Galmed Pharmaceuticals

Mount Sinai and Galmed Pharmaceuticals to Collaborate in an Investigator Initiated Phase IIa Trial to Evaluate the Effect of AramcholTM in Combination with Vitamin D for the Treatment of Patients with Fibrotic Nonalcoholic Fatty Liver Disease

TEL AVIV, Israel, May 3, 2016 /PRNewswire/ -- Galmed Pharmaceuticals Ltd. (Nasdaq: GLMD) ("Galmed" or the "Company"), a clinical-stage biopharmaceutical company focused on the development of a once-daily, oral therapy for the treatment of liver diseases, announced today that it has signed an investigator initiated clinical trial agreement with the Icahn School of Medicine at Mount Sinai, entitled "A Placebo-controlled Single-blinded Study of Aramchol^{TM} with Supplemental Vitamin D in Patients with Vitamin D Deficiency and Nonalcoholic Fatty Liver Disease (NAFLD) and Fibrosis" (the "Study"). The Study, which is a Phase IIa trial, will be conducted under the leadership of principal investigator, Andrea Branch, PhD, Professor of Medicine in the Icahn School of Medicine at Mount Sinai, United States, and an additional center in Israel. Galmed has filed a patent application for the composition of matter patent on the new combination therapy.

The Study will enroll 80 patients with NAFLD and fibrosis, and is anticipated to be completed in the first half of 2018. The Study design includes four dose alternatives: (a) Aramchol^{TM} 400 mgs, (b) Vitamin D, (c) Aramchol^{TM} 400 mgs and Vitamin D in combination, and (d) Placebo, administrated for 24 weeks, followed by a 4-week follow-up period. The Study's primary endpoint is the change in liver stiffness (baseline to end of treatment), measured by Magnetic Resonance Elastography (MRE). Secondary endpoints include changes in the intrahepatic fat content (measured by MRI and FibroScan/CAP), and other metabolic parameters.

According to a recent study published in American Journal of Gastroenterology, "[vitamin D deficiency] in humans and animal models indicate that [vitamin D deficiency] also contributes to increased oxidative stress, systemic inflammation, decreased adiponectin levels, toll-like receptor activation, and nonalcoholic fatty liver disease … we have found that [vitamin D deficiency] in our NAFLD subjects was associated with a definitive diagnosis of NASH, increased lobular inflammation, more ballooning and the presence of fibrosis." [Nelson JE, et. al. Am J Gastroenterol 2016;doi:10.10385/ajg.2016.51].

According to Dr. Branch, "The liver is a key regulator of lipid metabolism and frequently becomes inflamed and damaged in patients with metabolic abnormalities, including type-2 diabetes and obesity. Aramchol^{TM}, a bile acid-fatty acid conjugate, was previously shown to decrease liver fat. Vitamin D_3 is a key regulatory hormone that reduces inflammation and improves the barrier function of the intestine, potentially protecting the liver from harmful bacterial products that would otherwise reach the liver and cause injury. In addition to the innovative dual therapy, the trial has several more novel features: It will be open to patients with NASH and well-compensated liver cirrhosis (unlike many trials that exclude these

patients), as well as to patients with less extensive liver damage, and it will not require a liver biopsy for participation."

Dr. Branch continued, "I am excited to be conducting this study with Galmed and with my colleagues at Mount Sinai, including Dr. Meena Bansal, the study hepatologist, Dr. Charissa Chang, an expert in the clinical management of NASH, and Drs. Sara Lewis and Bachir Taouli, who are innovators in liver imaging. In addition to clinical endpoints, the study will provide information about the impact of Aramchol^{TM} and vitamin D_3 on the intestinal flora comprising the microbiome." Dr. Branch concluded, "These studies will be carried out in collaboration with Dr. Inga Peter and her research team in the Department of Genetics and Genomic Sciences at the Icahn School of Medicine at Mount Sinai."

Galmed Pharmaceuticals President and Chief Executive Officer, Allen Baharaff added, "As we've discussed for some time, Galmed is seeking to address the treatment of NASH through a comprehensive portfolio approach, rather than a single "shot-on-goal"; a combination therapy, now with Vitamin D, fits perfectly into that strategy. NASH is a complex, multifactorial disease, which requires therapeutic approaches with multiple mechanisms of action." Mr. Baharaff concluded, "We will continue to investigate compounds complementary to Aramchol^{TM}, including safe, FDA-approved compounds repositioned to treat fibrosis, as well as new chemical entities aiming to develop an ultimate treatment for NASH."

About Nonalcoholic Fatty Liver Disease and Nonalcoholic Steatohepatitis:
Nonalcoholic fatty liver disease (NAFLD) is the most common cause of chronic liver disease inthe United States and it affects almost 30% of adults in Western countries. With climbing obesity rates and more sedentary patient populations, the prevalence of NAFLD is increasing worldwide and is becoming the predominant cause of chronic liver disease in parts of the world. NAFLD represents a spectrum of diseases ranging from simple excess liver fat, or steatosis, to nonalcoholic steatohepatitis (NASH). NASH is the progressive form of fatty liver disease that can lead to cardiovascular disease, cirrhosis and liver-related mortality in persons who drink little or no alcohol. NASH represents the more severe end of this spectrum and is characterized by steatosis, ballooning degeneration and lobular inflammation with or without fibrosis. Long-term risks of NASH include cardiovascular disease, cirrhosis, hepatocellular carcinoma and end stage liver disease requiring liver transplantation.

About Galmed Pharmaceuticals Ltd.:
Galmed is a clinical-stage biopharmaceutical company focused on the development of a novel, once-daily, oral therapy for the treatment of liver diseases utilizing its proprietary first-in-class family of synthetic fatty-acid/bile-acid conjugates, or FABACs. Galmed believes that its product candidate, Aramchol^{TM}, has the potential to be a disease modifying treatment for fatty liver disorders, including NASH, which is a chronic disease that Galmed believes constitutes a large unmet medical need. Galmed is currently conducting the ARREST Study, a multicenter, randomized, double blind, placebo-controlled

Phase IIb clinical study designed to evaluate the efficacy and safety of Aramchol^{TM} in subjects with NASH, who are overweight or obese, and who are pre-diabetic or type-II-diabetic. More information about the ARREST Study may be found on ClinicalTrials.gov identifier: NCT02279524.

Forward-Looking Statements:

This press release may include forward-looking statements. Forward-looking statements may include, but are not limited to, statements relating to Galmed's objectives, plans and strategies, as well as statements, other than historical facts, that address activities, events or developments that Galmed intends, expects, projects, believes or anticipates will or may occur in the future. These statements are often characterized by terminology such as "believes," "hopes," "may," "anticipates," "should," "intends," "plans," "will," "expects," "estimates," "projects," "positioned," "strategy" and similar expressions and are based on assumptions and assessments made in light of management's experience and perception of historical trends, current conditions, expected future developments and other factors believed to be appropriate. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statements. Applicable risks and uncertainties include those identified under the heading "Risk Factors" included in Galmed's most recent Annual Report on Form 20-F filed with the Securities and Exchange Commission, or the SEC, on March 22, 2016, and in other filings that Galmed has made and may make with the SEC in the future. The forward-looking statements contained in this press release are made as of the date of this press release and reflect Galmed's current views with respect to future events, and Galmed does not undertake and specifically disclaims any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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Additional assets available online: Photos (1)

https://galmedpharma.investorroom.com/2016-05-03-Mount-Sinai-and-Galmed-Pharmaceuticals-to-Collaborate-in-an-Investigator-Initiated-Phase-IIa-Trial-to-Evaluate-the-Effect-of-AramcholTM-in-Combination-with-Vitamin-D-for-the-Treatment-of-Patients-with-Fibrotic-Nonalcoholic-Fatty-Liver-Disease