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**BETA BIONICS AWARDED UP TO \$2 MILLION NIH SMALL BUSINESS INNOVATION RESEARCH (SBIR) GRANT**

- Award from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
- Grant provides up to \$2 million in funding over the next 24 months under the Fast-Track mechanism (pending demonstration of successful achievement of Phase I milestones)
- Research activities directed toward the Beta Bionics insulin-only and bihormonal bionic pancreas technology.

**Boston, MA – October 2, 2018:** Beta Bionics, Inc. – a medical technology company leveraging lifelong machine learning and artificial intelligence to develop and commercialize the world’s first autonomous bionic pancreas – today announced that it has been awarded up to \$2 million in the form of an SBIR grant ([R44-DK120234](#)) by the NIDDK, which is part of the U.S. National Institutes of Health (NIH).

Beta Bionics is the developer of the iLet™ Bionic Pancreas System, which is currently undergoing home-use clinical trials in adults and children with type 1 diabetes (T1D). The iLet consists of a dual-chamber, autonomous, infusion pump that mimics a biological pancreas. Embedded in the system are clinically-tested dosing algorithms driven by lifelong machine learning to autonomously calculate and dose insulin or glucagon as needed based on data from the patient’s continuous glucose monitor (CGM). With unprecedented simplicity of use, the iLet requires only body weight for initialization after which it autonomously controls the individual’s blood-glucose levels, continuously adapting to that individual’s ever-changing requirements.

The SBIR grant was reviewed and awarded under the NIH Fast-Track mechanism where the Phase I will include R&D activities centered around (1) establishing and implementing the final design and use requirements of the iLet Bionic Pancreas System, (2) building and testing the clinical-ready prototypes, and (3) submitting the investigational device exemption (IDE) application to the US Food and Drug Administration (FDA). Pending demonstration of successful achievement of Phase I milestones, Phase II activities will include R&D activities centered around designing, testing, implementing, and optimizing automation equipment within the Beta Bionics manufacturing facility.

“This SBIR grant represents an important contributing source of support to Beta Bionics to aid in its effort to bring this transformational technology to people who face the relentless, daily, life-long challenges of managing diabetes,” said Ed Damiano, co-founder and CEO of Beta Bionics and Professor of Biomedical Engineering at Boston University. “The iLet has grown out of technology developed at my lab at Boston University and subsequently at Beta Bionics. The progress we have made through over 10 years of clinical research and technology development simply would not have been possible without the financial support and resources provided by the NIDDK and the Special Diabetes Program to my lab and my clinical collaborators, and now to Beta Bionics. This SBIR grant will allow Beta Bionics to leverage all of the NIDDK’s past clinical research support of the bionic pancreas technology and its current clinical research support of the iLet technology through another ongoing NIDDK award (UC4-DK108612) to Boston University.”

“This SBIR award reflects NIDDK’s commitment to support the development of novel technologies by small business concerns in order to improve self-management of diabetes, reduce the burden of care and prevent acute and chronic complications,” said Guillermo Arreaza-Rubín, M.D., director of the NIDDK Diabetes Technology Program.

In May and July, Beta Bionics announced a first-of-its-kind, US-based, multicenter, multi-arm, cross-over clinical trial to test the iLet in its insulin-only configuration in adults and children with T1D. This clinical trial is currently underway, testing insulin lispro and conventional insulin aspart with the iLet using the Dexcom G5 CGM in children with T1D. This trial is also testing insulin lispro, conventional insulin aspart, and Novo Nordisk’s recently approved ultra-rapid-acting, insulin-analog formulation called Fiasp®, with the iLet using the Dexcom G5 and Senseonics Eversense CGMs in adults with T1D. Both Dexcom and Senseonics are development partners with Beta Bionics. Beta Bionics plans to enter pivotal trials with its final iLet design in 2019 and expects to launch its first product in 2020.

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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 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, the user enters only their body weight. Thereafter, iLet 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.

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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 driven by mathematical dosing algorithms, which incorporate machine-learning artificial intelligence to autonomously control glycemia. These 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, 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](http://www.betabionics.com) or follow Beta Bionics Facebook, YouTube, Instagram, LinkedIn and Twitter @BetaBionics.

The content of this news release is solely the responsibility of the authors and does not necessarily represent the official views or imply endorsement of the National Institutes of Health.

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