



NuSirt Biopharma Plans Clinical Trial in Non-Alcoholic Fatty Liver Disease

*Company raises additional Series C financing to expand research and development
for its patented technology*

Nashville, Tenn. (October 8, 2015) - [NuSirt Biopharma](#), a company dedicated to improving the lives of those with chronic metabolic diseases, is planning to launch a clinical trial to determine if its [patented technology](#) has potential to become a new treatment for non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH).

The company has raised additional Series C financing to fuel its clinical program for NAFLD and NASH. The additional funding comes from two new investors and existing stockholders, including [Hatteras Venture Partners](#), [Mountain Group Partners](#) and [TriStar Technology Ventures](#), and brings the total Series C financing to \$10 million.

“Statistics show that as many as one-third of Americans have non-alcoholic fatty liver disease, and that up to 30 percent of these individuals are at risk for NASH, which can lead to cirrhosis and liver failure,” said [Michael Zemel, Ph.D.](#), founder and chief scientific officer of NuSirt Biopharma. “We are hopeful that this trial will show that NuSirt technology can assist in reducing excess liver fat and potentially offer a new medical therapy for these conditions. The possibility of creating a treatment for NASH is particularly exciting because there are currently no medicines approved to treat it.”

NuSirt’s [patented technology](#) combines a naturally occurring amino acid, leucine, with existing pharmaceuticals. [Pre-clinical studies](#) have shown that NuSirt’s combination of leucine, metformin and phosphodiesterase type 5 (PDE5) inhibitors, such as sildenafil, may be able to reverse NAFLD, reduce symptoms of the disease, and prevent the onset of NAFLD and NASH. Research presented by NuSirt at the [American Diabetes Association 75th Scientific Sessions](#) showed that a combination of leucine and sub-therapeutic levels of sildenafil and metformin could reverse obesity-induced liver fat accumulation and fibrosis in mice.

The planned Phase 2A clinical trial is a randomized, 16-week, placebo-controlled, double-blind study with a primary objective to evaluate the change in liver fat content. In this three-arm study, subjects will receive either a placebo or one of two fixed-dose combinations of NuSirt’s patented combination of leucine, metformin and sildenafil, from week one of the study to week 16. Subjects’ liver fat content will be assessed by proton-density-fat-fraction (PDFF) using magnetic resonance imaging (MRI). Secondary objectives include assessing a variety of liver, metabolic and inflammatory markers.

“Pre-clinical research demonstrates great potential for NuSirt’s triple combination as a new treatment option for the millions of Americans with NAFLD and NASH,” said [Joseph C. Cook, Jr.](#), president and executive chairman of the board of NuSirt Biopharma. “We look forward to validating our preclinical

results in this proof of concept trial as well as continuing our work in diabetes, hyperlipidemia and other metabolic diseases.”

For more information about the trial, which is scheduled to start Q4 2105, contact info@nusirt.com or visit <https://clinicaltrials.gov/ct2/show/study/NCT02546609?term=nusirt&rank=1>.

About Non-Alcoholic Fatty Liver Disease (NAFLD) and Non-Alcoholic Steatohepatitis (NASH)

Non-alcoholic fatty liver disease (NAFLD) is a result of fat building up in the liver, preventing the organ’s ability to remove toxins from the blood. It affects [up to 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.

Non-alcoholic steatohepatitis (NASH) occurs in [10 to 30 percent](#) of those with NAFLD. It 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. The consequences of NASH include cardiovascular disease, liver cancer, 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.