NuSirt Biopharma Receives FDA Fast Track Designation for Non-Alcoholic Fatty Liver Disease Treatment

Phase 2A clinical trial enrolls first patients this week

Nashville, Tenn. (December 10, 2015) - NuSirt Biopharma today announced the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for its development program focused on non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH). NuSirt also announced the start of enrollment for its Phase 2A clinical trial targeting this disease at nine U.S. research sites.

"NAFLD and NASH represent serious unmet medical needs for which there are no approved therapies," said Joseph C. Cook, Jr., president and executive chairman of the board of NuSirt Biopharma. "It is estimated that 75-100 million people in the U.S. have NAFLD, and 10-20 million have progressed to NASH. The NuSirt team is dedicated to improving the lives of those with serious metabolic diseases. We are delighted to have received Fast Track designation, which is designed to facilitate the development and expedite the review of drugs that treat serious conditions and fill an unmet medical need. This designation helps get important new drugs to patients earlier."

NuSirt's patented technology combines a naturally occurring amino acid, leucine, with existing pharmaceuticals. In pre-clinical studies, NuSirt's triple combination of leucine, metformin and sildenafil showed the potential to reverse NAFLD, reduce symptoms of the disease, and prevent the onset of NAFLD and NASH. Additional animal studies have shown that the triple combination could reverse obesity-induced liver fat accumulation, inflammation and fibrosis in mice. This research was presented at the American Association for the Study of Liver Diseases (AASLD)'s annual The Liver Meeting® in November 2015.

The Phase 2A clinical trial, named TRIPLN, is a randomized, 16-week, placebo-controlled, double-blind study. The TRIPLN study is evaluating the change in liver fat content in subjects receiving two fixed-dose combinations of NuSirt's patented triple combination of leucine, metformin and sildenafil. Secondary objectives include assessing a variety of liver, metabolic and inflammatory markers. Initial results of the TRIPLN study are expected the 2H 2016.

"Pre-clinical studies have shown the potential of NuSirt technology to target the three pathophysiological aspects of NASH: steatosis, inflammation and fibrosis," said Michael Zemel, Ph.D., founder and chief scientific officer of NuSirt Biopharma. "As we begin our first human trial in NAFLD and NASH, we look forward to further exploring how our triple-combination therapy could help the millions affected by this disease."

For more information about the trial, 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)

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.

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 Biopharma, a TNInvestco company, is headquartered in Nashville and dedicated to improving the lives of people living with chronic metabolic diseases. The company has a unique technology platform based on research from the University of Tennessee 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
615-610-0305
nicole.cottrill@dvlseigenthaler.com