

Exsulin Corporation Announces Publication Of Phase 2 Trial Results For Novel Islet Regeneration Treatment In Type 1 & Type 2 Diabetes

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Exsulin Corporation announced milestones achieved and immediate plans to move forward as a well supported Minnesota-based company dedicated to the development of regeneration therapies for the treatment of diabetes mellitus. Exsulin's focus is on development of a drug with potential to become a breakthrough therapy for patients suffering from type 1 (T1DM) and type 2 diabetes (T2DM). Phase II human clinical trial data of Exsulin(TM) (INGAP peptide), a peptide drug product aimed at restoring the ability of the pancreas to produce insulin normally in people with diabetes mellitus, have just been published online by Diabetes/Metabolism Research and Reviews.

Exsulin Corporation, founded by diabetes industry professionals, is supported by a proven clinical, development and regulatory management team and is advised by globally recognized diabetes experts. To follow on and support the results documented in the recent trial data publication, Exsulin has received clearances for a trial in patients with established (not newly diagnosed) T1DM, a population subset with no other currently active clinical trials. Other milestones achieved by Exsulin include reformulation and procurement of drug product, support of key independent laboratory research, and securing regulatory authorization to initiate a new clinical trial.

"Since the landmark discovery of insulin in 1921, only incremental progress has been made in insulin therapy, which remains difficult and hazardous - particularly for people with T1DM," said G. Alexander Fleming, MD, founder and chairman, Exsulin Corporation. "These study results are very encouraging that Exsulin therapy could restore normal insulin secretion, which would allow insulin dependent T1DM and T2DM patients to achieve normal glucose control while decreasing or ending their dependence on insulin treatment."

The first two phase II placebo-controlled 12-week trials - one in T1DM patients and one in T2DM patients - tested two doses of once-daily injected Exsulin and found that continued study for both T1DM and T2DM treatment is warranted. Exsulin is a hormone that is being studied for its ability to regenerate islets in the pancreas, which contain the insulin-producing beta cells. Restoration of insulin secretion could potentially reduce or eliminate the challenges of maintaining normal glucose control for all patients with T1DM and insulin dependent T2DM.

In the T1DM study (SPIRIT 1), Arginine-stimulated C-peptide (AUC0-30) significantly increased from baseline in the 600 mg group ($p = 0.0058$ versus placebo) while in the T2DM patients (SPIRIT 2) stimulated C-peptide was significantly better preserved in the 600 mg group 30 days after washout ($p = 0.031$ versus placebo). In T2DM patients, A1C decreased significantly more in the 600 mg group compared to placebo at day 90 (-0.94% versus -0.47%, respectively, $p = 0.009$) and day 120, 30 days after washout (-0.73% versus -0.24%, respectively, $p = 0.013$). This was accompanied by significant reductions in mean glucose. Placebo-adjusted A1C trended downward in T1DM patients. Stimulated C-peptide is recommended by experts as the best measure of endogenous insulin secretion and has been acknowledged by FDA to be the primary regulatory efficacy endpoint for T1DM therapies. Increasing evidence underscores that even small amounts of retained insulin secretion helps to prevent complications and serious hypoglycemia in people with T1DM.

Diabetes is a life threatening condition affecting nearly 24 million people in the United States and over 200 million worldwide. Diabetes has remained one of medicine's most significant and costly

chronic diseases without a cure. By restoring natural insulin secretion, Exsulin may potentially reduce the high risk of dangerous complications associated with diabetes such as life-threatening hypoglycemia, blindness, kidney failure, cardiac failure, and amputation. There are more than two million North Americans who have T1DM and more than twice as many with insulin dependent T2DM. In T2DM, insulin-secreting beta cell mass is already reduced by 50% at the time of diagnosis and continues to decline throughout the course of the disease. Patients with a significant loss of beta cell mass are totally dependent on injected insulin. Insulin therapy poses substantial challenges including danger of life threatening low blood sugar levels.

"We believe these trial results and further studies will confirm the potential for Exsulin as a breakthrough in diabetes treatment," said Lisa Jansa, founder and CEO, Exsulin Corporation. "Exsulin will soon begin new Phase II clinical trials at leading diabetes research centers."

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About Exsulin Corporation

Based in Minneapolis, Exsulin Corporation has global rights to a platform that enables research and development of islet cell regeneration approaches for reversing a fundamental cause of type 1 and type 2 diabetes. Exsulin aims to change the future of diabetes care and win significant cost savings for the healthcare system. Exsulin works with leading research labs and clinical investigators in multiple countries to advance understanding and treatment of diabetes.

Source: Exsulin Corporation

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