

Helsinn Group Grants Exclusive Licensing Rights to Berlin-Chemie AG, a company of the Menarini Group, for ONICIT[®]/ALOXI[®] and AKYNZEO[®] in Russia and CIS region

- Berlin-Chemie AG has been granted exclusive rights to import, distribute, promote, market and sell AKYNZEO[®] and ONICIT[®] (ALOXI[®]) in Russia and CIS region from January 2020
- The two products will provide clinicians and patients with a comprehensive offering to manage chemotherapy-induced nausea and vomiting

Lugano, Switzerland and Berlin, Germany, January 27, 2020: Helsinn Group (“Helsinn”), a Swiss pharmaceutical group focused on building quality cancer care products, has granted exclusive licensing rights to commercialize AKYNZEO[®] and ONICIT[®] (ALOXI[®]) in Russia and the CIS region for the prevention of chemotherapy-induced nausea and vomiting (CINV) to Berlin-Chemie AG (“Berlin-Chemie”), the German-based affiliate of the Menarini Group.

AKYNZEO[®], a fixed dose combination anti-emetic therapy targeting both critical pathways of acute and delayed CINV, was granted registration in Russia in October 2019 and the product will be launched in the country in 2020.

ONICIT[®], an anti-emetic for the prevention of CINV, was registered in Russia in 2011 and will be relaunched with AKYNZEO[®].

Besides Russia, the licensing agreements with Berlin-Chemie cover the following territories: Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Turkmenistan, Ukraine and Uzbekistan. AKYNZEO[®] has obtained a registration in Ukraine and Kazakhstan while ALOXI[®] holds a registration in Ukraine.

Under the terms of the agreements, Helsinn will retain all international development rights, including clinical development activities, and the supply of AKYNZEO[®] and ONICIT[®]/ALOXI[®]. Berlin-Chemie will have the exclusive rights to promote, distribute and commercialize AKYNZEO[®] and ONICIT[®]/ALOXI[®] in all countries of the assigned territories.

Riccardo Braglia, Helsinn Group Vice Chairman and CEO commented: “We’re delighted to have signed these agreements with Berlin-Chemie, which has established a strong presence and recognition in Russia and the CIS region. We look forward to being able to offer cancer patients greater choice for treating CINV, which remains a major issue during chemotherapy.”

“This is an important step for cancer patients across Russia and the CIS region. We look forward to working closely with Helsinn as we seek to launch AKYNZEO® and re-launch ONICIT® in the year ahead. We have been impressed by Helsinn’s commitment to the highest quality cancer care products and are pleased to extend our partnership with them.” **said Michael Sirotovitch, COO of Berlin-Chemie AG.**

ENDS

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 over 100 countries.

About ONICIT®/ALOXI® (palonosetron HCl)

ONICIT®/ALOXI® injection 0.25 mg/5 is used in adults to help prevent nausea and vomiting on the day of chemotherapy that is highly likely to cause nausea and vomiting, and up to five days following chemotherapy that is moderately likely to cause nausea and vomiting.

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

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 BERLIN-CHEMIE AG and the MENARINI Group

BERLIN-CHEMIE AG is a subsidiary of the MENARINI Group, the leading pharmaceutical company in Italy with an annual revenue of more than 3.6 billion euros and more than 17,000 employees worldwide. This puts the Group in 13th place out of 5,345 companies in Europe and 36th out of 21,587 companies worldwide (Source: IQVIA). The MENARINI Group has always pursued two strategic objectives: research and internationalization, and has a strong commitment to oncology research and development. As part of such commitment to oncology, MENARINI, is developing four investigational new oncological drugs. Two of them are biologics, namely the anti CD157 antibody MEN1112, and the toxin-conjugated, anti CD205

antibody MEN1309. In addition, MENARINI has recently added two small molecules to its oncology pipeline, the dual PIM and FLT3 kinase inhibitor MEN1703, and the PI3K inhibitor MEN1611, in clinical development for the treatment of a variety of hematological and/or solid tumors. MENARINI is active commercially in the most important therapeutic areas with products for cardiology, gastroenterology, pneumology, infectious diseases, diabetology, inflammation, and analgesia.

With 16 production sites and 7 Research and Development centers, the MENARINI Group has a strong presence throughout Europe and Asia, Africa, Central and South America. MENARINI Group products are available in 136 countries worldwide. For further information: www.menarini.com

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