

SUCCESSFUL INSPECTION OF HELSINN BIREX PHARMACEUTICALS DUBLIN, IRELAND BY THE US FOOD AND DRUG ADMINISTRATION

Dublin, Ireland, July 22nd, 2008 – Helsinn is pleased to announce that Helsinn Birex Pharmaceuticals, its drug facility in Dublin Ireland, has undergone a successful inspection by the US Food and Drug Administration (FDA) without any Form 483 observations. The FDA visit, which lasted 5 days, was a pre-approval inspection related to Helsinn’s supplemental New Drug Application (sNDA) for the softgel form of Palonosetron which is currently under review by the FDA, and also a general Good Manufacturing Practice (GMP) inspection relating to all products supplied to the US market. “We are very pleased with this outcome which confirms the ongoing high standards of Good Manufacturing Practice (cGMP) compliance at the company, its management and staff as well as the investment in high quality facilities and systems by Helsinn”, said Dr. Riccardo Braglia, CEO.

Helsinn Birex Pharmaceuticals is the Drug Product manufacturing and supply services subsidiary of the Helsinn Group producing

finished pharmaceuticals for Helsinn’s partners globally and managing the outsourcing of specialist dosage forms for existing and new products. The Company, originally established in 1982, employs more than 140 people and has been in operation in its current facility since 1997. The main products supplied from Helsinn Birex Pharmaceuticals are Nimesulide (non steroidal anti-inflammatory), Palonosetron (anti-emetic) and Klean-Prep[®] (a gastro intestinal lavage). In 2007 it completed the construction of a 2500 sq m extension of the existing premises to accommodate new additional temperature controlled warehouse space, employee facilities, new office and plant services space as well as additional production capacity. To date Helsinn has invested over €10 million in facilities and equipment for the production of the various Palonosetron product lines.



About HELSINN HEALTHCARE SA

HELSINN HEALTHCARE SA is a privately owned pharmaceutical group with headquarters in Switzerland and is the worldwide licensor of palonosetron. HELSINN's core business is the licensing of pharmaceuticals in therapeutic niche areas. The company's business strategy is to in-license early stage new chemical entities and complete their development from the performance of pre-clinical/clinical studies and CMC development to the attainment of market approvals in strategic markets (U.S. and Europe). HELSINN's products are eventually out-licensed to its marketing partners for distribution. The active pharmaceutical ingredients and the finished dosage forms are manufactured at HELSINN's cGMP facilities and supplied worldwide to its customers. For more information about HELSINN, please visit the company's Web site at www.helsinn.com.

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