

## **BETA BIONICS AND ZEALAND PHARMA ANNOUNCE SUPERIOR GLYCEMIC CONTROL IN PHASE 2 HOME-USE CLINICAL TRIAL TESTING THE iLet™ BIONIC PANCREAS USING DASIGLUCAGON**

- **First home-use trial of the iLet Bionic Pancreas System using pre-filled cartridges of dasiglucagon compatible with iLet has been successfully completed**
- **The preliminary study results reveal superior blood glucose control during the study period that used the bihormonal configuration of the iLet with dasiglucagon compared to the period that used the insulin-only configuration**
- **iLet therapy was initialized with body weight only, with no device training periods, and with no physician intervention to optimize therapy**

**Boston, MA and Copenhagen, Denmark – June 6, 2019** – Beta Bionics, Inc. and Zealand Pharma A/S (NASDAQ: ZEAL) announced today that a home-use study of dasiglucagon in the iLet™ Bionic Pancreas System has been successfully completed.

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 (T1D). In addition to dosing insulin, the iLet doses dasiglucagon — a glucagon analog with a unique stability profile in a ready-to-use aqueous solution. Dasiglucagon is in development by Zealand Pharma.

This home-use clinical trial was conducted by Dr. Steven Russell and his clinical research team at the Massachusetts General Hospital (MGH) and was designed as a randomized, two-period, cross-over trial to assess whether the iLet operated as intended. The trial compared operational performance of the iLet in the insulin-only configuration for one week versus the bihormonal configuration for one week in 10 adult participants with T1D. Trial participants started therapy by entering only their body weight into the device; there was no device training period and no physician intervention to optimize therapy. The iLet is designed to autonomously and continuously adapt to each patient's changing insulin needs. This adaptation is typically most pronounced in the first 24 hours after the initiation of therapy.

The iLet operated as expected, meeting the primary aim of the study. Preliminary data analysis demonstrated that the bihormonal iLet using dasiglucagon provided superior glycemic control over the insulin-only iLet. During the bihormonal period, participants achieved a mean glucose level, as measured by continuous glucose monitoring (CGM), of 139 mg/dL on days 2–7 of use, versus 149 mg/dL during the insulin-only period ( $p < 0.01$ ). During the bihormonal period, participants spent 79% of the time with their CGM glucose level in range (70–180 mg/dL) on days 2–7 of use, versus 71% during the insulin-only period ( $p < 0.01$ ). During the bihormonal period, 90% of participants had a mean CGM glucose level of  $< 154$  mg/dL, a level that corresponds to an HbA1c level of 7%, the therapeutic goal for adults recommended by the American Diabetes Association. In contrast, 50% of participants had a mean CGM glucose level  $< 154$  mg/dL during the insulin-only period.

Hypoglycemia was observed to be low throughout the study. The mean percentage of time CGM glucose was < 54 mg/dL was 0.3% during the bihormonal period versus 0.6% during the insulin-only period. The mean percentage of time CGM glucose was < 70 mg/dL was 2.4% during the bihormonal period versus 3.6% during the insulin-only period.

“We are extremely pleased to have now tested the performance of our bihormonal iLet Bionic Pancreas System with dasiglucagon — the first-ever, liquid-stable glucagon analog — in a convenient ready-to-use, pre-filled cartridge designed to fit our system,” said **Ed Damiano, Co-founder and President & CEO of Beta Bionics**. “Preliminary results from this trial have helped reaffirm the final implementation of our dosing algorithms in the bihormonal configuration of the iLet. I am ecstatic about this historic achievement for Beta Bionics, Zealand Pharma, and our clinical collaborators at MGH, and I am looking forward with eager anticipation to the day when people with T1D can enjoy the real-life benefits of combining ready-to-use dasiglucagon with the iLet.”

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.

“The bihormonal iLet Bionic Pancreas System demonstrated tight glycemic control in a home-use setting with dasiglucagon,” commented **Emmanuel Dulac, President and Chief Executive Officer at Zealand Pharma**. “We look forward to proceeding with the Phase 3 trial and continuing to demonstrate the transformational opportunity that the iLet with dasiglucagon could offer for improved and fully automated diabetes management.”

Beta Bionics and Zealand Pharma are planning for a Phase 3 pivotal trial testing the bihormonal configuration of the iLet with dasiglucagon in 2020. That trial is intended to support regulatory submission to the U.S. FDA of a pre-market approval (PMA) application and a new drug application (NDA) for the bihormonal configuration of the iLet with dasiglucagon in people with T1D.

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## **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 dosing control 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 Pharma-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).

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### **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 mathematical dosing algorithms 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.

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