New Study: NuSirt Technology Could Aid in Treatment of Non-alcoholic Steatohepatitis (NASH) and Type 2 Diabetes

Recently published research shows that a combination of NuSirt technology and low doses of marketed pharmaceuticals can reverse symptoms of fatty liver disease and improve insulin sensitivity in mice

Nashville, Tenn. (May 27, 2015) – NuSirt Biopharma today announced publication of new research showing that its technology combining leucine, an amino acid, with very low doses of phosphodiesterase 5 (PDE5) inhibitors has the potential to become a new medical therapy for diseases such as non-alcoholic fatty liver disease (NAFLD) and Type 2 diabetes. If results of the study, which was published in *Diabetes, Metabolic Syndrome and Obesity: Targets and Therapy*, are confirmed in humans, NuSirt's combination of leucine and PDE5 inhibitors could lead to medicines to treat non-alcoholic steatohepatitis (NASH), a condition for which there are no currently approved therapies.

"The results of this study indicate that NuSirt technology may offer a completely novel approach to treating diseases like Type 2 diabetes, non-alcoholic fatty liver disease and NASH, which impact millions of Americans each year," said NuSirt Founder and Chief Scientific Officer Michael Zemel, Ph.D. "On their own, leucine and commonly used PDE5 inhibitors have little utility in managing and treating these conditions, but in these studies they demonstrate remarkable synergy. We look forward to exploring this area further."

NuSirt's patented technology utilizes a naturally occurring compound, leucine, coupled with existing pharmaceuticals. In the published paper titled, "Interaction between leucine and phosphodiesterase 5 inhibition in modulating insulin sensitivity and lipid metabolism," researchers from Georgia State University's Center for Obesity Reversal and NuSirt detailed a study in which they evaluated the potential of combining leucine and PDE5 inhibitors to improve insulin sensitivity and lipid metabolism. Both play important roles in diabetes and fatty liver disease.

To begin, researchers demonstrated via cell culture that leucine and PDE5 inhibitors could be paired to significantly impact fat oxidation, nitric oxide production, and mitochondrial biogenesis in hepatocytes, adipocytes and myotubes. The researchers employed diet-induced, obese mice to test the ability of leucine and PDE5 inhibitors to improve insulin sensitivity, glycemic control and lipid metabolism.

The mice exhibited several conditions associated with obesity including high blood sugar, insulin resistance, impaired glucose tolerance, and hepatic steatosis, which is also known as fatty liver disease. These conditions were not affected when mice were given leucine alone. However, when leucine and a very low dose of a PDE5 inhibitor were introduced for six weeks, mice showed significant improvements in blood sugar and glucose tolerance, and their insulin response became normal. Additionally, fatty liver disease in the mice was reversed, and fat accumulation in the liver and symptoms such as liver inflammation were significantly reduced.

Pending regulatory feedback, NuSirt plans to initiate a Phase 2A study to evaluate its technology combining leucine with a PDE5 inhibitor and a common diabetes medicine to treat non-alcoholic fatty liver disease and non-alcoholic steatohepatitis in humans.

"This study demonstrates yet again the potential for NuSirt technology to enhance and improve the effectiveness of established pharmaceutical products," said Joe Cook Jr., president and executive chairman of the board of NuSirt Biopharma. "Our preclinical work in other diseases has shown that NuSirt technology can lower the needed dosage of existing medications. Now our technology is demonstrating promise in opening up entirely new indications for known drugs. The prospect of using it to treat non-alcoholic steatohepatitis is particularly encouraging because there are currently no approved medical therapies for the disease."

Non-alcoholic steatohepatitis (NASH) occurs in up to 30 percent of those with non-alcoholic fatty liver disease (NAFLD). NAFLD is a result of fat building up in the liver, preventing the organ's ability to remove toxins from blood. It affects an estimated one-third of the general population. Although there are no known causes for NAFLD, obesity, high cholesterol, diabetes and high blood pressure are all considered risk factors.

While NAFLD is not considered life-threatening in many who have it, NASH can lead to serious health complications. NASH happens when the liver of a person with NAFLD becomes inflamed, causing severe liver cell damage. Over time, this can result in permanent scarring and hardening of the liver, which leads to cirrhosis. The consequences of cirrhosis include muscle wasting fluid retention, intestinal bleeding, and liver failure.

About NuSirt Biopharma
NuSirt Sciences, Inc., headquartered in Nashville, is dedicated to improving the lives of people living with chronic metabolic diseases. The company has a unique technology platform that uses a patented combination of leucine, an essential amino acid, and existing human medicines targeted at diseases that may be addressed by activating sirtuin pathways. In pre-clinical studies, these combinations have shown promise in preventing and treating metabolic diseases and enhancing the effectiveness of existing pharmaceuticals. For more information, please visit www.nusirt.com.

###

Contact:
Nicole Cottrill
615-327-7999
nicole.cottrill@dvlseigenthaler.com