Gemphire Announces Amended and Restated Gemcabene License Agreement with Pfizer Inc.

August 6, 2018 4:00 PM ET

LIVONIA, Mich., Aug. 06, 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 amended and restated the license agreement with Pfizer Inc. covering gemcabene.

Gemphire licensed exclusive worldwide commercial rights to gemcabene from Pfizer in an agreement signed in April 2011. Under the original agreement, Pfizer had the right to terminate the license if the drug was not adequately commercialized by April 2021. The amended and restated agreement contains a number of changes to the license, including extending the date of the agreed deadline for the first commercial sale. As amended, Pfizer has the right to terminate the license if the first commercial sale has not occurred by April 2024. The royalty period in countries in which gemcabene becomes approved for commercial sale, if any, has been extended, and the royalty rates that are payable upon achieving certain aggregate sales levels of gemcabene have increased slightly, ranging from the high single digits to the mid-teens depending on the level of net sales, in consideration for such extension.

"We are pleased to enter into this amended and restated agreement with Pfizer that includes provisions that we believe benefit both parties," said Dr. Steven Gullans, CEO of Gemphire. "The extension to the agreed date by which we need to commercialize gemcabene provides us with additional flexibility to focus on the optimal development path and timeline for gemcabene. Additionally, we believe the extension will remove any near-term considerations by investors and potential strategic partners about our ability to achieve commercialization under the license agreement. Based on our current projections, however, we believe we will be successful in bringing gemcabene to market in at least one of our chosen disease indications well before this date."

For further details on the amended and restated license agreement, refer to our Current Report on Form 8-K filed with the Securities and Exchange Commission on August 6, 2018.

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 TGs with currently approved therapies, primarily statins. Gemcabene's mechanism of action (MOA) enhances the clearance of very low-density lipoproteins (VLDLs) in the plasma and inhibition of the production of cholesterol and TGs 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 TGs. 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 TG 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 nearly 1,200 subjects across 25 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 and one trial in SHTG have been completed under NCT02722408, NCT02634151 and NCT02944383, respectively, and the Company has initiated two proof-of-concept trials for NAFLD/NASH. Please visit www.gemphire.com for more information.

Forward Looking Statements

Any statements in this press release about Gemphire's future expectations, milestones, goals, 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 gemcabene, including the expected timing to bring gemcabene to market in an indication, expectations for the future competitive environment for gemcabene, expectations regarding operating expenses and cash used in operations, and other statements containing the words "believes," "anticipates," "estimates," "expects," "intends," "plans," "predicts," "projects," "promising," "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: 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 annual report 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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