

Positive Gemcabene Results in Proof-of-Concept Preclinical NASH Study Presented at The Liver Meeting® 2017

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Data Support Clinical Evaluation of Gemcabene as a Potential Treatment For NAFLD/NASH

Clinical Trial in NAFLD/NASH Planned to Begin 4Q-2017

LIVONIA, Mich., Oct. 23, 2017 (GLOBE NEWSWIRE) -- Gemphire Therapeutics Inc. (NASDAQ:GEMP), a clinical-stage biopharmaceutical company focused on developing and commercializing therapies for cardiometabolic disorders, including dyslipidemia and NASH, announced today the presentation of preclinical results demonstrating proof of concept efficacy of gemcabene in a well-established animal model of nonalcoholic steatohepatitis (NASH). The results are featured in a poster presentation today at The Liver Meeting®, the annual meeting of the Association for the Study of Liver Diseases (AASLD), taking place in Washington, D.C. Gemphire plans to initiate a clinical study in patients suffering from fatty liver disease and NASH in the fourth quarter of 2017. Approximately 6 million adult patients in the U.S. are affected by NASH for which there is currently no effective treatment available.

In this study, gemcabene was evaluated in the STAM™ mouse model of NASH, in which diabetic mice fed a high fat diet rapidly develop fatty liver disease. Animals were treated with either gemcabene (at doses of 30, 100 and 300 mg/kg daily), a reference drug telmisartan (Micardis®, Boeringer Ingelheim) or vehicle. Key findings were as follows:

- At the highest dose level gemcabene-treated mice demonstrated a significant histological reduction in Non-Alcoholic Fatty Liver Disease (NAFLD) Activity Score (NAS). Gemcabene also showed significant decreases in the fibrosis area at all doses compared to the vehicle group.
- Gene expression analysis showed that, in animals treated with 100 and 300 mg/kg gemcabene, there was a statistically significant decrease in mRNA expression levels of inflammation markers in the liver (TNF- α , MCP-1, MIP-1 β , CCR5, CCR2, NF- κ B), suggesting gemcabene hits multiple inflammatory targets and has a hepatoprotective effect on liver pathology.
- Genes related to stellate cell activation and collagen and fibrosis markers were down-regulated in this murine model of NASH.

“The effects of gemcabene on the liver histology and gene expression levels associated with inflammation revealed by this study are complementary to the results observed in dyslipidemia patients, and support our plans to move forward with the clinical evaluation of gemcabene in NAFLD/NASH,” said Dr. Charles L. Bisgaier, Co-founder and Chief Scientific Officer of Gemphire. “Given what we know about gemcabene’s ability to impact multiple targets including LDL-C, triglycerides, CRP and the glucose disposal rate in human clinical trials, we believe that gemcabene may be a good clinical candidate for the treatment of NAFLD/NASH. These attributes, combined with gemcabene’s safety profile and lack of liver or muscle toxicities in completed clinical trials, which included high-intensity statin therapies, may provide gemcabene a unique advantage to the other treatments in development for NAFLD/NASH,” concluded Dr. Bisgaier.

About NAFLD/NASH

Nonalcoholic steatohepatitis (NASH) is a severe disease of the liver caused by hepatocyte inflammation and a buildup of fat in the organ. In the United States, NASH affects approximately 2-5% of the population. An additional 10-30% of Americans have fat in their liver, but no inflammation or liver damage, a condition called NAFLD or “fatty liver.” The underlying cause of NASH is unclear, but it most often occurs in persons who are middle-aged and overweight or obese.

Many patients with NASH have elevated serum lipids, diabetes or pre-diabetes. Progression of NAFLD/NASH can lead to liver cirrhosis, fibrosis, hepatocellular carcinoma, liver failure and liver-related death. Liver transplantation is currently the only treatment for advanced cirrhosis with liver failure. At this time, there are no FDA-approved treatments for NAFLD/NASH.

Gemcabene's mechanism of action and safety profile are highly differentiated from other clinical candidates

Gemphire's product candidate gemcabene is a first-in-class, once-daily, oral therapy that may be suitable for patients who are unable to achieve normal levels of LDL-C or triglycerides with currently approved therapies, primarily statins. Gemcabene's mechanism of action (MOA) is designed to enhance the clearance of very low-density lipoproteins (VLDLs) in the plasma and inhibition of the production of cholesterol and triglycerides in the liver. The combined effect of these mechanisms has been clinically observed to result in a reduction of plasma non-HDL-C, VLDL-C, LDL-C, apolipoprotein B and triglycerides. In addition, gemcabene has been shown to markedly lower C-reactive protein in humans and improve insulin sensitization. Gemcabene's MOA is liver-directed involving downregulation of hepatic apolipoprotein C-III (apoC-III) mRNA expression and decrease of plasma apoC-III levels. Gemcabene also reduces acetyl-CoA carboxylase (ACC1) and CCR2/CCR5 receptor mRNA levels, markers involved in the progression of non-alcoholic steatohepatitis (NASH)/non-alcoholic fatty liver disease (NAFLD). Gemcabene has demonstrated proof of concept efficacy for NASH in the rodent STAM™ model developed at SMC Laboratories in Tokyo, Japan. Gemcabene has been tested as monotherapy and in combination with statins and other drugs in 956 subjects across 20 Phase 1 and Phase 2 clinical trials. Given this profile of efficacy across multiple pathological pathways, as well as evidence of safety and tolerability, particularly when used as an add-on to many other therapeutic drugs, gemcabene has attributes that support studies in humans for NASH.

About Gemphire

Gemphire is a clinical-stage biopharmaceutical company that is committed to helping patients with cardiometabolic disorders, including dyslipidemia and NASH. The Company is focused on providing new treatment options for cardiometabolic diseases through its complementary, convenient, cost-effective product candidate gemcabene as add-on to the standard of care, especially statins, that will benefit patients, physicians, and payors. Gemphire has initiated 3 clinical trials for homozygous familial hypercholesterolemia (HoFH), heterozygous familial hypercholesterolemia (HeFH)/atherosclerotic cardiovascular disease (ASCVD), and severe hypertriglyceridemia (SHTG) under NCT02722408, NCT02634151, and NCT02944383, respectively, with a fourth planned trial in NASH to initiate in the fourth quarter of 2017. Please visit www.gemphire.com for more information.

Forward Looking Statements

Any statements in this press release about Gemphire's future expectations, plans and prospects, including statements about Gemphire's financial prospects, future operations and sufficiency of funds for future operations, clinical development of Gemphire's product candidate, expectations regarding future clinical trials, regulatory submissions and meetings and future expectations and plans and prospects for Gemphire, expectations regarding operating expenses and cash used in operations, and other statements containing the words "believes," "anticipates," "estimates," "expects," "intends," "plans," "predicts," "projects," "targets," "may," "potential," "will," "would," "could," "should," "continue," "scheduled" and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the success and timing of Gemphire's regulatory submissions and pre-clinical and clinical trials; regulatory requirements or developments; changes to Gemphire's clinical trial designs and regulatory pathways; changes in Gemphire's capital resource requirements; Gemphire's ability to obtain additional financing; Gemphire's ability to successfully market and distribute its product candidate, if approved; Gemphire's ability to obtain and maintain its intellectual property protection; and other factors discussed in the "Risk Factors" section of Gemphire's Annual Report on Form 10-K for the year ended December 31, 2016, Gemphire's Quarterly Report on Form 10-Q for the quarter ended June 30, 2017 and in other filings Gemphire makes with the SEC from time to time. In addition, the forward-looking statements included in this press release represent Gemphire's views as of the date hereof. Gemphire anticipates that subsequent events and developments will cause Gemphire's views to change. However, while Gemphire may elect to update these forward-looking statements at some point in the future, Gemphire specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Gemphire's views as of any date subsequent to the date hereof.

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