

Company announcement - No. 44 / 2019

Zealand Pharma partner Beta Bionics receives FDA Breakthrough Device Designation for the iLet[™] Bionic Pancreas System

- The iLet is a pocket-sized, wearable investigational medical device that autonomously controls blood sugar in people with diabetes and other conditions -- it is the world's first bionic pancreas system
- FDA's Breakthrough Device Designation Program provides Beta Bionics with priority review among other benefits related to FDA interaction
- The iLet Bionic Pancreas System was granted breakthrough designation in all configurations (insulin-only, glucagon-only, and bihormonal), including use with Zealand Pharma's dasiglucagon, a glucagon analog with a unique stability profile in a ready-to-use aqueous solution

Copenhagen, December 10, 2019 – Zealand Pharma A/S ("Zealand") (NASDAQ: ZEAL), a Copenhagenbased biotechnology company focused on the discovery and development of innovative peptide-based medicines, announces that partner Beta Bionics, Inc. has received Breakthrough Device designation from the U.S. Food and Drug Administration (FDA) for its iLet Bionic Pancreas System.

The iLet Bionic Pancreas System is a pocket-sized, wearable investigational medical device that is designed to autonomously control blood-sugar levels. The Breakthrough Designation for the iLet Bionic Pancreas system contemplates configurations with most insulin analogs approved for pumping as well as dasiglucagon, Zealand Pharma's stable glucagon analog, which has a unique stability profile in a ready-to-use aqueous solution.

"We are thrilled for Beta Bionics to receive Breakthrough Device designation from the FDA," said **Emmanuel Dulac, President and Chief Executive Officer** at Zealand Pharma. "We are further thrilled for the positive development this could be for people with insulin-dependent diabetes, and look forward to progressing dasiglucagon in the bihormonal artificial pancreas system into Phase 3 development."

Please refer to the attached original announcement from Beta Bionics, Inc.

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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 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 and pre-clinical license collaboration with Alexion Pharmaceuticals.

Zealand is based in Copenhagen (Søborg), Denmark. For further information about the Company's business and activities, please visit <u>www.zealandpharma.com</u> or follow Zealand on LinkedIn or Twitter @ZealandPharma.