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New hope for diabetics: Innovative treatment begins clinical trials at MUHC

Study of new Exsulin™ peptide treatment for type 1 diabetes starts this month

Montreal, February 10, 2010 - A clinical trial of Exsulin, an innovative new treatment that targets the underlying cause of type 1 diabetes, has begun at the McGill University Health Centre (MUHC). Under the direction of Dr. George Tsoukas of the MUHC and the McGill University Faculty of Medicine, the study will assess the effectiveness of Exsulin.

This potentially groundbreaking therapy was made possible by fundamental research led by Dr. Lawrence Rosenberg of the MUHC and McGill University Faculty of Medicine. The study is conducted in partnership with the Mayo Clinic in Rochester, Minnesota.

Type 1 diabetes is triggered when a patient's immune system attacks and destroys insulin-producing beta cells in the pancreas. This prevents normal insulin secretion and the normal regulation of blood sugar levels. There is currently no cure for type 1 diabetes and it can only be controlled through regular insulin injections. Although these injections partially avoid sugar level fluctuations in the blood they do not prevent the onset of other complications.

Dr. Rosenberg and his colleagues have been working on an Exsulin-based treatment to stimulate the regrowth of insulin-producing beta cells in diabetic patients for more than 25 years.

"Exsulin has already been tested in animal models of diabetes," he explained. "These experiments demonstrated that Exsulin injections help restore insulin production in animals whose insulin production had been lost. For example, mice injected with this new molecule were cured of their diabetes."

The results of previously conducted human trials have indicated that Exsulin triggers at least a partial recovery of natural insulin secretion. Although at this stage of development it may not completely control the amount of circulating glucose, Exsulin does improve glucose homeostasis, which prevents the dramatic fluctuations that can lead to the main complications of diabetes: neuropathy, renal failure, blindness and heart disease. This new clinical trial aims to test a new formulation of Exsulin and to establish the best dosing schedule, as well as the most effective dosage.

In vitro experiments on human pancreatic tissue have shown that Exsulin acts on stem-like cells by causing them to differentiate into new insulin-producing beta cells, as well as the three other types of endocrine cells that make up the islets of Langerhans. In a healthy pancreas, these "islets," or small groups of cells, house all cells that produce glucagon, somatostatin, pancreatic polypeptide, as well as those that produce insulin.

"This means that Exsulin could help rebuild the islets' entire structure, restoring near-normal metabolic control—something that insulin injections alone cannot do," concluded Dr. Rosenberg.

Dr. Lawrence Rosenberg is Chief of the Division of Surgical Research, and Professor of Surgery and Medicine at McGill's Faculty of Medicine. He holds the A.G. Thompson Chair in Surgical Research at the MUHC and is also an investigator in the Endocrinology, Diabetes, Nutrition and Kidney Diseases Axis of the Research Institute of the MUHC. Dr Rosenberg is also Chief of Surgical Services at the SMBD-Jewish General Hospital.

Dr. George Tsoukas is a senior member of the Department of Endocrinology at the MUHC and he currently supervises the Montreal General Hospital Diabetes Clinic at the MUHC. He is also a clinical investigator in the "Musculoskeletal Disorders" axis at the Research Institute of the MUHC and has been involved in many clinical trials involving diabetes and associated illnesses. Dr. Tsoukas is an Associate Professor in the Faculty of Medicine at McGill University.

Funding

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On the Web

- Research Institute of the McGill University Health Centre: www.muhc.ca/research
- McGill University: www.mcgill.ca
- Exsulin Corporation: www.exsulin.com

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