



For Immediate Release
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DiaKine Therapeutics' Lead Compound in Phase 2 Clinical Trial

Lisofylline studied to improve outcomes of islet cell transplants in diabetic patients

CHARLOTTESVILLE, VA (October 14, 2008) – [DiaKine Therapeutics](#), developers of drugs designed to cause diabetes to go into remission, announced today that a Phase 2 Clinical Trial with the Company's lead drug candidate, Lisofylline (LSF), is underway.

Use of LSF may improve the long-term success of transplanting islets (the insulin-producing cells of the pancreas) into people with type 1 diabetes. The trial is part of the [Clinical Islet Transplantation \(CIT\) Consortium](#) created by National Institutes of Health. The protocol, CIT-02, will focus on treating islets pre-transplant, and recipients - during and post-transplant - with LSF.

LSF is a synthetic small molecule with novel anti-inflammatory properties that blocks autoimmune damage to insulin producing cells. Lisofylline has demonstrated that it can effectively prevent type 1 diabetes in preclinical models. Lisofylline and related compounds are being commercialized into therapies for type 1 and type 2 diabetes and related complications by Dr. Jerry Nadler, DiaKine's co-founder, Chairman, and Chief Science Officer of DiaKine Therapeutics and the Chief of Medicine at the [Eastern Virginia Medical School](#) in Norfolk, Virginia.

“LSF is included in the trial because of its unique ability to protect islets from damage caused by inflammation and improper immune response, a primary cause of type 1 diabetes,” said Dr. Nadler. “We believe that LSF has the potential to improve the viability and long-term function of transplanted islets, thereby increasing the number of successful transplants and improving the quality of life for more people with type 1 diabetes.”

The primary objective of this study is to determine the proportion of patients who become insulin independent at 75 ± 5 days post-transplant with a single islet infusion, the standard islet transplant regimen (a modified Edmonton Protocol) and the addition of LSF. LSF will be compared, as a secondary analysis, to subjects in a concurrent Phase 3 protocol, CIT-07, which uses only the standard immunosuppressive regimen. Secondary efficacy endpoints include a percent reduction in insulin requirements, measurements of HbA1c and C-peptide/glucose x creatinine. Islets will be processed at the University of Miami (UM), and recipients will be recruited and transplanted at the UM. The secondary site for this study will be at the University of Chicago in Illinois.

“DiaKine is honored to be part of this major collaborative effort from the NIH, and in particular have our lead drug candidate, LSF, selected by the University of Miami for inclusion as one of the new test agents,” said Keith Ignatz, President and Chief Executive Officer for DiaKine Therapeutics. “We also wish to thank the Type 1 Diabetes Rapid Access to Intervention Development (T1D RAID) program of the NIDDK for producing the clinical trial supplies for the study.”

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the National

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Institute of Allergy and Infectious Disease (NIAID) of the National Institutes of Health are the trial's sponsors. The NIDDK and NIAID funded this major new Clinical Islet Transplantation Consortium in 2004 to overcome barriers in islet transplantation by developing novel therapies for type 1 diabetes.

In addition to potentially improving islet transplant outcomes, DiaKine's pipeline includes oral and parenteral drugs to reverse type 1 diabetes, treat type 2 diabetes and a number of diabetes-related complications.

About DiaKine --

DiaKine Therapeutics, Inc. is a development-stage company commercializing novel immune modulators for the treatment of diabetes and related complications. These drugs have the potential to stop the progression of diabetes and reverse damage already caused by the disease. Therapeutics under development by DiaKine include: adjunct therapy to islet cell transplants (in Phase 2 clinical trial), halting the progression of type 1 diabetes in newly diagnosed adults, treatment and prevention of Latent Autoimmune Diabetes of Adults (LADA), treatment and prevention of insulin requiring type 2 diabetic, treatment and prevention of diabetes complications. DiaKine would like to thank the National Institute of Diabetes & Digestive & Kidney Diseases/National Institutes of Health (NIDDK/NIH) for producing the clinical trials supplies for the trial. For more information, visit www.diakine.com.

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