

DIOBEX ANNOUNCES SUCCESSFUL COMPLETION OF PHASE 2A TRIAL OF DIO-902, A NOVEL CORTISOL SYNTHESIS INHIBITOR FOR TYPE 2 DIABETES

Diobex

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DiObex, Inc., a privately-held biopharmaceutical company focused on the development of therapeutics to treat metabolic diseases, today announced positive phase 2a results for DIO-902, a novel Cortisol Synthesis Inhibitor.

In a recently completed multi-center, randomized, placebo-controlled trial, patients with type 2 diabetes were treated for two weeks to evaluate the safety, pharmacokinetics and activity of three dose levels of DIO-902. After two weeks of treatment, patients at all dose levels of DIO-902 showed significant reductions in total and LDL-cholesterol as well as trends toward an improvement in glycemic control as measured by HbA1c, fructosamine and fasting blood glucose. Mean levels of C-reactive protein, an inflammatory marker, were also significantly reduced. In contrast, metabolic control in patients in the placebo group remained stable or deteriorated slightly. These data lend support to the concept that abnormalities in cortisol activity may play an important role in the causation of type 2 diabetes and metabolic syndrome, a cluster of co-morbidities commonly associated with type 2 diabetes and insulin resistance. In the growing number of patients with type 2 diabetes and metabolic syndrome, co-morbidities such as hypertension and abnormal lipoprotein levels dramatically increase the risk of cardiovascular disease.

DiObex, Inc.

DIO-902 is one of two enantiomers contained within racemic ketoconazole, a marketed drug. Results of a separate drug-interaction study, conducted in normal healthy volunteers, in which Lipitor(R) (atorvastatin) was co-administered with DIO-902, support the co-administration of DIO-902 with the most commonly used doses of atorvastatin. This study also provided clinical evidence of a significant differential effect of DIO-902 and racemic ketoconazole on the metabolism of atorvastatin, thereby reducing the potential for toxicity. DIO-902 has been proven to be both more effective and safer than the racemic mixture in preclinical studies.

"We are delighted with the preliminary data that we have generated to date, and at the prospect of taking the leading Cortisol Synthesis Inhibitor to the next level of clinical development. DIO-902 is clearly at the head of the pack in the advancement of this exciting new drug category," commented Daniel Green, DiObex President.

"DIO-902 offers the possibility of adding a new therapy to the armamentarium which may have an impact on the underlying cause of type 2 diabetes. The prospect of significantly reducing multiple cardiac risk factors with a single drug is an extremely attractive opportunity to enhance patient compliance and convenience while reducing the need for polypharmacy," said Bernice Welles, M.D., Vice President of Development at DiObex.

DiObex plans on initiating a 16-week phase 2b dose-ranging study with DIO-902 in mid 2007.