Gemphire Therapeutics Enrolls First Patients in the ROYAL-1 Trial Investigating Gemcabene in Hypercholesterolemia

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ROYAL-1 is a Phase 2b Study to Determine Safety and Tolerability of Gemcabene in Hypercholesterolemia Not Adequately Controlled on High-Intensity or Moderate-Intensity Stable Statin Therapy

Topline Data Readout Anticipated in Second Half 2017

LIVONIA, Mich., Nov. 28, 2016 (GLOBE NEWSWIRE) -- Gemphire Therapeutics Inc. (Nasdaq:GEMP), a clinical-stage biopharmaceutical company focused on developing and commercializing therapies for the treatment of dyslipidemia, a serious medical condition that increases the risk of life threatening cardiovascular disease, and NAFLD/NASH (nonalcoholic fatty liver disease), today announced enrollment of its first patients in ROYAL-1, a Phase 2b trial designed to investigate gemcabene in the treatment of patients with hypercholesterolemia not adequately controlled on high-intensity or moderate-intensity stable statin therapy. It is designed to enroll a broad patient population, including patients with heterozygous familial hypercholesterolemia (HeFH) and atherosclerotic cardiovascular disease (ASCVD), who have baseline LDL-C ("bad cholesterol") values ≥ 100 mg/dL.

"The patient groups we plan to enroll in the ROYAL-1 trial, including patients with HeFH and patients with ASCVD, particularly those with diabetes, represent some of the more prevalent hypercholesterolemia conditions," said Mina Sooch, President and Chief Executive Officer of Gemphire. "If we are successful in obtaining approval for gemcabene in these populations, we expect to be able to reach a large market of over 10 million patients just in the U.S. that are currently unable to attain their LDL-C goals despite current statin and ezetimibe therapies. Gemcabene, if approved, may offer a competitive and complementary profile as compared with anti-PCSK9 monoclonal antibodies (MAbs), a recently approved class of LDL-C lowering drugs."

The randomized, placebo-controlled, double-blind Phase 2b trial, "*A 12-Week, Phase 2 Study of Gemcabene in Hypercholesterolemia Patients on Stable Moderate and High-Intensity Statins (ROYAL-1)*" will enroll up to 104 adult patients at clinical sites in the United States. Patients meeting eligibility requirements are being randomized in a 1:1 ratio to 600mg of gemcabene or placebo. The primary endpoint is the percent change from baseline of LDL-C at 12 weeks. Secondary endpoints include the change from baseline in non-HDL-C, total cholesterol, triglycerides, ApoB, and hsCRP at the 12-week time point.

"We have seen significant interest in the study from principal investigators in the first week of enrollment which reinforces this large unmet patient need despite current available therapies," shared Dr. Lee Golden, Chief Medical Officer. "Gemcabene is an oral once-daily drug candidate with broad lipid-lowering and anti-inflammation attributes in patients on background stable statin therapy that has been previously studied in a Phase 2 trial and summarized in a recently published paper in the *Journal of Clinical Lipidology*."

Gemphire currently anticipates the 12-week study to complete enrollment and all patient follow-up visits in the second half of 2017. Additional information on the trial design, including eligibility criteria and site locations, can be found at www.clinicaltrials.gov, using the NCT Identifier NCT02634151.

About Gemcabene

Gemphire's product candidate, gemcabene (CI-1027), is a novel, 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 observed to result in a reduction of plasma VLDL-C, LDL-C, and triglycerides, as well as markedly lowering C-reactive protein. Gemcabene is liver-directed and reduces apoC-III mRNA and plasma levels and may also inhibit

acetyl-CoA carboxylase (ACC) which has applications in NASH/NAFLD. 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 Heterozygous Familial Hypercholesterolemia (HeFH)
The HeFH patient population is generally comprised of individuals who have one defective gene that leads to elevated LDL-C levels between 190 mg/dL and 500 mg/dL. These patients are prone to premature cardiovascular events. The incidence of patients with HeFH is estimated to be one in 200 and one in 500, and accordingly, Gemphire estimates there are approximately 0.5 to 1.5 million patients with HeFH in the United States and 15 to 30 million in the rest of the world.

Current approved treatments for HeFH include statins, ezetimibe, bile acid sequestrants and the recently approved injectable PCSK9 inhibitors. Despite the availability of various treatments, many patients are still unable to achieve recommended LDL-C levels. In addition, patients, physicians and payors may prefer more convenient, cost-effective, oral drugs.

About Atherosclerotic Cardiovascular Disease (ASCVD)
ASCVD represents patients who have experienced or are at risk of a cardiovascular event and are unable to meet their LDL-C lowering goal of less than 70 mg/dL with maximally tolerated statin therapy. This population also includes many patients who, in addition to not being able to meet their LDL-C lowering goal, have elevated triglyceride levels greater than 150 mg/dL and less than 500 mg/dL, categorized as mixed dyslipidemia. Gemphire estimate that approximately 10 million patients in the United States and 200 million patients in the rest of the world have a need for additional therapies to effectively and safely bring them closer to their LDL-C and triglyceride lowering goals.

Currently approved treatments for both primary hypercholesterolemia and ASCVD include statins, ezetimibe, bile acid sequestrants, niacin, fibrates and recently approved PCSK9 inhibitors. While these drugs have demonstrated efficacy in lipid-lowering in this population, they do not sufficiently address the patients with mixed dyslipidemia who need to lower both LDL-C and triglycerides.

About Gemphire
Gemphire is a clinical-stage biopharmaceutical company focused on developing and commercializing therapies for the treatment of dyslipidemia, a serious medical condition that increases the risk of life threatening cardiovascular disease, and NAFLD/NASH (nonalcoholic fatty liver disease). Gemphire has initiated 3 clinical trials for HoFH, HeFH/ASCVD, and SHTG under NCT02722408, NCT02634151, and NCT02944383, respectively. 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 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 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 Quarterly Report on Form 10-Q for the quarterly period ended September 30, 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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