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## **DiaKine Therapeutics and Kinexum Metabolics to Develop Novel Combination Treatment to Type 1 Diabetes**

*Lisofylline and INGAP peptide combo therapy set for Phase 2 clinical trial*

CHARLOTTESVILLE, VA and HARPER'S FERRY, WV (May 6, 2008) DiaKine Therapeutics, Inc. and Kinexum Metabolics, Inc. today announced an agreement to jointly develop a new combination therapy, that has shown in preclinical studies, to cause type 1 diabetes to go into remission by protecting and promoting the growth of new insulin-producing cells.

A Phase 2 human clinical trial with the new combination therapy, consisting of DiaKine's Lisofylline (LSF) and Kinexum's INGAP peptide, is expected to begin in late 2008. The trial will be unique in that patients who are beyond the 'newly diagnosed' period will be included in the study. Current trials seeking to treat people with type 1 diabetes do not include those with established disease.

"We believe these two drugs in combination create a unique and highly-effective treatment that could restore endogenous insulin to people with type 1 diabetes," said Dr. Jerry Nadler, Chief Scientific Officer for DiaKine Therapeutics. "It is becoming abundantly clear that a combination therapy is the best path for restoring the body's natural ability to regulate blood sugar and giving people with type 1 diabetes their lives back."

"Pursuing a cure for type 1 diabetes remains the strongest interest and commitment in my career. I see great promise in this scientific and corporate collaboration for achieving a definitive treatment of this difficult disease," said Alexander "Zan" Fleming, M.D., who headed diabetes drug review at FDA and now serves as Chief Medical Officer of Kinexum Metabolics.

"We believe that the combination therapy of Lisofylline and INGAP peptide has the potential to be a blockbuster drug," said Keith D. Ignatz, President and CEO of DiaKine Therapeutics. "We believe that, if successful, this new therapy could dramatically change the approach to treating diabetes." Kevin Roché, CEO of Kinexum Metabolics, added "It is clear that we will not get to a cure for type 1 diabetes

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if we don't use a combination of therapies. This collaboration is part of the plan for doing that sooner than later.”

Lisofylline is a synthetic small molecule with novel anti-inflammatory properties. LSF has demonstrated that it can effectively prevent Type-1 diabetes in preclinical models. LSF has shown to improve cellular mitochondrial function and to reduce interleukin 12 (IL-12) signaling and STAT-4 activation in target cells and tissues. IL-12 and STAT 4 activation are important pathways linked to inflammation and immune damage to insulin producing cells.

Islet neogenesis associated protein (INGAP) is a member of the Reg3 family of pancreatic proteins. INGAP peptide, the active portion of the larger protein, induces islet regeneration in multiple species including humans. It is currently under development by Kinexum Metabolics, Inc.

#### **About Kinexum Metabolics, Inc–**

Kinexum Metabolics, Inc. is a biopharmaceutical company focused on the development of therapies for the treatment of Type 1 and Type 2 diabetes and other metabolic conditions. The company was founded by partners from Kinexum LLC, which provides strategic development, regulatory, and commercial guidance and other services across the international life sciences industry. For more information, visit [www.kinexummetabolics.com](http://www.kinexummetabolics.com) and [www.kinexum.com](http://www.kinexum.com).

#### **About DiaKine --**

DiaKine Therapeutics, Inc. is a development-stage company commercializing novel immune modulators initially targeting the treatment of autoimmune and inflammatory diseases such as diabetes and related complications. These new drugs regulate cytokines, part of the body's immune system, which mistakenly attack tissue and cause inflammation. The Company designed its first product, IsletLife-LSF Media 1, to improve the viability and insulin producing capabilities of harvested islet cells prior to transplant. IsletLife-LSF Media 1 thus can potentially improve the success rate of the procedure. Additional therapeutics under development by DiaKine include: adjunct therapy to islet cell transplants, 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 diabetics, treatment and prevention of diabetes complications. For more information, visit [www.diakine.com](http://www.diakine.com).

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