Zealand Pharma Completes Enrollment in EASE-SBS 1 Phase 3 Trial Assessing Glepaglutide in Patients with Short Bowel Syndrome

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- Full trial results of EASE-SBS 1 expected in the third quarter of 2022
- Pending positive pivotal data, Zealand intends to file for marketing approval with the U.S. Food and Drug Administration

Copenhagen, DK and Boston, MA, U.S. January 20, 2022 - Zealand Pharma A/S (Nasdaq: ZEAL) (CVR-no. 20045078,) a biotechnology company focused on the discovery, development and commercialization of innovative peptide-based medicines, today announced completion of patient enrollment in its pivotal Phase 3 trial (EASE-SBS 1) of glepaglutide, the company's long-acting GLP-2 analog, for the potential treatment of short bowel syndrome (SBS). Glepaglutide is being investigated for once or twice weekly administration with an autoinjector and has received Orphan Drug Designation by the U.S. FDA.

The trial sample size has been reduced to approximately 108 patients from the original sample size of 129 patients to mitigate expected recruitment challenges caused by the renewed COVID outbreak. The trial will have 95% power (versus the original 98%) to detect a treatment effect on the primary endpoint. Due to the current plan, extent of patient roll-over into long-term extension trials, and prolonged follow-up caused by COVID disruptions, the cumulative exposure to glepaglutide at the time of the potential NDA submission will be larger than originally anticipated at the End of Phase 2 meeting with the U.S. FDA.

Full results of the trial are expected in the third quarter of 2022 as a result of increased recruitment over the recent months. The previously announced interim analysis is therefore no longer required, preserving statistical power for the full analysis.

"We are very pleased to have achieved this important milestone for Zealand Pharma and look forward to the full results of the EASE-SBS 1 trial, expected in the third quarter of 2022," said Dr. Adam Steensberg, Chief Medical Officer and Head of R&D. "Glepaglutide holds important potential to make a difference in the lives of people living with SBS and our team is now fully engaged in preparing for the potential NDA submission with the FDA in the event of a positive data readout for the trial."

With completion of patient enrollment into EASE-SBS 1, the EASE-SBS 2 extension trial has been amended to allow for direct enrollment without prior participation in EASE-SBS 1. The EASE-SBS 2 trial is a two-year Phase 3b trial assessing safety and efficacy of glepaglutide dosed once and twice weekly. In this long term safety study, there is no placebo arm.

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 Glepaglutide

Glepaglutide is a long-acting GLP-2 analog in development as a potential treatment option for short bowel syndrome (SBS). Glepaglutide is being developed as a liquid product in an autoinjector designed for subcutaneous administration, aimed to reduce, or eliminate, the need for parenteral support in people living with SBS. The pivotal Phase 3 trial, EASE-SBS 1, with enrollment of up to 108 patients with SBS, is a randomized, double-blind and placebo-controlled study, with both once- and twice-weekly dosing regimens. The primary endpoint in EASE-SBS 1 is the absolute reduction in parenteral support achieved by the end of the trial. Patients will be treated for six months in EASE-SBS 1, whereafter they are offered four years continuous follow-up treatment with glepaglutide in the extension trials, EASE-SBS 2 and 3. A Phase 3b trial, EASE-SBS 4, was initiated in Q3 2021 and will assess long-term effects of glepaglutide on intestinal fluid and energy uptake. The U.S. Food and Drug Administration (FDA) has granted orphan drug designation for glepaglutide for the treatment of SBS.

About Zealand Pharma A/S

Zealand Pharma A/S (Nasdaq: ZEAL) ("Zealand") is a biotechnology company focused on the discovery, development, and commercialization of peptide-based medicines. More than 10 drug candidates invented by

Zealand have advanced into clinical development, of which two have reached the market and three candidates are in late-stage development. In addition, license collaborations with Boehringer Ingelheim and AstraZeneca create opportunities for more patients to potentially benefit from Zealand-invented peptide investigational agents currently in development.

Zealand was founded in 1998 in Copenhagen, Denmark, and has presence throughout the U.S. that includes key locations in Boston, and Marlborough (MA). For more information about Zealand's business and activities, please visit http://www.zealandpharma.com.

Forward-Looking Statement

This press release contains "forward-looking statements", as that terms is defined in the Private Securities Litigation Reform Act of 1995, as amended, that provide Zealand Pharma's expectations or forecasts of future events regarding the research, development and commercialization of pharmaceutical products. These forward-looking statements may be identified by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "possible," "potential," "will," "would" and other words and terms of similar meaning. You should not place undue reliance on these statements, or the scientific data presented. The reader is cautioned not to rely on these forward-looking statements. Such forward-looking statements are subject to risks, uncertainties and inaccurate assumptions, which may cause actual results to differ materially from expectations set forth herein and may cause any or all of such forwardlooking statements to be incorrect, and which include, but are not limited to, the occurrence of adverse safety events; risks of unexpected costs or delays; unexpected concerns that may arise from additional data, analysis or results obtained during clinical trials; failure to protect and enforce our data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates or expansion of product labeling; failure to obtain regulatory approvals in other jurisdictions; product liability claims; and the direct and indirect impacts of the ongoing COVID-19 pandemic on our business, results of operations and financial condition. If any or all of such forward-looking statements prove to be incorrect, our actual results could differ materially and adversely from those anticipated or implied by such statements. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. All such forward-looking statements speak only as of the date of this press release and are based on information available to Zealand Pharma as of the date of this release. We do not undertake to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof. Information concerning pharmaceuticals (including compounds under development) contained within this material is not intended as advertising or medical advice.

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