Galmed Pharmaceuticals

Galmed Pharmaceuticals Announces Publication of Data on Aramchol™ Mechanism of Action in Hepatology Communications. Data Will Also Be Presented at AASLD

TEL AVIV, Israel, Oct. 5, 2017 /PRNewswire/ -- Galmed Pharmaceuticals, Inc. (GLMD), a clinical-stage biopharmaceutical company focused on the development of a once-daily, oral therapy for the treatment of nonalcoholic steatohepatitis, or NASH and other liver diseases, today announced the publication of a paper entitled "Role of Aramchol™ in steatohepatitis and fibrosis in mice" in *Hepatology Communications*, a peer-reviewed, online open access journal.

The paper summarizes the work conducted by a collaboration of key international, basic and clinical scientists, who are well known NASH experts. "The paper reinforced the previously published effects of Aramchol on steatosis in patients," said Dr. Liat Hayardeny, Chief Scientific Officer of Galmed. Dr. Hayardeny continued, "The data have helped us understand the mechanism by which Aramchol exerts its effect on steatosis and steato-fibrosis and identify its potential direct anti fibrotic effects".

Prof. José M Mato, senior author, and director of CIC bioGUNE commented, "We have identified two disparate consequences of Aramchol treatment that result in antisteatotic, anti-inflammatory and antifibrotic effects. Aramchol treatment improved steatohepatitis and steato-fibrosis by decreasing SCD1 and by maintaining cellular redox homeostasis. Our MCD model resembles the metabolic phenotype observed in NASH patients, which supports the potential use of Aramchol for this indication."

Prof. Arun Sanyal, co-author, and Professor of Medicine and Chairman, Division of Gastroenterology, Hepatology and Nutrition at the Virginia Commonwealth University (VCU) department of Internal Medicine and Chairman of the NIH NASH Clinical Research Network and the Liver Forum for NASH and fibrosis added: "This pre-clinical study provides a strong pathophysiological rationale for the use of Aramchol. The results of the ongoing clinical trial are now eagerly awaited."

"The ongoing ARREST Phase IIb study is designed to evaluate the efficacy and safety of two Aramchol doses versus placebo in patients with NASH. One of the key secondary endpoints is measuring the ability of Aramchol to improve fibrosis without worsening of NASH, and over 60% of the 248 enrolled patients showed advanced fibrosis at baseline biopsy," said Dr. Tali Gorfine, Chief Medical Officer of Galmed. Top line ARREST study data are expected to be available in Q2 2018.

The company will present the preclinical data at the Liver Meeting® AASLD which will take place in Washington D.C., 20-24 October 2017.

The paper can be accessed online at: http://onlinelibrary.wiley.com/doi/10.1002/hep4.1107/full

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 Aramchol™ and Non-alcoholic Steatohepatitis (NASH)

Aramchol™ (arachidyl amido cholanoic acid) is a novel fatty acid bile acid conjugate, inducing beneficial modulation of intra-hepatic lipid metabolism. Aramchol™'s ability to modulate hepatic lipid metabolism was discovered and validated in animal models, demonstrating down regulation of the three key pathologies of NASH: steatosis, inflammation and fibrosis. The effect of Aramchol™ on fibrosis is mediated by down regulation of steatosis and directly on human collagen producing cells. Aramchol™ has been granted Fast Track designation status by the FDA for the treatment of NASH.

NASH is an emerging world crisis impacting an estimated 3% to 5% of the U.S. population and an estimated 2% to 4% globally. It is the fastest growing cause of liver cancer and liver transplant in the U.S. due to the rise in obesity. NASH is the progressive form of non-alcoholic fatty liver disease that can lead to cardiovascular disease, cirrhosis and liver-related mortality.

About Galmed Pharmaceuticals Ltd.:

Galmed is a clinical-stage biopharmaceutical company focused on the development of Aramchol™, a first in class, novel, once-daily, oral therapy for the treatment of NASH for variable populations, as well as other liver associated disorders. 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. Galmed also sponsors the ARRIVE Study, a proof-of-concept Phase IIa clinical trial designed to evaluate the safety and efficacy of Aramchol in up to 50 patients with HIV-associated NAFLD and lipodystrophy. The ARRIVE Study is an investigator-initiated trial, conducted at the University of California San Diego by Professor Rohit Loomba. More information about the ARREST Study and the ARRIVE Study may be found on ClinicalTrials.gov identifiers: NCT02279524 and NCT02684591, respectively.

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. Many factors could cause Galmed's actual activities or results to differ materially from the activities and results anticipated in forward-looking statements, including, but not limited to, the following: the timing and cost of Galmed's ongoing Phase IIb ARREST Study, and planned Phase III trials for Aramchol™, or whether Phase III trials will be conducted at all; completion and receiving favorable results of these Phase IIb ARREST Study and Phase III trials for Aramchol™; regulatory action with respect to Aramchol™ by the FDA or the EMA; the commercial launch and future sales of Aramchol™ or any other future products or product candidates; Galmed's ability to comply with all applicable post-market regulatory requirements for Aramchol™ in the countries in which it seeks to market the product; Galmed's ability to achieve favorable pricing for Aramchol™; Galmed's expectations regarding the commercial market for NASH in patients who are overweight or obese and have pre diabetes or type II diabetes mellitus; third-party payor reimbursement for Aramchol™; Galmed's estimates regarding anticipated capital requirements and Galmed's needs for additional financing; market adoption of Aramchol™ by physicians and patients; the timing, cost or other aspects of the commercial launch of Aramchol™; the development and approval of the use of Aramchol™ for additional indications or in combination therapy; and Galmed's expectations regarding licensing, acquisitions and strategic operations. More detailed information about the risks and uncertainties affecting Galmed is contained under the heading "Risk Factors" included in Galmed's most recent Annual Report on Form 20-F filed with the SEC on March 23, 2017, 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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