Gemphire Therapeutics Announces Publication of Phase 2 Data for Gemcabene in the Journal of Clinical Lipidology

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Gemcabene as Add-On to Stable Statin Therapy in Hypercholesterolemic Patients Demonstrated Additional Dose Dependent and Statistically Significant Reductions in LDL-C and CRP Compared to Placebo

LIVONIA, Mich., Sept. 19, 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 the publication of data from a Phase 2 clinical trial evaluating its proprietary lipid-regulating compound, gemcabene, in the *Journal of Clinical Lipidology*.

The paper *Efficacy and Safety of Gemcabene as Add-On To Stable Statin Therapy in Hypercholesterolemic Patients* discusses the results of an eight week, double-blind, placebo-controlled, randomized, multicenter Phase 2 clinical trial (1027-018) evaluating two dose levels of gemcabene (300mg QD, 900mg QD) versus placebo, added on top of stable statin therapy, in 66 hypercholesterolemic patients whose low-density lipoprotein cholesterol (LDL-C) remained ≥ 130 mg/dL. The primary endpoint was the mean percent change from baseline LDL-C at week 8. Secondary endpoints included; percentage change from baseline in total cholesterol (TC), triglycerides (TGs), VLDL-C, HDL-C, apoB and c-reactive protein (CRP). Safety and tolerability were also assessed.

The study demonstrated that gemcabene, when added to stable statin therapy, resulted in a clinically meaningful reduction in LDL-C and other key parameters after eight weeks. Patients randomized to 300mg and 900mg once-daily (QD) doses of gemcabene plus statins achieved reductions in LDL-C of -23.4% and -27.7%, respectively, versus -6.2% for placebo. Gemcabene was well-tolerated with a safety profile on top of statins similar to statin therapy alone.

“Elevated LDL-C is the most validated and modifiable risk factor resulting in atherosclerotic cardiovascular disease (CVD). Despite the effectiveness of statins, there remain a significant percentage of patients with CVD, or at high risk of CVD, who cannot achieve optimal LDL-C levels with statins alone. There are also large numbers who are unable to tolerate statins at effective doses,” said Dr. Evan Stein, Director Emeritus of the Metabolic and Atherosclerosis Research Center in Cincinnati, and co-author of the publication. “In these patients PCSK9 inhibitors are effective additions or alternatives for lowering LDL-C, but are costly and require self-injection every 2 or 4 weeks. This leaves a significant unmet need for an effective, well-tolerated, and less expensive oral option.”

Dr. Charles Bisgaier, Chief Scientific Officer and Co-Founder of Gemphire added, “These data demonstrate that gemcabene can further lower LDL-C and hsCRP levels in patients that cannot achieve sufficient reduction when taking a low, moderate, or high dose of stable statin therapy. Gemcabene is a well-tolerated oral agent that would be administered once a day and warrants continued clinical evaluation in patients with uncontrolled lipid profiles.”

Additional study findings:

- Significant reductions in non-HDL-C were observed in gemcabene-treated patients versus placebo. Patients randomized to 300mg QD and 900mg QD of gemcabene on top of statins achieved additional reductions in non-HDL-C of -19.8% and -23.9%, respectively, as compared to -6.9% for placebo.
- Patients randomized to 300mg QD and 900mg QD of gemcabene on top of statins achieved additional reductions in apoB of -11.9% and -17.2%, respectively, versus -2.8% for placebo.
- Patients randomized to 300mg QD and 900mg QD of gemcabene on top of statins achieved additional reductions in CRP of -26.1% and -53.9%, respectively, versus a reduction of -11.1% for the placebo group.

“We are pleased to announce this first of several planned publications by Gemphire in peer reviewed journals that showcase gemcabene’s extensive Phase 1 and Phase 2 clinical data package,” added Mina Sooch, MBA and President and

CEO of Gemphire. “These data provide strong support for our three planned Phase 2b clinical studies COBALT-1, ROYAL-1, and INDIGO-1. Gemcabene has a differential product profile and the potential to be a novel treatment for dyslipidemia, a large and growing global health challenge."

The full publication on *Journal of Clinical Lipidology*, the official journal of the National Lipid Association, can be accessed online at: http://www.lipidjournal.com/article/S1933-2874(16)30275-6/fulltext.

About Gemcabene

Gemphire’s lead 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 differentiated 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 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). 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," 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 June 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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