

Helsinn Group and Mundipharma announce the launch of AKYNZEO® hard capsule for oral use in Brazil

Lugano, Switzerland, and São Paulo, Brazil; May 18, 2018 – Helsinn, a Swiss pharmaceutical group focused on building quality cancer care products, and the Mundipharma network of independent associated companies, today announce the launch of AKYNZEO® hard capsule in Brazil.

AKYNZEO® is a fix combination anti-emetic therapy targeting both critical pathways of acute and delayed chemotherapy-induced nausea and vomiting (CINV). It showed High complete response rates were observed both in the cisplatin (with a rate of 90% in the overall phase (0-120 hours), primary endpoint of the study) and in the AC settings (with a rate around 77% in the delayed phase, 25-120 hours), primary endpoint of the study). Akynzeo® is recommended by all major antiemesis guidelines (ASCO, NCCN and MASCC/ESMO) as an option to prevent CINV.

CINV is one of the most common side effects of cancer chemotherapy. The prevention of CINV has significantly evolved over the past several decades. Currently the combination treatment of antiemetic medicines with different mechanisms of actions is recommended by the main international antiemetic guidelines for the prevention of CINV in most settings.

The safety profile of Akynzeo was evaluated in 1169 cancer patients receiving at least one cycle of highly emetogenic or moderately emetogenic cancer chemotherapies in three double blind, active-controlled studies. Common adverse reactions reported with Akynzeo were headache (3.6%), constipation (3.0%) and fatigue (1.2%). None of these events was serious (please refer to the professional product information approved in Brazil for Full Safety Information).

Mundipharma has exclusive marketing, promotion and sales of AKYNZEO® in Brazil. Besides Brazil, China, Hong Kong and Macao, Mundipharma also has distribution agreements in key markets in Asia-Pacific, the Middle-East and Africa.

Riccardo Braglia, Helsinn Group Vice Chairman and CEO, commented: “*Helsinn is committed to helping people with cancer live their lives to the full. AKYNZEO® has demonstrated compelling efficacy in helping patients manage the side-effects of cancer chemotherapy: it is the first and only combination anti-emetic therapy targeting at the same time two main CINV*

pathways, to achieve high complete response rates over five days in cancer chemotherapy-treated patients. We're delighted to be working with Mundipharma, a trusted partner, to bring this medicinal product to Brazil, a large market with a significant unmet need in cancer supportive care."

Hugo Saavedra, General Manager Mundipharma Brazil, commented: "Cancer is an increasing health burden in Brazil, and cancer supportive care is a major focus for Mundipharma, alongside our existing activities in oncology and pain. We're very keen to offer a more comprehensive package of cancer supportive care solutions and we are very pleased to be able to offer AKYNZEO® in this major market. Mundipharma and Helsinn have worked together in a number of territories and we are delighted to be partnering with Helsinn in Brazil."

Oral NEPA has been recommended by all major antiemetic guidelines: the National Comprehensive Cancer Network (NCCN) antiemetic guidelines, both in Highly Emetogenic Chemotherapy (HEC; inclusive of AC and carboplatin AUC \geq 4)) and Moderately Emetogenic Chemotherapy (MEC); the American Society for Clinical Oncology (ASCO) guidelines for antiemetics in oncology, in HEC, including AC, and carboplatin (AUC \geq 4) regimens and the MASCC/ESMO Guidelines in HEC, AC and carboplatin-based chemotherapy. Helsinn currently has 20 licensing partners for Akynzeo® in 167 countries.

About Akynzeo (netupitant/palonosetron)

AKNYZEO approval was granted by ANVISA on 26 December 2017. AKYNZEO® is indicated for adults in cases of prevention of acute or delayed nausea and vomiting associated with highly emetogenic cisplatin-based antineoplastic (for cancer) chemotherapy; prevention of acute or delayed nausea and vomiting associated with moderately emetogenic antineoplastic (for cancer) chemotherapy.

For additional information please see the [professional product information approved in Brazil](#).

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, and the U.S., Monaco and China, as well as a product presence in approximately 190 countries globally.

About the Mundipharma network

The Mundipharma global network of privately-owned independent associated companies was founded in 1956 by doctors, and now operates in over 120 countries worldwide. We are focused on developing business partnerships to identify and accelerate meaningful technology across an increasingly diverse portfolio of therapy areas including respiratory, oncology, pain, and biosimilars. Consistent with our entrepreneurial heritage, we like to think we see what others don't by challenging conventional wisdom and asking different and challenging questions. By working in partnership with all our stakeholders, the Mundipharma network develops medicines that create value for patients, payers and wider healthcare systems.

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Building quality cancer care together



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