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METABOLIC SOLUTIONS DEVELOPMENT COMPANY REPORTS POSITIVE TOP-LINE RESULTS FROM PHASE 2A STUDY OF ITS SECOND COMPOUND TO TREAT TYPE 2 DIABETES

- Results From This Trial Form Basis For Larger, Longer Phase 2b Study In Q1 2012 -

KALAMAZOO, Mich., (September 08, 2011) - Metabolic Solutions Development Company, LLC (MSDC) confirmed today the potential of MSDC-0602 to achieve significant glucose control in type 2 diabetes patients and increase insulin sensitivity based on preliminary analysis from its Phase 2a trial of MSDC-0602, a novel insulin sensitizer.

Importantly, given the blood glucose (HbA1c) lowering shown in this short study, these data support the company's expectation of a ≥ 1.5 percent reduction in HbA1c potentially without the undesirable weight gain and other PPAR-related side-effects¹. According to the [Diabetes Control and Complications Trial](#), as HbA1c is lowered, the risks of diabetic complications such as eye, nerve and heart disease is significantly reduced.

"This proof-of-concept trial affirmed the potential of this novel insulin sensitizer to lower blood glucose and increase insulin sensitivity without the side-effects found with currently marketed products," said Jerry Colca, Ph.D., president and Chief Scientific Officer of MSDC. "The data are encouraging and we are proceeding to design a Phase 2b study of longer duration."

The safety, tolerability and efficacy of MSDC-0602 were evaluated in a 28-day, randomized, double-blind, comparator- and placebo-controlled, multi-dose study in 129 patients with type 2 diabetes. Patients were randomized to MSDC-0602, 45 mg of pioglitazone or placebo. No safety concerns were uncovered for any treatments and all treatments were well tolerated. This study follows the completion of two Phase 1 trials

¹<http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm109136.htm>

in which no safety concerns were observed. Additional safety and expanded efficacy data will be obtained from a Phase 2b study of MSDC-0602 that is targeted to begin in the first quarter of 2012.

MSDC-0602 is an insulin sensitizer that is selective for a molecular target connecting mitochondrial metabolism to cell function. Additionally, the compound's PPAR-independent pharmacology has not produced the side effects associated with activation of PPAR γ .

Insulin sensitizing compounds exert important metabolic effects on mitochondrial metabolism that invoke a molecular switch that controls important cellular processes including sensitivity to insulin. MSDC has identified a novel molecular target through which its two lead insulin sensitizers, MSDC-0602 and MSDC-0160, work to treat type 2 diabetes. The compounds selectively modulate mitochondrial control of certain metabolic-signaling and nutrient-sensing pathways resulting in improved insulin action and generation of brown adipose tissue without fluid retention or weight gain.

EASD Oral Presentation

There is an expectation there will be weight control over longer treatments with MSDC-0602 given the "browning" of adipose stores. Several recent studies^{2,3} have shown that brown adipose tissue or BAT exists in some adult humans. BAT is brown in color because it has a high concentration of mitochondria. Unlike white adipose tissue, BAT is designed to burn rather than store fat. The amount of brown fat is inversely proportioned to body weight (and white adipose tissue). MSDC compounds favor the development of brown fat in animal models and human cells in tissue culture.

MSDC will present study results on the impact of its insulin sensitizing agents on the browning of progenitor cells from the axillary fat pad in a PPAR-independent manner at the upcoming [47th European Association for the Study of Diabetes Annual Meeting](#) in Lisbon, Portugal on Tuesday, September 12 - 16, 2011:

[*New insulin sensitisers produce differentiation of brown-like adipose cells from a subcutaneous fat depot and increase secretion of adiponectin in vitro*](#)

W.G. McDonald et al, Oral Presentation 21 in Brown adipose tissue and mitochondria, Tuesday, September 13, 11:15 AM – 11:30 AM, Hispano Hall.

About Metabolic Solutions Development Company

Metabolic Solutions Development Company (www.msdrx.com) is a drug discovery and development company investigating novel molecular targets and new therapies for metabolic diseases associated with mitochondrial dysfunction, especially insulin resistance and type 2 diabetes. The company has raised more than \$55 million to support development of its lead compounds MSDC-0160 and MSDC-0602.

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²Cypress AM, et al. *NEJM*. 2009 Apr9; 360:1509-1517.

³Cannon B. and Nedergaard J. *Physiol Rev*. 2004. 84:277-359.