Galmed Pharmaceuticals

Aramchol™ Demonstrates Significant Anti-Fibrotic Effect in a Pre-clinical Model of Fatty Liver Disease

TEL AVIV, Israel, March 30, 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 pre-clinical data demonstrating significant anti-fibrotic activity of Aramchol™ in methionine and choline deficient (MCD) diet in mice.

The new pre-clinical studies demonstrated both a statistically significant reduction of inflammation (65% decrease in F4/80, and 80% decrease in CD64), as well as a statically significant effect on liver fibrosis (70% decrease in Sirius Red). The repeated studies were performed by CIC bioGUNE in Spain under the supervision of Professor José Mato, a notable NASH pre-clinical researcher.

Professor José Mato, CIC bioGUNE General Director, commented on the results of the pre-clinical studies, "Aramchol™ showed a potent effect on the hepatic accumulation of fatty acids in the MCD at the high dose (5 mg/kg/day) and much less at the low dose (1 mg/kg/day)." Professor Mato continued, "This data support the operating hypothesis that, at least in this model, Aramchol™ acts through two independent mechanisms: The first is an anti-inflammatory mechanism, and the second is through improving lipid metabolism. We are currently investigating transcriptomics and metabolomics data from this study, which may give new insights into the mechanisms that lead to this anti-fibrotic effect of Aramchol™."

Professor Scott Friedman, Chief, Division of Liver Diseases, Icahn School of Medicine at Mount Sinai in New York and a member of Galmed Scientific Advisory Board also commented ,"These results reinforce the potential efficacy of Aramchol™ in human NASH, but continued pre-clinical evaluation, use of new models, and elucidation of mechanisms-of-action remain ongoing priorities while we seek to establish Aramchol™'s efficacy in clinical trials in patients with NASH."

"The reason that we believe these new findings are material, incremental and noteworthy is because we had previously understood that Aramchol™'s primary clinical objective was to treat NASH through its ability to reduce excess liver fat (steatosis), which is commonly understood to be the underlying cause of the disease," stated Galmed's President and Chief Executive Officer, Allen Baharaff. "This new data," Mr. Baharaff concluded, "suggests that Aramchol™ has, in addition, a direct, significant effect against hepatic fibrosis and inflammation, which are crucial for liver regeneration."

Full data regarding this pre-clinical research will be submitted to the 2016 AASLD Liver Meeting in Boston.

About Methionine and Choline Deficiency (MCD) Mouse Model:

Feeding mice a methionine and choline deficient (MCD) diet constitutes a commonly used nutritional model of NASH that induces aminotransferase elevation and changes in hepatic histological features characterized by steatosis, local inflammation, hepatocyte necrosis and fibrosis. These changes occur rapidly and have been shown to be morphologically close to those observed in human 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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