



Company Announcement No. 15/2013

Zealand and Helsinn announce Helsinn's decision to advance the development of elsiglutide into Phase IIb for the prevention of chemotherapy-induced diarrhea

 The decision follows promising findings from a Phase IIa Proof-of-Concept study

— Helsinn is planning a Phase IIb study with elsiglutide, and study activities are expected to start in H2 2013

Copenhagen, Denmark and Lugano, Switzerland – 28 May 2013 – Zealand Pharma A/S (NASDAQ OMX Copenhagen: ZEAL) ("Zealand") and its partner, the Swiss pharmaceutical group Helsinn, a leading player in the cancer supportive care area, jointly announce that Helsinn has concluded a Phase IIa study with elsiglutide for the prevention of chemotherapy-induced diarrhea in cancer patients, with positive results. Elsiglutide is a potent and selective glucagon-like-peptide-2 (GLP-2) receptor agonist invented by Zealand and licensed to Helsinn for the development and use in cancer supportive care.

In a randomized, double-blind, placebo-controlled Proof-of-Concept Phase IIa clinical study, Helsinn has assessed the efficacy and safety of elsiglutide for the prevention of chemotherapy-induced diarrhea. The study was conducted under an open Initial New Drug (IND) application with the U.S. Food and Drug Agency in 19 European centers and enrolled 138 colorectal cancer patients. The patients were treated with 5-fluorouracil (5-FU) based chemotherapy (ClinicalTrials.gov Identifier: NCT01543451). Concurrently, Helsinn has completed a Phase Ib study, showing that elsiglutide is safe and tolerated at doses well above expectable therapeutic level.

Based on the results from the proof-of-concept study, Helsinn is now planning a Phase IIb study to further evaluate the efficacy of elsiglutide as a novel therapy to prevent chemotherapy induced diarrhea in cancer patients.

In a comment to the news, **David Solomon, President and Chief Executive Officer of Zealand, said:** "We are highly encouraged by the important progress our partner Helsinn is making with elsiglutide. Helsinn has a strong position in Cancer Supportive Care, and the promising findings from the Proof-of-Concept study leave further support for the potential of

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this Zealand invented peptide drug candidate as a novel preventative therapy that may offer cancer patients relief from chemotherapy induced diarrhea. Diarrhea is a common and in many cases severe complication of chemotherapy, resulting in reduced quality of life, dehydration, hospitalization and in some cases non-optimal cancer treatment. We look forward to seeing elsiglutide be advanced to the next step in its development."

Riccardo Braglia, Chief Executive Officer of Helsinn Group, commented: "We are pleased of the promising advance of elsiglutide in an underserved medical area. The overall positive outcome of this Phase IIa clinical study is an important milestone in the development of an effective treatment for chemotherapy-induced diarrhea, a debilitating and potentially life threatening side effect of chemotherapy. This is another step forward in Helsinn's commitment to working not only to improve the health of the Patient but to improve and maintain the overall quality of life of the Person."

Terms of the agreement with Helsinn and Financial outlook for 2013

Under the agreement with Helsinn, Zealand is eligible to milestone payments of up to EUR 140 million in total, (of which EUR 14 million have been received) on elsiglutide plus royalties on global sales of the product. Zealand retains an option to obtain commercial rights to elsiglutide in the Nordic countries.

The promising results of Phase IIa and Helsinn's decision to advance elsiglutide into Phase IIb development are not associated with a milestone payment and thus do not change Zealand's financial outlook for 2013 as announced in the company's Q1 2013 Interim report on 15 May 2013.

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About Elsiglutide

Elsiglutide is a novel, potent and selective glucagon-like-peptide-2 (GLP-2) agonist. GLP-2 is a peptide hormone produced primarily by the small intestine. It is secreted in response to food ingestion and acts by binding to the GLP-2 receptor, which is predominantly found in the gastrointestinal tract. GLP-2 plays a key role in intestinal growth and formation by promoting regeneration of the epithelial surface in this indication damaged by chemotherapy, the underlying cause of chemotherapy-induced diarrhea.

About Chemotherapy Induced Diarrhea

Diarrhea is one of the most common side effects of cancer treatment, resulting in significantly reduced patient's quality of life and can have a profound effect on patient's compliance with chemotherapy regimens and schedules leading even, in the most severe cases, to discontinuation of therapy and death.

The incidence and severity of Chemotherapy Induced Diarrhea (CID) varies considerably with the nature and dose of the cytotoxic therapy, with regimens containing Irinotecan and 5-fluorouracil (5-FU) being associated with rates as high as 80%. Current pharmacologic treatments are palliative at best and help to control and treat symptoms rather than to prevent the onset of diarrhea.

About Helsinn Group

Helsinn is a privately owned pharmaceutical group with headquarters in Lugano, Switzerland, 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 therapeutic niche areas. Helsinn is an important player in cancer supportive care. Helsinn Group in-licenses early-to-late stage new chemical entities, completes their development through the performance of pre-clinical/clinical studies and Chemistry, Manufacturing, and Control (CMC) development, and files and attains their market approvals worldwide. Helsinn's products are out-licensed to its network of local marketing and commercial partners, selected for their deep in-market knowledge and know-how whom Helsinn assists and supports by providing 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 products are manufactured according to the highest quality, safety, and environmental standards at Helsinn's GMP facilities in Switzerland and Ireland and supplied worldwide to its customers.

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

About Zealand

Zealand Pharma A/S (NASDAQ OMX Copenhagen: ZEAL) ("Zealand") is a biotechnology company based in Copenhagen, Denmark. Zealand specializes in the discovery, optimization and development of novel peptide drugs and has a broad and mature pipeline of drug candidates identified through its own drug discovery activities. The company's focus lies in the field of diabetes/metabolic diseases, and its lead drug invention is lixisenatide, a once-daily GLP-1 agonist, which is licensed to Sanofi for the treatment of Type 2 diabetes. Lixisenatide is approved and launched (March 2013) in Europe under the name of Lyxumia[®], and under regulatory review in a large number of other countries globally, including in the US (NDA filed in Dec 2012) and Japan (NDA filed in June 2012).

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Zealand has a partnering strategy for the development and commercialization of its products and in addition to the collaboration with Sanofi in Type 2 diabetes, the company has partnerships with Boehringer Ingelheim in diabetes/obesity, Helsinn Healthcare in chemotherapy induced diarrhea and AbbVie in acute kidney injury.

For further information: <u>www.zealandpharma.com.</u> Zealand can also be followed on Twitter: @ZealandPharma