

Helsinn and CJ Healthcare announce the approval of AKYNZEO® oral formulation in Korea

- *CINV is one of the most common and distressing side effects of cancer chemotherapy*
- *Included as a treatment option in the ASCO, NCCN and MASCC/ESMO antiemesis guidelines*

Lugano, Switzerland and Seoul, Republic of Korea, July 31, 2018 – Helsinn, a Swiss pharmaceutical group focused on building quality cancer care products, and CJ Healthcare announce that on June 28, 2018, the Korean Ministry of Food and Drug Safety (MFDS) approved the oral formulation of AKYNZEO® for use in Korea.

AKYNZEO® is approved for prevention of acute and delayed nausea and vomiting associated with highly emetogenic cancer chemotherapy and prevention of acute and delayed nausea and vomiting associated with moderately emetogenic cancer chemotherapy.

CJ Healthcare plans to launch the oral formulation of AKYNZEO® in Korea by the end of the year.

CINV is one of the most common and distressing side effects of cancer chemotherapy. The prevention of CINV 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.

AKYNZEO® is an oral fixed combination product, composed by a highly-selective NK₁ receptor antagonist, netupitant, and palonosetron, the pharmacologically and clinically distinct 5-HT₃ receptor antagonist which prevents nausea and vomiting during both the acute and delayed phase after cancer chemotherapy.

Riccardo Braglia, Helsinn Group Vice Chairman and CEO, commented: “Helsinn is committed to helping people live with the side effects of cancer in a way which allows them to get the best out of every day. AKYNZEO® has demonstrated compelling efficacy in helping patients manage the side-effects of cancer chemotherapy.”

“We’re delighted that the Korean Ministry of Food & Drug Safety has approved AKYNZEO®. We are also delighted to be working with CJ Healthcare, a trusted local partner who we believe will help us work to reach as many people as possible to help them to benefit from this new treatment option.”

Seok-Hee Kang, Chief Executive Officer of CJ HealthCare commented: “AKYNZEO® is able to offer significant benefits to patients in enabling them to manage the side effects of cancer chemotherapy and improve quality of life. We are delighted that it is now approved for use in Korea and look forward to working with Helsinn to bring this to more of the patients who need it, and to consolidate our strong market position in supportive care products in Korea.”

CJ HealthCare licensed AKYNZEO® from Helsinn in 2012.

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About AKYNZEO® (netupitant/palonosetron)

In the EU:

AKYNZEO® (netupitant 300mg/palonosetron 0.5mg) capsules for oral use was approved in May 2015 in the EU. Akynzeo oral is indicated in the EU for adults for the prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy and moderately emetogenic cancer chemotherapy.

For additional information please see the [EU Summary of Product Characteristics](#)

Oral netupitant combined with oral palonosetron (NEPA) has been recommended by various international antiemetic guidelines: the National Comprehensive Cancer Network (NCCN) antiemetic guidelines, both in Highly Emetogenic Chemotherapy (HEC; inclusive of AC and carboplatin AUC≥4) and in Moderately Emetogenic Chemotherapy (MEC) for selected patients with additional risk factors or who have failed previous cycles of CINV prevention with steroid plus setron; the American Society for Clinical Oncology (ASCO) guidelines, in HEC, including AC, and carboplatin (AUC≥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 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, the U.S., Monaco, and China, as well as a product presence in approximately 190 countries globally.

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

About CJ Healthcare

CJ HealthCare started its business as a Medicines Division for CJ CheilJedang in 1984 and established itself as a company based on its three decades of know-how about pharmaceutical business. CJ HealthCare, which launched as a professional pharmaceutical subsidiary of CJ Group on April 1, 2014 and became Kolmar Group on April 18, 2018.

CJ HealthCare, as one of representative Korean pharmaceutical companies, discovers, develops, manufactures and markets mainly prescription drugs, active ingredients and Health & Beauty products. CJ is preparing for the future through its active investment in R&D and Open Innovation from innovative new drugs, biopharmaceuticals and incremental new drug.

Please visit www.cjp.co.kr

For more information:

Helsinn Group Media Contact

Paola Bonvicini

Group Head of Communication

Lugano, Switzerland

Tel: +41 (0) 91 985 21 21

Info-hhc@helsinn.com

For more information, please visit www.helsinn.com and follow us on [Twitter](#), [LinkedIn](#) and [Vimeo](#).

CJ Healthcare Media Contact

SeoungPhil SHIN

Seoul, KOREA

Tel: +82 - 2 - 6477 - 0121

E-mail: sp.shin@cj.net