



Diasome Announces Dosing of First Type 1 Diabetes Patient in Randomized Phase 2b Clinical Trial of Injectable Hepatocyte Directed Vesicle (“HDV”) Technology With Insulin

The ISLE-1 program will study the effect of HDV Insulin on glucose control in patients with Type 1 diabetes over a six-month dosing period.

Diasome Pharmaceuticals, Inc., a clinical stage life-sciences company developing novel liver hepatocyte targeting systems for injectable insulin therapies to improve the treatment of Type 1 and Type 2 diabetes, announced that patient dosing has commenced in its ISLE-1 (“InSulin Liver Effect – 1”) Study, a multi-center, double-blinded, randomized controlled Phase 2b clinical trial of HDV Insulin, a first-in-class liver hepatocyte targeted form of commercially available rapid-acting insulin.

“The initiation of this randomized study represents an important milestone for Diasome and for patients with Type 1 diabetes,” said W. Blair Geho, MD, PhD, Chief Scientific Officer of Diasome Pharmaceuticals. “Given the fundamental and routine role of insulin in the liver in maintaining normal glycemic control, the ability to use a sophisticated and very novel liver cell targeting system as an additive to already approved insulins could provide insulin requiring patients much better overall glucose management. The goal of the ISLE-1 study is to demonstrate that people with Type 1 diabetes can achieve better and safer glucose control when a portion of their injected insulin is able to mimic the normal action of insulin from the pancreas during a meal.”

The ISLE-1 study is expected to enroll up to 200 subjects with Type 1 diabetes at 25 sites, randomized in a 2:1 ratio to either HDV added to a leading commercial pre-meal insulin or that commercial insulin without HDV. The study will evaluate the effect of HDV as an insulin additive over six months of dosing on a variety of standard diabetes outcomes, including overall glycemic control.

About Hepatocyte Directed Vesicle Technology

HDV is a unique liver hepatocyte targeting system that is being evaluated as an additive to commercially available insulin therapies. In nonclinical studies, HDV has been shown under a variety of test conditions to deliver critical amounts of injected insulin directly and preferentially to hepatocytes, thereby providing pre-meal insulin in a manner that more closely mimics the normal release of insulin from the pancreas in response to a carbohydrate meal. In completed human studies, HDV has been shown to significantly lower post-meal peripheral glucose levels in comparison to identical amounts of untargeted commercial insulin therapy.

About Diasome Pharmaceuticals, Inc.

Diasome is a clinical stage life-sciences company focused on developing novel liver hepatocyte targeting systems for injectable insulin therapies to improve the treatment of Type 1 and Type 2 diabetes. Diasome's lead technology, the HDV system for injected insulin therapies, is under evaluation as an additive to pre-meal injected insulin therapy. The Company also has programs related the development of other novel, liver-specific therapies for treating diabetes.



Contact Information

Robert Geho

Diasome Pharmaceuticals, Inc.

<http://www.diasome.com>

216-444-7110