Helsinn and Zealand announce the advance of elsiglutide into Phase IIB development for the prevention of chemotherapy-induced diarrhea

- **Elsiglutide is a GLP-2 receptor agonist with potential as a first-ever therapy to help cancer patients avoid a serious and life-threatening condition**
- **The first patients have been treated in this Phase IIB dose-finding trial and study results are expected in H1 2016**

Lugano, Switzerland and Copenhagen, Denmark, February 5, 2015 – Helsinn Healthcare S.A. ("Helsinn") and Zealand Pharma A/S ("Zealand") (Nasdaq Copenhagen: ZEAL) jointly announce that Helsinn has started a Phase IIB clinical dose-finding trial of elsiglutide for the prevention of chemotherapy-induced diarrhea (CID). The first patients out of a planned total of 600 patients with colorectal cancer treated with chemotherapy have been dosed in the trial.

Elsiglutide is a novel GLP-2 peptide receptor agonist invented by Zealand. Global development and commercial rights to elsiglutide for its use in cancer supportive care outside the Nordic countries are licensed to Helsinn.

Many cancer patients who receive chemotherapy, in particular 5-fluorouracil (5-FU)-based regimens such as FOLFOX and FOLFIRI, suffer from severe diarrhea induced by damage to their intestines caused by the chemotherapy. The condition can lead to dehydration, hospitalization, sub-optimal cancer treatment and markedly reduced quality-of-life for the patients. 5-FU based chemotherapy regimens are used in particular to treat colorectal, head and neck as well as breast cancers.

In Phase I and Phase IIA clinical trials, elsiglutide demonstrated favorable results in the prevention of diarrhea in colorectal cancer patients receiving chemotherapy and a good safety profile. In pre-clinical studies, elsiglutide has been shown to consistently stimulate growth of the small intestinal mucosa and decrease the incidence and severity of CID, in addition to improving bowel function, which supports its potential use in the treatment of gastro-intestinal disorders. Currently, no effective treatment exists for CID.

Riccardo Braglia, Chief Executive Officer of Helsinn, said: *"Chemotherapy-induced diarrhea is a debilitating side-effect of chemotherapy which significantly impacts on the ability of patients to benefit from cancer treatment regimens. It is a significant area of unmet need in the treatment of cancer. Helsinn is committed to supporting patients with the highest-quality cancer supportive care treatments, and elsiglutide has shown strong promise in preclinical and early clinical studies. We are excited to be advancing this product into the next phase of its development."*

Britt Meelby Jensen, President and Chief Executive Officer of Zealand, commented: *"The advance of elsiglutide into Phase IIB development is an important milestone for Zealand, as it adds further to the progress and potential in our portfolio of proprietary and partnered novel therapeutics. Helsinn has a world leading position in cancer supportive care and, if the beneficial effects seen with elsiglutide can be confirmed, it opens important new treatment options for cancer patients of not only relieving a serious side-effect but also of providing a more effective cancer treatment."*

Elsiglutide Phase IIB design and development status

The Phase IIB trial with elsiglutide is a randomized, double-blind, parallel group, placebo-controlled, dose finding study, which is planned to enroll up to 600 colorectal cancer patients receiving 5-FU-based chemotherapy regimens (FOLFOX or FOLFIRI). The trial includes a subgroup of 120 patients who will be treated also with an approved monoclonal antibody. The study objective is to assess the efficacy of three different doses of subcutaneous elsiglutide versus placebo in the prevention of CID. The primary endpoint is the proportion of patients experiencing diarrhea of grade 2 or more during the first cycle of 5-FU based chemotherapy. The results of the Phase IIB trial are expected to be available in the first half of 2016.

Helsinn is also conducting a large international, multi-center, prospective, cohort observational study involving more than a hundred sites in six European countries and in the United States to better understand the incidence and clinical impact of chemotherapy-induced diarrhea in colorectal and breast cancer patients.

Results from the Phase IIB trial together with the outcomes of the observational study will help shape the design of a potential Phase III pivotal development program for elsiglutide.

About the Helsinn Group

Helsinn is a family run, privately owned pharmaceutical group focused on building quality cancer care with a large portfolio of products. Founded in 1976 with headquarters in Lugano, Switzerland, Helsinn also has operating subsidiaries in Ireland, the United States and a representative office in China. Helsinn's business model is focused on the licensing of pharmaceuticals, medical devices and nutritional supplement products in the therapeutic area of cancer care.

Helsinn Group in-licenses early-to-late stage new chemical entities, completing their development by performing preclinical and clinical studies and associated manufacturing activities. Helsinn then prepares necessary regulatory filings in order to achieve marketing approvals worldwide. Helsinn's products are out-licensed to its global network of marketing and commercial partners that have been selected for their local market knowledge. Helsinn supports these partners by providing a full range of product and scientific management services, including commercial, regulatory, and medical marketing advice. In March 2013, Helsinn established a new commercial organization within its subsidiary, Helsinn Therapeutics (U.S.), Inc., in order to conduct direct sales and marketing activities within the U.S. market. Helsinn's products are manufactured according to the highest quality, safety, and environmental standards at Helsinn's GMP facilities in Switzerland and Ireland from where they are then supplied worldwide to customers.

Further information on Helsinn Group is available at www.helsinn.com

About Zealand Pharma A/S

Zealand Pharma A/S ("Zealand") (Nasdaq Copenhagen: ZEAL) is a biotechnology company based in Copenhagen, Denmark. Zealand has leading expertise in the discovery, design and development of novel peptide medicines and possesses in-house competences in clinical trial design and management with a therapeutic focus on metabolic diseases and acute care indications. The company is advancing a proprietary pipeline of novel medicines alongside a partnered product and development portfolio.

Zealand's first invented medicine, lixisenatide, a once-daily prandial GLP-1 agonist for the treatment of Type 2 diabetes, is marketed globally (ex-US) as Lyxumia® and in Phase III development as a single-injection combination with Lantus® (LixiLan), both under a global license agreement with Sanofi. US regulatory filings for both products are planned for 2015 ─ summer for Lyxumia® and as early as end 2015 for LixiLan.

Zealand proprietary pipeline includes danegaptide (prevention of Ischemic Reperfusion Injury) and the stable glucagon product, ZP4207 (treatment of severe hypoglycemia) as well as several preclinical peptide therapeutics. Partnering represents an important component of strategy to leverage in-house expertise, share development risk in large clinical trials, provide funding and commercialize the company's products. Zealand currently has global license agreements and partnerships with Sanofi, Helsinn Healthcare, Boehringer Ingelheim and Eli Lilly.

Further information: www.zealandpharma.com

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