Gemphire Completes Patient Enrollment in INDIGO-1 Trial in Severe Hypertriglyceridemia (SHTG) Patients

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On Track to Report Top-Line Data from Phase 2b Trial in Second Quarter of 2018

LIVONIA, Mich., Jan. 17, 2018 (GLOBE NEWSWIRE) -- Gemphire Therapeutics Inc. (NASDAQ:GEMP), a clinical-stage biopharmaceutical company focused on developing and commercializing therapies for cardiometabolic disorders, including dyslipidemia and nonalcoholic steatohepatitis (NASH), today announced that it has achieved its enrollment goal of 90 subjects across 39 sites in its Phase 2b INDIGO-1 trial investigating gemcabene in severe hypertriglyceridemia (SHTG) patients. The Company remains on track to report top-line results from the study in the second quarter of 2018.

“The INDIGO-1 trial is part of a comprehensive clinical program to develop gemcabene for a broad spectrum of dyslipidemia conditions,” said Dr. Steven Gullans, Interim CEO of Gemphire. “SHTG represents one of the more prevalent indications with approximately 3.5 million patients in the United States alone. These patients are in urgent need of a fast and effective lowering of their triglyceride levels in order to reduce the risk of developing acute pancreatitis. We are pleased to reach this milestone of enrollment completion in INDIGO-1 and look forward to announcing top-line data in the second quarter of 2018.”

INDIGO-1 is a 12 week, multicenter, double-blind, placebo-controlled, randomized trial in patients with SHTG (TG ≥ 500mg/dL) with or without background statin therapy. Patients are enrolled into one of three arms: gemcabene 300 mg, gemcabene 600 mg or placebo once daily. The primary endpoint is triglyceride (TG) reduction from baseline after 12 weeks. Other endpoints include LDL-C, hsCRP, apoB, non-HDL-C, VLDL-C and total cholesterol. Safety is being assessed by adverse event monitoring, clinical laboratory assessments, ECGs, physical examinations and vital sign assessments. Additional information on the INDIGO-1 trial, including inclusion/exclusion criteria, can be found at www.clinicaltrials.gov, with the NCT Identifier #02944383.

Pursuing SHTG may enable gemcabene to reach a large population of patients with TG levels above 500 mg/dL and offer a convenient, oral, once-daily dosing with no food effects that may have the potential to result in better efficacy than standard of care, while being well-tolerated with statins. Based on a 1.1% prevalence rate of TG ≥ 500mg/dL in the United States, as published by the American Heart Association, Gemphire estimates there are approximately 3.5 million patients with SHTG in the United States and 75 million patients in the rest of the world, whom are at risk for developing acute pancreatitis.

“Given gemcabene’s record of safety in over 950 human subjects to date, including its demonstrated ability to provide therapeutic benefits as add-on therapy to maximally-tolerated statins, we believe that it has the potential to become a foundational therapy for SHTG patients,” added Dr. Lee Golden, Gemphire’s Chief Medical Officer. “Millions of patients are seeking a safe, well-tolerated approach to controlling their severe hypertriglyceridemia.”

About Severe Hypertriglyceridemia (SHTG)
SHTG is a condition in which patients have TGs present in the bloodstream at a level of greater than 500 mg/dL. These high TG levels are associated with an increase in the risk for cardiovascular disease and acute pancreatitis. Current first-line treatments for SHTG, as recommended by the ATP III guidelines, include dietary modifications to lower the intake of fatty foods and the use of fibrates, prescription fish oils and/or niacin. Current therapies, limited by insufficient efficacy, drug-drug interaction potential or side-effects, may be inadequate to lower the TG levels below 500 mg/dL, the level at which patients are at risk for increased pancreatitis.

About Pancreatitis
Pancreatitis is an inflammation of the pancreas. Once the gland becomes inflamed, the condition can progress to swelling of the gland and surrounding blood vessels, bleeding, infection, and damage to the gland. Digestive juices become trapped and

start digesting the pancreas itself. If the damage persists, the gland may not be able to carry out normal functions. Pancreatitis may be acute (new, short-term) or chronic (ongoing, long-term). Either type can be very severe, and lead to serious complications.

Acute pancreatitis usually begins soon after the damage to the pancreas begins. Attacks are typically very mild. Mild attacks may last for a short time and usually resolve completely as the pancreas returns to normal. Some people only have one attack, whereas other people may have more than one attack. About 20% of cases, however, are very severe. Chronic pancreatitis begins as acute pancreatitis. If the pancreas becomes scarred during the attack of acute pancreatitis, it cannot return to its normal state. The damage to the gland continues, worsening over time. There are reports that more than 300,000 patients are admitted per year for pancreatitis in the United States, and about 20,000 of those patients die from the disease. Pancreatitis can occur in people of all ages, although it is very rare in children. Pancreatitis occurs in men and women, although chronic pancreatitis is more common in men than women.

High levels of triglycerides are associated with acute pancreatitis and considerable morbidity and mortality. In September 2002, the National Institutes of Health published its Third Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). Although the focus of the report is on LDL-cholesterol and HDL-cholesterol levels, it also provides guidance for treatment of patients with high triglyceride levels. The report states that in cases in which a person's triglycerides are very high (≥500mg/dL), the initial aim of therapy is to prevent acute pancreatitis through triglyceride lowering.

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 has also been shown to reduce liver sulfatase-2 mRNA levels, known to be elevated in diabetic and obese patients. Elevated sulfatase-2 is thought to reduce the effectiveness of the liver VLDL-remnant receptor (also known as Syndecan-1), that normally plays a role in removing triglyceride containing particles from the plasma. Gemcabene also reduces acetyl-CoA carboxylase (ACC1) and CCR2/CCR5 receptor mRNA levels, markers involved in the progression of NASH/NAFLD. Gemcabene has demonstrated POC 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's Phase 2 clinical program is evaluating the efficacy and safety of gemcabene in hypercholesterolemia, including FH and ASCVD, SHTG and NASH/NAFLD. Two trials supporting hypercholesterolemia have been completed under NCT02722408 and NCT02634151. Gemphire has completed recruitment for a clinical trial for SHTG under NCT02944383, and has initiated a trial for 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, 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 September 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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