Swissmedic approves ALOXI® for use in the Prevention of Chemotherapy Induced Nausea and Vomiting (CINV) in Children in Switzerland

- *Swiss approval of ALOXI® for paediatric use follows EMA approval in February 2015 and FDA approval in May 2014* -

Lugano and Villars-sur-Glâne, Switzerland, October 25th, 2016: Helsinn, the Swiss pharmaceutical Group focused on building quality cancer care, and Vifor Pharma, announced today that Swissmedic, the Swiss Agency For Therapeutic Products, has approved ALOXI®, an anti-nausea therapeutic medicine for the prevention of acute nausea and vomiting associated with highly emetogenic cancer chemotherapy and the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy, in paediatric patients one month of age and older. The approval was granted on 19 August 2016.

This is the first Swiss approval of a therapy for the prevention of acute chemotherapy-induced nausea and vomiting (CINV) in children aged one to six months, providing an important new therapeutic option to young infants undergoing cancer therapy in Switzerland, which is critical since childhood cancer incidence tends to be higher within the first years of life. ALOXI® is also indicated for children up to 17 years of age through this approval.

CINV is among the most common side effects following therapy in patients with cancer. In clinical trials in paediatric patients, CINV frequency varied from 35 to 80 percent depending on the age of the patient, the site of the tumour and the type of chemotherapy given. Helsinn has conducted four paediatric clinical trials with ALOXI®.

The approval of the paediatric indication is based on a randomized, double-blind, non-inferiority pivotal trial (n=502) comparing single-dose intravenous (IV) ALOXI® 20 µg/kg given 30 minutes prior to chemotherapy to a standard of care IV ondansetron regimen of 0.15 mg/kg given 30 minutes prior to chemotherapy followed by ondansetron infusions four and eight hours after the first dose. Within the first 24 hours after chemotherapy, Complete Response, defined as no vomiting, no retching and no antiemetic rescue medication, was achieved in 59 percent of

patients in both groups: those that received ALOXI® 20 µg/kg and those that received the ondansetron regimen.
Treatment-emergent adverse events (TEAEs) were comparable across both treatments, with headache being the most frequent event in the palonosetron group. Although paediatric patients were administered a higher dose per kg than adults to prevent CINV, palonosetron safety profile was consistent with its established profile in adults.

Giorgio Calderari, Helsinn Group General Manager, commented: "Approval of ALOXI® for the prevention of acute nausea and vomiting in children aged one month or more by Swissmedic opens new treatment options for infants with cancer. Helsinn is a world leader in cancer supportive care and we are pleased that, alongside our partner Vifor Pharma, we are now able to provide a critical cancer supportive care solution to young and vulnerable children suffering from the side effects of cancer treatment, in our home market."

Josef Troxler, General Manager Vifor Pharma Switzerland and Austria, said: "With this new indication, ALOXI® covers an unmet medical need which will allow healthcare professionals to better control chemotherapy induced nausea and vomiting. Young infants and children will benefit from the efficacy of a leading medication in its home market of Switzerland. Supportive care is a key focus for both Vifor Pharma and the Helsinn Group, and thriving to excellency in this domain is our common goal.

About the Helsinn Group

Helsinn is a privately owned cancer supportive care pharmaceutical group with an extensive portfolio of marketed products and a broad development pipeline. Since 1976, Helsinn has been improving the everyday lives of patients, guided by core family values of respect, integrity and quality, through a unique integrated licensing business model working with long standing partners in pharmaceuticals, medical devices and nutritional supplement products. Helsinn is headquartered in Lugano, Switzerland, with operating subsidiaries in Ireland and the US, a representative office in China, as well as a product presence in about 90 countries globally.

For more information, please visit www.helsinn.com.

About Vifor Pharma

Vifor Pharma, a company of the Galenica Group, is a world leader in the discovery, development, manufacturing and marketing of pharmaceutical products for the treatment of iron deficiency. The company also offers a diversified portfolio of prescription medicines. Vifor Pharma, headquartered in Zurich, Switzerland, has an increasingly global presence and a broad network of affiliates and partners around the world. The Swiss affiliate is located in Villars-sur-Glâne (Canton Fribourg).
For more information about Vifor Pharma and its parent company Galenica, please visit www.viforpharma.com – www.viforpharma.ch and www.galenica.com.

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