Diatech Diabetes Awarded a $300,000 Phase 1 SBIR Grant for Preclinical Development of Innovative Infusion Monitoring and Failure Detection Insulin Pump Algorithm

Memphis, TN -- September 7th, 2021 -- Diatech Diabetes (Diatech) has announced today its reception of a $300,000 Small Business and Innovation Research (SBIR) Phase 1 grant from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), an institute within the National Institutes of Health (NIH). The grant (award number R43DK130036) will support the preclinical development of Diatech's first product, SmartFusion™, which will reduce the impact of insulin pump infusion failures for patients living with type 1 diabetes.

The project will be led by John "JC" Gray (Diatech Chief Scientific Officer), Luis E. Blanco (Diatech Chief Technology Officer), and sub-award principal investigator Marzia Cescon, PhD (David C. Zimmerman Assistant Professor, University of Houston). When asked about the Notice of Award, Diatech's Chief Executive Officer, John Wilcox, said, "I am extremely proud of our company for securing this NIH grant. This is a huge opportunity for us as a young team and as first-time grant recipients. As a patient with diabetes myself, it is awesome to see the progress we have made with SmartFusion and we are grateful to have the support of the NIDDK as we continue to build something we hope that people with diabetes will benefit from." Last year 3,620 SBIR Phase 1 applications were submitted to the NIH with 450 awards being issued (12% success rate for applicants).

What are infusion failures?

Infusion failures are instances in which a patient using an infusion pump does not get the expected dosage of medication in the correct time frame. For type 1 diabetes patients, insulin pump infusion failure can result in a dangerous lack of blood sugar control and, while uncommon, can even lead to hospitalization or death. Current insulin pumps can fail to correctly alert to most classes of failures, which vary due to their underlying causes (e.g. line occlusions, leaks, kinks in tubing, tissue degradation). This leads to the all too common situation where patients are first made aware of their infusion failure from debilitating high blood sugar, only then finding out that there has been a small leak or tube kink at their infusion site.

What is SmartFusion™?

SmartFusion, an infusion monitoring and failure detection algorithm, is designed to take advantage of data from interconnected devices like onboard insulin pump sensors, glucose monitors, and mobile applications to monitor and measure how much of the insulin a patient doses from their pump verifiably makes it into their body. A combination of machine learning techniques then allows these measurements to better predict a patient's blood sugar and crucially provide advanced early detection to different types of infusion failures. By measuring infusion failure for the first time, SmartFusion will also be able to provide personalized recommendations for patients and their healthcare teams on how to reduce chronic infusion failure, helping reduce both insulin and supplies waste, as well as improving both short and long-term health outcomes.

A 2020 Diatech study of the effects of insulin pump infusion failure on patients with diabetes was recently published at the American Diabetes Association's 81st Scientific Sessions in June 2021. After analyzing the responses of 707 survey participants, 97% reported that they have experienced infusion failure regardless of their pump brand, age, or experience level. Additionally, 41% of the participants indicated that they experience at least one infusion failure per month. Patients with ≥1 infusion failure a month were significantly more likely to be first alerted of infusion failure by hyperglycemia and symptoms rather than by the pump's alarm, feel more burnt out by their diabetes technology, and want to end insulin pump use.

Study Link: Insulin Pump Infusion Set Failure (IPISF) Management: T1D Exchange Survey

After the survey, 50 random respondents volunteered to be interviewed about their experiences with insulin pump use and infusion failure. These patients overwhelmingly cited the pump's inability to provide accurate notifications of infusion failures as a factor that damages their trust in the technology. Out of the interviewee group, 64% said they want to or would consider changing their primary insulin pump of choice for one with better failure detection capabilities.

Despite the failure rates found in commercially available insulin pumps (having been reported as the most common medical device to appear in the FDA's adverse event database), the technology continues to see broad support among doctors and patients as a significantly effective treatment of type 1 diabetes. As insulin pumps become more automated (Automatic Insulin Delivery systems) and are worn on the body longer (7-day Extended Wear Infusion Sets), there is a major need for technology that helps adult patients, pediatric patients, and caregivers better monitor insulin infusion and avoid deleterious health impacts from insulin pump infusion failure.

Diatech's upcoming Phase 1 SBIR preclinical study will seek to establish proof that new techniques for monitoring insulin infusion can lead to improved health outcomes and reduced insulin waste. After the success of this NIH-NIDDK supported research, Diatech aims to conduct clinical trials with patients with type 1 diabetes in 2023.

About the National Institutes of Health's Small Business Programs

The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, also known as America's Seed Fund, are some of the largest sources of early-stage capital for technology commercialization in the United States. These programs allow US-owned and operated small businesses to engage in federal research and development that has a strong potential for commercialization.

NIH's SBIR and STTR programs invest over 1 billion dollars into health and life science companies that create innovative technologies and align with NIH's mission to improve the health and lives of patients. A key objective is to translate promising technologies into the private sector and enable life-saving innovations to reach consumer markets.

About Diatech Diabetes

Diatech Diabetes is a Memphis-based medical device startup focused on developing smart technologies that improve the lives of all patients who rely on infusion therapy. Diatech's team of industry leaders are personally committed to advancing the field of diabetes and are driven by a mission to implement solutions that address problems patients with diabetes face with their care technology.

Learn more about our company and mission by visiting www.diatechdiabetes.com.

To contact a member of our team with questions or interest in investment opportunities, please email us at info@diatechdiabetes.com.

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