metabolic solutions development company

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Metabolic Solutions Development Company announces publication of Phase 2b data in *Clinical Pharmacology & Therapeutics*

Data show prototype mTOT Modulator™ lowered glucose with less weight gain, fluid retention versus Actos® in patients with type 2 diabetes

KALAMAZOO, Mich., Jan. 24, 2013 - Metabolic Solutions Development Company, LLC (MSDC) announced today the publication of data from a Phase 2b study of the company's prototype insulin sensitizer in patients diagnosed with type 2 diabetes. The data demonstrate MSDC-0160, a novel once-a-day oral insulin sensitizer and the first in a new class of therapeutic agents called mTOT Modulators™, met the study's primary endpoint of significantly reducing fasting plasma glucose (FPG) and significantly reduced hemoglobin A1c (HbA1c).

Of particular importance, the data showed that changes in body weight, hemoglobin, and an important biomarker associated with the production of white fat were significantly less in type 2 diabetic patients treated with MSDC-0160 than in patients treated with a comparator drug, pioglitazone 45 mg, a PPARγ agonist. The mTOT paper is available online and is expected to be published in the print edition shortly.

The research was led by MSDC co-founder Jerry Colca, PhD, who was among the original researchers in the field of insulin sensitizers, and who selected and led the early development of Actos (pioglitazone). Dr. Colca's career-long study of the endocrine control of metabolism is the basis for MSDC's research and development of novel compounds that may treat the root causes of disease of diabetes, insulin resistance and defects in pancreatic beta cell function. The research has led to the discovery of a new target for insulin sensitizers.

"This data confirms our hypothesis that insulin sensitization by mTOT modulators can produce the same

lowering of glucose as drugs like pioglitazone, but without the side effects caused by PPARγ agonists," said Jerry Colca, PhD, president and chief scientific officer. "This prototype and its successor MSDC-0602 represent the next generation of insulin sensitizers."

MSDC's novel insulin sensitizing agents selectively modulate mTOT, a protein complex located in the inner mitochondrial that appears to coordinate carbohydrate, lipid, and amino acid metabolism. This new drug target may also play a role in other diseases of aging such as Alzheimer's disease and Parkinson's disease, as well certain genetic diseases such as polycystic kidney disease.

Phase 2 Clinical Results Support New Target Hypothesis

The publication supports MSDC researchers' long-held hypothesis that lowering of plasma glucose can be achieved without having to activate a nuclear receptor called PPARγ, thus providing a new way forward for insulin sensitizers without the side effects that have prevented the development of new drugs Previously, it was believed that both the activity and the side-effects of the only approved class of drugs used to treat insulin resistance -- the core problem for persons diagnosed with type 2 diabetes -- were mediated through PPARγ. These studies provide a fresh approach and a new target for new drugs to treat diabetes.

About the MSDC-0160 Phase 2b Study

This study was a 90-day, randomized, double-blind, comparator- and placebo-controlled, multi-dose study completed in 258 patients with type 2 diabetes. The study compared three doses of MSDC-0160 (50 mg, 100 mg and 150 mg) to maximum dose Actos (pioglitazone 45 mg) or placebo taken orally once daily for 12 weeks. All treatments were well tolerated. There were no serious adverse events attributed by investigators to the MSDC drug.

Key top-line data from this study include the following:

- Both 100 mg/day and 150 mg/day of MSDC-0160 significantly lowered fasting plasma glucose (primary study endpoint).
- Both 100 mg/day and 150 mg/day of MSDC-0160 lowered hemoglobin A1c similar to 45 mg/day pioglitazone.

- MSDC-0160 produced significantly less volume expansion than pioglitazone at any dose. There was a statistically significant difference between MSDC-0160 and pioglitazone in the effects the compounds had on circulating total hemoglobin and red blood cells (markers of plasma volume expansion).
- No dose of MSDC-0160 was able to increase adiponectin as much as pioglitazone, supportive of less increase in calorie storing white adipose tissue (i.e., white fat).
- The 100 mg dose of MSDC-0160 was effective with significantly less weight gain and no increase in waist circumference.

About Metabolic Solutions Development Company

Metabolic Solutions Development Company (www.msdrx.com) is a drug discovery and development company investigating novel molecular targets and developing new therapeutics to treat metabolic diseases associated with age-related mitochondrial dysfunction, especially type 2 diabetes.

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