

PRESS RELEASE: FOR IMMEDIATE RELEASE

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**

Boston, MA – December 10, 2019 – Beta Bionics, Inc. — a medical technology company developing and aiming to commercialize the world's first fully automated bionic pancreas — today announced it has received Breakthrough Device designation from the U.S. Food and Drug Administration (FDA) for its investigational 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 on-body wear is similar to that of an insulin pump. Unlike insulin pump therapy, however, the investigational system is designed such that users enter only their body weight for the iLet to initialize therapy. 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 designed to function as 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 using insulin and glucagon. The insulin-only and bihormonal configurations may be helpful in diabetes. The glucagon-only configuration may be helpful in rare conditions that often lead to chronic, low blood-sugar conditions, such as congenital hyperinsulinism (CHI). Beta Bionics is committed to obtaining regulatory approval and commercializing all three iLet configurations.

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 pumpable glucagon analog, which has a unique stability profile in a ready-to-use aqueous solution.

"We believe the iLet Bionics Pancreas System represents a true breakthrough therapy for the management of glycemia, particularly in type 1 diabetes," said Ed Damiano, President and CEO of Beta Bionics. "We are particularly excited by the possibility that the iLet may be able to provide safer and more effective therapy in far more people than current therapies due to its simplicity of use."

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 lifelong autonomous learning to automatically 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 pursuing regulatory approval of its insulin-only bionic pancreas, followed by its dual-hormone system, which will also administer a glucagon analog in order to raise blood-sugar levels without the need to consume carbohydrates.

Beta Bionics operates in Massachusetts and California. For further information, please visit www.betabionics.com or follow Beta Bionics Facebook, YouTube, Instagram, LinkedIn and Twitter @BetaBionics.

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