Gemphire Provides Update On Development of Gemcabene

August 6, 2018

FDA requests the Company provide additional data regarding the partial clinical hold

Company continues Phase 2 development of gemcabene for NAFLD/NASH

Company amends loan agreement with SVB to provide additional flexibility

Conference call and webcast today, Monday, August 6, at 4:30 p.m. Eastern Time

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 the U.S. Food and Drug Administration (FDA) has requested that the Company produce data from a sub-chronic toxicology study to provide information to support lifting the partial clinical hold on gemcabene with respect to clinical trials of longer than six months in duration. The FDA also informed the Company that the End of Phase 2 meeting, and consequently the initiation of Phase 3 trials investigating gemcabene in dyslipidemia indications and long-term safety exposure trials needed for registration, will not take place until the partial hold has been lifted.

Gemphire's ongoing Phase 2a proof-of-concept (POC) studies investigating gemcabene as a treatment for familial partial lipodystrophy (FPL) and for pediatric NAFLD are not affected by the FDA's request for additional data and the Company continues to expect that these studies will produce top-line interim data in late 2018 and in the first half of 2019, respectively. In addition, the Company continues to be free to conduct clinical trials that do not extend beyond six months in duration.

Beginning in 2004, the FDA began issuing partial clinical holds to all sponsors of PPAR agonists or agents deemed to have PPAR-like properties from preclinical studies. The FDA takes the position that PPAR agonists are potential liver toxins, but recognizes that rodent observations are often not relevant to humans. In 2004, the FDA determined that gemcabene has PPAR agonist properties and issued a partial clinical hold. The partial clinical hold permits clinical trials of up to six months for gemcabene and also required the Company to conduct two-year rat and mouse carcinogenicity studies that are reviewed by the agency in view of all other preclinical data and completed clinical trials before allowing clinical trials of longer than six months.

As previously disclosed, we believe gemcabene acts through PPARα to cause peroxisome proliferation and tumor formation in rodents and these effects are likely rodent-specific phenomena. Based on historical nonclinical and clinical experience on these type of compounds, we believe rodents share little apparent relevance for human risk assessment. In recently completed PPAR agonist receptor binding assays, we observed weak or no gemcabene direct binding to the mouse, rat, or human PPARα, PPARβ/d, or PPARγ receptors. We have also observed that gemcabene induces markers of peroxisome proliferation in wild-type mice but not in PPARα knockout mice. We believe the PPARα responses in rats and mice are secondary and perhaps related to the mobilization or formation of a naturally occurring molecule that binds to PPARα in response to gemcabene administration.

The Company recently submitted the results of the two-year rat and mouse carcinogenicity studies to the FDA. As would be expected for an activator of PPARα, the results showed the presence of liver tumors. The Company also provided results from a short-term, 8 day study demonstrating that in PPARα knockout mice, gemcabene did not induce known markers of peroxisome proliferation, providing evidence that gemcabene works through PPARα. Similar observations in PPARα knockout mice have been seen with other agents, such as gemfibrozil, that cause tumors in rodents but not in humans.

In response the FDA has requested that, as part of a complete response, Gemphire must provide additional data including a subchronic (13 week) study in PPARα knock-out mice and PPAR transactivation assays using monkey and canine PPAR isoforms, to further understand the human relevance of the preclinical findings. The Company has initiated plans to conduct these required studies and expects to submit the additional results to the FDA in the second quarter of 2019.

"We are working closely with the FDA to release the partial clinical hold on gemcabene, with the goal of proceeding to an End of Phase 2 meeting and reaching agreement on the design of a Phase 3 clinical program," said Dr. Steven Gullans, CEO of Gemphire. "Our confidence in gemcabene's safety profile is supported by the fact that it has been observed to be safe in nearly 1,200 human subjects in 24 Phase 1 and 2 clinical trials. In fact, gemcabene's safety performance in previous human clinical provided the basis for the FDA to allow the agent to be evaluated in a multi-center, investigator-led ongoing NAFLD trial in pediatric patients.

"In the meantime, we are continuing to execute on our ongoing Phase 2a POC clinical trials of gemcabene in NAFLD/NASH. Gemphire is well capitalized, with $28 million cash on hand as of June 30 2018. Based on current projections, taking into account the delay of significant cash expenditures for clinical trials and manufacturing and the amended terms of the loan agreement with SVB, we believe we have sufficient resources to

fund operations into the fourth quarter of 2019."

Amended loan agreement with SVB

On July 31, 2018, Gemphire amended its loan agreement with Silicon Valley Bank ("SVB") to provide additional flexibility to the Company. The original agreement established a term loan facility of up to $15 million in aggregate principal amount to be funded in up to three tranches. The Company received the first two tranches, $10 million in aggregate, in July 2017.

Among other provisions, the loan amendment with SVB:

1. Extends the date by which the FDA must lift the 6-month partial clinical hold from July 31, 2018 to September 30, 2019 for purposes of the requirement to provide cash security to SVB or prepayment of the loan, which could also be required if the Company's unrestricted cash balance falls below a minimum amount prior to such time.
2. Extends the date that the third tranche of $5 million is available for draw down by the Company to November 30, 2018, should the conditions set forth in the amended loan agreement be met by such date.
3. Extends the interest-only monthly payment period from August 1, 2018 to November 1, 2018, which may be subject to further extension if certain conditions set forth in the loan agreement are met.

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

Second Quarter Financial Results

Gemphire plans to announce its financial results for the second quarter ending June 30, 2018 after market close on Monday, August 13.

Conference Call
The Company will host a conference call today Monday, August 6, at 4:30 pm Eastern Time. To access the audio conference, please dial (844) 494-0188 (domestic) or +1 (425) 278-9114 (international) and reference conference ID 1056909. A webcast replay will be available on the News & Events section of the Gemphire website for all interested parties following the call and will be archived and available for 90 days.

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, expected timing of top-line results of such trials, timing and expectations for regulatory submissions and meetings and future expectations and plans and prospects for gemcabene, 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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