

## Beta Bionics and Zealand Pharma initiate home-use trial of the iLet™ bionic pancreas with dasiglucagon for autonomous bihormonal treatment of Type 1 diabetes

---

- **First home-use trial of the bihormonal iLet Bionic Pancreas System with dasiglucagon in a pre-filled, commercial-ready, pump cartridge has been initiated by a clinical team at Massachusetts General Hospital**
- **The iLet Bionic Pancreas System is a pocket-sized, wearable medical device that autonomously controls blood-sugar levels in people with diabetes**
- **Dasiglucagon is a potential first-in-class stable glucagon analog**

*Boston, MA and Copenhagen, Denmark, May 22, 2019* – Beta Bionics, Inc. and Zealand Pharma A/S (NASDAQ: ZEAL) announced today the first patients dosed in a clinical trial investigating the home-use of dasiglucagon in the iLet™ Bionic Pancreas System. The iLet, developed by Beta Bionics, is the world's first autonomous bionic pancreas device — a bihormonal system leveraging lifelong machine learning and artificial intelligence to deliver insulin and glucagon analogs for the autonomous treatment of type 1 diabetes. In addition to dosing insulin, the iLet doses dasiglucagon — a glucagon analog developed by Zealand Pharma with a unique stability profile in a ready-to-use aqueous solution.

This home-use clinical trial is being conducted by Dr. Steven Russell and his clinical research team at the Massachusetts General Hospital. The current trial is designed as a randomized, two-arm, cross-over trial to assess whether the iLet operates as designed. It compares the operational performance of the iLet in its insulin-only configuration to its bihormonal configuration using dasiglucagon in adults with type 1 diabetes. Secondary objectives of the study include assessing the impact of the insulin-only and bihormonal configurations of the iLet Bionic Pancreas System on glycemic control, quality of life, and treatment satisfaction among study participants, their caregivers, partners, and/or family members.

“The start of this home-use clinical trial with the iLet in its bihormonal configuration — autonomously and independently pumping both insulin and Zealand’s dasiglucagon — marks the achievement of a long-awaited and eagerly anticipated milestone,” said **Ed Damiano, Co-founder and President & CEO of Beta Bionics**.

Beta Bionics and Zealand Pharma have partnered to carry out several co-development activities with the primary goal of obtaining regulatory approval to use dasiglucagon in the bihormonal configuration of the iLet.

“Fully automated diabetes care, realized by a dual-hormone artificial pancreas system using insulin together with dasiglucagon, could significantly improve life for millions of people living with type 1 diabetes,” said **Emmanuel Dulac, President and Chief Executive Officer at Zealand Pharma**.

**For further information, please contact:****Beta Bionics**

Ed Damiano  
[edamiano@betabionics.com](mailto:edamiano@betabionics.com)

Ed Raskin  
[eraskin@betabionics.com](mailto:eraskin@betabionics.com)

**Investor Relations Contact**

Jeremy Feffer  
[jeremy@lifesciadvisors.com](mailto:jeremy@lifesciadvisors.com)

**Zealand Pharma**

**Emmanuel Dulac**  
President and Chief Executive Officer  
+45 50 60 36 36  
[edu@zealandpharma.com](mailto:edu@zealandpharma.com)

**Lani Pollworth Morvan**  
Investor Relations and Communication  
+45 50 60 37 78  
[lpm@zealandpharma.com](mailto:lpm@zealandpharma.com)

**About the iLet**

The iLet bionic pancreas system is a pocket-sized, wearable medical device that autonomously controls blood-sugar levels in people with diabetes. The lifelong, machine-learning, mathematical dosing algorithms integrated into the iLet were licensed by Beta Bionics from Boston University. In previous home-use studies in adults and children with T1D, these algorithms demonstrated dramatic improvements in glycemic control relative to the standard of care. These improvements included significant reductions in blood-glucose levels, in hypoglycemia, and in intersubject and intrasubject glycemic variability (New England Journal of Medicine. 2014, 371:313-25; Lancet Diabetes and Endocrinology. 2016, 4:233-43; Lancet. 2016, 389:369-80).

To initialize the iLet, users enter only their body weight. Immediately thereafter, the iLet begins controlling blood-sugar levels automatically, without requiring the user to count carbohydrates, set insulin delivery rates, or deliver bolus insulin for meals or corrections. The iLet is effectively three medical devices in one. It can be configured as an insulin-only bionic pancreas, a glucagon-only bionic pancreas, or a bihormonal bionic pancreas (insulin and glucagon). The glucagon-only configuration may be helpful in rare, chronic, low blood-sugar conditions, such as congenital hyperinsulinism (CHI) and insulinoma syndrome. Beta Bionics is committed to obtaining regulatory approval and commercializing all three iLet configurations.

**About dasiglucagon for use in other indications**

Dasiglucagon is a Zealand-invented glucagon analog with a unique stability profile in a ready-to-use aqueous solution. It is also in development for two additional indications: treatment of severe hypoglycemia, and treatment for children born with a genetic mutation that causes congenital hyperinsulinism (CHI).

**About Beta Bionics**

Beta Bionics is a for-profit Massachusetts public benefit corporation founded in 2015 to commercialize the iLet, a revolutionary bionic pancreas system that is driven by machine-learning artificial intelligence to autonomously control glycemia. These mathematical dosing algorithms were developed in the Damiano Lab at Boston University and refined based on results from home-use clinical trials in adults and children with T1D. Beta Bionics is a Certified B Corporation™ whose founders—in addition to Ed Damiano—include other parents of children with type 1 diabetes and people with type 1 diabetes. Beta Bionics is committed to acting in the best interests of the diabetes community and to profoundly disrupting the diabetes medical device industry by bringing the iLet to market as expeditiously and responsibly as possible.

Beta Bionics is operated out of Boston, Massachusetts and Irvine, California. For further information, please visit [www.betabionics.com](http://www.betabionics.com) or follow Beta Bionics Facebook, YouTube, Instagram, LinkedIn and Twitter @BetaBionics.

**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 (Glostrup), Denmark. For further information about the Company's business and activities, please visit [www.zealandpharma.com](http://www.zealandpharma.com) or follow Zealand on LinkedIn or Twitter @ZealandPharma.