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## **Helsinn and Riemser Extend Relationship in Germany / License Agreement for Germany on New Therapy in Development for the Prevention of Chemotherapy-induced Nausea and Vomiting (CINV)**

*Germany (ots) -*

Helsinn Healthcare SA, Switzerland and Riemser Arzneimittel AG, German licensee of Helsinn's second generation 5-HT<sub>3</sub> receptor antagonist palonosetron, announce today the signing of a licensing agreement granting Riemser the commercialization rights for a next-generation treatment in development by Helsinn for the prevention of chemotherapy-induced nausea and vomiting (CINV) in Germany. The new product is a fixed-dose combination (in both oral and IV forms) containing netupitant, a neurokinin-1 (NK1) receptor antagonist, and palonosetron.

Under the terms of the agreement, Helsinn will be responsible for all development activities (CMC, preclinical and clinical), obtaining regulatory approvals, and holding the New Drug Application. Helsinn will also be responsible for the supply of the product for commercial use in Germany. "Since Helsinn decided to concentrate R&D efforts in the oncology field, and in particular in the cancer supportive care arena an important yet underserved area, we have always been very attentive to choose partners which shared our same vision: building pharmaceuticals and shaping alliances dedicated to the quality of life of the patient," Riccardo Braglia, CEO of Helsinn group, said. "We are very proud of having further reinforced this successful collaboration with our German partner Riemser", he concluded.

"We are very pleased that we can expand our excellent partnership with Helsinn for this promising new fixed-combination product which will further strengthen our franchise in the area of supportive oncology. This is a key milestone for us in executing our strategy as a growing specialty pharmaceutical company", said Michael Mehler, CEO of Riemser Arzneimittel AG. "We are very grateful to collaborate with an outstanding partner such as Helsinn to bring an innovative medicine to the market that will help to alleviate the tremendous burden of cancer patients" he added.

### About Netupitant

Netupitant is a highly selective NK1 receptor antagonist, an antiemetic that works by blocking the action of Substance P, an endogenous neurotransmitter contained in high concentrations in the vomiting center of the brainstem that can stimulate the vomiting reflex. The fixed-dose combination of netupitant and palonosetron is entering Phase III for the prevention of acute and delayed nausea and vomiting following both highly and moderately emetogenic chemotherapy.

### About Palonosetron (Aloxi<sup>®</sup>, Onicit<sup>®</sup>, Paloxi<sup>®</sup>)

Palonosetron (palonosetron hydrochloride) is a second generation 5-HT<sub>3</sub> Receptor Antagonist, developed for the prevention of chemotherapy-induced nausea and vomiting (CINV) in patients with cancer, with a long half-life of 40 hours and at least 30 times higher receptor binding affinity than currently available compounds. Palonosetron demonstrates, in clinical trials and clinical practice, a unique long-lasting action in the prevention of CINV. A single intravenous dose of palonosetron provides better protection from CINV than first-generation 5-HT<sub>3</sub> receptor antagonists.

Palonosetron is contraindicated in patients known to have hypersensitivity to the drug or any of its components. The most commonly reported adverse reactions (incidence greater-than-or-equal 2 percent) in CINV trials with palonosetron were headache (9 percent) and constipation (5 percent), and they were similar to the comparators. Palonosetron has been developed by the Helsinn Group in Switzerland and today it is marketed as Aloxi<sup>®</sup>, Onicit<sup>®</sup>, and Paloxi<sup>®</sup> in more than 60 countries world-wide. Palonosetron, marketed as Aloxi<sup>®</sup>, is the leading brand in the USA within the CINV Day of Chemo segment, and it is steadily growing in the European markets.

For more information about palonosetron, please visit the website:  
[www.aloxi.com](http://www.aloxi.com)

### About the Helsinn Group

Helsinn is a privately owned pharmaceutical group with headquarters in Lugano, Switzerland, and operating subsidiaries in Ireland and USA. Helsinn's business model is focused on the licensing of pharmaceuticals and

medical devices in therapeutic niche areas. The Group in-licenses early to late stage new chemical entities, completes their development from the performance of pre- clinical/clinical studies and Chemistry, Manufacturing and Control (CMC), development to the filing for and attainment of their market approval worldwide. Helsinn's products are sold directly through the Group's subsidiaries or out-licensed to its network of local marketing and commercial partners, selected for their deep in-market knowledge and know-how, and assisted and supported with a full range of product and scientific management services, including commercial, regulatory, financial, legal and medical marketing advice. The active pharmaceutical ingredients and the finished dosage forms are manufactured at Helsinn's cGMP facilities in Switzerland and Ireland, and supplied worldwide to its customers. For more information about Helsinn Group, please visit the website: [www.helsinn.com](http://www.helsinn.com)

About Riemser Arzneimittel AG: A company with a tradition and a future

Riemser Arzneimittel AG with headquarters in Greifswald, Germany, is a mid-sized specialty pharmaceutical company which markets and distributes its products in Germany and 72 countries worldwide. Riemser focuses mainly on human prescription-only medicines in selected therapeutic niches with high medical need.

Core therapeutic areas cover supportive oncology, anti-infectives and dermatology. In its dental group Riemser provides solutions for oral regenerative, oral implant and oral healing medicine. For further information please contact: [www.riemser.com](http://www.riemser.com)

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