

Press release - No. 21/2018

## Zealand Pharma enrolls first patient in Phase 3 trial with glepaglutide for the treatment of short bowel syndrome

- The Phase 3 registration trial has enrolled the first short bowel syndrome (SBS) patient with reduced or complete loss of intestinal function
- Glepaglutide has shown to increase intestinal absorption in patients with SBS
- Glepaglutide is a long-acting GLP-2 analog with potential for once-weekly dosing in an auto-injector pen

Copenhagen, October 4 2018 – Zealand Pharma A/S ("Zealand") (NASDAQ: ZEAL), a Copenhagen-based biotechnology company focused on the discovery and development of innovative peptide-based medicines, today announces the enrollment of the first patient in a global Phase 3 trial evaluating the potential of glepaglutide as a novel short bowel syndrome (SBS) treatment.

"The initiation of our Phase 3 registration trial with glepaglutide is a major milestone for Zealand. We are committed to developing glepaglutide as a potentially life-changing treatment for patients with short bowel syndrome, who suffer from reduced or complete loss of intestinal function," commented Adam Steensberg, Executive Vice President and Chief Medical and Development Officer at Zealand Pharma.

The Phase 3 trial seeks to demonstrate efficacy and safety of once- and twice-weekly subcutaneous injections of 10 mg glepaglutide in SBS patients on parenteral support. 129 patients will be enrolled at approximately 40 highly dedicated investigational sites across the United States, Canada and Europe. The trial will be placebo-controlled, randomized, parallel-group, double-blind, and with fixed dose injection. The primary objective is to confirm the efficacy of glepaglutide in reducing parenteral support volume in SBS patients. The secondary objectives are to evaluate additional efficacy endpoints, as well as safety and tolerability.

Principal Investigator of the Phase 3 trial, Professor Palle Bekker Jeppesen, MD, PhD, Department of Gastroenterology, Rigshospitalet, University of Copenhagen, commented,

"Following the impressive Phase 2 results with glepaglutide, I am excited that the Phase 3 trial has now been initiated. Patients with short bowel syndrome need better treatment options and with potential for weekly dosing, I see glepaglutide as a promising new drug candidate."

The U.S. FDA has granted orphan drug designation for glepaglutide for the treatment of SBS. Glepaglutide is a long-acting GLP-2 analog with an effective half-life of approximately 50 hours. The preceding glepaglutide Phase 2 trial in patients with SBS demonstrated increases in intestinal absorption following only 3 weeks of treatment, thereby providing the basis for initiating the Phase 3 trial.

## For further information, please contact:

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## **About Short Bowel Syndrome (SBS)**

SBS is a complex chronic and severe condition associated with reduced or complete loss of intestinal function. Many patients have to be connected to infusion lines and pumps every day, which pose significant restrictions on their ability to engage in daily activities. In addition, they are at risk of experiencing a number of serious and life-threatening complications such as sepsis, blood clots, liver damage and renal impairment.

## **About Zealand Pharma A/S**

Zealand Pharma A/S (Nasdaq Copenhagen and New York: ZEAL) ("Zealand") is a biotechnology company focused on the discovery and development of innovative peptide-based medicines. More than 10 drug candidates invented by Zealand have advanced into clinical development, of which two have reached the market. Zealand's current pipeline of internal product candidates focus on specialty gastrointestinal and metabolic diseases. Zealand's portfolio also includes two clinical license collaborations with Boehringer Ingelheim.

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 LinkedIn or Twitter @ZealandPharma.