Gemphire Therapeutics Announces Presentation at ACC Meeting of Phase 2 Clinical Trial Investigating Effect of Gemcabene on Insulin Sensitization

March 21, 2017 9:17 AM ET

Gemcabene Demonstrated a Doubling of the Glucose Disposal Rate and 40% LDL-C Reduction

LIVONIA, Mich., March 21, 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 results of a Phase 2 trial that investigated insulin sensitization and LDL-C lowering by gemcabene in non-diabetic, obese patients. The results were featured in a poster presentation at the recent American College of Cardiology (ACC) 66th Annual Scientific Session in Washington, D.C.

"We are very encouraged by the meaningful effects on both the glucose disposal rate and LDL-C reduction in this study showcasing the differentiated cardiometabolic effects of gemcabene," said Mina Sooch, CEO of Gemphire. "As we progress the clinical development of gemcabene to include a Phase 2 trial (AZURE-1) in patients with NASH, the ability for gemcabene to impact severe glucose metabolism abnormalities could be another potential benefit in these patients who often have increased insulin resistance. Also, the 40% reductions in LDL-C continue to support the potential for gemcabene to impact this important cardiovascular risk factor in ASCVD patients (which we are studying in the ROYAL-1 trial) particularly those with metabolic syndrome or type 2 diabetes. We look forward to a transformational year in 2017 with data readouts expected from all three of our Phase 2b trials in dyslipidemia patients."

Rebecca Bakker-Arkema, Gemphire's Vice President of Drug & Clinical Development, presented the results of the double-blind, randomized, placebo controlled, Phase 2 trial (1027-014). Fifty-three subjects, ranging in age from 26 to 63 years, BMI 30 to 40kg/m^2, and fasting glucose <126mg/dL, entered the study. Following a 2-week screening phase, subjects were randomized to receive either 900 mg gemcabene or placebo on Day 2 through Week 4. A euglycemic hyperinsulinemic clamp study quantified glucose disposal rate (GDR), a measure of how well insulin is able to remove glucose from the circulation, before administration of study drug on Day 1 and again 1 hour following the last dose of gemcabene at the end of the fourth week of treatment.

The primary efficacy endpoint was insulin sensitivity as defined by average GDR (mg/kg per min) during the last 30 minutes of the 3-hour euglycemic hyperinsulinemic clamp study. An increase in the GDR suggests an improvement in insulin function. The percentage change from baseline in the GDR was compared for the placebo and 900 mg gemcabene group using a 2-sample t-test. Additionally, a post-hoc analysis was performed on mean percent change in LDL-C, total cholesterol (TC), TGs and GDR using a paired t-test.

Gemcabene was associated with a doubling of 13% mean increase in GDR compared to a 6.8% increase for placebo. Although statistical significance was not observed in the pre-specified analysis, a post-hoc analysis more applicable to the size of this study showed a statistically significant change from baseline to Day 29 in GDR for gemcabene 900 mg ($p<0.0178$) versus a non-significant effect for placebo.

In addition, gemcabene 900 mg lowered LDL-C by 40% ($p<0.0001$) and TC by 27% ($p<0.0001$) consistent with past results in hypercholesterolemic subjects. Gemcabene was generally well-tolerated. There were no deaths, serious adverse events, or withdrawals due to adverse events during the study.

"The current clinical study was conducted in response to preclinical studies that showed increased insulin sensitivity in mouse 3T3 L1 adipocytes and obese diabetic rats by gemcabene," said Charles Bisgaier, Ph.D., Chief Scientific Officer and Co-founder of Gemphire. "The results from this clinical study support the evaluation of gemcabene on glycemic control measures and dyslipidemia in diabetic subjects expected to enroll across our planned clinical programs."

To view the poster, please refer to the "Publications and Presentations" section of the company's website at

www.gemphire.com.

About Gemcabene

Gemphire's product candidate, gemcabene (CI-1027), 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 is designed to enhance the clearance of very low-density lipoproteins (VLDLs) in the plasma and inhibit the production of cholesterol and triglycerides in the liver. The combined effect for these mechanisms has been clinically observed to result in a reduction of plasma VLDL-C, LDL-C, and triglycerides. In addition, gemcabene has been shown to markedly lower C-reactive protein. Gemcabene is liver-directed and reduces apoC-III mRNA and plasma levels. Gemcabene also reduces acetyl-CoA carboxylase (ACC) and CCR2/CCR5 receptor mRNA levels, which may have applications in non-alcoholic steatohepatitis (NASH)/non-alcoholic fatty liver disease (NAFLD). Gemcabene has demonstrated proof of concept efficacy in the STAM™ model for NASH developed at SMC Laboratories in Tokyo, Japan. Gemcabene has been tested as monotherapy and in combination with statins and other drugs in 895 subjects across 18 Phase 1 and Phase 2 clinical trials and has demonstrated promising evidence of efficacy, safety and tolerability.

About Gemphire

Gemphire is a clinical-stage biopharmaceutical company that is committed to helping patients with cardiometabolic disorders, including dyslipidemia and NASH. We are focused on providing new treatment options for cardiometabolic diseases through our 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. 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 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 period ended December 31, 2016, 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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