

NuSirt Biopharma and OWL Metabolomics Partner to Advance Treatment of NASH / Non-alcoholic Steatohepatitis

September 21, 2016 – Nashville, Tennessee, and Derio, Spain: NuSirt Biopharma, a company dedicated to improving the lives of those with chronic metabolic diseases, and One Way Liver S.L. (OWL Metabolomics), a leader in the field of metabolomics and liver diseases diagnostics, today announced they have initiated a strategic partnership to develop novel diagnostic tools for ongoing drug evaluation trials for NuSirt's fatty liver drug research candidate, NS-0200.

Through their research collaboration, NuSirt and OWL will evaluate drug-induced lipidomic changes in human trials for non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH) and explore the potential of developing a unique liquid-biopsy companion diagnostic (CDx) for NS-0200.

"Millions of people have NAFLD/NASH, but there are few medical therapies available to treat them," said Joe C. Cook, Jr., Executive Chairman and President, NuSirt Biopharma. "OWL is a leader in diagnostics for liver diseases, and we are delighted to partner with its team to not only investigate our own potential new treatment, but also examine how molecular diagnostics could broadly advance the diagnosis, treatment and monitoring of these diseases."

NuSirt has completed enrollment for their Phase 2 TRIPLN clinical trial designed to determine the effects of its patented drug technology on patients diagnosed with NAFLD/NASH. In addition to MRI-based diagnosis known as PDFF, serial patient liquid biopsy samples from trial participants will be further analyzed via OWL Metabolomics' lipidomic signature analysis at pre-determined time intervals.

"OWL Metabolomics and our team of liver research professionals are very excited to begin this important partnership with NuSirt," said OWL's CEO, Pablo Ortiz, MD, PhD. "Newly developed drugs are becoming more targeted and personalized for prevalent diseases, and regulatory authorities are seeking more precise technologies in evaluating the effects of early-stage drug candidates and determining the most appropriate patient selection. We are hopeful that our novel metabolomics-based testing technology will serve as an effective surrogate marker for specific histopathological changes within the liver and help enhance the care of NASH patients and the development of effective medical therapies to treat their condition."

About Nonalcoholic Steatohepatitis (NASH)

NASH is a progressive form of NAFLD characterized by inflammation caused by excess fat in liver cells unrelated to alcohol consumption [1]. NASH dramatically increases the risks of cirrhosis, liver failure, and hepatocellular carcinoma (HCC), and is an increasingly frequent reason for liver transplantation [2]. Currently, an invasive liver-tissue biopsy is considered the 'gold standard' for NASH disease recognition and, although cumbersome and potentially risky, liver biopsy remains the only method for the definitive diagnosis of NASH.

About NuSirt Biopharma

NuSirt Biopharma, headquartered in Nashville, Tenn., is dedicated to improving the lives of people living with chronic metabolic diseases. The company has developed a unique technology platform that uses patented combinations of leucine, an essential amino acid, with existing human medicines to target diseases that have shown promise in preventing and treating metabolic diseases by enabling new

applications for existing pharmaceuticals and enhancing their effectiveness. For more information, please visit www.nusirt.com.

About OWL Metabolomics

OWL Metabolomics is a biotechnology company committed to the identification, validation and global commercialization of diagnostic assays for the liver and other prevalent human diseases, including the identification of potential therapeutic targets associated with disease evolution. Since its inception in 2002, OWL has pioneered novel diagnostic research within the fatty liver space.

The 'OWL Liver' and 'OWL Liver Care' assays are the world's first patented metabolomics-based in-vitro tests for diagnosing NASH and hepatic steatosis (NAFLD), respectively, using micro-blood samples (<0.5 ml) versus today's diagnostic gold-standard which mandates an invasive liver biopsy.

OWL Metabolomics is a privately-held company based in Derio, Spain, and collaborates globally with hospitals, liver research centers, biotechnology groups and the pharmaceutical industry.

More information - <http://www.owlmetabolomics.com/liver-disease-diagnosis.aspx>

[1] <http://www.liverfoundation.org/abouttheliver/info/nafld/>

[2] <http://www.nature.com/nrgastro/journal/v10/n11/full/nrgastro.2013.183.html>