



Gemphire Therapeutics Announces Review of Strategic Alternatives and Provides Corporate Update

December 3, 2018

LIVONIA, Mich., Dec. 03, 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 its Board of Directors is conducting a review of a range of strategic alternatives focused on maximizing stockholder value. The Company has engaged Ladenburg Thalmann & Co. Inc. to act as its strategic financial advisor for this process.

The Board of Directors has established a committee to oversee this review. Potential strategic alternatives that may be evaluated include, but are not limited to, an acquisition, merger, business combination, in-licensing, or other strategic transaction involving the Company. There can be no assurance that this process will result in Gemphire pursuing any transaction or that any transaction, if pursued, will be completed. The Company does not intend to discuss or disclose further developments regarding the strategic review process unless and until its Board of Directors has approved a specific action or otherwise determined that further disclosure is appropriate or required by law.

"As we have previously disclosed, the recent request by the U.S. Food and Drug Administration (FDA) for additional preclinical data on gemcabene means that our planned Phase 3 programs, initially focused in hypertriglyceridemia, are expected to start later than originally planned," said Steven Gullans, Ph.D., CEO of Gemphire. "We continue to be encouraged by the results from 25 clinical trials in nearly 1,200 adult patients in which gemcabene demonstrated statistically significant signs of efficacy with no severe adverse events or drug-drug interactions. We remain confident that we will be able to meet the FDA's requests to enable it to reconsider lifting the partial clinical hold on gemcabene. However, we believe it is prudent to fully leverage our resources by exploring strategic alternatives."

The Phase 2a study investigating gemcabene in Familial Partial Lipodystrophy (FPL) disease recently completed enrollment. This open-label investigator-led study, being conducted by Dr. Elif Oral at the University of Michigan, is assessing gemcabene's efficacy, including its effects on plasma triglyceride and inflammatory markers, as well as liver fat determined by MRI-PDFF. To date, no drug-related toxicities have been detected, and two patients have completed the 24 week gemcabene treatment regimen. Top-line results are expected in mid-2019.

The Company continues to make progress with the ongoing preclinical studies recently requested by the FDA with the goal of providing the FDA with the data it requires to lift the partial clinical hold on gemcabene. Results are expected to be provided to the FDA in the second half of 2019.

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, hypertriglyceridemia and fatty liver disease, including FH, SHTG, NASH/NAFLD, and ASCVD. Two trials supporting hypercholesterolemia and one trial in SHTG have been completed under NCT02722408, NCT02634151 and NCT02944383, respectively. Please visit www.gemphire.com for more information.

Forward Looking Statements

Any statements in this press release that are not statements of historical fact, including statements about Gemphire's future expectations, milestones, goals, plans and prospects, such as statements about the plan of the Board of Directors to conduct a review of strategic alternatives to maximize stockholder value, the clinical development of Gemphire's product candidate, gemcabene, expectations regarding clinical trials, expected timing of top-line results of such trials, timing and expectations for pre-clinical studies, regulatory submissions and meetings, future expectations and plans and prospects for gemcabene, and other statements containing the words "believes," "anticipates," "estimates," "expects," "intends," "plans," "predicts," "projects," "promising," "targets," "may," "potential," "will," "would," "could," "should," "continue," "scheduled," "goal" 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 ability of the Company to successfully and timely negotiate and consummate a possible transaction on terms that are favorable to the Company; whether desirable products and combinations can be identified; risks related to cost reduction efforts; Gemphire's ability to analyze the results and understand the reasons for the unexpected events in the Phase 2a pediatric NAFLD trial; that MRI-PDFF scans or other follow-up tests of patients show similar increases in liver fat content or other undesirable side effects; uncertainties inherent in the clinical drug development process and the regulatory approval process, including the risk that gemcabene may have properties that could delay or prevent regulatory approval; Gemphire's substantial dependence on its product candidate, gemcabene; developments in the capital markets; 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; the actions of Gemphire's competitors; 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 most recent annual report, subsequent quarterly reports 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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