



For Immediate Release
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DiaKine Therapeutics Diabetes Immune Modulator Drug Set for Human Clinical Trial

Lisofylline in Phase 1 – 2A trial after new IND in effect

CHARLOTTESVILLE, VA (May 12, 2009) – A drug being developed by [DiaKine Therapeutics, Inc.](#), which has shown in animals to prevent type 1 diabetes when given as a single therapy and to reverse diabetes when given in combination with a growth factor, is set to begin the first Company-sponsored clinical trial in humans. It is also the first clinical trial where [Lisofylline](#) (LSF) will be given to subjects under the skin (subcutaneously) using a convenient, ambulatory pump and the first time the drug will be tested to determine the effect it might have on certain inflammatory markers of type 1 diabetes.

The trial is expected to begin May 25, 2009 and is an open-label, single-dose, randomized, two-period, two-treatment, crossover study in healthy subjects and in subjects with type 1 diabetes. There will be two treatment groups: LSF as a continuous subcutaneous infusion over 24 hours and LSF as a continuous intravenous infusion over 24 hours. The objectives of the study are to compare the safety, tolerability, and bioavailability of the two, 24 hour dosing methods and will also examine the early efficacy of LSF. The study will be conducted in approximately eight people, four with type 1 diabetes and four healthy subjects. For more information about the trial, please go to <http://clinicaltrials.gov/ct2/show/NCT00896077> at ClinicalTrials.gov Identifier: [NCT00896077](#).

“It is very exciting to see this clinical trial begin. We hope that this is the first step in developing new ways to help people with type 1 diabetes,” said Dr. Jerry Nadler, Chairman, and Chief Science Officer of DiaKine Therapeutics and the Chief of Medicine at the Eastern Virginia Medical School in Norfolk, Virginia. “If this trial is successful, the next step will be to move forward with key trials to use LSF alone in patients with new onset type 1 diabetes and in combination with a beta cell growth factor to help restore the patient’s own insulin production.”

The Company’s Investigational New Drug (IND) application with the Division of Metabolism and Endocrinology, Center for Drug Evaluation and Research of the Food and Drug Administration went into effect on May 6, 2009.

“This new IND and the clinical trial are major milestones for the Company and the diabetes community,” said Keith Ignatz, President, and Chief Executive Officer for DiaKine Therapeutics. “Successful completion, with positive outcomes should greatly increase DiaKine’s value and that of our library of other immune modulating compounds.”

LSF is a synthetic small molecule with novel anti-inflammatory properties that has been shown to block autoimmune damage to insulin producing cells and to improve insulin action in type 2 diabetes. Lisofylline has also demonstrated that it can effectively prevent type 1 diabetes in preclinical models.

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“We wish to thank the Iacocca and Farish Foundations for their financial support and Frontage Laboratories and Advanced Biomedical Research for their services that lead to the submission of the new IND,” said Dr. Nadler.

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. For more information, visit www.diakine.com.

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