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## **Lankenau Hospital physicians research a new treatment for diabetes**

*(with photo – jpg)*

WYNNWOOD, Pa. – Two endocrinologists at Lankenau Hospital in collaboration with the Lankenau Institute for Medical Research (LIMR) are conducting groundbreaking research they hope will produce a new treatment for diabetes, a disease that affects 20.8 million adults and children in the United States.

Claresa Levetan, MD, and Rita El-Hajj, MD, are working with Lisa Laury-Kleintop, Ph.D., of LIMR, who is collaborating on the research. The physicians believe their approach, which combines advances in the study of proteins and cell biology, has the potential to reverse diabetes by establishing new insulin-producing islets in the pancreas, the organ that makes the hormone.

“An individual who has diabetes does not produce or properly use insulin, which is necessary for the body to convert sugar, starches, and other food into energy,” says Dr. Levetan. “Our research indicates that it may be possible to repopulate the pancreas with cells that can produce insulin.”

Dr. Levetan and Dr. El-Hajj are the founding physicians of CureDM, Inc., a biopharmaceutical company they established to develop new therapies that may prevent, ameliorate, or reverse diabetes.

“Diabetes is a serious threat to the health of Americans, putting them at risk for complications including cardiovascular, kidney, eye diseases, and nerve damage,” said Dr. El-Hajj. “We are optimistic that our research can one day help stem the surge in diabetes cases.”

According to Drs. Levetan and El-Hajj, CureDM has discovered a novel human peptide (Human proIslet Peptide or HIP) that stimulates precursor cells in the pancreas to become insulin-producing islets.

“We think we can achieve pancreatic function by treating diabetics with this peptide,” said Dr. Levetan. “If we’re successful, diabetes will no longer be a chronic disease; it will be a transient metabolic disorder.”

Until the last decade, scientists thought people were born with a fixed number of insulin-producing islets. “We now know that these precursor cells exist even in patients with diabetes, and that means we can apply our approach to treating both type 1 and type 2 diabetes,” said Dr. Levetan.

As new islets are formed, the researchers believe, the secretion of insulin returns, and other hormones that are deficient among diabetes patients, such as amylin, are also restored, as is the physiological control for these hormones.

Type 1 diabetes, an auto-immune disease, is usually diagnosed in children and young adults, and was previously known as juvenile diabetes. Type 2 diabetes, the most common form, is also a result of premature death of insulin producing cells, but for reasons other than auto-immunity. In both types of diabetes, the body does not produce enough insulin.

One of the advantages of the approach that Drs. Levetan and El-Hajj are taking is that it requires no embryonic stem cell research. And unlike islet transplants, only auto-immune suppression is involved and only for the type 1 diabetes patients.

In addition to its partnership with the Lankenau Institute, CureDM is affiliated with Calvert Laboratories, a research laboratory in Scranton, Pa., which is conducting preclinical testing of the peptide to provide data required to meet the standards set by the U.S. Food and Drug Administration Safety for human clinical trials.

Lorraine V. Upham, chief executive officer of CureDM, says the company recently achieved two milestones:

- The completion of studies that defined structural improvements to stabilize the peptide for human therapeutic use.
- A study with mice that showed the peptide reversed diabetes in a treatment group as compared with the placebo group. One treatment group was able to stop using insulin by the 21st day of treatment with HIP.

“Demonstrating efficacy in mice is tremendously exciting,” says Ms. Upham. “Ultimately, we believe that HIP will be shown to be capable of restoring normal glucose metabolism in humans.”

Among CureDM’s next steps is to design a human clinical trial. The pre-clinical process is well-underway with Calvert laboratories, and CureDM expects to submit an application for a Investigational New Drug (IND) approval to the FDA later this year.

The partnership with LIMR "opens up exceptional opportunities for CureDM," adds MS. Upham. "Being on the Lankenau campus gives us access to leading researchers, which we hope will allow us to accelerate the development of novel therapeutic compounds for diabetes and establish new strategies for treating metabolic diseases."

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**Photo Caption:**

Groundbreaking research to find a new treatment for diabetes is being conducted through a collaborative effort at Lankenau Hospital and the Lankenau Institute for Medical Research (LIMR). Lankenau Hospital endocrinologists Dr. Claresa Levetan and Dr. Rita El-Hajj are the founding physicians of CureDM, Inc., a biopharmaceutical company they established to develop new therapies that may prevent, ameliorate, or reverse diabetes. They are working on the research with Dr. Lisa Laury-Kleintop of LIMR. In photo from left: Dr. Laury-Kleintop, Dr. El-Hajj, CureDM CEO Lorraine V. Upham, and Dr. Levetan.

**Editor’s Note:** Of 20.8 million people who have diabetes, nearly one-third do not even know it, according to the American Diabetes Association. The total annual economic cost of diabetes in 2002 was estimated to be \$132 billion, or one out of every 10 health care dollars spent in the United States.