Gemphire Announces First Quarter 2017 Financial Results and Provides Corporate Update

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LIVONIA, Mich., May 09, 2017 (GLOBE NEWSWIRE) -- Gemphire Therapeutics Inc. (NASDAQ:GEMP), a clinical-stage biopharmaceutical company focused on developing and commercializing therapies for cardiometabolic disorders, including dyslipidemia and NASH, today announced financial results for the first quarter ended March 31, 2017, and provided a corporate update.

"The first quarter was a very productive start to 2017 for Gemphire, highlighted by continued progress in developing gemcabene, our first-in-class, once-daily, oral drug candidate for the treatment of dyslipidemia and NALFD/NASH," said Mina Sooch, President and CEO of Gemphire. "We are currently conducting three late stage clinical trials for gemcabene: our COBALT-1 trial for HoFH patients; our ROYAL-1 trial for hypercholesterolemia, including HeFH and ASCVD patients on maximally tolerated statins; and, our INDIGO-1 trial for SHTG patients. During the quarter, we completed enrollment of both our COBALT-1 and ROYAL-1 trials, on or ahead of schedule, and enrolled our first patients in our INDIGO-1 trial. We expect to report top line data from our COBALT-1 and ROYAL-1 studies in June and third quarter 2017, respectively. The third trial, INDIGO-1, is currently enrolling and we expect top line data in early 2018. Based on gemcabene's lipid-lowering and anti-inflammatory mechanism of action, and on the strength of positive preclinical data we announced during the first quarter, we also have plans to launch a Phase 2 clinical development program in NASH this year."

First Quarter & Recent Corporate Highlights

- In January, we announced positive preclinical proof of concept data on gemcabene in the treatment of nonalcoholic steatohepatitis (NASH) and plans to launch a clinical development program in NASH.
- In January, we announced positive interim data on the LDL-C primary endpoint from the ongoing open label COBALT-1 trial investigating gemcabene in homozygous familial hypercholesterolemia (HoFH) patients. No serious adverse events (SAEs) have been reported and the safety profile remains consistent with previous studies.
- In March, we presented results of a double-blind, randomized, placebo controlled, Phase 2 trial that investigated the insulin sensitization and LDL-C lowering of gemcabene in non-diabetic, obese patients at the American College of Cardiology 66th Annual Scientific Session in Washington, D.C. Gemcabene was associated with a doubling of mean increase in glucose disposal rate to 13% compared to a 6.8% increase for placebo, and it lowered LDL-C by 40%, consistent with past results in hypercholesterolemia subjects.
- In March, we closed a $12.5 million private placement that extends the Company's projected cash runway to late 2018. The net proceeds provide funding for the planned clinical development program for gemcabene in NASH patients, manufacturing and related process development activities, and general corporate purposes.
- In May, we presented a poster on gemcabene's mechanism of action at the Arteriosclerosis, Thrombosis and Vascular Biology | Peripheral Vascular Disease (ATVB|PVD) 2017 Scientific Sessions, which took place in Minneapolis, MN.

Upcoming 2017 and 2018 Clinical Milestones

- Top-line results from COBALT-1 Phase 2b trial are expected in late June 2017.
- Top-line results from ROYAL-1 Phase 2b trial are expected in the third quarter of 2017.
- Top-line results from INDIGO-1 Phase 2b trial are targeted for the first quarter of 2018 based on current pace of enrollment.
- Plan to initiate Phase 2 clinical development program (AZURE-1) in NASH in the second half of 2017 with top-line results targeted for second half of 2018.

First Quarter 2017 Financial Update

Research and development expenses for the three months ended March 31, 2017 were $5.3 million compared to $1.2 million for the three months ended March 31, 2016. The increase was primarily attributable to increased clinical trial activities encompassing three separate Phase 2b clinical trials on-going in the current year period versus no active clinical studies in the prior year period. Research and development expenses included $0.3 million in share‑based compensation expense during the three months ended March 31, 2017. There was no share‑based compensation expense included in research and development expense during the three months ended March 31, 2016.

General and administrative expenses for the three months ended March 31, 2017 were $2.2 million compared to $1.1 million for the three months ended March 31, 2016. Increased infrastructure costs to support the clinical trials and public company requirements, focused primarily in increased personnel costs, including share-based compensation expense, and professional services were the primary drivers of the increase over the prior year period. General and administrative expenses included $0.6 million and $0.1 in share‑based compensation expense during the three months ended March 31, 2017 and 2016, respectively.

Net loss attributable to common stockholders for the three months ended March 31, 2017 was $7.5 million or ($0.79) per basic and diluted share, compared to $2.3 million, or ($0.65) per basic and diluted share in the same period of 2016.

Cash and cash equivalents at March 31, 2017 totaled $29.3 million compared to $24.0 million at December 31, 2016. On March 15, 2017, the Company closed its previously announced private placement and received gross proceeds of approximately $12.5 million.

As we previously guided, management expects full year operating expenses and cash used in operating activities to be approximately double 2016 levels, primarily in research and development as we fund our ongoing clinical trials, and to be more heavily weighted in the first two quarters of 2017, aligned with the activity levels of ongoing trials. Accordingly, we expect second quarter 2017 operating expenses and cash used in operations to continue to be substantially above comparable prior period levels, and to be above first quarter 2017 levels. In addition, management expects quarterly non-cash, share-based compensation levels to trend at or above first quarter levels through 2017. Based on the Company's current operating plans, management believes existing cash, including the net proceeds from the private placement, is sufficient to fund operations through completion of all three of the ongoing dyslipidemia trials, as well as the new NASH Phase 2 trial expected to be complete in the second half of 2018.

Corporate Update

In January 2017, Gemphire announced plans to initiate clinical development of gemcabene in NASH. The decision to rapidly advance in NASH was based on multiple completed clinical trials in which gemcabene has shown the ability to lower biomarkers for blood lipids such as triglycerides (fat) and inflammation, both of which are relevant in the pathogenesis of NASH along with positive results from the recent preclinical NASH model. In a preclinical study conducted in diabetic mice, a hepatoprotective effect preventing liver disease progression was observed with gemcabene, in contrast to the control group. Specifically, gemcabene treatment resulted in a significant lowering of the liver NAFLD activity score (NAS), a composite measure of fatty liver disease comprised of measures of steatosis, inflammation, and hepatocyte ballooning. Progression of liver fibrosis was also significantly reduced with gemcabene treatment. The data from the preclinical NASH study has been submitted for publication in a peer review journal. Following the acceptance of gemcabene's IND in NASH, Gemphire plans to initiate the Phase 2 AZURE-1 trial for NASH in the second half of 2017. The Company believes gemcabene's ability to lower both triglycerides and inflammation while also reducing the progression of fibrosis through multiple mechanisms, may represent a differentiated treatment option for NASH patients.

Also in January 2017, the Company announced positive interim data on the LDL-C primary endpoint from the ongoing open label COBALT-1 trial. COBALT-1 is evaluating gemcabene in HoFH patients. The results from two genetically-confirmed HoFH patients through 8 weeks of treatment showed that gemcabene 600 mg decreased mean LDL-C by 28% on top of maximum statin and/or ezetimibe. No SAEs have been reported, where reported AEs have been mild to moderate and are consistent with previously completed studies. HoFH is an extremely rare disease, and the Company

believes the total number of subjects in its trial will be sufficient to support advancement into Phase 3.

In March, the Company announced the results of a Phase 2 trial that investigated insulin sensitization and LDL-C lowering by gemcabene in non-diabetic, obese patients. The results were featured in a poster presentation at the American College of Cardiology 66th Annual Scientific Session in Washington, D.C. Fifty-three subjects entered the trial, ranging in age from 26 to 63 years, BMI 30 to 40kg/m2, and fasting glucose <126mg/dL, entered the study. Following a 2-week screening phase, subjects were randomized to receive either 900 mg gemcabene or placebo on Day 2 through Week 4. Gemcabene was associated with a doubling of 13% mean increase in glucose disposal rate (GDR) compared to a 6.8% increase for placebo. Although statistical significance was not observed in the pre-specified analysis, a post-hoc analysis more applicable to the size of this study showed a statistically significant change from baseline to Day 29 in GDR for gemcabene 900 mg ($p<0.0178$) versus a non-significant effect for placebo. In addition, gemcabene 900 mg lowered LDL-C by 40% ($p<0.0001$) and plasma total cholesterol by 27% ($p<0.0001$) consistent with past results in hypercholesterolemia subjects. Gemcabene was generally well-tolerated. There were no deaths, SAEs, or withdrawals due to adverse events during the study.

In May, the Company presented a Poster at the Arteriosclerosis, Thrombosis and Vascular Biology | Peripheral Vascular Disease (ATVB|PVD) 2017 Scientific Sessions confirming the pleiotropic effects with multiple mechanisms of action for gemcabene in *in vitro* models. Across the various models, gemcabene was shown to lower hepatic gene biomarkers for lipid regulation (ACC1, APOC-III, Sulfatase 2,ADH4, and HMG-CoA Synthase 2) and inflammation (CRP, TNF-α, MCP-1, CCR2, CCR5, NF-Kβ, MIP-1β) as well as plasma biomarkers (LDL-C, TG, hsCRP).

About Gemcabene

Gemphire's product candidate, gemcabene (CI-1027), 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 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 inhibition of the production of cholesterol and triglycerides in the liver. The combined effect for these mechanisms has been clinically observed to result in a reduction of plasma VLDL-C, LDL-C, and triglycerides. In addition, gemcabene has been shown to markedly lower C-reactive protein and improve insulin sensitization. Gemcabene is liver-directed and reduces apoC-III mRNA and plasma levels. Gemcabene also reduces acetyl-CoA carboxylase (ACC1) and CCR2/CCR5 receptor mRNA levels, which may have applications in non-alcoholic steatohepatitis (NASH)/non-alcoholic fatty liver disease (NAFLD). Gemcabene has demonstrated proof of concept efficacy in the STAM™ model for NASH developed at SMC Laboratories in Tokyo, Japan. 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 that is committed to helping patients with cardiometabolic disorders, including dyslipidemia and NASH. We are focused on providing new treatment options for cardiometabolic diseases through our 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 has initiated 3 clinical trials for homozygous familial hypercholesterolemia (HoFH), heterozygous familial hypercholesterolemia (HeFH)/atherosclerotic cardiovascular disease (ASCVD), and severe hypertriglyceridemia (SHTG) under NCT02722408, NCT02634151, and NCT02944383, respectively with a fourth planned trial in NASH to initiate in second half of 2017. 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, expectations regarding operating expenses and cash used in operations, 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 requirements or 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 Annual Report on Form 10-K for the year ended December 31, 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.

Gemphire Therapeutics Inc.
Balance Sheet Data
(in thousands)

	March 31, 2017 (unaudited)	December 31, 2016
Cash and cash equivalents	$ 29,282	$ 24,033
Total assets	29,842	24,754
Accounts payable and accrued liabilities	4,543	4,121
Total liabilities	4,545	4,122
Common stock	18	17
Additional paid–in capital	59,834	47,674
Accumulated deficit	(34,555)	(27,059)
Total stockholders’ equity	25,297	20,632

Condensed Statements of Comprehensive Loss
(in thousands, except per share amounts)

	For the Three Months Ended March 31,	
	2017 (unaudited)	2016
Operating expenses:		
General and administrative	$ 2,223	$ 1,050

Research and development	5,280	1,176
Total operating expenses	7,503	2,226
Loss from operations	(7,503)	(2,226)
Interest and other income (expense), net	7	123
Net loss	$ (7,496)	$ (2,103)
Adjustment to redemption value on Series A convertible preferred stock	—	(149)
Net loss attributable to common stockholders	$ (7,496)	$ (2,252)
Net loss per share:		
Basic and diluted	$ (0.79)	$ (0.65)
Number of shares used in per share calculations:		
Basic and diluted	9,521	3,469

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