

Helsinn Group and Glenmark Pharmaceuticals enter into an exclusive licensing agreement for launch of AKYNZEO® in India and Nepal

- AKYNZEO®, containing netupitant 300mg and palonosetron 0.5mg, is used for prevention of chemotherapy-induced nausea and vomiting (CINV)
- The licensing agreement with Glenmark for AKYNZEO® represents Helsinn's first such agreement in India

Lugano, Switzerland; Mumbai, India; April 4, 2018: Helsinn Group ("Helsinn"), a Swiss pharmaceutical group focused on building quality cancer care products, and Glenmark Pharmaceuticals Ltd, a research-led global integrated pharmaceutical company, are pleased to announce that they have entered into an exclusive licensing agreement to introduce AKYNZEO® in India and Nepal.

AKYNZEO®, an oral fixed combination of netupitant 300mg and palonosetron 0.5mg in capsule form, is used for prevention of chemotherapy-induced nausea and vomiting (CINV). The licensing agreement with Glenmark for AKYNZEO® represents Helsinn's first such agreement in India. Glenmark will have exclusive marketing rights for AKYNZEO® in India and Nepal.

Glenmark has received marketing approval for AKYNZEO® from the Central Drugs Standard Control Organization (CDSCO).

AKYNZEO® is the first and only combination anti-emetic prophylaxis with high complete response rates for five days in cancer chemotherapy treated patients, having demonstrated 90% complete response rates through five days compared to 77% for oral palonosetron in patients receiving HEC cisplatin-based chemotherapy. It has been included among the recommended options in the MASCC/ESMO, ASCO and NCCN antiemesis guidelines. Delayed nausea is still a problem for up to 82% of patients receiving MEC (Moderately Emetogenic Chemotherapy) and HEC (Highly Emetogenic Chemotherapy), representing a significant unmet medical need.

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 SmPC (Summary of Product Characteristics) for Full Safety Information).

AKYNZEO® was developed by Helsinn and it is currently marketed in EU, in the U.S., and several other leading markets of the world.

Andrea Meoli, Helsinn Group Chief Commercial Officer, commented: “We are excited to begin our first collaboration agreement in India with our new partner Glenmark Pharmaceuticals. Glenmark’s renowned expertise in sales, marketing and distribution in this region will mean that AKYNZEO®, a key anti-emetic product, will be made available to more patients suffering from the side effects of cancer treatment in the important markets of India and Nepal.”

“We are happy to partner with Helsinn, a leader in cancer supportive care. AKYNZEO® will help Indian patients undergoing chemotherapy and struggling to manage CINV to address this issue in a much better manner. I am sure the launch of AKYNZEO® will fortify our presence in oncology, which is a key therapeutic focus area for the company,” **said Sujesh Vasudevan, President – India Formulations, Middle East and Africa at Glenmark.**

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 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 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 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 Glenmark Pharmaceuticals Ltd:

Glenmark Pharmaceuticals Ltd. (GPL) is a research-driven, global, integrated pharmaceutical organization. It is ranked among the top 75 Pharma & Biotech companies of the world in terms of revenue (SCRIP 100 Rankings published in the year 2017). Glenmark is a leading player in the discovery of new molecules both NCEs (new chemical entity) and NBEs (new biological entity). Glenmark has several molecules in various stages of clinical development and is focused in the areas of oncology, dermatology and respiratory.

The company has a significant presence in the branded generics markets across emerging economies including India. Glenmark has 16 manufacturing facilities across five countries and has six R&D centers. The Generics business of Glenmark services the requirements of the US and Western European markets. The API business sells its products in over 80 countries,

including the US, various countries in the EU, South America and India.

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