## Pilot Study at Nemours Children's Specialty Care Helps Advance Research to Develop Artificial Pancreas

New device could eliminate manual blood sugar tests for patients with Type 1 Diabetes

Nemours Children's Specialty Care in Jacksonville, FL, is performing cutting age research in diabetes and is one of four research centers in the U.S. testing a novel closed-loop insulin delivery system, known as iLet®, a bionic pancreas. Researchers leading this clinical pilot study have been studying the use of the device in children with Type 1 Diabetes to determine advantages of this technological innovation over standard care of an insulin pump for management of the disease.

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"Type 1 diabetes is not an easy disease to live with, however great strides are being made to advance our understanding of the disease and develop new treatments to reduce the impact it has on children's lives," said Nelly Mauras, MD, Chief of Pediatric Endocrinology at Nemours Children's Specialty Care and Principal Investigator at Nemours. "I'm very hopeful that over the next few years, we're going to change the standard of care in diabetes."

Type 1 Diabetes is a the second most common chronic disease of childhood in which the pancreas produces little or no insulin, the hormone that lowers blood sugar. Treatment of this lifelong condition focuses on constantly managing blood sugar levels with insulin, diet and lifestyle to prevent complications.

The iLet® device, developed by Ed Damiano, PhD, Professor of Biomedical Engineering at Boston University, uses catheters placed under the skin to automatically detect blood sugars and deliver doses of insulin using proprietary mathematical dosing algorithms. The device operates autonomously, but shares data and information with children, parents and the clinical team using Bluetooth-enabled technology to ensure efficient monitoring. To test the device with young children, Dr. Mauras and her team enrolled six children, ages 6-11 years, and their families to participate in the pilot over a two-week period, scheduled as a "mini-camp" to ensure all participants had similar activity levels during the study.

Children were randomized to use the iLet® for five continuous days and nights during either the first or second week of the clinical pilot, alternating with usual care of insulin pumps to determine if the device provided better management of each child's T1D. The study is being funded by the National Institutes of Health.

"Beyond the camaraderie of the camp experience, this study shows me there is a future for my daughter where she will not constantly be worried about managing her disease," said Lisa Moore, mother of Josephine Moore (11).

The device can be configured as an insulin-only bionic pancreas, as studied in this trial, a glucagon-only bionic pancreas, or a dual-hormone bionic pancreas, to most effectively manage patient's disease. The results of this research will help advance knowledge of closed-loop insulin delivery devices with the ultimate intent to simplify diabetes care. Following this stage of research, the device will continue to be refined and studied in clinical settings before it is commercially available.

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