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Metabolic Solutions Development Company Receives \$1.1 Million NIH Grant to Further Investigate MSDC-0602 for the Treatment of Fatty Liver Disease

- Federal Funds Matched by the Michigan Emerging Technology Fund -

KALAMAZOO, Mich., October 6, 2011 - Metabolic Solutions Development Company, LLC (MSDC) announced today it has received a \$1.1 million multi-year Small Business Technology Transfer Program (STTR) grant from the National Institute on Alcohol Abuse and Alcoholism (NIAAA) of the National Institutes of Health (NIH). MSDC will use this new funding to further evaluate MSDC-0602 in animal models of fatty liver disease (FLD). FLD occurs worldwide and refers to a group of conditions which lead to an accumulation of excess fat in the liver of people who consume excessive alcohol or who are obese¹.

MSDC-0602 is a novel insulin sensitizer that is selective for a molecular target, mTOT, which functions as a "switch" connecting mitochondrial metabolism to important cell functions. In a recently completed Phase 2a study in patients diagnosed with type 2 diabetes, MSDC-0602 was shown to achieve significant glucose control and increase insulin sensitivity in a PPAR-independent manner.

"Our unique understanding of the mTOT biochemical pathway will enable MSDC's researchers, working in collaboration with our colleagues at the Washington University School of Medicine, to select compounds that treat the root cause of some of the most pressing health issues facing Americans today," said Stephen Benoit, chief executive officer, MSDC. "Importantly for patients diagnosed with fatty liver disease, these new therapeutics won't have the unwanted side effects associated with currently available insulin sensitizers."

Studies conducted under this grant will be led by principal investigators, Rolf Kletzien, PhD, senior vice president of research at MSDC, and Brian Finck, PhD, assistant professor in

¹<u>Reddy JK, Rao MS (2006). "Lipid metabolism and liver inflammation. II. Fatty liver disease and fatty acid oxidation". Am. J. Physiol. Gastrointest. Liver Physiol. 290 (5): G852–8.</u>

medicine, Washington University School of Medicine, Division of Geriatrics and Nutritional Science.

In previous preclinical studies funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the PPAR-independent pharmacology of MSDC-0602 was shown in a rodent model of FLD to improve insulin sensitivity and increase the ability of the liver to oxidize and clear fat. Those data provided the basis for the NIAAA's award of this new grant funding, which will enable the continued investigation of MSDC-0602 as a potential treatment for FLD. In addition, work under this grant is expected to identify a biomarker which potentially could be useful in the detection of early disease and monitoring therapeutic progress in future clinical trials.

It is estimated that 14-24 percent of the general population and up to 80 percent of morbidly obese individuals have FLD². FLD is associated with the complex of metabolic disorders that include diabetes, obesity, elevated blood lipids such as cholesterol and triglycerides, as well as high blood pressure. Although there are no treatments currently available for FLD, the relationship of this condition to insulin resistance and metabolic disease suggests treatments originally developed as insulin sensitizers to treat diabetes may be effective³.

Through a program funded through the Michigan 21st Century Jobs Fund, MSDC was also awarded a matching grant of \$125,000 from the Michigan Emerging Technology Fund (ETF). The mission of the ETF is to increase the numbers and competitiveness of Michigan Small Business Investigational Research (SBIR) / Small Business Technology Transfer Program (STTR) grant proposals. This additional award will assist MSDC in bringing its products to market for the benefit of patients diagnosed with metabolic diseases.

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.

² <u>http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3002571/</u> 3 <u>http://www.acg.gi.org/patients/gihealth/fld.asp</u>