
Beta Bionics Receives IDE Approval from the FDA to Begin a Home-Use Clinical Trial Testing the New iLet™ Bionic Pancreas System

- First trial to test Fiasp® – Novo Nordisk’s latest formulation of fast-acting insulin aspart – using autonomous insulin delivery
- The bionic pancreas will also be tested with the conventional formulations of insulin aspart and insulin lispro in both adults and children with type 1 diabetes who use either an insulin pump or multiple daily injection therapy for their usual care
- Trial to use Dexcom’s Continuous Glucose Monitoring System

Boston, MA – May 21, 2018 – Beta Bionics, Inc. – a medical technology company leveraging machine learning artificial intelligence to develop and commercialize the world’s first autonomous bionic pancreas – today announced that it has received FDA approval to begin recruitment for home-use studies testing the insulin-only configuration of its iLet bionic pancreas system in a series of groundbreaking trials in adults and children with type 1 diabetes (T1D). Adults 18 years and older with T1D will be recruited through Massachusetts General Hospital and Stanford University, and children 6-17 years old with T1D will be recruited through Nemours Children’s Health System, the Barbara Davis Center for Diabetes at the University of Colorado, and Stanford University.

The US-based multicenter, multi-arm, cross-over, clinical trial is the first of its kind, testing Novo Nordisk’s recently approved, fast-acting insulin called Fiasp® with the iLet bionic pancreas system in adults with T1D, and insulin lispro and conventional insulin aspart using the iLet in adults and children with T1D. This trial is also the first to use the new Beta Bionics-manufactured iLet device, which is capable of dosing only insulin, only glucagon, or both hormones as needed.

The iLet consists of a dual-chamber, autonomous, infusion pump that mimics a biological pancreas. Embedded in the system are clinically tested mathematical dosing algorithms driven by machine learning to autonomously calculate and dose insulin and/or glucagon as needed, based on data from a continuous glucose monitor. With unprecedented simplicity of use, the iLet requires only body weight for initialization. Once initialized, the iLet engages its machine-learning, artificial intelligence to

autonomously control the individual's blood-glucose levels, and to continuously adapt to the individual's ever-changing insulin needs. The iLet to be used in this trial integrates glucose data from the Dexcom G5 Continuous Glucose Monitoring (CGM) System.

"The design of this ambitious insulin-only bionic pancreas study builds on the foundation of previous studies we have conducted with our clinical collaborators testing our bionic pancreas algorithms with previous investigational platforms," said Ed Damiano, Founder and CEO of Beta Bionics, and Principal Investigator of the trial. Dr. Damiano is also a Professor of Biomedical Engineering at Boston University. "This trial is exciting not only because it represents the first time we will be able to test our bionic pancreas algorithms with our own proprietary iLet platform, and not only because it will include both children and adults with T1D, and not only because it will draw upon those who use MDI therapy in equal number to those who use insulin pumps for their usual care, but also because we will be breaking new ground by being the first group to test autonomous insulin delivery using Fiasp®."

"The iLet Bionic Pancreas System trial is a concrete example of patient-centered innovation, and it is ultimately through innovation and research that we'll defeat diabetes", said Stephen Gough, Global Chief Medical Officer of Novo Nordisk. "We are proud that Fiasp®, our ultra-fast acting insulin, has been chosen for this trial, among other rapid-acting insulins and look forward to see the results. The intent is to show meaningful benefits for people living with diabetes in need of this technology".

Novo Nordisk, an investor in Beta Bionics, has partnered with Beta Bionics to carry out several co-development activities. Eli Lilly and Zealand Pharma are also investors and development partners. Dexcom is a development partner with Beta Bionics as well and recently received FDA approval of its G6 Dexcom under the new interoperable CGM designation (iCGM).

"We have worked with Beta Bionics and Ed Damiano's team for many years to provide our highly accurate and reliable CGM technologies to drive the bionic pancreas," said Steve Pacelli, Executive Vice President of Strategy and Corporate Development at Dexcom. "We support the efforts of Beta Bionics to bring their iLet bionic pancreas system to market and look forward to seeing our G6 system incorporated into their future iLet platform and validated in future clinical trials."

Beta Bionics plans to enter pivotal trials with its final iLet design in 2019 and expects to launch its first product in 2020.

About the IDE and PMA process

Investigational use of the iLet was approved by the FDA under an investigational device exemption (IDE). An IDE allows testing of an investigational device in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) application to the FDA. An IDE application is approved only after extensive review by the FDA of the device and clinical trial design.

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 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, reductions in hypoglycemia, and reductions 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).

The iLet is initialized by entering body weight only and does not require the patient 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 dual-hormone bionic pancreas. 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 Fiasp® (insulin aspart injection) 100 U/mL

Fiasp® is a fast-acting mealtime insulin indicated to improve glycemic control in adults with type 1 and type 2 diabetes. Fiasp® is the first fast-acting mealtime insulin injection that does not have a pre-meal dosing recommendation. Fiasp® should be administered at the beginning of a meal or within 20 minutes after starting a meal due to its appearance in the blood in approximately 2.5 minutes.*

*Reference: Fiasp® [package insert]. Plainsboro, NJ: Novo Nordisk Inc; September 2017.

About Beta Bionics

Beta Bionics is a for-profit Massachusetts public benefit corporation founded in 2015 to commercialize the iLet, a revolutionary bionic pancreas that is driven by mathematical dosing algorithms, which incorporate 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. 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 pursuing regulatory approval of its insulin-only bionic pancreas, which will be followed by its dual-hormone system that will also administer a glucagon analog in order to raise blood-sugar levels without the need to consume carbohydrates.

Beta Bionics is headquartered in Boston, Massachusetts with certain operations in Irvine, California. For further information, please visit www.betabionics.com or follow Beta Bionics Facebook, YouTube, Instagram, LinkedIn and Twitter @BetaBionics.

Company Contacts

Ed Damiano
edamiano@betabionics.com

Ed Raskin
eraskin@betabionics.com

Investor Relations Contact

Jeremy Feffer
jeremy@lifesciadvisors.com
