEO of Helsinn Group, said:** “Helsinn is delighted to sign this latest agreement with Stendhal, which enlarges the range of our joint work in cancer supportive care including now the chemotherapy-induced nausea and vomiting field. By having multiple agreements in place with the same partner, we are aiming to give to physicians a full range of available treatment options, to be provided by a single source for the benefit of the patients affected by the many side effects of cancer treatments. We look forward to working with Stendhal and building upon our already strong relationship.”

#### ***Notes to editors***

#### **About NEPA (Oral Netupitant 300 mg + Oral Palonosetron 0.50 mg)**

NEPA is a novel single-day oral fixed combination of a highly selective NK<sub>1</sub> receptor antagonist, netupitant, and a pharmacologically and clinically distinct 5-HT<sub>3</sub> receptor antagonist, palonosetron, targeting two signaling pathways associated with CINV.

#### ***About the Helsinn Group***

Helsinn is a family run, privately owned pharmaceutical group focused on building quality cancer care with a large portfolio of products. Founded in 1976 with headquarters in Lugano, Switzerland, Helsinn also has operating subsidiaries in Ireland, the USA and a representative office in China. Helsinn's business model is focused on the licensing of pharmaceuticals, medical devices and nutritional supplement products in the therapeutic area of cancer care.

Helsinn in-licenses early-to-late stage new chemical entities, completing their development by performing pre-clinical/clinical studies as well as associated manufacturing activities. Helsinn then prepares necessary regulatory filings in order to achieve marketing approvals worldwide. Helsinn's products are out-licensed to its global network of marketing and commercial partners that have been selected for their local market knowledge. Helsinn supports these partners by



providing a full range of product and scientific management services, including commercial, regulatory, and medical marketing advice. Helsinn has built a large product portfolio of cancer care products with the alliance of over 65 global partners. In March 2013, Helsinn established a new commercial organization within its subsidiary, Helsinn Therapeutics (U.S.), Inc., in order to conduct direct sales and marketing activities within the U.S. market. Helsinn's products are manufactured according to the highest quality, safety, and environmental standards at Helsinn's GMP facilities in Switzerland and Ireland from where they are then supplied worldwide to customers. Further information on Helsinn Group is available at [www.helsinn.com](http://www.helsinn.com)

#### **About Stendhal International**

Stendhal is a privately-held specialty pharmaceutical company based in Mexico City and operating in 14 countries in Latin America. Stendhal's business is developing strong partnerships and launching innovative branded products in the region in order to bring best-in-class products to patients in Latin America. Stendhal's success is based upon long-term partnerships with market leaders in the following therapeutic areas: HIV, Multiple Sclerosis, CNS, Genetic Disorders, Cardiovascular and Infectious Diseases and, most recently, Oncology. Stendhal is dedicated to being the best choice as a Latin American partner with expertise in local clinical trials, market access, regulatory strategy and commercialization in Latin America. Further information on Stendhal is available at <http://www.stendhalpharma.com>.

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