The iLet® Bionic Pancreas Significantly Reduced HbA1c and Improved Time in Range vs Standard of Care for a Diverse Range of People with Type 1 Diabetes

Caution: The iLet® Bionic Pancreas is an investigational device limited by Federal (or United States) law to investigational use. Not available for sale.

- The trial achieved key primary and secondary endpoints, demonstrating improved outcomes over standard of care for people living with type 1 diabetes.
- The study population — 440 adults and children 6 years and older with type 1 diabetes — was more diverse and representative of the U.S. type 1 diabetes population than any previous pivotal trial of automated insulin delivery systems.
- The iLet® Bionic Pancreas is a pocket-sized, wearable, investigational medical device designed to autonomously determine and deliver insulin doses to control blood glucose levels in people with diabetes.
- Dr. Steven J. Russell, principal investigator, presented the results from the multi-center randomized Insulin-Only Bionic Pancreas Pivotal Trial at Advanced Technologies & Treatments for Diabetes (ATTD) on Saturday, April 30, 2022.
- The study results have been included in a comprehensive submission package to the FDA for regulatory review.

CONCORD, Mass., April 30, 2022 (GLOBE NEWSWIRE) — Beta Bionics, Inc. — The results of the multi-center randomized Insulin-Only Bionic Pancreas Pivotal Trial (IO BPPT) were presented today by Dr. Steven J. Russell, Associate Professor of Medicine, Harvard Medical School, at the International Conference on Advanced Technologies & Treatments for Diabetes (ATTD).

Insulin-Only Bionic Pancreas Pivotal Trial Results & Background

The pivotal trial was designed to test the safety and efficacy of the iLet Bionic Pancreas relative to a standard of care control group over a 13-week study period. The standard of care group was comprised approximately one-third each on automated insulin delivery (AID) systems, insulin-pump therapy with continuous glucose monitoring (CGM), and multiple daily injection therapy with CGM. The trial was conducted in a home-use setting and enrolled 440 adults and children aged 6 years and older with type 1 diabetes. The primary analysis of the trial compared the iLet, using Humalog® or Novolog®, versus standard of care in 326 adults and children; the remaining 114 adult participants used the iLet with Fiasp®.

The iLet Bionic Pancreas met all key endpoints in the IO BPPT. The primary analysis demonstrated improved outcomes over standard of care in the following domains:

- **Significant reduction in HbA1c:** After 13 weeks, the average HbA1c in the people who used the iLet Bionic Pancreas was reduced by 0.5% compared to those using standard of care. In an analysis of participants who had a baseline HbA1C greater than 7%, there was a 0.7% reduction of HbA1c in the iLet Bionic Pancreas arm vs standard of care.
- **No increased risk of hypoglycemia:** People with diabetes who used the iLet Bionic Pancreas did not experience any significant increase in the average time they spent with their CGM values less than 54 mg/dL over 13 weeks compared to those using standard of care.
- **Increased time in range:** People who used the iLet Bionic Pancreas had an average of 2.6 hours more time in range per day over the 13 weeks than those using standard of care.

Beta Bionics is committed to making its type 1 diabetes management technology accessible to the many, not just the few, by reducing the cognitive burden of living with type 1 diabetes. The trial was designed to reach a broad demographic with respect to not only race, ethnicity, age, and therapy type but also baseline glycemic control. The IO BPPT population was more diverse and representative of people with type 1 diabetes in the United States than any previous pivotal trial of an AID system.1 The racial and ethnic composition in the primary analysis included 74% White non-Hispanic, 10% Black non-Hispanic, 10% Hispanic or Latino and 6% other or more than one race.

"The results of this trial confirm that the iLet Bionic Pancreas may serve a population of people who are otherwise unable to reach glycemic goals with currently available diabetes technology," said Jeanne Jacoby, FNP, CDCES, Director of Medical Affairs, Beta Bionics. "As a medical professional and a person with diabetes, I look forward to us being able to offer a solution that may change the lives of this underserved population."
The IO BPPT was a multi-center, randomized controlled trial funded, in part, by a grant from the National Institutes of Health to Boston University, and conducted in collaboration with the IDE sponsor and study coordinator, the Jaeb Center for Health Research, and 16 clinical research centers across the U.S.

**Addressing the Cognitive Burden of Type 1 Diabetes**
The cognitive and emotional impact of diabetes can lead to data and decision-making overload. Adults with type 1 diabetes in the U.S. ranked simpler management as the greatest unmet need and reduced mental effort as the fourth greatest unmet need in current diabetes technology. Despite advances in medications and technology, approximately 80% of people with type 1 diabetes are not meeting the American Diabetes Association (ADA) therapy goal of an HbA1c below 7%.

Recent advances in type 1 diabetes technology lack the flexibility to support the diverse needs, experiences, and resources of those living with diabetes. If cleared by the U.S. Food and Drug Administration (FDA), Beta Bionics hopes the iLet Bionic Pancreas will improve the lives of people living with diabetes by improving glycemic control relative to the standard of care and by helping reduce data and decision-making overload. The iLet Bionic Pancreas received breakthrough device designation in 2019 from the FDA and its regulatory submission is currently under review.

“We are committed to improving the lives of people living with diabetes by helping to reduce the data and decision-making overload,” said Martha Goldberg Aronson, Interim CEO and Board Director, Beta Bionics. “The IO BPPT results show significantly reduced HbA1c without increasing the risk of hypoglycemia utilizing technology requiring only the user’s weight to initialize.”

Even with the technology that is currently available, the management of type 1 diabetes requires a significant number of mathematical inputs. The iLet Bionic Pancreas is designed to serve those beyond the current market — those who do not reach their ADA goal, are overloaded by data or are tired of math and numbers. The iLet Bionic Pancreas requires only one numerical input to get started—the user’s weight.

“Ever since my son developed type 1 diabetes as an infant almost 22 years ago, I had hoped that technological advancements would bring even better glycemic control to people with diabetes, and without the relentless demand that insulin-dosing decisions fall to them or their health care providers,” said Dr. Ed Damiano, Founder and Executive Chair, Beta Bionics. “I see the results of this pivotal trial as being truly pivotal for the type 1 diabetes community, as the culmination of two decades of technological evolution that brings me great joy and a wonderful sense of accomplishment and pride in our team at Beta Bionics, the clinical collaborators who conducted the study, our strategic partners and investors who supported us over the years, and the industriousness of human innovation.”

**About the iLet Bionic Pancreas**
The iLet® is a pocket-sized, wearable investigational medical device designed to autonomously dose insulin. It is designed to be worn like an insulin pump; however, iLet® users would enter only their body weight to initialize therapy and would not set any insulin regimen parameters. The iLet® is designed to then automatically titrate and infuse insulin without requiring the user to count carbohydrates, set insulin-to-carbohydrate ratios, set insulin basal rates, set correction factors, or determine bolus insulin for meals or corrections. The technology is designed to help a broad base of people who wish to use technology to manage diabetes.

**About Beta Bionics**
Beta Bionics® is a clinical stage medical technology company focused on the design, development, and commercialization of its iLet® Bionic Pancreas in both the insulin dosing (the iLet®) and bihormonal (iLet Duo™) configurations. The iLet Bionic Pancreas platform is designed to use adaptive, self-learning, control algorithms, together with continuous glucose monitoring and pump technology, to autonomously compute and administer doses of insulin and/or glucagon and mimic the body’s natural ability to maintain tight glycemic control. Beta Bionics is a for-profit, public benefit corporation and Certified B Corporation™. Since its founding in 2015, its mission is to help improve health outcomes and the quality of life of children and adults living with diabetes and other conditions of glycemic dysregulation.

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