Gemphire to Host Expert Panel Call to Discuss Pediatric Nonalcoholic Fatty Liver Disease (NAFLD) and NASH

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Conference Call and Live Webcast on February 28 at 12:00pm EST

LIVONIA, Mich., Feb. 21, 2018 (GLOBE NEWSWIRE) -- Gemphire Therapeutics Inc. (NASDAQ:GEMP), a clinical-stage biopharmaceutical company focused on developing and commercializing therapies for cardiometabolic disorders, including dyslipidemia, non-alcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH), will host an expert panel call and live webcast to discuss pediatric NAFLD on Wednesday, February 28 at 12:00pm Eastern Time.

The call will feature a live presentation by pediatric thought leaders Miriam Vos, MD (Emory University, Children's Healthcare of Atlanta) and Saul Karpen, MD, PhD (Emory University, Children's Healthcare of Atlanta), who will present an overview of the current treatment landscape for pediatric patients with nonalcoholic fatty liver disease (NAFLD) and NASH. They will discuss emerging therapies, including Gemphire’s gemcabene, and their regulatory pathway for the treatment of pediatric liver diseases. Drs. Vos and Karpen will be available to answer questions following the presentation.

On January 31st, Gemphire announced the initiation of a Phase 2a proof-of-concept clinical trial investigating gemcabene as a treatment for pediatric NAFLD. The trial is part of a broader program to develop gemcabene in NAFLD/NASH, and will run in parallel with the recently initiated clinical trial investigating gemcabene in familial partial lipodystrophy (FPL). Top line results from the pediatric NAFLD trial are expected in early 2019.

Miriam Vos, MD, MSPH, is an Assistant Professor in the Department of Pediatrics at Emory University School of Medicine, and a physician on staff at Children’s Healthcare of Atlanta. She specializes in the treatment of gastrointestinal disease in children as well as fatty liver disease and obesity. She received an MD-MSPH from the University of Louisville School of Medicine and completed her pediatric residency in Louisville, Kentucky. Dr. Vos then completed a fellowship in Pediatric Gastroenterology at Louisville School of Medicine followed by an Advanced Hepatology Fellowship at Siragusa Transplantation Center, Children’s Memorial Hospital, Feinberg School of Medicine, Northwestern University, in Chicago, Illinois before joining Children’s Healthcare Atlanta as an attending hepatologist in 2006. Her research focuses on the “real world” aspects of diagnosing and treating pediatric NAFLD including: non-invasive imagining technologies, metabolomics to develop blood based NAFLD biomarkers, and feeding studies including the role of fructose and added sugars as contributing factors to managing lipids and NAFLD in children. Dr. Vos led the first national guideline for pediatric NAFLD, which was published by North American Society of Pediatric Gastroenterology, Hepatology and Nutrition and endorsed by the American Academy of Pediatrics, a rare two-society endorsement. She now serves as the Pediatric Chair for the Target NASH cohort, a “real world” cohort designed to validate biomarkers, solve natural history questions and monitor drug use and side effects. Dr. Vos is also the author of *The No-Diet Obesity Solution for Kids*.

Saul J. Karpen, MD, PhD is Professor of Pediatrics, Raymond F. Schinazi Distinguished Biomedical Chair, Chief of the Division of Pediatric Gastroenterology, Hepatology, and Nutrition at Emory University School of Medicine/Children’s Healthcare of Atlanta. He received an MD-PhD degree from the Mount Sinai School of Medicine, studying transcriptional regulation of HBV. He then went to Yale School of Medicine for a pediatrics residency and Pediatric GI/Hepatology Fellowship, before joining Faculty from 1994-2000, where his research focused on newly-emerging fields of nuclear receptor regulation of liver metabolism and cholestasis. Dr. Karpen has published over 130 peer-reviewed articles on both clinical and basic research topics, held leadership roles in several national societies and NIH consortia, and organized multiple international conferences. His overall goals are to develop integrative programs to improve clinical care through research and discover rational therapeutic targets to develop safe and effective pharmaceuticals—all focused upon the unique and pressing needs of infants and children with liver diseases, including biliary atresia, as well as other forms of cholestasis and NAFLD.

Conference Call and Webcast

The call and webcast with slides will take place on Wednesday, February 28 at 12:00 pm EST. To participate, please dial (866) 548-4713 (domestic) or +1 (323) 794-2093 (international) and reference conference ID 6854389. The live webcast can be accessed via the following link: http://public.viavid.com/index.php?id=128519. 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.

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 triglycerides with currently approved therapies, primarily statins. Gemcabene's mechanism of action (MOA) 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 of these mechanisms has been clinically observed to result in a reduction of plasma non-HDL-C, VLDL-C, LDL-C, apolipoprotein B and triglycerides. 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 triglyceride containing particles from the plasma. Gemcabene also reduces acetyl-CoA carboxylase (ACC1), CCR2/CCR5 receptor and TNF-α mRNA levels, markers thought to be 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 1100 subjects across 23 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 have been completed under NCT02722408 and NCT02634151. Gemphire has completed recruitment for a clinical trial for SHTG under NCT02944383, and has initiated separate trials for adult NASH and pediatric NAFLD. 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 the timing and terms of Gemphire's proposed offering of securities and its anticipated use of the net proceeds therefrom, and 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 Gemphire, 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," "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 on Form 10-K for the year ended December 31, 2016, Gemphire's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017 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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