Galmed Pharmaceuticals

Galmed Pharmaceuticals and the University of California, San Diego Enter into an Investigator-Initiated Clinical Trial Agreement to Assess Aramchol™ Effects Juvenile Population

TEL AVIV, Israel, Sept. 22, 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, today announced that it has signed an Investigator-Initiated Clinical Trial Agreement with the University of California, San Diego, School of Medicine (the "University"). The proposed study is a Phase I/IIa trial to assess safety, tolerability, efficacy, and pharmacokinetics of Aramchol™ in a juvenile population with nonalcoholic fatty liver disease (NAFLD) (the "ARTISAN Study"). The ARTISAN Study (**AR**amchol™ **T**rial to **I**mprove **S**teatosis in **A**dolescent **N**AFLD) is to be led by Dr. Jeffrey Schwimmer, Professor of Clinical Pediatrics at the University.

Fatty liver disease in children has been increasingly recognized as an important pediatric health problem. Pediatric NAFLD has some features that are similar to adults and several features that are unique to children. In the United States, there are an estimated 5 to 8 million children with NAFLD. The prevalence of NAFLD in children across the developed world is 5 to 10%. From a liver standpoint, the major concern is that NAFLD is a risk factor for cirrhosis and liver cancer. Beyond the risk for serious liver problems, children with NAFLD are also at increased risk for other important health problems including type 2 diabetes and atherosclerotic heart disease.

"NAFLD is the leading cause of chronic liver disease, yet there is no approved therapy in children or adults. Based upon promising data in adults, the University is developing a proof-of-concept trial for Aramchol™ in adolescents with NAFLD," said Jeffrey Schwimmer, MD, professor of pediatrics, University of California, San Diego, School of Medicine and Director, Fatty Liver Clinic, Rady Children's Hospital, San Diego.

The ARTISAN Study is subject to receipt of regulatory approvals and is currently expected to be initiated in the first half of 2017.

Galmed's President and Chief Executive Officer, Mr. Allen Baharaff, stated "The ARTISAN Study marks the third investigator-initiated clinical trial and continues our strategy of collaborating with leading investigators to evaluate Aramchol™'s efficacy across different populations and indications. We believe addressing the unmet need for treatment of juvenile population with NAFLD should not await the clinical development for adults. Based on Aramchol™'s safety profile and mechanism-of-action, we decided to approach this important indication in parallel with our ongoing adult studies."

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™, 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™ 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 risks and uncertainties associated with the initiation, timing, progress and results of the Company's research, preclinical studies and clinical trials as well as risks and uncertainties 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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For further information: Investor Contact: Josh Blacher, CFO, Galmed Pharmaceuticals Ltd., josh@galmedpharma.com, +1-646-780-7605

Additional assets available online: Photos (1)

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