Galmed Pharmaceuticals

Galmed Pharmaceuticals to Host Key Opinion Leader Meeting on Non-Alcoholic Steato-Hepatitis (NASH)

TEL AVIV, Israel, Oct. 19, 2017 /PRNewswire/ -- Galmed Pharmaceuticals, Inc. (Nasdaq: 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 that it will host a Key Opinion Leader (KOL) meeting on NASH on Thursday, October 26, 2017 in New York City.

The meeting will feature a presentation by KOL Professor Scott Friedman, MD (Icahn School of Medicine at Mount Sinai), who will discuss the current treatment landscape and unmet medical need for patients with NASH. Professor Friedman will be available to answer questions at the conclusion of the event.

Galmed's management team will also provide an overview of the scientific rationale and ongoing clinical development program of Aramchol™, a novel, once-daily, oral therapy for the treatment of NASH. The Company's ARREST Phase IIb study in 248 patients is evaluating the efficacy and safety of two Aramchol™ doses versus placebo in patients with NASH. Top-line data is expected to be reported in Q2 2018.

Professor Scott L. Friedman, MD is Dean for Therapeutic Discovery and Chief of the Division of Liver Diseases, at Icahn School of Medicine at Mount Sinai in New York. A graduate of the Icahn School of Medicine at Mount Sinai, Professor Friedman served as President of Alpha Omega Alpha Honor Society and was awarded the Arthur Aufses, Sr. Prize in Surgery. He was a Medical Resident at Beth Israel Hospital, Harvard Medical School, Boston, and Gastroenterology Fellow at UCSF before assuming a 10-year faculty position there. Recipient of many international honors, Professor Friedman has mentored over 75 postdoctoral fellows and students, and is listed among "America's Top Doctors." He has been a named lecturer or Visiting Professor at more than 30 institutions worldwide, and has authored more than 300 peer-reviewed publications. Professor Friedman is a member of the American Society of Clinical Investigation, Association of American Physicians and has been elected Fellow of the American Gastroenterological Association, American College of Physicians, American Association for the Study of Liver Diseases (where he is also past-president) and American Association for the Advancement of Science. Professor Friedman is Associate Editor for the Journal of Hepatology and Series Editor for the Mount Sinai Handbooks of Disease, having previously been Associate Editor of Hepatology. He has served on multiple Editorial Boards and is on the Scientific Advisory Board of the US–Israel Binational Science Foundation. He currently consults for over 40 pharmaceutical and biotech companies, and is widely viewed as one of the leading experts in fibrosis in the world.

This event is intended for institutional investors, sell-side analysts, investment bankers, and business development professionals only. Please RSVP in advance if you plan to attend, as space is limited. For those who are unable to attend in person, a live webcast will be accessible here.

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 downregulation of the three key pathologies of NASH: steatosis, inflammation and fibrosis. The effect of Aramchol™ on fibrosis is mediated by downregulation 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.

SOURCE Galmed Pharmaceuticals, Inc

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Additional assets available online: Photos (1)

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