

Company announcement - No. 6/2018

Zealand Pharma to present Phase 2 results on glepaglutide at the ASPEN 2018 Conference in Las Vegas, U.S.

- Glepaglutide is in development as a potential new treatment for patients with short bowel syndrome
- Oral presentation is based upon the abstract being designated as an International Abstract of Distinction by the American Society for Parenteral and Enteral Nutrition organizing committee (ASPEN)
- The Phase 3 clinical trial is expected to start in 2018

Copenhagen, January 23, 2018 – Zealand Pharma (Zealand) and Rahim M. Naimi, MD, Department of Gastroenterology, Rigshospitalet, University of Copenhagen, Denmark, will present Phase 2 key results for glepaglutide at the ASPEN 2018 Nutrition Science and Practice Conference on January 23, 2018 in Las Vegas, U.S (Abstract number 2829969t). Glepaglutide is a GLP-2 analog being developed for the treatment of short bowel syndrome (SBS).

The trial was conducted at Rigshospitalet, University of Copenhagen, Denmark, one of the world's leading centers for the treatment of SBS and top-line results were reported in June 2017. The trial was a 3-week proof-of-concept, double-blind, cross-over, dose-finding trial investigating the efficacy and safety of three different doses of glepaglutide (10 mg, 1 mg and 0.1 mg per day). A total of 16 SBS patients completed the trial.

Glepaglutide was observed to be safe and well tolerated. The primary efficacy endpoint of reducing fecal wet weight output (ostomy output or diarrhea) was successfully met for both the 1 mg and 10 mg doses, with reductions of 592 g/day (P=0.002) and 833 g/day (P=0.0002), corresponding to a relative reduction of 23% and 30% for the mid and high dose groups, respectively. No effects were seen with the lowest dose. Key secondary endpoints were also met for the two high doses, including an absolute change in intestinal wet weight absorption of 645 g/day and 786 g/day and a relative increase in urine output of 40% and 32% for the mid and high doses, respectively. More detailed results from the trial focusing on micro- and macronutrients, intestinal morphology and intestinal transit time will be presented at further scientific conferences in 2018.

Based on results from a recently completed pharmacokinetic trial both a once- and twice-weekly dosing regimen is proposed for Phase 3 and the trial is expected to enroll between 120 and 150 patients. Meetings with U.S. and EU regulatory authorities to agree on the final trial design are planned with the aim of commencing Phase 3 clinical trials in 2018.

Principal Investigator of the Phase 2 trial, Professor Palle Bekker Jeppesen, MD, PhD, Department of Gastroenterology, Rigshospitalet, University of Copenhagen, Denmark, comments: "We have been truly impressed with the results of the Phase 2 trial and I view glepaglutide as a promising new potential treatment opportunity for patients with short bowel syndrome. These patients need better treatment opportunities and I look very much forward to participating in the Phase 3 trial for glepaglutide."

Adam Steensberg, Executive Vice President, Chief Medical and Development Officer of Zealand, comments: "We are very pleased that the results from our Phase 2 trial with glepaglutide are now shared with the broader scientific community. With the recently announced clinical results demonstrating the potential for once-weekly dosing, we are in final preparations to initiate the Phase 3 trial later this year. We believe that glepaglutide has the potential to become the standard of care for patients with short bowel syndrome".



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About Zealand Pharma A/S

Zealand Pharma A/S (Nasdaq Copenhagen and New York: 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 and Boehringer Ingelheim as well as a pipeline of internal product candidates focusing on specialty gastrointestinal and metabolic diseases.

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.