

Patient recruitment completed for phase II trial with glepaglutide for treatment of short bowel syndrome

- **Results of the phase II trial are expected mid 2017**
- **Glepaglutide is a novel GLP-2 analogue with the potential to improve treatment of patients with short bowel syndrome**

Copenhagen, February 6, 2017 – Zealand Pharma A/S (“Zealand”) announces that the last patient has been dosed in a phase II proof-of-concept, dose-finding trial with glepaglutide¹ for the treatment of short bowel syndrome (SBS). SBS is a serious condition involving intestinal function failure following the surgical removal of large parts of the small or large intestine due to cancer, ischemia or Crohn’s disease. Patients suffering from SBS have compromised intestinal absorptive capacity and lack the ability to maintain protein-energy, fluid, electrolyte and nutrient balances on a conventional diet. Many are therefore dependent on intravenous supplements in the form of fluids, salts and nutrition delivered through a central catheter to maintain body functions.

Zealand is developing glepaglutide as a novel GLP-2 analogue, with a half-life in humans of up to 17 hours, for the treatment of SBS. Significant preclinical effects on the small and large bowels have been demonstrated, and glepaglutide was concluded to be safe and well tolerated in a phase 1 clinical trial. Glepaglutide has been designed to be stable in liquid formulations for easy and convenient daily subcutaneous dosing in an injection pen.

The primary objective of the phase II trial is to assess the effect of glepaglutide on improving patients’ intestinal absorption capacity. Results from the phase II trial are expected in the summer of 2017.

“Patients with short bowel syndrome have reduced quality of life due to constant diarrhea and dependency on daily parenteral support. SBS is associated with a high risk of sepsis, blood clots, liver damage and renal impairment, so we are desperately in need of better treatment options,” says Palle Jeppesen, Principal Investigator of the phase II trial and Professor MD, Department of Gastroenterology, Copenhagen University Hospital, Denmark.

In a comment about this release, Adam Steensberg, Senior Vice President and Chief Medical and Development Officer of Zealand, said: “We are very happy to announce that patient recruitment has been completed for the phase II dose-finding trial with glepaglutide for short bowel syndrome. Living with short bowel syndrome can be very burdensome, with some patients being dependent on intravenous infusion of liquids and nutrition for up to 16 hours per day. We are thankful for the commitment the clinical staff and patients have demonstrated in order to reach this milestone and look forward to seeing the results of the trial later this year. We are committed to bringing this product candidate through full development and hope to be able to offer this group of patients a new, convenient treatment option.”

¹ Glepaglutide is a proposed International Nonproprietary Name (pINN).



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About short bowel syndrome

Short bowel syndrome (SBS) is a complex chronic disease characterized by severe loss of intestinal function. SBS can result from either physical removal of portions of the small intestine and colon or from loss of function as a result of bowel damage. The primary underlying causes of SBS are Crohn's disease, colon cancer, ischemia and radiation.

Patients with SBS have compromised intestinal absorptive capacity and lack the ability to maintain protein-energy, fluid, electrolyte and nutrient balances on a conventional diet. Many are therefore dependent on increased and frequent intake intravenous supplements in the form of fluids, salts and nutrition delivered through a central catheter to maintain body homeostasis. There are currently estimated to be 10,000-20,000 SBS patients in the EU and a similar number in the US.

Patients dependent on regular intravenous support experience a number of serious and life-threatening complications associated with their disease and treatment. These include shortened life expectancy as well as high risk of sepsis and other infections, blood clots, liver damage and renal impairment. In addition, patients have markedly reduced quality of life due to constant diarrhea and dependency on daily intravenous support, which can take up to 16 hours overnight, causing sleep disturbance and restricting their daily activities.

Teduglutide (Gattex®/Revestive®), a GLP-2 receptor agonist, was approved in 2012 and launched in 2014 in both the US and Europe as the first medicine indicated for the treatment of SBS.

About Zealand Pharma A/S

Zealand Pharma A/S (Nasdaq Copenhagen: ZEAL) ("Zealand") is a biotechnology company focused on the discovery, design and development of innovative peptide-based medicines. Zealand has a portfolio of medicines and product candidates under license collaborations with Sanofi, Boehringer Ingelheim and Helsinn, and a pipeline of proprietary product candidates that primarily target specialty diseases with significant unmet needs.

Zealand's first invented medicine, lixisenatide, a once-daily prandial GLP-1 analogue for the treatment of type 2 diabetes, is licensed to Sanofi. Lixisenatide is marketed as Adlyxin™ in the US and Lyxumia® in the rest of the world. Lixisenatide has been developed in a fixed-ratio combination with basal insulin glargine (Lantus®) and is marketed as Soliqua™ 100/33 in the US and has been approved as Suliqua™ in Europe.

Zealand's pipeline includes: dasiglucagon* (ZP4207, single-dose rescue treatment) for acute, severe hypoglycemia (phase II); glepaglutide* (ZP1848) for short bowel syndrome (phase II); dasiglucagon* (ZP4207, multiple-dose version) intended for use in a dual-hormone artificial pancreas system for better hypoglycemia control and diabetes management (phase II) and other earlier-stage clinical and preclinical peptide therapeutics.

Zealand is based in Copenhagen (Glostrup), Denmark. For further information about the company's business and activities, please visit www.zealandpharma.com or follow Zealand on Twitter @ZealandPharma.

* Dasiglucagon and glepaglutide are proposed International Nonproprietary Names (pINN).